

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 11, 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 August 11, 2021, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the three and six months ended June 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.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Press Release dated August 11, 2021 providing a business update and reporting second quarter 2021 financial results (furnished herewith)</u></a>

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**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 11, 2021



## **DiaMedica Therapeutics Provides a Business Update and Announces Second Quarter 2021 Financial Results**

- *Phase 2/3 ReMEDy2 Trial in AIS for Stroke Outcomes and Stroke Recurrence on Track for Initiation Summer 2021*
- *Positive REDUX Phase 2 Interim Data Announced for CKD: IgA Nephropathy Data Indicate Statistically & Clinically Significant 33% Reduction in Albuminuria (UACR).*
- *Board of Directors Strengthened with Election of Two Pharma Industry Veterans*

*Conference Call and Webcast August 12 at 8:00 am Eastern Time / 7:00 am Central Time*

**Minneapolis, Minnesota – August 11, 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 June 30, 2021. DiaMedica will host a conference call Thursday, August 12, 2021, at 7:00AM Central Time/8:00AM Eastern Time to discuss its business update and second quarter financial results.

### ***Pivotal Phase 2/3 ReMEDy Trial on Track for Summer 2021 Initiation; Prevention of Stroke Recurrence is being Added as Independent Co-Primary Endpoint***

DiaMedica's Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for an adaptive Phase 2/3 clinical trial of DM199 was accepted by the FDA in mid-May 2021, and the Company expects to formally initiate the study by the end of this summer.

The clinical trial design is 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 with 24-hour treatment window from onset of stroke symptoms. The prevention of stroke recurrence is being added as an independent co-primary endpoint for this study based on the statistically significant 13% absolute reduction in severe recurrent strokes observed in the ReMEDy Phase 2 study. Secondary endpoints will include mRS shift, NIHSS and Barthel Index scores, deaths, safety and tolerability measures, and biomarkers relating to KLK1.

The trial population includes acute ischemic stroke (AIS) patients who are not eligible for and/or who do not receive tissue plasminogen activator (tPA) and do not have large vessel occlusions. This group represents up to 80% of all AIS patients, for whom there is no treatment option other than supportive care. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

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### ***DM199 for the Treatment of Chronic Kidney Disease (CKD)***

Interim data from the Phase 2 REDUX trial was announced in June 2021. The Company highlights that DM199 demonstrated clinically meaningful improvements in kidney function in IgA Nephropathy as measured by simultaneously stabilizing estimated glomerular filtration rate (eGFR) and decreasing urinary albumin-to-creatinine ratio (UACR). Interim data from 11 subjects with moderate to severe albuminuria (baseline UACR>500) showed an average decrease in UACR of -33% (P=0.002) with stable eGFR.

Additionally, DM199 was well tolerated across all cohorts, with no DM199 related severe adverse events or discontinuations due to drug-related adverse events (AEs). The AEs observed were generally mild to moderate in severity, with the most common being local injection site irritation that resolved without medical intervention.

DiaMedica is preparing to provide a more complete update on the interim study results to be presented at the *American Society of Nephrology* Annual Meeting in November 2021.

As of July 31, 2021, DiaMedica had enrolled 75 subjects, including 20 African American subjects into Cohort I, 22 subjects with IgAN into Cohort II and completed enrollment with 33 subjects with Type 2 diabetes, hypertension and albuminuria into Cohort III. The Company has continued to experience slower than expected enrollment in the first two Cohorts of the REDUX study and believes this is due to continued concerns of potential study subjects related to visiting clinical study sites. DiaMedica is evaluating the effects of the recent surge in COVID-19 infections related to the Delta variant and will provide an update on the anticipated completion of Cohort I and Cohort II when the Company is able to reasonably estimate timing.

### ***Two Pharma Industry Veterans Added to DiaMedica Board of Directors***

In July 2021, the Company announced the election of two experienced executives to its Board of Directors. Joining the Board are:

- Amy Burroughs, has held senior leadership and advisory roles with a broad range of public and private biopharmaceutical companies over the last 20 years. She is currently president and chief executive officer of Cleave Therapeutics, a clinical stage, venture backed oncology company. Previously, she served as executive in residence at 5AM Ventures, a leading venture capital firm focused on building next-generation life science companies, and a senior advisor to Crinetics (NASDAQ: CRNX). She began her biopharmaceutical career at Genentech, where she held key roles in commercial strategy and planning across the portfolio and led the neurology commercial team.
  - Charles Semba, M/D., has over 20 years of drug development experience in public and private biotechnology companies and is a recognized expert in endovascular therapy, thrombolysis, mechanical thrombectomy, and endovascular surgery. He is Chief Medical Officer (CMO) at Eluminex Biosciences and has served as CMO for SARcode Bioscience (acquired by Shire/Takeda), ForSight VISION5 (acquired by Allergan), and Graybug Vision (NASDAQ: GRAY). He has held senior leadership roles as Vice President Ophthalmic Medicine at Shire/Takeda and Ophthalmology Group Head at Genentech. Dr. Semba led the clinical development of ranibizumab (LUCENTIS®) and lifitegrast (XIIDRA®). He also led FDA approval for CathFlo Activase® (Alteplase) for ischemic stroke.
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## Financial Results

Research and development (R&D) expenses increased to \$2.2 million for the three months ended June 30, 2021, up from \$1.6 million for the three months ended June 30, 2020, an increase of \$0.6 million. R&D expenses increased to \$4.6 million for the six months ended June 30, 2021, compared to \$2.9 million for the six months ended June 30, 2020, an increase of \$1.7 million. The increase for the six-month comparison was primarily due to a number of factors including costs incurred for the pivotal ReMEDy2 clinical study, increased year-over-year costs related to manufacturing process development and the REDUX Phase 2 CKD study, as well as increased personnel costs associated with additional staff added to support R&D operations. These increases were partially offset by decreased costs incurred for the ReMEDy Phase 2 stroke study which completed in the prior year.

General and administrative (G&A) expenses were \$1.2 million for the three months ended June 30, 2021, up from \$1.1 million for the three months ended June 30, 2020. G&A expenses increased to \$2.4 million for the six months ended June 30, 2021, up \$0.2 million from \$2.2 million for the six months ended June 30, 2020. The increase for the six-month comparison was primarily due to increased professional services costs and increased personnel costs to support the Company's expanding clinical programs.

## Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of \$21.3 million, current liabilities of \$1.4 million and working capital of \$20.2 million as of June 30, 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 associated with preparing for the ReMEDy2 Phase 2/3 stroke study, costs related to the REDUX Phase 2 CKD study and increased costs related manufacturing development.

Net cash used in operating activities for the six months ended June 30, 2021 was \$6.4 million compared to \$3.8 million for the six months ended June 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.

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## Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and second quarter 2021 financial results on Thursday, August 12, 2021, at 7:00AM Central Time:

Date: Thursday, August 12, 2021  
Time: 7:00 AM CT / 8:00 AM ET  
Web access: <https://event.on24.com/wcc/r/3192933/FBC5C2BE41E26E2C70F89B28EC5DB100>  
Dial In: (844) 557-8483 (domestic)  
(825) 312-2381 (international)  
Conference ID: 4148874

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 19, 2021, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), and entering the replay passcode: 4148874.

### 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 South Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke and patients with chronic kidney disease.

### About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering 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 (AIS) and chronic kidney disease (CKD). For more information visit our website at [www.diamedica.com](http://www.diamedica.com).

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## 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 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. 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, including the fact that the interim REDUX study data previously released is preliminary and interim and final results may differ materially from the data previously released; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the possibility of unfavorable results from subsequent analysis of existing or future data from the REDUX study or future studies of DM199; 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, including its 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 by DiaMedica. 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,	
	2021	2020	2021	2020
<b>Operating expenses:</b>				
Research and development	\$ 2,156	\$ 1,600	\$ 4,562	\$ 2,949
General and administrative	1,209	1,108	2,422	2,163
Operating loss	(3,365)	(2,708)	(6,984)	(5,112)
<b>Other income:</b>				
Governmental assistance - research incentives	-	(65)	-	(180)
Other income, net	(98)	(178)	(102)	(51)
Total other income	(98)	(243)	(102)	(231)
Loss before income tax expense	(3,267)	(2,465)	(6,882)	(4,881)
Income tax expense	7	9	14	18
Net loss	(3,274)	(2,474)	(6,896)	(4,899)
<b>Other comprehensive income (loss)</b>				
Unrealized gain (loss) on marketable securities	—	(13)	1	27
Net loss and comprehensive loss	\$ (3,274)	\$ (2,487)	\$ (6,895)	\$ (4,872)
Basic and diluted net loss per share	\$ (0.17)	\$ (0.17)	\$ (0.37)	\$ (0.36)
Weighted average shares outstanding – basic and diluted	18,786,157	14,139,074	18,776,461	13,623,400

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

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,228	\$ 7,409
Marketable securities	19,067	20,098
Amounts receivable	16	340
Prepaid expenses and other assets	318	74
Total current assets	<u>21,629</u>	<u>27,921</u>
Non-current assets:		
Operating lease right-of-use asset	72	100
Property and equipment, net	73	74
Total non-current assets	<u>145</u>	<u>174</u>
Total assets	<u>\$ 21,774</u>	<u>\$ 28,095</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 239	\$ 1,099
Accrued liabilities	1,132	864
Finance lease obligation	5	6
Operating lease obligation	64	59
Total current liabilities	<u>1,440</u>	<u>2,028</u>
Non-current liabilities:		
Finance lease obligation, non-current	5	7
Operating lease obligation, non-current	11	46
Total non-current liabilities	<u>16</u>	<u>53</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,786,157 and 18,746,157 shares issued and outstanding, as of June 30, 2021 and December 31, 2020, respectively	—	—
Paid-in capital	96,126	94,925
Accumulated other comprehensive loss	(3)	(2)
Accumulated deficit	(75,805)	(68,909)
Total shareholders' equity	<u>20,318</u>	<u>26,014</u>
Total liabilities and shareholders' equity	<u>\$ 21,774</u>	<u>\$ 28,095</u>

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

	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,896)	\$ (4,899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	957	829
Amortization of premium (discount) on marketable securities	38	(23)
Non-cash lease expense	28	26
Depreciation	12	11
Changes in operating assets and liabilities:		
Amounts receivable	324	504
Prepaid expenses and other assets	(244)	(146)
Accounts payable	(860)	370
Accrued liabilities	239	(494)
Net cash used in operating activities	<u>(6,402)</u>	<u>(3,822)</u>
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(25,244)	(8,799)
Maturities of marketable securities	26,235	6,000
Purchases of property and equipment	(13)	(2)
Proceeds from disposition of property and equipment	2	—
Net cash provided by (used in) investing activities	<u>980</u>	<u>(2,801)</u>
<b>Cash flows from financing activities:</b>		
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	(3)	(3)
Net cash provided by financing activities	<u>241</u>	<u>7,695</u>
Net increase (decrease) in cash and cash equivalents	(5,181)	1,072
Cash and cash equivalents at beginning of period	<u>7,409</u>	<u>3,883</u>
Cash and cash equivalents at end of period	<u>\$ 2,228</u>	<u>\$ 4,955</u>