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 13, 2019**

DIAMEDICA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

British Columbia	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Carlson Parkway, Suite 260 **Minneapolis, Minnesota**	**55447**
(Address of principal executive offices)	(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 November 13, 2019, DiaMedica Therapeutics Inc. (the "Company") announced its condensed consolidated financial results for the quarter ended September 30, 2019. 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 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" 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*.

Exhibit No.	Description
99.1	Press Release dated November 13, 2019 providing a business update and reporting third quarter 2019 financial results (furnished herewith)

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 13, 2019

DiaMedica Therapeutics Announces Third Quarter 2019 Financial Results and Provides Business Update

- ***Phase II Study of DM199 in Chronic Kidney Disease Commences Screening***
- ***REMEDY Phase II Study of DM199 in Acute Ischemic Stroke Completes Enrollment***
- ***Management Team Strengthens with Sydney Gilman, Ph.D., Vice President of Regulatory Affairs***
- ***Conference Call with Management Tomorrow, November 14 at 7am CT***

Minneapolis, Minnesota – November 13, 2019 (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 reported its financial results for the three and nine months ended September 30, 2019.

Clinical Developments

DM199 for the Treatment of Chronic Kidney Disease

Phase Ib Clinical Study in Patients with CKD Completed

DiaMedica has completed its Phase Ib clinical trial of DM199, a recombinant form of the endogenous human tissue kallikrein protein (KLK1), in patients with moderate or severe Chronic Kidney Disease (CKD) caused by Type I or Type II diabetes mellitus. The study was performed to assess the pharmacokinetics (PK) of three dose levels of DM199 (3, 5 and 8 µg/kg), administered in a single subcutaneous dose, as well as the evaluation of safety, tolerability and secondary pharmacodynamic (PD) endpoints.

The Company previously announced positive interim results. PK profiles, at the 3µg/kg dose level, were similar between moderate and severe CKD patients, and consistent with healthy subjects (normal kidney function) tested previously. Therefore, the Company does not believe dosing adjustment is warranted, based on the presence or severity of CKD and a full renal study will likely not be required. Final study results indicated that DM199 was observed to be well tolerated with no dose-limiting tolerability. There were no deaths, no discontinuations due to a treatment-related adverse event (AE), and no treatment-related significant adverse events (SAEs). AEs were minor and consistent with standard treatment(s) in the CKD patient population.

Favorable overall PD results were also observed including short-term improvements in Nitric Oxide (NO), average increase of 35.2%, Prostaglandin E2 (PGE2), average increase of 41.2%, estimated glomerular flow rate (eGFR), average increase of 4.08 mL/min/173^2, and the urinary albumin to creatinine ratio (UACR), average decrease of 18.7%. PD results appeared to be drug related in that greatest improvements occurred at approximately 24 hours after DM199 administration and subsequently declined.

DiaMedica intends to release full study results at an upcoming conference, including a breakout analysis of moderate and severe patients and results by dose level.

Phase II Clinical Study in CKD Caused by IgA Nephropathy and African Americans with Hypertension – Screening Commenced

The U.S. Food and Drug Administration (FDA) has accepted the Company's Phase II clinical trial protocol for the treatment of CKD caused by rare or significant unmet diseases. This study is designed to investigate the safety, efficacy, PK and PD of DM199. Screening of patients has commenced and the enrollment and dosing is expected in the near term.

The Phase II trial named REDUX, latin for restore, is a multi-center, open-label investigation of approximately 60 participants with CKD, who are being enrolled in two cohorts (30 per cohort). The study is being conducted in the United States at up to 10 sites and will be focused on participants with CKD: Cohort I is focused on non-diabetic, hypertensive African Americans with Stage II or III CKD. African Americans are at greater risk for CKD than Caucasians, and those 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 is focused on participants with IgA Nephropathy (IgAN). The 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, proteinuria and kidney function, which will be evaluated by changes from baseline in eGFR and albuminuria, as measured by the UACR.

"We are pleased with the results from our CKD Phase Ib study and our ability to now commence Phase II studies," commented Dr. Harry Alcorn, DiaMedica's Chief Medical Officer. "We look forward to our Phase II study building on our successful Phase Ib data and we have engaged a number of study sites that have the patient populations and experience in obtaining high quality data to better understand the potential of DM199 in benefitting individuals suffering with CKD, whose current treatment options are very limited."

DM199 for the Treatment of Acute Ischemic Stroke

DM199 Acute Ischemic Stroke Phase II "REMEDY" Trial Update – Enrollment Completed

DiaMedica has recently completed enrollment in the REMEDY trial, the Company's Phase II study assessing the safety, tolerability and markers of therapeutic efficacy of DM199 in participants suffering from Acute Ischemic Stroke (AIS). Final enrollment was 92 participants. The markers of therapeutic efficacy will include multiple plasma-based biomarkers (e.g. C-reactive protein), the Modified Rankin Scale, National Institutes of Health Stroke Scale and the Barthel Index. These markers are assessed at multiple points throughout the study, including 90 days post-stroke.

Organizational Update

Dr. Sydney A. Gilman has joined DiaMedica as its Vice President of Regulatory Affairs. Dr. Gilman has over 30 years of pharmaceutical industry experience holding senior positions including at Elan Pharmaceuticals and Amylin Pharmaceuticals. Dr. Gilman also spent six years as a CMC reviewer with the FDA's Center for Drug Evaluation and Research group. In his most recent role as founder and Senior Regulatory Consultant of Trident Rx Consulting, Dr. Gilman has been involved in the development and implementation of strategic plans for drug development and regulatory strategy for new drugs and biologics. In addition he has lead a variety of global regulatory submissions, including INDs, NDAs, BLAs, MAAs, global CTAs, 510Ks, PMAs, orphan and Fast Track submissions, and clinical study reports.

"We continue to make great progress with our clinical programs with the commencement of our Phase II CKD studies and the completion of enrollment in our REMEDY Phase II study, and I wish to thank our clinical team for their skill and dedication," stated Rick Pauls, DiaMedica's President and CEO. " I would also like to welcome Dr. Gilman, who is a strong addition at this critical time. His proven track record in leading regulatory affairs is instrumental as we transition DM199 into Phase II and Phase III clinical trials and work to improve the lives of CKD and AIS patients."

Financial Results

Research and development (R&D) expenses increased to $1.6 million for the three months ended September 30, 2019, up from $1.2 million for the three months ended September 30, 2018, an increase of $0.4 million. R&D expenses increased to $6.1 million for the nine months ended September 30, 2019, compared to $3.1 million for the nine months ended September 30, 2018, an increase of $3.0 million. The increase for the nine months ended September 30, 2019 was due to costs of approximately $1.4 million incurred for a new production run of the DM199 drug substance, as well as costs incurred in conjunction with the Phase Ib and Phase II clinical studies in CKD patients and related non-clinical testing. Increased personnel and non-cash share-based compensation costs also contributed to the increase. The increase for the three months ended September 30, 2019 was due to costs incurred in conjunction with the Phase Ib and Phase II CKD studies and non-cash share-based compensation costs, partially offset by a decline in costs incurred in conjunction with the REMEDY Phase II stroke study.

General and administrative (G&A) expenses were $1.0 million for the three months ended September 30, 2019, compared to $777,000 for the three months ended September 30, 2018. G&A expenses increased to $2.7 million for the nine months ended September 30, 2019, up from $2.1 million for the nine months ended September 30, 2018. These increases were primarily due to costs associated with our status as a Nasdaq-listed U.S. public reporting company, which commenced in December 2018, including increased professional services, compliance and non-cash share-based compensation costs. Increased personnel costs also contributed to the increase on a year to date basis.

Total other income increased to $225,000 for the three months ended September 30, 2019, up from $157,000 for the prior year period. Total other income decreased to $683,000 for the nine months ended September 30, 2019, compared to $946,000 for the nine months ended September 30, 2018. The year-to-date decrease is primarily related to the initial recognition of R&D incentives from the Australian Government paid for qualifying research work performed by DiaMedica Australia Pty Ltd. during the nine months ended September 30, 2018. The increase in the quarterly comparison relates to increased study costs, compared to the prior year period, driving an increase in the eligible R&D incentive. The year-to-date decrease was partially offset by, and the current quarter increase was augmented by, increased interest income earned on marketable securities during the three and nine months ended September 30, 2019.

Balance Sheet and Cash Flow

The Company had cash and cash equivalents of $4.7 million, marketable securities of $5.0 million, current liabilities of $1.3 million and working capital of $9.6 million as of September 30, 2019, compared to $16.8 million in cash and cash equivalents, $1.3 million in current liabilities and $16.7 million in working capital as of December 31, 2018. The decreases in combined cash and cash equivalents and marketable securities and in working capital are due primarily to the Company's operating loss incurred for the nine months ended September 30, 2019.

Net cash used in operating activities was $7.2 million for the nine months ended September 30, 2019, compared to $3.8 million for the nine months ended September 30, 2018. The net cash used in each of these periods primarily reflects the net loss for these periods, and was partially offset by non-cash charges for stock-based compensation and the net effects of changes in operating assets and liabilities.

Conference Call Information

DiaMedica management will host a conference call to discuss these results on Thursday, November 14, 2019, at 7:00 a.m. Central Time:

Date:	Thursday, November 14, 2019
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://event.on24.com/wcc/r/2120577/625481B71D93A3177784DC7A779612B0
Dial In:	(844) 557-8483 (domestic)
	(825) 312-2381 (international)
Conference ID:	4594493

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 our 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 21, 2019, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), replay passcode 4594493.

About DM199

DM199 is a recombinant (synthetic) form of the human serine protease, KLK1. The KLK1 protein 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

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 STATEMENT 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 success of DM199, the timing and requirements of its clinical programs, including enrollment and 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, 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; the perceived benefits of DM199 over existing treatment options; ability to obtain required regulatory approvals; the potential size of the markets for DM199 and its ability to serve those markets; the success, cost and timing of planned clinical trials, as well as reliance on collaboration with third parties to conduct clinical trials; its ability 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, 2018, and subsequent SEC 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.

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,	
	2019	**2018**	**2019**	**2018**
Operating revenues:				
License revenues	$ —	$ 500	$ —	$ 500
Operating expenses:				
Research and development	1,617	1,210	6,098	3,071
General and administrative	1,044	777	2,725	2,073
Operating loss	(2,661)	(1,487)	(8,823)	(4,644)
Other (income) expense:				
Governmental assistance - research incentives	(263)	(196)	(663)	(1,046)
Other (income) expense, net	38	39	(20)	61
Change in fair value of warrant liability	—	—	—	39
Total other (income) expense	(225)	(157)	(683)	(946)
Loss before income tax expense	(2,436)	(1,330)	(8,140)	(3,698)
Income tax expense	12	57	29	74
Net loss	(2,448)	(1,387)	(8,169)	(3,772)
Other comprehensive income				
Unrealized (gain) loss on marketable securities	5	—	(6)	—
Net loss and comprehensive loss	$ (2,453)	$ (1,387)	$ (8,163)	$ (3,772)
Basic and diluted net loss per share	$ (0.20)	$ (0.18)	$ (0.68)	$ (0.51)
Weighted average shares outstanding – basic and diluted	12,006,874	7,836,683	11,981,233	7,406,378

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

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,741	$ 16,823
Marketable securities	5,002	—
Amounts receivable	664	780
Deposits	310	—
Prepaid expenses and other assets	89	369
Total current assets	10,806	17,972
Non-current assets:		
Operating lease right-of-use asset	165	—
Property and equipment, net	68	96
Deposits	—	271
Total non-current assets	233	367
Total assets	$ 11,039	$ 18,339
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 312	$ 483
Accrued liabilities	837	808
Finance lease obligation	5	5
Operating lease obligation	51	—
Total current liabilities	1,205	1,296
Non-current liabilities:		
Finance lease obligation, non-current	14	18
Operating lease obligation, non-current	120	—
Total non-current liabilities	134	18
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 12,006,874 and 11,956,874 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	63,831	62,993
Accumulated other comprehensive income	6	—
Accumulated deficit	(54,137)	(45,968)
Total shareholders' equity	9,700	17,025
Total liabilities and shareholders' equity	$ 11,039	$ 18,339

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (8,169)	$ (3,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	763	555
Amortization of discount on marketable securities	(68)	—
Non-cash lease expense	36	—
Depreciation	16	10
Change in fair value of warrant liability	—	39
Changes in operating assets and liabilities:		
Amounts receivable	116	(963)
Prepaid expenses	280	(99)
Deposits	(39)	—
Accounts payable	(171)	(264)
Accrued liabilities	(1)	698
Net cash used in operating activities	(7,237)	(3,796)
Cash flows from investing activities:		
Purchase of marketable securities	(10,928)	—
Maturities of marketable securities	6,000	—
Disposition of property and equipment, net	12	—
Purchase of property and equipment	—	(63)
Net cash used in investing activities	(4,916)	(63)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	75	43
Principal payments on finance lease obligations	(4)	—
Proceeds from issuance of common shares and warrants, net of offering costs	—	5,840
Proceeds from the exercise of common share purchase warrants	—	521
Net cash provided by financing activities	71	6,404
Net increase (decrease) in cash and cash equivalents	(12,082)	2,545
Cash and cash equivalents at beginning of period	16,823	1,353
Cash and cash equivalents at end of period	$ 4,741	$ 3,898