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

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) ofThe Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 13, 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) | (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))

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. ☒

**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 |

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

On May 13, 2019, DiaMedica Therapeutics Inc. ("DiaMedica") announced its condensed consolidated financial results for the quarter ended March 31, 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 DiaMedica 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 May 13, 2019 announcing first quarter 2019 financial results and a business update (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: May 13, 2019

**Exhibit 99.1**

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

- ***Phase Ib study of DM199 in Chronic Kidney Disease nearing full enrollment***
- ***Completion of new cGMP manufacturing run of DM199***
- ***Conference call with management tomorrow, May 14, 2019 at 7am CT***

**Minneapolis, Minnesota – (Globe Newswire – May 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 months ended March 31, 2019.

**Clinical Developments**

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

*Phase Ib Clinical Study in Patients with CKD Nearing Full Enrollment*

As previously announced, DiaMedica initiated 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 mellitus. Enrollment of patients in this Phase Ib study began in February 2019 at three U.S. sites and the Company anticipates dosing the last patients in the coming weeks. Enrollment to-date has progressed slightly ahead of the original plan and the Company expects to report top-line clinical results in June 2019. "We are pleased with the safety and tolerability of DM199 observed thus far in this trial, which included three dosage levels up to 8 µg/kg," commented Harry Alcorn, DiaMedica's Chief Medical Officer. "The lack of any significant adverse events is consistent with prior studies and gives us confidence as we prepare for our upcoming Phase II CKD studies."

The Phase Ib CKD study is an open label clinical trial evaluating three dose levels of DM199, administered in a single subcutaneous ("SC") dose, in 32 patients with moderate or severe CKD. Endpoints include safety, tolerability, pharmacokinetics, change in KLK1 levels, pharmacodynamics and biomarkers of kidney function measured over a 12-day period. This study is intended to evaluate the safety and tolerability of DM199 in CKD patients and assist in identifying dose levels for use in subsequent Phase II trials.

The Company continues to plan its Phase II study in patients with CKD caused by rare underlying diseases. This study is anticipated to start in the second half of 2019. The Company expects to provide updates on the targeted rare form diseases that will be studied in Phase II and other details in May or June 2019.

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

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

As previously disclosed, targeted enrollment for the REMEDY trial was increased from 60 to approximately 100 patients in order to provide additional data to support the design of a robust and efficient Phase III study. Enrollment 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 with the enrollment in our REMEDY Phase II study and our Phase Ib study in CKD patients and building upon the results of the CKD study, we plan to provide an update shortly on the targeted rare form diseases that we will study in Phase II." stated Rick Pauls, DiaMedica's President and CEO. "We also wish to thank the study sites, physician investigators and patients for their support in advancing the study of DM199 for patients suffering from chronic kidney disease and acute ischemic stroke."

*Completion of New cGMP Manufacturing Run for DM199*

DiaMedica has completed a new 250 liter cGMP manufacturing run of DM199 active pharmaceutical ingredient, or drug substance. This manufacturing run follows previous manufacturing runs of 100 and 200 liters. The successful completion of this run further demonstrates DiaMedica's technical abilities to consistently generate large quantities of high quality DM199 drug substance rapidly and efficiently to meet the needs of the development program and eventually the marketplace.

**Financial Results**

Research and development expenses were $2.6 million for the three months ended March 31, 2019, an increase of $1.8 million, or 230%, from $791,000 for the three months ended March 31, 2018. This increase was due to costs incurred of approximately $1.0 million related to the initiation of 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 slightly to the increase.

General and administrative expenses were $814,000 for the three months ended March 31, 2019, an increase of $299,000, or 63.3%, from $515,000 for the three months ended March 31, 2018. This increase was primarily due to increased costs associated with the Company's status as a Nasdaq-listed U.S. public reporting company, which commenced in December 2018. Increased personnel costs also contributed to the increase.

Total other income decreased 72.9% to $178,000 for the three months ended March 31, 2019 down from $657,000 for three months ended March 31, 2018. The 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, during the three months ended March 31, 2018. This decrease was partially offset by increased interest income earned on marketable securities during the three months ended March 31, 2019.

**Balance Sheet and Cash Flow**

The Company had cash and cash equivalents of $2.8 million, marketable securities of $11.0 million, current liabilities of $1.4 million and working capital of $13.5 million as of March 31, 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 three months ended March 31, 2019.

Net cash used in operating activities was $3.1 million for the three months ended March 31, 2019, compared to $935,000 for the three months ended March 31, 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 Tuesday, May 14, 2019, at 7:00 a.m. Central Time:

| | |
|---|---|
| Date: | Tuesday, May 14, 2019 |
| Time: | 7:00 AM CT |
| Web access: | **https://edge.media-server.com/m6/p/qrb8q6a5** |
| Dial In: | (866) 962-3583 (domestic) |
| | (630) 652-5857 (international) |
| Conference ID: | 8177137 |

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 May 21, 2019, by dialing 1(855) 859-2056 (US Toll Free Dial In), (404) 537-3406 (international), replay passcode 8177137.

**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 of its clinical programs, including completed enrollment and clinical results, ability to achieve clinical milestones, and ability to produce sufficient quantities of DM199 to support clinical development and future sales into the marketplace. 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
Phone: (763) 496-5118
skellen@diamedica.com

Paul Papi
Vice President of Business Development
Phone: (617) 899-5941
info@diamedica.com

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Operating expenses: | | |
| Research and development | 2,607 | $ 791 |
| General and administrative | 814 | 515 |
| Total operating expenses | 3,421 | 1,306 |
| Operating loss | (3,421) | (1,306) |
| Other (income) expense: | | |
| Governmental assistance – research incentives | (174) | (731) |
| Other (income) expense | (4) | 35 |
| Change in fair value of warrant liability | — | 39 |
| Total other income | (178) | (657) |
| Loss before income tax benefit | (3,243) | (649) |
| Income tax expense | 9 | 1 |
| Net loss | (3,252) | (650) |
| Other comprehensive income | | |
| Unrealized gain on marketable securities | 3 | — |
| Net loss and comprehensive loss | $ (3,249) | $ (650) |
| Basic and diluted net loss per share | $ (0.27) | $ (0.10) |
| Weighted average shares outstanding—basic and diluted | 11,956,874 | 6,546,780 |

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

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | (Unaudited) | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,759 | $ 16,823 |
| Marketable securities | 10,958 | — |
| Amounts receivable | 929 | 780 |
| Prepaid expenses and other assets | 298 | 369 |
| Total current assets | 14,944 | 17,972 |
| | | |
| Non-current assets: | | |
| Deposit | 271 | 271 |
| Operating lease right-of-use asset | 189 | — |
| Property and equipment, net | 90 | 96 |
| Total non-current assets | 550 | 367 |
| | | |
| Total assets | $ 15,494 | $ 18,339 |
| | | |
| **LIABILITIES AND EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 685 | $ 483 |
| Accrued liabilities | 686 | 808 |
| Finance lease obligation | 5 | 5 |
| Operating lease obligation | 49 | — |
| Total current liabilities | 1,425 | 1,296 |
| | | |
| Non-current liabilities: | | |
| Finance lease obligation, non-current | 17 | 18 |
| Operating lease obligation, non-current | 146 | — |
| Total non-current liabilities | 163 | 18 |
| | | |
| Shareholders' equity: | | |
| Common shares, no par value; unlimited authorized; 11,956,874 shares issued and outstanding, as of March 31, 2019 and December 31, 2018, respectively | — | — |
| Additional paid-in capital | 63,123 | 62,993 |
| Accumulated other comprehensive income | 3 | — |
| Accumulated deficit | (49,220) | (45,968) |
| Total shareholders' equity | 13,906 | 17,025 |
| Total liabilities and shareholders' equity | $ 15,494 | $ 18,339 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (3,252) | $ (650) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 130 | 153 |
| Amortization of discount on marketable securities | (26) | — |
| Non-cash lease expense | 12 | — |
| Depreciation | 6 | 4 |
| Change in fair value of warrant liability | — | 39 |
| Changes in operating assets and liabilities: | | |
| Amounts receivable | (150) | (709) |
| Prepaid expenses | 72 | 13 |
| Accounts payable | 201 | (30) |
| Accrued liabilities | (127) | 245 |
| Net cash used in operating activities | (3,134) | (935) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchase of marketable securities | (10,928) | — |
| Purchase of property and equipment | — | (32) |
| Net cash used in financing activities | (10,928) | (32) |
| | | |
| **Cash flows from financing activities:** | | |
| Principal payments on finance lease obligations | (2) | — |
| Proceeds from issuance of common shares and warrants, net offering costs | — | 5,840 |
| Proceeds from the exercise of common share purchase warrants | — | 484 |
| Net cash provided by (used in) financing activities | (2) | 6,324 |
| | | |
| Net increase (decrease) in cash | (14,064) | 5,357 |
| Cash and cash equivalents at beginning of period | 16,823 | 1,353 |
| Cash and cash equivalents at end of period | $ 2,759 | $ 6,710 |