**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): **March 19, 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**<br>(Address of principal executive offices) | **55447**<br>(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. ☒

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

On March 19, 2019, DiaMedica Therapeutics Inc. ("DiaMedica") announced its consolidated financial results for the full year ended December 31, 2018. 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 March 19, 2019 announcing full year 2018 financial results and providing corporate 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: March 19, 2019

**Exhibit 99.1**

# DiaMedica Therapeutics Announces 2018 Financial Results and Provides Corporate Update

- ***Dosed first patients in Phase Ib study of DM199 in Chronic Kidney Disease patients under an IND accepted by the FDA in 2018; Plan to initiate Phase II studies in 2H 2019***
- ***Acute ischemic stroke Phase II REMEDY clinical trial expanded from 60 to 100 patients***
- ***Initial public offering in the United States raised $16.4 million in gross proceeds; uplisted to The Nasdaq Capital Market***
- ***Strong cash position provides funding to advance development priorities through Phase II, including efficacy read-outs for chronic kidney disease and acute ischemic stroke***
- ***Conference call with management tomorrow, March 20, 2019 at 8am CT***

**Minneapolis, Minnesota – (Globe Newswire – March 19, 2019)** – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for kidney diseases and neurological disorders, provided a business update and reported its financial results for the year ended December 31, 2018.

**Business Highlights**

"In the past year, DiaMedica has achieved important development goals for our two lead programs, DM199 for chronic kidney disease and acute ischemic stroke. We expect to build upon this success in 2019 as we work toward advancing our pipeline of clinical programs, which hold the potential to have significant impact on patients suffering from chronic kidney disease and acute ischemic stroke," stated Rick Pauls, DiaMedica's President and CEO. "After our successful Nasdaq IPO in December, we have sufficient capital to obtain Phase II read-outs in our two lead programs. We are well positioned to execute on our clinical development plans to achieve meaningful milestones in the next year, and we look forward to sharing our progress."

***U.S. IPO, Nasdaq Uplisting and U.S. Reporting Company***

On December 6, 2018, DiaMedica completed an initial public offering ("IPO") of its common shares in the United States and uplisted to the Nasdaq Capital Market, raising $16.4 million in gross proceeds and $14.7 million in net proceeds. This was an important milestone for DiaMedica that expanded its investor base, adding several U.S. institutional investors, and strengthened its balance sheet. The IPO also provided the capital to complete Phase II clinical trials for DM199 in patients suffering acute ischemic strokes ("AIS") and chronic kidney disease ("CKD").

***License of DM199 with Ahon Pharma, subsidiary of Fosun Pharma.***

In September 2018, DiaMedica signed a license and collaboration agreement with Fosun Pharma's Ahon Pharma subsidiary for acute ischemic stroke in China. Fosun is one of the largest Chinese pharmaceutical firms with an extensive hospital sales force. The agreement provides exclusive rights to clinically develop and commercialize DM199 solely for acute ischemic stroke in China, Taiwan, Hong Kong and Macau. Under the terms of the agreement, DiaMedica may receive approximately $32 million in milestone payments, plus sales-based royalties of up to approximately 10%. In addition, DiaMedica has retained full control over the manufacturing of DM199. Ahon Pharma is currently preparing an application for an investigational new drug application to the China National Medical Products Administration. In China, a form of the KLK1 protein extracted from human urine, known as u-KLK1 or Kailikang®, has been approved and is considered a standard of care for AIS patients.

**Clinical Developments**

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

*Enrolling Patients in Phase Ib Clinical Study in Patients with CKD*

In December 2018, the United States Food & Drug Administration ("FDA") accepted DiaMedica's investigational new drug ("IND") application to study DM199 in patients with CKD. In February 2019, the Company began enrolling patients in its Phase Ib clinical study, which is being conducted at 3 sites in the U.S. and all sites are actively enrolling patients. The open label clinical trial is evaluating three dose levels of DM199, administered in a single subcutaneous ("SC") dose, in 32 patients with moderate or severe CKD. Primary endpoints include safety, tolerability, pharmacokinetics, change in KLK1 levels, albumin to creatine ratios and kidney biomarkers measured over a 12-day period. This study is intended to assist in identifying dose levels for use in subsequent Phase II trials. The Company expects a readout on the results of the CKD study in mid-2019.

*Released Chronic Kidney Disease White Paper*

Today, DiaMedica also released a **white paper** that further details the potential of KLK1/DM199 to treat patients with chronic kidney disease. The paper can be accessed at www.diamedica.com/product-candidates/chronic-kidney-disease.

DiaMedica is currently planning a randomized Phase II study in patients with rare forms of chronic kidney disease to be initiated in the second half of 2019. The Company will have updates on the rare forms to be targeted in this study and other details to follow.

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

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

In 2018, the Company initiated treatment of patients in its Phase II randomized, double-blind, placebo-controlled multi-center evaluation to assess the safety, tolerability and markers of DM199 in acute ischemic stroke patients, the REMEDY trial. With the success of its IPO, DiaMedica raised its target enrollment in the REMEDY trial from 60 to approximately 100 patients to provide additional data to support the design of a robust and efficient Phase III study. In this trial, the 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 will be assessed at multiple points throughout the study, including 90 days post-stroke. This study will also include multiple tests to investigate DM199's therapeutic potential. With the increase in the enrollment target, the Company expects to complete this trial in the fourth quarter of 2019 or first quarter of 2020.

*AIS Review Paper Supporting the Use of DM199 for AIS Published in Peer-Reviewed Journal*

On January 22, 2019, DiaMedica announced that a manuscript titled "Human Tissue Kallikrein in the Treatment of Acute Ischemic Stroke*"* was published in the peer-reviewed medical journal "*Therapeutic Advances in Neurological Disorders (TAND)*." The paper reviews the scientific literature covering the biochemical role of KLK1 and presents the mechanistic rationale for using KLK1 as an additional pharmacological treatment for AIS. In addition to the biochemical mechanism of KLK1, the paper highlights supporting results from human genetics and preclinical animal models of brain ischemia. It also reviews published clinical results for treatment of AIS by a form of KLK1 that is isolated from human urine. This form has been approved for post-infarct treatment of AIS in China and data has been published on clinical trials involving over 4,000 patients. The paper offers a series of testable therapeutic hypotheses for demonstrating the long-term beneficial effect of KLK1 treatment in AIS patients and the reasons for this action.

**Financial Results**

License revenue for 2018 was comprised of the initial $500,000 license payment DiaMedica received in connection with the license and collaboration agreement with Ahon Pharma.

Research and development expenses were $4.5 million for the year ended December 31, 2018 compared to $3.2 million for the year ended December 31, 2017, an increase of $1.3 million. The increase was primarily due to the additional preclinical testing and related costs required to support an application for an investigational new drug application in the United States, higher study costs for the REMEDY Phase II stroke study as compared with the DM199 bridging study which was substantially completed in 2017, and increased personnel and non-cash stock-based compensation costs.

General and administrative expenses were $2.7 million for the year ended December 31, 2018 compared to $1.3 million for the year ended December 31, 2017. General and administrative costs increased due to one-time costs incurred associated with the Company's planned IPO in the United States, primarily the Nasdaq listing process and related legal and accounting fees. Higher salaries, fees and short-term benefits due to the addition of staff and higher share-based compensation also contributed to the increase during 2018.

Other income, net, was $1.1 million for the year ended December 31, 2018 compared to $259,000 for 2017. The increase resulted primarily from the recognition of the research and development incentive from the Australia Government paid for qualifying research work performed by DiaMedica Australia. This increase was partially offset by increased foreign currency transaction losses.

**Balance Sheet and Cash Flow**

Total cash resources were $16.8 million as of December 31, 2018, compared to $1.4 million as of December 31, 2017. Total current assets were $18.0 million and $1.5 million as of December 31, 2018 and December 31, 2017, respectively. These increases resulted primarily from net proceeds of $20.6 million received from the sale of common shares and warrants during 2018, partially offset by the use of cash to fund operations in the current year,

Current liabilities increased to $1.3 million as of December 31, 2018, compared to $1.0 million as of December 31, 2017. The increase in current liabilities resulted primarily from the increase in costs accrued related to clinical trials.

Net cash used in operating activities was $5.7 million for the year ended December 31, 2018, up from $3.9 million for the year ended December 31, 2017. 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 March 20, 2019, at 8:00 a.m. Central Time:

| | |
|---|---|
| Date: | Wednesday, March 20, 2019 |
| Time: | 8:00 AM CT |
| Web access: | https://edge.media-server.com/m6/p/idbwv4bq |
| Dial In: | (866) 962-3583 (domestic) |
| | (630) 652-5857 (international) |
| Conference ID: | 6773627 |

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 March 28, 2019, by dialing 1(855) 859-2056 (US Toll Free Dial In), (404) 537-3406 (international), replay passcode 6773627.

**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", "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, ability to achieve milestones and the sufficiency of its capital resources. 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 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 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, its annual report on Form 10-K for the fiscal year ended December 31, 2018 which it intends to file in the next few days, 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)

| | Year Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Operating revenues: | | |
| License revenues | $ 500 | $ — |
| | | |
| Operating expenses: | | |
| Research and development | 4,522 | $ 3,206 |
| General and administrative | 2,739 | 1,313 |
| Total operating expenses | 7,261 | 4,519 |
| | | |
| Operating loss | (6,761) | (4,519) |
| Other (income) expense: | | |
| Governmental assistance – research incentives | (1,214) | (244) |
| Other (income) expense | 68 | (6) |
| Change in fair value of warrant liability | 39 | (9) |
| Total other income | (1,107) | (259) |
| | | |
| Loss before income tax benefit | (5,654) | (4,260) |
| | | |
| Income tax expense | 80 | — |
| | | |
| Net loss and comprehensive loss | $ (5,734) | $ (4,260) |
| | | |
| Basic and diluted net loss per share | $ (0.74) | $ (0.72) |
| Weighted average shares outstanding—basic and diluted | 7,743,520 | 5,935,790 |

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

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 16,823 | $ 1,353 |
| Amounts receivable | 780 | 80 |
| Prepaid expenses | 369 | 61 |
| Total current assets | 17,972 | 1,494 |
| Deposit | 271 | 271 |
| Property and equipment, net | 96 | 37 |
| Total non-current assets | 367 | 308 |
| Total assets | $ 18,339 | $ 1,802 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 1,291 | $ 919 |
| Capital lease obligation | 5 | — |
| Warrant liability | — | 84 |
| Total current liabilities | 1,296 | 1,003 |
| Long-term liabilities: | | |
| Capital lease obligation, non-current | 18 | — |
| Total long-term liabilities | 18 | — |
| Stockholders' deficit: | | |
| Common shares, no par value; unlimited authorized; 11,956,874 and 6,370,664 shares issued and outstanding, as of December 31, 2018 and 2017, respectively | — | — |
| Additional paid-in capital | 62,993 | 41,033 |
| Accumulated deficit | (45,968) | (40,234) |
| Total stockholders' equity | 17,025 | 799 |
| Total liabilities and stockholders' deficit | $ 18,339 | $ 1,802 |

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

| | Year Ended December 31, | |
|---|---|---|
| | **2018** | **2017** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (5,734) | $ (4,260) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 620 | 409 |
| Change in fair value of warrant liability | 39 | (9) |
| Depreciation | 15 | 4 |
| Changes in operating assets and liabilities: | | |
| Amounts receivable | (700) | (27) |
| Prepaid expenses | (308) | 6 |
| Deposits | — | (271) |
| Accounts payable and accrued liabilities | 372 | 248 |
| Net cash used in operating activities | (5,696) | (3,900) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (50) | (22) |
| Net cash used in financing activities | (50) | (22) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common shares, net of offering costs | 14,726 | 2,917 |
| Proceeds from issuance of common shares and warrants, net offering costs | 5,840 | — |
| Proceeds from the exercise of common share purchase warrants | 607 | 615 |
| Proceeds from exercise of stock options | 43 | 7 |
| Net cash provided by financing activities | 21,216 | 3,539 |
| | | |
| Net increase (decrease) in cash | 15,470 | (383) |
| Cash at beginning of year | 1,353 | 1,736 |
| Cash at end of year | $ 16,823 | $ 1,353 |
| | | |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ 11 | $ 57 |
| | | |
| **Supplemental disclosure of non-cash transactions:** | | |
| Reclassification of warrant liability upon warrant exercise | $ 123 | $ — |
| Assets acquired under capital lease | $ 24 | $ — |