

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 14, 2023

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.)

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 2.02. Results of Operations and Financial Condition.

On August 14, 2023, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the three and six-month periods ended June 30, 2023. 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 14, 2023 providing a business update and announcing second quarter 2023 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 14, 2023



DiaMedica Therapeutics Provides a Business Update and Announces Second Quarter 2023 Financial Results

Conference Call and Webcast August 15 at 8:00 am Eastern Time / 7:00 am Central Time

- *Company Resumes ReMEDy2 Clinical Trial after Clinical Hold Lifted*
- *Company Completed a \$37.5M “At-The-Market” Private Placement, Cash Runway Into 2026*
- *Company Completed an Additional Safety Cohort of ACEi Patients in its Phase 1C Healthy Volunteer Study*

Minneapolis, Minnesota – August 14, 2023 (Business Wire)– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal disease, today provided a business update and financial results for the quarter ended June 30, 2023. Management will host a conference call Tuesday, August 15, 2023, at 7:00AM Central Time/8:00AM Eastern Time to discuss its business update and second quarter 2023 financial results.

Clinical Developments

Clinical Hold Lifted on ReMEDy2 Phase 2/3 Trial for Acute Ischemic Stroke

On June 21, 2023, the Company announced that the U.S. Food and Drug Administration (FDA) fully lifted the clinical hold on DiaMedica’s investigational new drug application for its ReMEDy2 clinical trial of DM199 in acute ischemic stroke (AIS) patients. The Company has rapidly re-engaged with its study support vendors and brought on a new contract research organization (CRO) with strong stroke experience, to assist with the planning and preparations for resuming the ReMEDy2 trial with a focus on ensuring that the right resources are in place to attract high quality study sites and ensure smooth and efficient clinical operations as patient enrollment resumes. The enrollment timeline projections and site selection are being finalized in collaboration with the new CRO. In addition, the Company is planning for the inclusion of study sites outside of the United States to increase the enrollment rate for both the interim analysis and the overall study. At this time, based upon enrollment rates in recent stroke trials and discussions with multiple CROs, the Company believes that full enrollment for the interim analysis can be completed in 2024.

“With the lifting of the clinical hold, we are thrilled to reengage with doctors and hospitals to work towards developing DM199 as a significant advance for the treatment of ischemic stroke patients,” commented Rick Pauls, DiaMedica’s Chief Executive Officer. “We look forward to keeping you updated on the progress of our trial.”

DiaMedica also completed an additional cohort of hypertensive patients (Part B) being treated with angiotensin-converting enzyme inhibitors (ACEi) in its Phase 1C open label, single ascending dose (SAD) study of DM199, administered with the polyvinylchloride (PVC) IV bags used in the ReMEDy2 trial. In the initial part of the study (Part A), DiaMedica confirmed in healthy volunteers that the revised IV dose of DM199, 0.5 µg/kg, was well-tolerated and achieved an appropriate DM199 blood concentration level in the desired therapeutic range, similar to prior clinical trials. In Part B, all ACEi patients received the full IV dose at the 0.5 µg/kg level with no instances of hypotension. DiaMedica believes that these results will provide further assurance to potential investigators that ACEi patients may be safely included in the ReMEDy2 trial. This Phase 1C study is now finished and the Company is completing final closing procedures.

“At-the-Market” Financing

As previously announced, DiaMedica completed a \$37.5 million private placement to accredited investors, including several members of DiaMedica’s management team. The Company sold approximately 11.0 million common shares a purchase price of \$3.40 per share, equal to the average per share closing price of the Company’s common shares for the five trading days ended June 20, 2023, except in the case of DiaMedica management who agreed to a higher purchase price of \$3.91 per share, equal to the closing sale price of the Company’s common shares on June 20, 2023. After deducting estimated offering expenses, the Company received net proceeds of approximately \$36.1 million.

DiaMedica expects to use the net proceeds from these sales to continue its clinical and product development activities for DM199 and for other working capital and general corporate purposes.

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of \$60.7 million, current liabilities of \$1.9 million and working capital of \$39.3 million as of June 30, 2023, compared to total cash, cash equivalents and investments of \$33.5 million, \$2.2 million in current liabilities and \$31.7 million in working capital as of December 31, 2022. The increases in cash and investments and in working capital were due primarily to the \$36.9 million of net proceeds from the June and April 2023 private placements, partially offset by cash used to fund operating activities during the six months ended June 30, 2023.

Net cash used in operating activities for the six months ended June 30, 2023 was \$10.1 million compared to \$6.4 million for the six months ended June 30, 2022. The increase in cash usage relates primarily to the increased net loss in the current year period over the prior year period, partially offset by non-cash share-based compensation and the effects of changes in operating assets and liabilities in the current year period.

Financial Results

Research and development (R&D) expenses increased to \$2.5 million for the three months ended June 30, 2023, up \$0.5 million from \$2.0 million for the three months ended June 30, 2022. R&D expenses increased to \$6.2 million for the six months ended June 30, 2023, up from \$3.9 million for the six months ended June 30, 2022. The increase for the six-month comparison was due primarily to costs incurred for the in-use study performed to address the recently lifted clinical hold on the Company’s ReMEDy2 AIS trial and costs incurred for the Phase 1C study determining the DM199 blood concentration levels achieved with the IV dose of DM199. Also contributing to the increase were increased manufacturing and process development costs, costs incurred to finalize the clinical data and perform related analyses for the REDUX trial, and increased personnel costs associated with expanding the clinical team. These increases were partially offset by decreased costs incurred for the Phase 2/3 ReMEDy2 AIS trial due to the recently lifted clinical hold.

General and administrative (G&A) expenses were \$2.2 million for the three months ended June 30, 2023, up from \$1.4 million for the three months ended June 30, 2022. G&A expenses were \$4.1 million for the six months ended June 30, 2023, up from \$3.0 million for the six months ended June 30, 2022. The increase for the six-month comparison was primarily due to increased legal fees incurred in connection with our lawsuit against PRA Netherlands and increased personnel costs incurred in conjunction with expanding the team. Increased professional service fees and non-cash share-based compensation also contributed to the increase.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and second quarter 2023 financial results on Tuesday, August 15, 2023, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Tuesday, August 15, 2023
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://app.webinar.net/DnqEOYkbbk6Z
Dial In:	(877) 550-1858
Conference ID:	2125#

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 playback on the Company'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 22, 2023, by dialing (800) 645-7964 (US Toll Free) and entering the replay passcode: 2125#.

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 acute ischemic stroke (AIS) patients. The trial is intended to enroll approximately 350 patients at up to 75 sites in the United States with planned global expansion. 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.

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 "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 press release include statements regarding the Company's expectations regarding timing for the resumption of and full enrollment for the interim analysis of the ReMEDy2 trial and the anticipated clinical benefits and success of DM199. 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, 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 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 cardio-renal 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 COVID-19, 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 cardio-renal 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, 2022 and subsequent U.S. Securities and Exchange Commission filings, including DiaMedica's quarterly report on Form 10-Q for the quarterly period ended June 30, 2023. 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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 2,543	\$ 1,955	\$ 6,161	\$ 3,929
General and administrative	2,198	1,409	4,101	2,971
Operating loss	(4,741)	(3,364)	(10,262)	(6,900)
Other income:				
Other income, net	271	13	527	48
Loss before income tax expense	(4,470)	(3,351)	(9,735)	(6,852)
Income tax expense	(7)	(7)	(14)	(14)
Net loss	(4,477)	(3,358)	(9,749)	(6,866)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(34)	(60)	11	(116)
Net loss and comprehensive loss	\$ (4,511)	\$ (3,418)	\$ (9,738)	\$ (6,982)
Basic and diluted net loss per share	\$ (0.16)	\$ (0.13)	\$ (0.36)	\$ (0.26)
Weighted average shares outstanding – basic and diluted	27,312,008	26,443,067	26,882,858	26,443,067

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,839	\$ 4,728
Short term marketable securities	34,529	28,774
Prepaid expenses and other assets	675	251
Amounts receivable	188	82
Total current assets	<u>41,231</u>	<u>33,835</u>
Non-current assets:		
Long term marketable securities	20,296	
Operating lease right-of-use asset, net	390	424
Property and equipment, net	133	136
Total non-current assets	<u>20,819</u>	<u>560</u>
Total assets	<u>\$ 62,050</u>	<u>\$ 34,395</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 856	\$ 734
Accrued liabilities	1,011	1,365
Operating lease obligation	76	63
Finance lease obligation	3	6
Total current liabilities	<u>1,946</u>	<u>2,168</u>
Non-current liabilities:		
Operating lease obligation, non-current	357	396
Finance lease obligation, non-current	4	4
Total non-current liabilities	<u>361</u>	<u>400</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,464,977 and 26,443,067 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Paid-in capital	165,732	128,078
Accumulated other comprehensive loss	(63)	(74)
Accumulated deficit	(105,926)	(96,177)
Total shareholders' equity	<u>59,743</u>	<u>31,827</u>
Total liabilities and shareholders' equity	<u>\$ 62,050</u>	<u>\$ 34,395</u>

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (9,749)	\$ (6,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	802	673
Amortization of discount on marketable securities	(432)	160
Non-cash lease expense	34	31
Depreciation	14	12
Changes in operating assets and liabilities:		
Amounts receivable	(106)	42
Prepaid expenses and other assets	(424)	(445)
Accounts payable	122	115
Accrued liabilities	(380)	(106)
Net cash used in operating activities	<u>(10,119)</u>	<u>(6,384)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(52,743)	(27,510)
Maturities of marketable securities	27,135	32,258
Purchases of property and equipment	(11)	(6)
Net cash (used in) provided by investing activities	<u>(25,619)</u>	<u>4,742</u>
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	36,852	—
Principal payments on finance lease obligations	(3)	(3)
Net cash provided by (used in) financing activities	<u>36,849</u>	<u>(3)</u>
Net increase (decrease) in cash and cash equivalents	1,111	(1,645)
Cash and cash equivalents at beginning of period	4,728	4,707
Cash and cash equivalents at end of period	<u>\$ 5,839</u>	<u>\$ 3,062</u>
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	<u>\$ —</u>	<u>\$ 10</u>
Cash paid for income taxes	<u>\$ 20</u>	<u>\$ 8</u>