# 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 12, 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**<br>**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 1.02. Termination of Definitive Material Agreement.**

As previously disclosed, DiaMedica Therapeutics Inc. (the "Company") in September 2018 entered into a license and collaboration agreement with Ahon Pharmaceutical Co., Ltd. ("Ahon Pharma"), which granted Ahon Pharma exclusive rights to develop and commercialize DM199 for acute ischemic stroke in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, the Company received an upfront payment of $500,000 on signing and was entitled to receive an additional payment of $4.5 million upon the earlier of regulatory clearance to initiate a clinical trial in China or July 1, 2019. The Company also had the potential to receive up to an additional $27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories were the sole responsibility of Ahon Pharma. On August 12, 2019, after extensive good faith discussions between Ahon Pharma and the Company, the parties were unable to agree upon mutually acceptable revised terms to the agreement and the Company terminated the agreement for non-payment of the $4.5 million milestone, thereby regaining worldwide rights for DM199 for acute ischemic stroke.

**Item 2.02. Results of Operations and Financial Condition.**

On August 13, 2019, the Company announced its condensed consolidated financial results for the quarter ended June 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 August 13, 2019 provided a business update and reported second 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: August 13, 2019

# DiaMedica Therapeutics Announces Second Quarter 2019 Financial Results and Provides Business Update

- ***Phase Ib study of DM199 in Chronic Kidney Disease enrollment complete***
- ***Encouraging early signals in mechanism biomarkers (NO and PGE2), Kidney function (eGFR) and urine albumin (UACR)***
- ***Phase II CKD protocol submitted, trial initiation expected H2 2019 with interim analysis Q1 2020***
- ***DiaMedica regains global rights to DM199 in acute ischemic stroke as a result ofits termination of Chinese license agreement***
- ***Conference call with management tomorrow, August 14, 2019 at 7am CT***

**Minneapolis, Minnesota – (Globe Newswire – August 13, 2019)** – 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 six months ended June 30, 2019.

**Clinical Developments**

***DM199 for the Treatment of Chronic Kidney Disease***

*Enrollment Complete in Phase Ib Clinical Study in Patients with CKD*

DiaMedica has completed enrollment and patient follow-up in its Phase Ib clinical trial of DM199 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.

As previously announced, interim results were positive. PK profiles, at the 3µg/kg dose level, were similar between moderate and severe CKD patients, and consistent with healthy subjects 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. Further, the Company believes that study results support the determination of a dose range to normalize KLK1 levels in CKD patients for its upcoming Phase II study work.

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%, eGFR, average increase of 4.08 mL/min/$173^2$, and 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.

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 SAEs. AEs were minor and consistent with standard treatment(s) in the CKD patient population.

DiaMedica is currently collecting results from the final four study subjects and expects to provide full results of the study in a peer-reviewed publication and/or poster presentation.

*Phase II Clinical Study in IgA Nephropathy and African Americans with Hypertension and CKD*

The Company has submitted a protocol to the U.S. Food and Drug Administration for its Phase II, multiple cohort study in patients with CKD caused by rare or significant unmet diseases. This study is anticipated to start in the second half of 2019. The target causes for two cohorts are IgA Nephropathy and Hypertensive African Americans with CKD.

One cohort is expected to enroll 30 subjects previously diagnosed with CKD caused by IgA nepropathy ("IgAN"). IgAN is a kidney disease that occurs when pathogenic immunoglobulin A (IgA) builds up in a patient's kidney resulting in mesangial depositions causing inflammation and impairing the kidney's filtration abilities. Approximately 140,000 people in the US suffer from IgAN, making it a rare disease, with no approved treatments. DM199 has the potential to treat IgAN through increasing Tregs, addressing the underlying autoimmune problems of IgAN, and thereby improving overall kidney function. The Company anticipates that a Phase III trial, based on other products currently in development, will require 200-400 subjects treated for 9 to 12 months for initial approval.

An additional cohort will enroll 30 hypertensive, non-diabetic African Americans with CKD, including both those with and without the APOL1 gene mutation. The APOL1 gene mutation accounts for a significant increase in the risk for chronic and end stage kidney disease in this patient population. There are approximately 7 million African Americans with CKD in the U.S. and they are three to four times more likely to suffer kidney failure than Caucasians. African Americans with the CKD and the APOL1 gene mutation (~15% of African American population) are two times more likely to progress into end stage renal disease than African Americans without the APOL1 gene. African Americans with CKD exhibit lower levels of KLK1, reduced renal blood flow and, 73% of those that are hypertensive, are salt sensitive, meaning less able to regulate sodium and potassium levels in the body; DM199 has the potential to be a successful treatment given its ability to replenish KLK1 levels and restore the function of the KKS, the results of which improve renal blood flow and regulation of sodium/potassium levels. KLK1 has also been shown to be more effective in salt sensitive pre-clinical models. There are currently no approved therapies for African Americans with CKD.

"We are pleased with the the results from our CKD Phase 1b study which confirmed the safety, tolerability and consistent PK of DM199," commented Dr. Harry Alcorn, DiaMedica's Chief Medical Officer. "This 32 patient study completed without any significant adverse events consistent with prior studies and further confirms the safety profile of DM199 and established a sound basis for determing dose levels for our upcoming Phase II study."

***DM199 for the Treatment of Acute Ischemic Stroke***

*DM199 Acute Ischemic Stroke Phase II "REMEDY" Trial Update*

The REMEDY trial continues to enroll subjects and there have been no drug-related serious adverse events. Enrollment has passed the two-thirds mark and is continuing at 12 sites and the Company expects to complete this trial in the fourth quarter of 2019 or first quarter of 2020.

In the REMEDY trial, study drug (DM199 or placebo) is administered as an intravenous ("IV") infusion within 24 hours of stroke symptom onset, followed by SC injections later that day and once every 3 days for 21 days (8 SC doses). Multiple plasma-based biomarkers (e.g. C-reactive protein), the Modified Rankin Scale, National Institutes of Health Stroke Scale and the Barthel Index are assessed at multiple points throughout the study, including 90 days post-stroke. This study also includes additional tests to further investigate DM199's therapeutic potential.

"We are very pleased to have completed the enrollment in our Phase Ib study in CKD patients and with the continued progress of the enrollment in our REMEDY Phase II study," stated Rick Pauls, DiaMedica's President and CEO. "With the submission of the protocol for our Phase II study in CKD, we are excited to turn our attention to engaging study sites and once again, we also wish to extend our sincere gratitude to the study sites, physician investigators and study subjects for their support in completing our Phase Ib study of DM199 for patients suffering from chronic kidney disease."

**Advancing American Kidney Health Initiative**

On July 10, President Donald Trump signed an executive order to launch Advancing American Kidney Health, a new initiative to improve the lives of Americans suffering from kidney disease. This groundbreaking proposal is focused on improving outcomes, lowering health system costs and offering quality-of-life benefits for patients with CKD. CKD impacts the lives of more than 30 million Americans; of those, more than 700,000 have end stage renal disease ("ESRD"), or kidney failure, and require dialysis treatment or an organ transplant to survive. The first goal identified in the executive order is a 25% reduction in the number of Americans developing ESRD by 2030. DiaMedica believes that DM199 may become an important treatment for CKD and may provide doctors an important therapeutic option to directly treat CKD and assist in reducing the number of patients progressing to ESRD.

**DiaMedica Regains Worldwide Rights for DM199 for Acute Ischemic Stroke**

In September 2018, the Company licensed DM199 for the clinical development and commercialization of DM199 for the treatment of acute ischemic stroke in China to Ahon Pharmaceutical Co Ltd (Ahon Pharma). On August 12, 2019, after extensive good faith discussions between Ahon Pharma and the Company, the parties were unable to agree upon mutually acceptable revised terms to the agreement and DiaMedica terminated this license agreement due to Ahon Pharma's non-payment of the milestone due upon the earlier of regulatory clearance to initiate a clinical trial in China or July 1, 2019. As a result of this termination, DiaMedica has regained worldwide rights for DM199 for acute ischemic stroke.

Despite the non-receipt of this milestone payment, the Company expects its current cash resources to be sufficient to allow it to complete the first two cohorts in the Phase II CKD study and the Phase II study in AIS and fund its planned operations into the fourth quarter of 2020.

**Financial Results**

Research and development expenses increased to $1.9 million for the three months ended June 30, 2019, up from $1.1 million for the three months ended June 30, 2018, an increase of $0.8 million. R&D expenses increased to $4.5 million for the six months ended June 30, 2019, compared to $1.9 million for the six months ended June 30, 2018, an increase of $2.6 million. The increase for the six months ended June 30, 2019, was due to costs of approximately $1.3 million incurred for a new production run of the DM199 drug substance, as well as costs incurred in conjunction with the Phase Ib clinical study in CKD patients and increased year over year costs for the REMEDY Phase II stroke study. Increased personnel costs also contributed to the increase.

General and administrative expenses were $867,000 for the three months ended June 30, 2019, compared to $780,000 for the three months ended June 30, 2018. G&A expenses increased to $1.7 million for the six months ended June 30, 2019, up from $1.3 million for the six months ended June 30, 2018. On a year-to-date basis, this increase was primarily due to costs associated with our status as a Nasdaq-listed U.S. public reporting company, which commenced in December 2018, and increased personnel costs, partially offset by a reduction in non-cash charges for share-based compensation.

Total other income increased to $280,000 for the three months ended June 30, 2019, up from $131,000 for the prior year period. Total other income decreased to $458,000 for the six months ended June 30, 2019, compared to $789,000 for the six months ended June 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 six months ended June 30, 2018. The current quarter other income primarily relates to increased study costs, compared to the prior year period, driving an increase in the related 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 six months ended June 30, 2019.

**Balance Sheet and Cash Flow**

The Company had cash and cash equivalents of $3.0 million, marketable securities of $8.0 million, current liabilities of $947,000 and working capital of $11.3 million as of June 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 six months ended June 30, 2019.

Net cash used in operating activities was $6.0 million for the six months ended June 30, 2019, compared to $2.0 million for the six months ended June 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 Wednesday, August 14, 2019, at 7:00 a.m. Central Time:

| | |
|---|---|
| Date: | Wednesday, August 14, 2019 |
| Time: | 7:00 AM CT |
| Web access: | **https://edge.media-server.com/mmc/p/xd9aks84** |
| Dial In: | (866) 962-3583 (domestic) |
| | (630) 652-5857 (international) |
| Conference ID: | 9274148 |

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 August 20, 2019, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), replay passcode 9274148.

**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 prostacyclin. 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 acute ischemic stroke and patients with chronic kidney disease.

**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's 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," "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 completed 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 acute ischemic stroke ("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:**

Scott Kellen
Chief Financial Officer
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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, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Operating expenses: | | | | |
| Research and development | $ 1,874 | $ 1,070 | $ 4,481 | $ 1,861 |
| General and administrative | 867 | 780 | 1,681 | 1,295 |
| Operating loss | (2,741) | (1,850) | (6,162) | (3,156) |
| | | | | |
| Other (income) expense: | | | | |
| Governmental assistance - research incentives | (226) | (118) | (400) | (850) |
| Other (income) expense | (54) | (13) | (58) | 22 |
| Change in fair value of warrant liability | — | — | — | 39 |
| Total other (income) expense | (280) | (131) | (458) | (789) |
| | | | | |
| Loss before income tax expense | (2,461) | (1,719) | (5,704) | (2,367) |
| | | | | |
| Income tax expense | 8 | 16 | 17 | 18 |
| | | | | |
| Net loss | (2,469) | (1,735) | (5,721) | (2,385) |
| | | | | |
| Other comprehensive income | | | | |
| Unrealized gain on marketable securities | 8 | — | 11 | — |
| | | | | |
| Net loss and comprehensive loss | $ (2,461) | $ (1,735) | $ (5,710) | $ (2,385) |
| | | | | |
| Basic and diluted net loss per share | $ (0.21) | $ (0.22) | $ (0.48) | $ (0.33) |
| Weighted average shares outstanding – basic and diluted | 11,979,401 | 7,821,496 | 11,968,200 | 7,187,659 |

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

| | June 30, 2019 (unaudited) | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,974 | $ 16,823 |
| Marketable securities | 7,992 | — |
| Amounts receivable | 1,112 | 780 |
| Prepaid expenses and other assets | 198 | 369 |
| Total current assets | 12,276 | 17,972 |
| Non-current assets: | | |
| Deposit | 271 | 271 |
| Operating lease right-of-use asset | 177 | — |
| Property and equipment, net | 73 | 96 |
| Total non-current assets | 521 | 367 |
| Total assets | $ 12,797 | $ 18,339 |
| **LIABILITIES AND EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 262 | $ 483 |
| Accrued liabilities | 630 | 808 |
| Finance lease obligation | 5 | 5 |
| Operating lease obligation | 50 | — |
| Total current liabilities | 947 | 1,296 |
| Non-current liabilities: | | |
| Finance lease obligation, non-current | 15 | 18 |
| Operating lease obligation, non-current | 133 | — |
| Total non-current liabilities | 148 | 18 |
| Shareholders' equity: | | |
| Common shares, no par value; unlimited authorized; 12,006,874 and 11,956,874 shares issued and outstanding, as of June 30, 2019 and December 31, 2018, respectively | — | — |
| Additional paid-in capital | 63,380 | 62,993 |
| Accumulated other comprehensive income | 11 | — |
| Accumulated deficit | (51,689) | (45,968) |
| Total shareholders' equity | 11,702 | 17,025 |
| Total liabilities and shareholders' equity | $ 12,797 | $ 18,339 |

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (5,721) | $ (2,385) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 312 | 445 |
| Amortization of discount on marketable securities | (53) | — |
| Non-cash lease expense | 24 | — |
| Depreciation | 11 | 6 |
| Change in fair value of warrant liability | — | 39 |
| Changes in operating assets and liabilities: | | |
| Amounts receivable | (332) | (242) |
| Prepaid expenses | 171 | (49) |
| Accounts payable | (221) | (61) |
| Accrued liabilities | (196) | 289 |
| Net cash used in operating activities | (6,005) | (1,958) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchase of marketable securities | (10,928) | — |
| Maturities of marketable securities | 3,000 | — |
| Purchase of property and equipment | — | (42) |
| Disposition of property and equipment, net | 12 | — |
| Net cash used in investing activities | (7,916) | (42) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from the exercise of stock options | 75 | 43 |
| Principal payments on finance lease obligations | (3) | — |
| Proceeds from issuance of common shares and warrants, net of offering costs | — | 5,840 |
| Proceeds from the exercise of common share purchase warrants | — | 490 |
| Net cash provided by financing activities | 72 | 6,373 |
| | | |
| Net increase (decrease) in cash and cash equivalents | (13,849) | 4,373 |
| Cash and cash equivalents at beginning of period | 16,823 | 1,353 |
| Cash and cash equivalents at end of period | $ 2,974 | $ 5,726 |