

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, 2020

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, 2020, DiaMedica Therapeutics Inc. (the “Company”) announced its consolidated financial results for the three and six months ended June 30, 2020. 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	<u>Press Release dated August 11, 2020 providing a business update and reporting second quarter 2020 financial results (furnished herewith)</u>

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, 2020



DiaMedica Provides a Business Update and Second Quarter 2020 Financial Results

- *DiaMedica Completes \$23M Public Offering of Common Shares*
- *Diabetic Kidney Disease Cohort Added to REDUX Study*
- *Post-Offering Cash and Investments of \$32.9 Million Providing Expected Two-Year Runway*
- *Conference Call with Management Tomorrow, August 12 at 7am CT*

Minneapolis, Minnesota – August 11, 2020 (Business Wire) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for kidney diseases and neurological disorders, today provided a business update and financial results for the three and six months ended June 30, 2020. DiaMedica will host a conference call tomorrow, August 12, 2020, at 7:00 a.m. Central Time to discuss its business update and second quarter financial results.

Clinical Developments

DM199 for the Treatment of Chronic Kidney Disease

Phase II Clinical Study in CKD Caused by IgA Nephropathy, in African Americans with Hypertension – Enrollment Continues

Initiation of Third Cohort in CKD caused by Type II Diabetes Mellitus

The Phase II REDUX (latin for restore) trial is a multi-center, open-label investigation of approximately 90 evaluable participants with chronic kidney disease (CKD), who are being enrolled in three cohorts (30 per cohort). The study is being conducted in the United States and a 13th site was added in July 2020.

REDUX targets participants with CKD. Cohort I of the study is focused on non-diabetic, hypertensive African Americans with Stage II or III CKD, a group which is at greater risk for CKD than Caucasians. African Americans who have the APOL1 gene mutation are at an even higher risk. The study is designed to capture the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II of the study is focused on participants with IgA Nephropathy (IgAN). Based upon additional data from DiaMedica's completed ReMEDy study showing significantly improved estimated glomerular flow rate (eGFR) and reduced blood glucose levels, and with a portion of the net proceeds from the recent public offering of common shares, the Company is initiating a third cohort, Cohort III, focused on participants with Type II diabetes mellitus, hypertension and albuminuria.

"The addition of this diabetic cohort is timely in that it leverages our current sites, which also have this patient population," commented Dr. Harry Alcorn, Jr., DiaMedica's Chief Medical Officer. "We look forward to this cohort expanding our understanding of the potential of DM199 in the treatment of diabetic patients with kidney disease."

In a post hoc analysis of endpoints in the ReMEDy trial, a sub-set of 25 participants with elevated blood glucose levels (>7 mmol/l) and impaired kidney function (eGFR <90) were observed to experience significant (mean +12.7 mL/min, p=0.03) improvement in kidney function as measured by the estimated glomerular filtration rate compared to placebo (mean increase 12.7 mL/min, p=0.03) and a trending reduction in blood glucose levels (mean 2.2 mmol/l) compared to placebo (mean decrease 2.2 mmol/l).

The REDUX study will evaluate two dose levels of DM199 within each cohort. Study participants will receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure, albuminuria and kidney function, which will be evaluated by changes from baseline in eGFR and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR). Secondary endpoints are focused on evaluating the potential for DM199 to positively impact the underlying disease causing each participant's CKD.

As of August 5, 2020, enrollment in the first two cohorts of the REDUX study was approximately one-third complete. Due to actions implemented to combat the novel strain of the coronavirus (COVID-19) pandemic, the Company has experienced and continues to experience slower than expected enrollment in the REDUX clinical trial. The Company believes this is due to a combination of the reduction or suspension of activities at its clinical study sites as they address staff and patient safety concerns and patient concerns related to visiting clinical study sites. The Company anticipates that the COVID-19 pandemic will likely continue to adversely affect its ability to recruit or enroll subjects and cannot provide any assurance as to when clinical sites will be able to resume enrollment at a normal rate or any guidance at this time as to when it will complete enrollment in the study. The Company added a 13th study site in July 2020 to assist with subject enrollment and will consider additional sites if conditions warrant. While results observed to date in the REDUX study indicate a safety profile consistent with past studies, there is insufficient data at this time for the Company to evaluate or comment upon efficacy.

DM199 for the Treatment of Acute Ischemic Stroke

DM199 Acute Ischemic Stroke Phase II "ReMEDy" Trial – Positive Top-Line Data

DiaMedica previously announced positive top-line results from its ReMEDy trial, a Phase II study assessing the safety, tolerability and therapeutic potential of DM199 in participants suffering from acute ischemic stroke (AIS). Final enrollment was 92 participants. The study met primary safety and tolerability endpoints and there were no DM199-related serious adverse events. In addition, there was also a demonstrated therapeutic effect in participants who received tissue plasminogen activator (tPA) prior to enrollment, but not in participants receiving mechanical thrombectomy prior to enrollment.

DM199 is intended to treat the approximately 90% of AIS patients who do not receive either mechanical thrombectomy or tPA. Treatment for these patients is limited to palliative therapies. When participants treated with mechanical thrombectomy are excluded from the study data set, a positive therapeutic effect was demonstrated. As shown in the table below, participants treated with DM199 (n=25) vs. palliative therapies and/or tPA (n=21), the results showed that 36% of participants receiving DM199 progressed to a full or nearly full recovery at 90 days (National Institutes of Health Stroke Score: 0-1), compared to 14% of participants in the placebo group. This represents a 22% absolute increase in the proportion of participants achieving a full or nearly full recovery. Additionally, subject deaths decreased from 24% in the placebo group to 12% in the active therapy group, a 50% relative reduction.

DM199 vs. Palliative Therapies and/or tPA

	NIHSS Outcomes at 90 Days			
	0-1	2-8	≥ 9	Death
Placebo (n=21)	14%	57%	5%	24%
DM199 (n=24)	36%	36%	16%	12%

DiaMedica is currently developing the protocol for a proposed Phase III study of DM199 in the treatment of AIS and preparing a request for a Type B meeting with the U.S. Food and Drug Administration (FDA). The meeting request is expected to be filed shortly and, if the FDA agrees, this meeting would likely take place in the fourth quarter of 2020.

With respect to the overall ReMEDy results, prior to enrollment, 44 of the 91 evaluable patients (48%) received a mechanical thrombectomy, a catheter-based treatment indicated for those who have a large vessel occlusion and can be treated within 6 to 24 hours of the onset of stroke symptoms. While approximately 20% of AIS patients are believed to be eligible for a mechanical thrombectomy, currently only about 5% to 10% receive the treatment due to elapsed time post-stroke or unavailability of the therapy at the hospital where they present. Due to the large volume of participants receiving mechanical thrombectomy prior to enrollment in ReMEDy, and a disproportionate distribution of these participants between the active treatment and placebo groups, DM199 did not produce a therapeutic effect in the overall study analysis.

Recent Public Offering

On August 10, 2020, the Company issued and sold an aggregate of 4,600,000 common shares in a public underwritten offering at a public offering price of \$5.00 per share, receiving gross proceeds of \$23.0 million, which includes a full exercise by the underwriters of their option to purchase additional shares, and net proceeds of \$21.1 million, after deducting the underwriting discount and estimated offering expenses.

Financial Results

Research and development (R&D) expenses decreased to \$1.6 million for the three months ended June 30, 2020, down from \$1.9 million for the three months ended June 30, 2019, a decrease of \$0.3 million. R&D expenses decreased to \$3.0 million for the six months ended June 30, 2020, compared to \$4.5 million for the six months ended June 30, 2019, a decrease of \$1.5 million. The decrease for the six month comparison was due primarily to non-recurring costs of approximately \$1.3 million incurred for a new production run of the DM199 drug substance during the prior year period, and a net decrease in year-over-year clinical study costs. The decrease in clinical study costs was due to a combination of the decreased ReMEDy stroke study expenses as it winds down and Phase 1b CKD study costs which study was started and completed in the prior year period. These decreases were partially offset by costs incurred for the REDUX Phase II CKD study initiated late in 2019 and increased non-cash share-based compensation costs.

General and administrative (G&A) expenses were \$1.1 million for the three months ended June 30, 2020, up from \$867,000 for the three months ended June 30, 2019. G&A expenses increased to \$2.1 million for the six months ended June 30, 2020, up \$0.4 million, from \$1.7 million for the six months ended June 30, 2019. The increase for the six-month comparison was due primarily to increased non-cash share-based compensation costs.

Total other income decreased to \$243,000 for the three months ended June 30, 2020, down from \$280,000 for the prior year period. Total other income decreased to \$231,000 for the six months ended June 30, 2020, compared to \$458,000 for the six months ended June 30, 2019. The decrease for the six-month comparison is primarily related to reduced R&D incentives associated with decreased ReMEDy stroke study costs during the six months ended June 30, 2019, partially offset by reduced foreign currency transaction losses.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of \$11.8 million, current liabilities of \$1.2 million and working capital of \$11.2 million as of June 30, 2020, compared to \$7.9 million in cash, cash equivalents and marketable securities, \$1.3 million in current liabilities and \$7.5 million in working capital as of December 31, 2019. The increases in the Company's combined cash, cash equivalents and marketable securities and in its working capital are due primarily to the February 2020 public offering of common shares.

Net cash used in operating activities was \$3.8 million for the six months ended June 30, 2020, compared to \$6.0 million for the six months ended June 30, 2019. The net cash used in each of these periods primarily reflects the net loss for these periods, non-cash charges for stock-based compensation and adjustments for the net effects of changes in operating assets and liabilities.

Conference Call Information

DiaMedica Management will host a conference call to discuss both its second quarter 2020 financial results and the top-line results from its ReMEDy study on Wednesday, August 12, 2020, at 7:00 a.m. Central Time:

Date: Wednesday, August 12, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: <http://www.directeventreg.com/registration/event/7689626>
Conference ID: 7689626

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. All participants on the conference call will be provided with the dial-in instructions and a unique passcode once they register, this information will also be sent in an email confirmation. The webcast will remain available for play back on DiaMedica's website, under investor events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until August 13, 2020, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), replay passcode 7689626.

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. is a clinical stage biopharmaceutical company focused on developing novel treatments for chronic kidney diseases and neurological disorders. DiaMedica shares are listed on The Nasdaq Capital Market under the trading symbol “DMAC.”

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 safety and efficacy of DM199, the assessment of the data from the ReMEDy study and regulatory path forward, the timing and requirements of its clinical programs, including enrollment, clinical results and ability to achieve clinical milestones; and the anticipated use of proceeds from its recent public offering. 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 additional clinical trials of DM199 or from subsequent analysis of existing data from the ReMEDy study or existing or new data received from additional ongoing and future studies 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 CKD and AIS 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 CKD and AIS, 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, 2019, and subsequent SEC filings by DiaMedica, including its quarterly report on Form 10-Q for the quarterly period ended June 30, 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.

Contact:

Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

DiaMedica Therapeutics Inc.
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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 1,629	\$ 1,874	\$ 3,010	\$ 4,481
General and administrative	1,079	867	2,102	1,681
Operating loss	(2,708)	(2,741)	(5,112)	(6,162)
Other (income) expense:				
Governmental assistance - research incentives	(65)	(226)	(180)	(400)
Other income, net	(178)	(54)	(51)	(58)
Total other income	(243)	(280)	(231)	(458)
Loss before income tax expense	(2,465)	(2,461)	(4,881)	(5,704)
Income tax expense	9	8	18	17
Net loss	(2,474)	(2,469)	(4,899)	(5,721)
Other comprehensive income				
Unrealized gain (loss) on marketable securities	(13)	8	27	11
Net loss and comprehensive loss	\$ (2,487)	\$ (2,461)	\$ (4,872)	\$ (5,710)
Basic and diluted net loss per share	\$ (0.17)	\$ (0.21)	\$ (0.36)	\$ (0.48)
Weighted average shares outstanding – basic and diluted	14,139,074	11,979,401	13,623,400	11,968,200

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

	<u>June 30, 2020</u> (unaudited)	<u>December 31, 2019</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,955	\$ 3,883
Marketable securities	6,844	3,995
Amounts receivable	319	823
Prepaid expenses and other assets	235	47
Deposits	46	88
Total current assets	<u>12,399</u>	<u>8,836</u>
Non-current assets:		
Operating lease right-of-use asset	127	153
Property and equipment, net	55	64
Total non-current assets	<u>182</u>	<u>217</u>
Total assets	<u>\$ 12,581</u>	<u>\$ 9,053</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 552	\$ 182
Accrued liabilities	609	1,076
Finance lease obligation	6	6
Operating lease obligation	50	54
Total current liabilities	<u>1,217</u>	<u>1,318</u>
Non-current liabilities:		
Finance lease obligation, non-current	10	13
Operating lease obligation, non-current	82	105
Total non-current liabilities	<u>92</u>	<u>118</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 14,139,074 and 12,006,874 shares issued and outstanding, as of June 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	72,759	64,232
Accumulated other comprehensive income	29	2
Accumulated deficit	(61,516)	(56,617)
Total shareholders' equity	<u>11,272</u>	<u>7,617</u>
Total liabilities and shareholders' equity	<u>\$ 12,581</u>	<u>\$ 9,053</u>

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (4,899)	\$ (5,721)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	829	312
Amortization of discount on marketable securities	(23)	(53)
Non-cash lease expense	26	24
Depreciation	11	11
Changes in operating assets and liabilities:		
Amounts receivable	504	(332)
Prepaid expenses	(188)	171
Deposits	42	—
Accounts payable	370	(221)
Accrued liabilities	(494)	(196)
Net cash used in operating activities	<u>(3,822)</u>	<u>(6,005)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(8,799)	(10,928)
Maturities of marketable securities	6,000	3,000
Purchase of property and equipment	(2)	—
Disposition of property and equipment, net	—	12
Net cash used in investing activities	<u>(2,801)</u>	<u>(7,916)</u>
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	7,682	—
Proceeds from the exercise of stock options	16	75
Principal payments on finance lease obligations	(3)	(3)
Net cash provided by financing activities	<u>7,695</u>	<u>72</u>
Net increase (decrease) in cash and cash equivalents	1,072	(13,849)
Cash and cash equivalents at beginning of period	3,883	16,823
Cash and cash equivalents at end of period	<u>\$ 4,955</u>	<u>\$ 2,974</u>