

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 4, 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 November 4, 2020, DiaMedica Therapeutics Inc. (the “Company”) announced its consolidated financial results for the three and nine months ended September 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 November 4, 2020 providing a business update and reporting third 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: November 4, 2020



DiaMedica Provides a Business Update and Third Quarter 2020 Financial Results

- *Diabetic Kidney Disease Cohort Added to REDUX Study, Near Fully Enrolled*
- *FDA Grants Meeting Request for Review of Planned Stroke Study Program*
- *Completed \$23M Public Offering of Common Shares*
- *Conference Call with Management Tomorrow, November 5 at 7am CT*

Minneapolis, Minnesota – November 4, 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 nine months ended September 30, 2020. DiaMedica will host a conference call tomorrow, November 5, 2020, at 7:00 a.m. Central Time to discuss its business update and third quarter financial results.

Clinical Developments

DM199 for the Treatment of Chronic Kidney Disease

Phase II Clinical Study in CKD Caused by IgA Nephropathy and 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). REDUX targets participants with CKD. Cohort I of the study is focused on non-diabetic, hypertensive African Americans with Stage II or III CKD and albuminuria, 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 for CKD. 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). Cohort III, is focused on participants with Type II diabetes mellitus, hypertension and albuminuria. Cohort III was added based upon additional data from DiaMedica's recently completed ReMEDy Phase II acute ischemic stroke study which showed significantly improved estimated glomerular flow rates (eGFR), mean increase of 12.7mL/Min/1.73², and also reduced blood glucose levels compared to placebo in those subjects with elevated blood glucose levels at the time of enrollment.

As of October 30, 2020, DiaMedica had enrolled 49 subjects, including 11 African American subjects in Cohort I, 13 subjects with IgAN in Cohort II and 25 subjects with Type II diabetes in Cohort III. The Company has continued to experience slower than expected enrollment in the first two cohorts of the REDUX trial. This is believed to be due to a combination of the reduction or suspension of activities at clinical study sites as they address staff and patient safety concerns and patient concerns related to visiting clinical study sites in light of the COVID-19 pandemic. Note that individuals eligible for the first two cohorts are generally considered to be in the group of individuals “at-risk” for COVID-19. To increase enrollment rates, the Company has added two additional study sites and is working with existing sites to resume screening activities and to reach out to surrounding clinics for additional potential subjects. The enrollment rate for Cohort III has been much more rapid, which is directly related to the much larger population of potential subjects. The Company anticipates that the COVID-19 pandemic will likely continue to adversely affect its ability to recruit or enroll subjects, and it cannot provide any assurance as to when clinical sites will be able to resume enrollment in Cohorts I and II at a normal rate or any guidance at this time as to when it will complete enrollment in the study. DiaMedica expects enrollment in Cohort III to complete by the end of the year with topline results available in the first half of 2021.

“While we are very pleased with the enrollment rate in Cohort III, we remain disappointed with the COVID-19 limitations impacting the ability of our sites to identify patients willing and eligible to participate in Cohorts I and II. We remain in close contact with our study sites to monitor local restrictions and explore options,” commented Dr. Harry Alcorn, Jr., DiaMedica’s Chief Medical Officer. “Recently, we have also added sites and will continue to evaluate additional sites and recruitment options in order to complete enrollment in our REDUX study.”

DM199 for the Treatment of Acute Ischemic Stroke

FDA Accepts Request for Type B Meeting

DiaMedica today announced that the US Food and Drug Administration (FDA) has accepted the Company’s request for a Type B meeting to review the Company’s cumulative clinical and nonclinical development, its proposed Phase 2/3 clinical study design and other regulatory questions regarding its planned AIS clinical program. The FDA indicated that it would provide written responses to the Company’s questions by December 4, 2020. Earlier this week, the Company provided a detailed package of information to the FDA.

\$23 Million 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 \$21.2 million, after deducting the underwriting discount and estimated offering expenses. As previously announced, DiaMedica is using the net proceeds from the offering to add a third cohort to its REDUX trial to study participants with chronic kidney disease and Type II diabetes mellitus, to continue its clinical study of DM199 in acute ischemic stroke and for other working capital and general corporate purposes.

Financial Results

Research and development (R&D) expenses increased to \$2.2 million for the three months ended September 30, 2020, up from \$1.6 million for the three months ended September 30, 2019, an increase of \$0.6 million, due primarily to costs incurred in connection with the REDUX trial, including the launching of Cohort III. R&D expenses decreased to \$5.2 million for the nine months ended September 30, 2020, compared to \$6.1 million for the nine months ended September 30, 2019, a decrease of \$0.9 million. The decrease for the nine-month comparison was primarily due to non-recurring costs of approximately \$1.3 million incurred for a new production run of the DM199 drug substance during the nine-months ended September 30, 2019 and a net decrease in year-over-year clinical study costs. The decrease in clinical study costs was due to a combination of the decrease in costs incurred for the ReMEDy stroke study as it wound down and non-recurring costs of the Phase 1b CKD study which was started and completed in the prior year period. These decreases were partially offset by costs incurred for the REDUX trial initiated late in 2019, increased manufacturing development costs and increased non-cash share-based compensation costs.

General and administrative (G&A) expenses were \$1.1 million for the three months ended September 30, 2020, up from \$1.0 million for the three months ended September 30, 2019. G&A expenses increased to \$3.2 million for the nine months ended September 30, 2020, up \$0.5 million from \$2.7 million for the nine months ended September 30, 2019. The increase for the nine-month comparison was primarily due to increased non-cash share-based compensation costs and increased professional service costs.

Total other income decreased to \$128,000 for the three months ended September 30, 2020, down from \$225,000 for the prior year period. Total other income decreased to \$359,000 for the nine months ended September 30, 2020, compared to \$683,000 for the nine months ended September 30, 2019. The decrease for the nine-month comparison is primarily related to reduced R&D incentives associated with decreased ReMEDy stroke study costs during the nine months ended September 30, 2020, partially offset by foreign currency transaction gains recognized in the current year.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of \$30.6 million, current liabilities of \$1.4 million and working capital of \$29.7 million as of September 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 Company's February and August 2020 public offerings.

Net cash used in operating activities was \$6.2 million for the nine months ended September 30, 2020, compared to \$7.2 million for the nine months ended September 30, 2019. The net cash used in each of these periods primarily reflects the net loss for these periods, non-cash charges for share-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 its third quarter 2020 financial results and business update on Thursday, November 5, 2020, at 7:00 a.m. Central Time:

Date: Thursday, November 5, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: <https://event.on24.com/wcc/r/2623032/5A77F53289171F7E16245B392065B627>
Conference ID: 4869514

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 events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until November 12, 2020, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), replay passcode 4869514.

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 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 September 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:

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DiaMedica Therapeutics Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 2,180	\$ 1,617	\$ 5,190	\$ 6,098
General and administrative	1,139	1,044	3,241	2,725
Operating loss	(3,319)	(2,661)	(8,431)	(8,823)
Other (income) expense:				
Governmental assistance - research incentives	(25)	(263)	(205)	(663)
Other (income) expense, net	(103)	38	(154)	(20)
Total other income	(128)	(225)	(359)	(683)
Loss before income tax expense	(3,191)	(2,436)	(8,072)	(8,140)
Income tax expense	2	12	20	29
Net loss	(3,193)	(2,448)	(8,092)	(8,169)
Other comprehensive income				
Unrealized gain (loss) on marketable securities	(19)	(5)	8	6
Net loss and comprehensive loss	\$ (3,212)	\$ (2,453)	\$ (8,084)	\$ (8,163)
Basic and diluted net loss per share	\$ (0.19)	\$ (0.20)	\$ (0.55)	\$ (0.68)
Weighted average shares outstanding – basic and diluted	16,689,074	12,006,874	14,652,749	11,981,233

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,797	\$ 3,883
Marketable securities	20,826	3,995
Amounts receivable	335	823
Prepaid expenses and other assets	138	47
Deposits	10	88
Total current assets	<u>31,106</u>	<u>8,836</u>
Non-current assets:		
Operating lease right-of-use asset	114	153
Property and equipment, net	50	64
Total non-current assets	<u>164</u>	<u>217</u>
Total assets	<u>\$ 31,270</u>	<u>\$ 9,053</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 720	\$ 182
Accrued liabilities	658	1,076
Finance lease obligation	6	6
Operating lease obligation	59	54
Total current liabilities	<u>1,443</u>	<u>1,318</u>
Non-current liabilities:		
Finance lease obligation, non-current	8	13
Operating lease obligation, non-current	61	105
Total non-current liabilities	<u>69</u>	<u>118</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,739,074 and 12,006,874 shares issued and outstanding, as of September 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	94,457	64,232
Accumulated other comprehensive income	10	2
Accumulated deficit	(64,709)	(56,617)
Total shareholders' equity	<u>29,758</u>	<u>7,617</u>
Total liabilities and shareholders' equity	<u>\$ 31,270</u>	<u>\$ 9,053</u>

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (8,092)	\$ (8,169)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,337	763
Amortization of discount on marketable securities	(24)	(68)
Non-cash lease expense	39	36
Depreciation	16	16
Changes in operating assets and liabilities:		
Amounts receivable	488	116
Prepaid expenses	(91)	280
Deposits	78	(39)
Accounts payable	538	(171)
Accrued liabilities	(458)	(1)
Net cash used in operating activities	<u>(6,169)</u>	<u>(7,237)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(25,048)	(10,928)
Maturities of marketable securities	8,249	6,000
Purchase of property and equipment	(2)	—
Disposition of property and equipment, net	—	12
Net cash used in investing activities	<u>(16,801)</u>	<u>(4,916)</u>
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	28,872	—
Proceeds from the exercise of stock options	16	75
Principal payments on finance lease obligations	(4)	(4)
Net cash provided by financing activities	<u>28,884</u>	<u>71</u>
Net increase (decrease) in cash and cash equivalents	5,914	(12,082)
Cash and cash equivalents at beginning of period	3,883	16,823
Cash and cash equivalents at end of period	<u>\$ 9,797</u>	<u>\$ 4,741</u>