

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 23, 2020**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia
(State or other jurisdiction
of incorporation)

2 Carlson Parkway, Suite 260
Minneapolis, Minnesota
(Address of principal executive offices)

001-36291
(Commission
File Number)

(763) 496-5454
(Registrant's telephone number, including area code)

Not Applicable
(IRS Employer
Identification No.)

55447
(Zip 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 March 23, 2020, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the year ended December 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 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 March 23, 2020 providing a business update and reporting full year 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: March 23, 2020



DiaMedica Therapeutics Announces 2019 Financial Results and Provides Business Update

- *REMEDY Phase II Study of DM199 in Acute Ischemic Stroke Completes Enrollment; Data Readout Expected in Q2 2020*
- *Phase II Study of DM199 in Chronic Kidney Disease Ongoing; Steps Being Taken to Mitigate Potential Impact of COVID-19*
- *Raised \$8.5 Million in Gross Proceeds in Public Offering with Biotech Investment Funds in February 2020*
- *Cash and Investments of \$7.9 Million, \$15.6 Million Pro Forma with Net Proceeds from February 2020 Public Offering; Runway Through 2021*
- *Conference Call with Management Tomorrow, March 24 at 7am CT*

Minneapolis, Minnesota – March 23, 2020 (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 year ended December 31, 2019.

"DiaMedica set out and achieved some ambitious goals for 2019. We completed a Phase Ib pharmacokinetic study in subjects with chronic kidney disease, which was required to prepare for Phase II work. We assembled a world-class advisory board to guide our chronic kidney disease (CKD) clinical program, and collectively identified several rare forms of CKD to study. We planned and initiated our Phase II work in chronic kidney disease. We accomplished all of this while completing enrollment in our enlarged REMEDY study in acute ischemic stroke. We expect to build upon these accomplishments in 2020 as we work toward advancing DM199, which holds 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. "We are excited and cautiously optimistic as we look forward to the Phase II clinical results during 2020 as part of continuing to execute on our clinical development plans during 2020 and we look forward to sharing results as they become available."

Clinical Developments

DM199 for the Treatment of Chronic Kidney Disease

Phase II REDUX Clinical Study in CKD Caused by IgA Nephropathy and African Americans with Hypertension

In October 2019, the FDA accepted the Company's Phase II clinical trial protocol for the treatment of CKD caused by rare or significant unmet diseases. The 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 participants per cohort). The study is being conducted in the United States at 12 sites and is focused on participants with two specific causes of 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, albuminuria and kidney function, which will be evaluated by changes from baseline in eGFR and albuminuria, as measured by the UACR. Participant enrollment and dosing for this study commenced in December 2019.

Subject enrollment has been slower than expected, primarily in the African American cohort. Enrollment in the African American cohort has been hindered by a higher level of screen failures related to finding individuals with Stage II or III CKD that are not diabetic. The Company has taken several measures to increase/complete enrollment including increasing the number of clinical study sites to 12. In addition, the current COVID-19 outbreak in the United States, and measures being taken to mitigate the spread of this virus, appear to be adversely affecting the ability of sites to recruit subjects. The REDUX study design provides for registered nurses to make home visits for the majority of subject treatments, a practice consistent with the principle of social distancing recommended by governmental authorities; therefore, the Company does not currently anticipate any treatment disruptions to patients already enrolled. The Company continues to evaluate the impact of COVID-19 on enrollment and is taking steps to mitigate any impact. The Company will provide additional information on when preliminary top-line information will be available as conditions allow.

“We are focused on working with our study sites and home nursing services to ensure that protocols are in place to maximize the safety of study participants and clinical personnel,” commented Dr. Harry Alcorn, DiaMedica’s Chief Medical Officer. “We are taking steps to revise our protocol to maximize the subject interactions occurring at home to minimize the impact of social isolation steps on study participation.”

DM199 for the Treatment of Acute Ischemic Stroke

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

As previously announced, DiaMedica 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. The last subject follow-up visit was completed in late January 2020 and the Company is in the process of verifying the completeness and accuracy of the information collected in the clinical database and analyzing the results. The Company expects to release preliminary top-line results in the next few weeks. Full results from REMEDY were expected to be reported at the European Stroke Conference in Vienna, Austria. However, since the conference has been postponed until November 7-9, 2020, the Company is evaluating alternatives for releasing full study results.

Recent Public Offering

On February 11, 2020, DiaMedica completed an offering of its common shares selling an aggregate of 2,125,000 common shares in a public, underwritten offering at a public offering price of \$4.00 per share, raising gross proceeds of \$8.5 million and net proceeds of \$7.7 million, after deducting the underwriting discount and offering expenses. This offering was completed with biotech investment funds. The additional capital should allow DiaMedica to complete its current Phase II clinical studies and fund its operations through 2021.

Financial Results

Research and development (R&D) expenses were \$7.9 million for the year ended December 31, 2019 compared to \$4.5 million for the year ended December 31, 2018, an increase of \$3.4 million. The increase 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 non-cash share-based compensation costs also contributed to the increase. These increases were partially offset by a reduction in costs incurred in conjunction with the REMEDY Phase II clinical study in AIS patients for which we completed enrollment in October 2019.

General and administrative (G&A) expenses were \$3.7 million and \$2.7 million for the years ended December 31, 2019 and 2018, respectively. This \$1.0 million increase was primarily due to costs associated with the Company's status as a Nasdaq-listed U.S. public reporting company, which commenced in December 2018, including increased professional service, compliance and non-cash share-based compensation costs. Increased personnel costs also contributed to the increase. This increase was partially offset by one-time costs of approximately \$360,000 incurred in 2018, associated with the Nasdaq listing process and related legal and accounting fees.

Total other income, net, was \$1.0 million for the year ended December 31, 2019 compared to \$1.1 million for 2018. This 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 2018, which included research work performed in 2017 and 2018. The decrease was partially offset by increased interest income earned on marketable securities during 2019.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of \$7.9 million, or \$15.6 million on a pro forma basis, including the \$7.7 million in net proceeds from its February 2020 public offering, current liabilities of \$1.3 million and working capital of \$7.5 million as of December 31, 2019, compared to \$16.8 million in cash, cash equivalents and marketable securities, \$1.3 million in current liabilities and \$16.7 million in working capital as of December 31, 2018. The decreases in cash, cash equivalents and marketable securities and working capital are mainly due to the use of cash to fund operating activities during 2019.

Net cash used in operating activities for the year ended December 31, 2019 was \$9.1 million compared to \$5.7 million for the year ended December 31, 2018. This increase relates primarily to an increase in the net loss, partially offset by non-cash expenses and the effects of the changes in operating assets and liabilities.

Conference Call Information

DiaMedica management will host a conference call to discuss these results on Tuesday, March 24, 2020, at 7:00 a.m. Central Time:

Date: Tuesday, March 24, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: <https://event.on24.com/wcc/r/2220355/5404D6138C67936A6D82BAC008903CD8>
Dial In: (844) 557-8483 (domestic)
(825) 312-2381 (international)
Conference ID: 9270458

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 March 31, 2020, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), replay passcode 9270458.

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," "potential," "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, and how long the Company's proceeds from its recent offering will last. 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, including enrollment and reliance on collaboration with third parties to conduct clinical trials; its ability to continue to obtain funding for its operations, including funding necessary to complete additional 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, 2019, 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, | |
|---|--------------------------------|-------------------|
| | 2019 | 2018 |
| Operating revenues: | | |
| License revenues | \$ — | \$ 500 |
| Operating expenses: | | |
| Research and development | 7,900 | 4,522 |
| General and administrative | 3,693 | 2,739 |
| Operating loss | (11,593) | (6,761) |
| Other (income) expense: | | |
| Governmental assistance - research incentives | (856) | (1,214) |
| Other (income) expense, net | (119) | 68 |
| Change in fair value of warrant liability | — | 39 |
| Total other income, net | (975) | (1,107) |
| Loss before income tax expense | (10,618) | (5,654) |
| Income tax expense | 31 | 80 |
| Net loss | (10,649) | (5,734) |
| Other comprehensive income | | |
| Unrealized (gain) loss on marketable securities | (2) | — |
| Net loss and comprehensive loss | <u>\$ (10,647)</u> | <u>\$ (5,734)</u> |
| Basic and diluted net loss per share | <u>\$ (0.89)</u> | <u>\$ (0.74)</u> |
| Weighted average shares outstanding – basic and diluted | <u>11,987,696</u> | <u>7,743,520</u> |

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

| | <u>December 31, 2019</u> | <u>December 31, 2018</u> |
|--|--------------------------|--------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 3,883 | \$ 16,823 |
| Marketable securities | 3,995 | — |
| Amounts receivable | 823 | 780 |
| Deposits | 88 | — |
| Prepaid expenses and other assets | 47 | 369 |
| Total current assets | <u>8,836</u> | <u>17,972</u> |
| Non-current assets: | | |
| Operating lease right-of-use asset | 153 | — |
| Property and equipment, net | 64 | 96 |
| Deposits | — | 271 |
| Total non-current assets | <u>217</u> | <u>367</u> |
| Total assets | <u>\$ 9,053</u> | <u>\$ 18,339</u> |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 182 | \$ 483 |
| Accrued liabilities | 1,076 | 808 |
| Finance lease obligation | 6 | 5 |
| Operating lease obligation | 54 | — |
| Total current liabilities | <u>1,318</u> | <u>1,296</u> |
| Non-current liabilities: | | |
| Finance lease obligation, non-current | 13 | 18 |
| Operating lease obligation, non-current | 105 | — |
| Total non-current liabilities | <u>118</u> | <u>18</u> |
| Shareholders' equity: | | |
| Common shares, no par value; unlimited authorized; 12,006,874 and 11,956,874 shares issued and outstanding, as of December 31, 2019 and 2018, respectively | — | — |
| Paid-in capital | 64,232 | 62,993 |
| Accumulated other comprehensive income | 2 | — |
| Accumulated deficit | (56,617) | (45,968) |
| Total shareholders' equity | <u>7,617</u> | <u>17,025</u> |
| Total liabilities and shareholders' equity | <u>\$ 9,053</u> | <u>\$ 18,339</u> |

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

| | Year Ended December 31, | |
|---|--------------------------------|------------------|
| | 2019 | 2018 |
| Cash flows from operating activities: | | |
| Net loss | \$ (10,649) | \$ (5,734) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation | 1,164 | 620 |
| Amortization of discount on marketable securities | (74) | — |
| Non-cash lease expense | 49 | — |
| Depreciation | 21 | 15 |
| Change in fair value of warrant liability | — | 39 |
| Changes in operating assets and liabilities: | | |
| Amounts receivable | (43) | (700) |
| Prepaid expenses | 322 | (308) |
| Deposits | 183 | — |
| Accounts payable | (301) | (30) |
| Accrued liabilities | 226 | 402 |
| Net cash used in operating activities | <u>(9,102)</u> | <u>(5,696)</u> |
| Cash flows from investing activities: | | |
| Purchase of marketable securities | (12,919) | — |
| Maturities of marketable securities | 9,000 | — |
| Disposition of property and equipment, net | 13 | — |
| Purchase of property and equipment | (2) | (50) |
| Net cash used in investing activities | <u>(3,908)</u> | <u>(50)</u> |
| Cash flows from financing activities: | | |
| Proceeds from the exercise of stock options | 75 | 43 |
| Principal payments on finance lease obligations | (5) | — |
| Proceeds from issuance of common shares, net of offering costs | — | 14,726 |
| Proceeds from issuance of common shares and warrants, net of offering costs | — | 5,840 |
| Proceeds from the exercise of common share purchase warrants | — | 607 |
| Net cash provided by financing activities | <u>70</u> | <u>21,216</u> |
| Net increase (decrease) in cash and cash equivalents | (12,940) | 15,470 |
| Cash and cash equivalents at beginning of period | 16,823 | 1,353 |
| Cash and cash equivalents at end of period | <u>\$ 3,883</u> | <u>\$ 16,823</u> |