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): **January 3, 2019**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Canada	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 7.01. Regulation FD Disclosure.

On January 3, 2019, DiaMedica Therapeutics Inc. (the "Company") announced that the United States Food and Drug Administration ("FDA") has accepted the Company's Investigational New Drug application ("IND") for the initiation of a Phase Ib clinical trial of DM199 in patients with moderate or severe Chronic Kidney Disease ("CKD") caused by Type I or Type II diabetes. A copy of the Company's press release announcing the FDA's acceptance of the IND is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information included in this Current Report on Form 8-K under this Item 7.01 (including Exhibit 99.1 hereto) is being "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the United States Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing. The information included in this report under this Item 7.01 (including Exhibit 99.1 hereto) will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 8.01. Other Events.

On January 3, 2019, the Company announced that the FDA has accepted the Company's IND for the initiation of a Phase Ib clinical trial of DM199 in patients with moderate or severe CKD caused by Type I or Type II diabetes.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated January 3, 2019

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: January 3, 2019

Exhibit 99.1

DiaMedica Announces FDA Clearance of IND Application To Study DM199 in Patients with Chronic Kidney Disease

Minneapolis, Minnesota – (Globe Newswire – January 3, 2019) – DiaMedica Therapeutics Inc. (“DiaMedica”) (NASDAQ:DMAC) (TSX-V:DMA) announced today that the U.S. Food and Drug Administration ("FDA") has accepted DiaMedica’s Investigational New Drug application ("IND") for the initiation of a Phase Ib clinical trial of DM199 in patients with moderate or severe Chronic Kidney Disease (“CKD”) caused by Type I or Type II diabetes. The multi-site clinical study will enroll 32 subjects to evaluate DM199 safety, tolerability and drug levels (pharmacokinetics) in this specific population. The study will enroll subjects over a 12 day period and will also include other end points that include renal biomarkers.

The results from this Phase Ib study will assist DiaMedica in the design of upcoming Phase II studies in patients suffering from rare diseases and CKD. The DM199 drug levels from this Phase Ib study will also help determine the optimal dose levels for testing in the Phase II studies.

Dr. Harry Alcorn, DiaMedica’s Chief Medical Officer commented, “The FDA has accepted our IND and protocol for the Phase Ib study and we are excited to initiate our first clinical trial with DM199 in patients with CKD caused by T1D or T2D in the United States.” Dr Alcorn further commented “We believe that DM199 has the potential to significantly improve the lives of patients with mild, moderate or severe CKD and we look forward to performing the clinical research required to evaluate DM199’s potential benefits.”

We are very pleased with the clinical team’s progress, both with finalizing the IND with the FDA and the selection of key clinical trial sites that have the knowledge and experience in conducting these types of studies in patients with kidney disease,” commented Rick Pauls, DiaMedica’s Chief Executive Officer. “We anticipate completing the Phase Ib study by mid-2019 and the Phase II study in Q4 2019 or Q1 2020.”

About CKD

CKD is a widespread health problem that generates significant economic burden throughout the world. According to the National Kidney Foundation, 30 million Americans and 120 million Chinese suffer from this debilitating and potentially life-threatening condition. CKD is a progressive condition causing the kidneys to lose function over time, increasing the risk of premature death, cardiovascular events, and hospitalization. End stage renal disease (“ESRD”) is the final stage of CKD and requires ongoing dialysis or a kidney transplant to survive, but many patients suffer serious health consequences or die from CKD prior to developing ESRD. Currently, there is no cure for CKD and treatment focuses on managing the symptoms of the disease. Blood pressure medications, such as angiotensin converting enzyme inhibitors (“ACEi”) or angiotensin receptor blockers (“ARB”), are often prescribed to control hypertension, and hopefully, slow the progression of CKD. Nevertheless, according to the National Kidney Foundation, many patients continue to show declining kidney function. DiaMedica believes DM199 offers a potentially novel approach for the treatment of CKD by managing KLK1 levels, as this protein plays a vital role in normal kidney function. Since patients with moderate to severe CKD often excrete abnormally low levels of KLK1 in their urine, DiaMedica believes that DM199 may prevent or reduce further kidney damage by replenishing endogenous KLK1 and restoring the protective kallikrein-kinin system to regulate the production and release of nitric oxide and prostacyclin.

About DM199

DM199 is a recombinant form of human tissue kallikrein-1 ("KLK1"). KLK1 is an endogenous serine protease (protein) produced in the kidneys, pancreas and salivary glands, which plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels which decreases blood pressure) in the body, as well as an important role in managing inflammation and oxidative stress (an imbalance between potentially damaging reactive oxygen species, or free radicals, and antioxidants in your body). 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 (pig) pancreas and human urine, has been used to treat patients in Japan, China and Korea. DM199 is currently being studied in a Phase II trial in patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company focused on developing novel treatments for neurological and kidney diseases. DiaMedica's common shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC" and on the TSX Venture Exchange under the trading symbol "DMA."

For more information, please visit www.diamedica.com, or follow us on **Twitter** (https://twitter.com/diamedica). To be added to the Company's email list and receive news directly, please visit https://ir.diamedica.com/email-alerts.

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", "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 design of the clinical trials and the anticipated timing of the expected completion of the Phase Ib and Phase II clinical trials. 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 our 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 its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 for CKD; the perceived benefits of DM199 over existing treatment options for CKD; ability to obtain required regulatory approvals of DM199 for CKD; 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 the risks identified under the heading "Risk Factors" in DiaMedica's final prospectus filed with the U.S. Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) promulgated under the U.S. Securities Act of 1933, as amended, dated December 6, 2018, in connection with DiaMedica's Registration Statement on Form S-1, as amended, 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.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of the contents of this press release.

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