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, 2024**

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.)

301 Carlson Parkway, Suite 210 **Minneapolis, Minnesota**	**55305**
(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 2.02. Results of Operations and Financial Condition.

On March 19, 2024, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the year ended December 31, 2023. 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 Item 2.02 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" with the Securities and Exchange Commission (the "SEC") 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 (the "Securities Act"), or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated March 19, 2024 providing a business update and announcing full year 2023 financial results (furnished herewith)
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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, 2024

Exhibit 99.1

DiaMedica Therapeutics Provides a Business Update and Announces Full Year 2023 Financial Results

Conference Call and Webcast March 20 at 8:00 AM Eastern Time / 7:00 AM Central Time

- **ReMEDy2 Clinical Site Activation Commenced in December 2023**
- **Strengthened Management Team with Lorianne Masuoka, M.D., as Chief Medical Officer**
- **$53 Million Cash with Runway to 2026**

Minneapolis, Minnesota – **March 19, 2024 (Business Wire)** – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal disease, today provided a business update and financial results for the year ended December 31, 2023. Management will host a conference call Wednesday, March 20, 2024, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and full year 2023 financial results.

ReMEDy2 Phase 2/3 AIS Clinical Developments

DiaMedica has been actively engaging with clinical study sites in the United States and globally. In the U.S., the first clinical sites were opened in December 2023 and as of the date of this press release, six sites have been opened. The majority of the U.S. sites are expected to be activated by the third quarter of 2024. With the support of the Canadian Stroke Consortium, the activation of study sites in Canada is expected to begin in the third quarter of 2024. In Australia, the Company has received provisional endorsement from the Australian Stroke Trials Network (ASTN) and Australian site activation is expected to commence in the fourth quarter of 2024. Initial steps are also being taken to expand ReMEDy2 into the United Kingdom and Europe.

As previously discussed, the Company submitted a protocol modification to the U.S. Food and Drug Administration (FDA) in October 2023 intended to enhance the probability of clinical success in the ReMEDy2 clinical trial. These modifications included focusing participant eligibility to those subjects with only moderate acute ischemic strokes (AIS) in the anterior circulation. Moderate strokes are commonly defined as those stroke patients having a baseline National Institutes of Health Stroke Score (NIHSS) of 5-15. Moderate severity strokes frequently result from occlusions in small vessels, and if diagnosed after the tissue plasminogen activator (tPA; ACTIVASE®) treatment window has closed, typically have limited treatment alternatives as they are generally not candidates for mechanical thrombectomy. The exclusion of posterior circulation strokes aligns with enrollment criteria used by Shanghai Pharmaceuticals, the marketer of urinary-derived KLK1, called KAILIKANG®, in its registration studies in China. Given the ReMEDy2 primary endpoint of modified Rankin Scale (mRS) score of 0-1 (excellent outcome), the Company believes that focusing on strokes of moderate severity will maximize the potential performance improvement in participants treated with DM199 vs. placebo, meaning that this change should increase the number of participants receiving DM199 achieving an excellent outcome as compared to the placebo group. This change is also consistent with results from the Company's Phase 2, ReMEDy1 stroke trial, where the subgroup of participants with moderate strokes, not receiving mechanical thrombectomy prior to enrollment, showed a greater percentage of patients on DM199 achieving an mRS of 0-1 compared to placebo, recognizing that the trial had a relatively small number of participants.

At this time, based upon information obtained from current and potential clinical study sites, the Company believes that full enrollment for the 144 patients for the interim analysis will be completed in the first quarter of 2025. For more information about the ReMEDy2 AIS Phase 2/3 clinical trial, please visit (www.remedytrial.com).

Dr. Lorianne Masuoka joined DiaMedica in January 2024 with more than 25 years of experience building and expanding high value pipelines in the biopharmaceutical industry that have resulted in drug approvals and strategic alliances. She is a board-certified neurologist, experienced in treating stroke patients, who has successfully created and overseen high performing teams to lead the clinical development of new medicines, with a focus in neurology and oncology. Dr. Masuoka served as Chief Medical Officer of Epygenix Therapeutics, Marinus Pharmaceuticals (Nasdaq: MRNS), Cubist Pharmaceuticals ($9.5B acquisition by Merck), and Nektar Therapeutics (Nasdaq: NKTR) where, as a member of executive management, she managed teams in the areas of clinical research, pharmacovigilance, biostatistics and data management, regulatory affairs, and clinical operations. Previously, she held various roles of increasing responsibility at FivePrime Therapeutics ($1.9B acquisition by Amgen) and Chiron (now Novartis). In addition to her executive roles, Dr. Masuoka most recently served as a Board member at Pfenex Inc. ($516M acquisition by Ligand) and served as a Board member at Opiant Pharmaceuticals (up to $500M acquisition by Indivior). Dr. Masuoka received her medical degree from the University of California, Davis, where she also completed her residency in neurology. She completed her epilepsy fellowship at Yale University and is board certified by the American Board of Psychiatry and Neurology. Lorianne also recruited a former colleague to join DiaMedica's team as Vice President of Clinical Operations. Ms. Rebekah de Vitry Fries has over 15 years of clinical operations experience including Epygenix Therapeutics; Takeda and Marinus Pharmaceuticals.

"We have been focused on engaging and activating high-quality stroke centers to set the foundation for patient enrollment," commented Dr. Masuoka. "We are encouraged by the level of interest from quality study sites and are committed to bringing DM199 to stroke patients."

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $52.9 million, current liabilities of $2.8 million and working capital of $50.9 million as of December 31, 2023, compared to total cash, cash equivalents and investments of $33.5 million, $2.2 million in current liabilities and $31.7 million in working capital as of December 31, 2022. The increases in cash, cash equivalents and investments and in working capital were due primarily to the $36.8 million of net proceeds from the April and June 2023 private placements, partially offset by cash used to fund operating activities during the year ended December 31, 2023.

Net cash used in operating activities for the year ended December 31, 2023 was $18.7 million compared to $11.5 million for the year ended December 31, 2022. The increase in cash used in operating activities was driven primarily by the Company's higher net loss and increased amortization of discounts on purchased marketable securities, partially offset by non-cash share-based compensation and the effects of the changes in operating assets and liabilities during 2023.

Financial Results

Research and development (R&D) expenses increased to $13.1 million for the year ended December 31, 2023, up from $7.8 million for the year ended December 31, 2022. The increase was driven principally by costs incurred for the in-use studies performed to address the previous clinical hold on the Company's ReMEDy2 AIS trial, costs incurred for the Phase 1C study and increased manufacturing and process development costs for DM199. Also contributing to the increase were higher personnel costs, including non-cash share-based compensation, associated with expanding the clinical team. DiaMedica expects its R&D expenses to increase moderately as we globally expand the ReMEDy2 trial. The increases will be moderated by the completion of prior clinical trials during 2023.

General and administrative (G&A) expenses were $8.2 million for the year ended December 31, 2023, up from $6.2 million for the year ended December 31, 2022. This increase was primarily driven by increased legal fees incurred in connection with the Company's lawsuit against Pharmaceutical Research Associates Group B.V. (PRA Netherlands) and increased personnel costs incurred in conjunction with expanding the Company's team. Increased costs for patent prosecution and non-cash share-based compensation also contributed to the increase. DiaMedica expects that its G&A costs we will remain steady or decline slightly as compared to prior periods.

Other income, net, was $1.9 million for the year ended December 31, 2023 compared to $0.4 million for 2022. This increase was driven by increased interest income recognized during 2023 as compared to 2022, related to both higher interest rates and increased marketable securities balances during 2023.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and full year quarter 2023 financial results on Wednesday, March 20, 2024, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Wednesday, March 20, 2024
Time:	7:00 AM CDT / 8:00 AM EDT
Web access:	https://app.webinar.net/VGMby1rgW87
Dial In:	(877) 550-1858
Conference ID:	1754341

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 playback on the Company's website, under investor relations - events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until March 27, 2024, by dialing (800) 645-7964 (U.S. Toll Free) and entering the replay passcode: 2125#.

About ReMEDy2 Trial

The ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial studying the use of the Company's product candidate, DM199, to treat acute ischemic stroke (AIS) patients. The trial is intended to enroll approximately 350 patients at up to 100 sites in the United States with planned global expansion. Patients enrolled in the trial will be treated for three weeks with either DM199 or placebo, beginning within 24 hours of the onset of AIS symptoms, with the final follow-up at 90 days. The trial excludes patients treated with tissue plasminogen activator (tPA) and/or mechanical thrombectomy. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

About DM199

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (rKLK1; rinvecalinase alpha). rKLK1 is identical to naturally produced KLK1, a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism that increases production of nitric oxide and prostacyclin. In the case of ischemic stroke, the administration of DM199 is intended to enhance blood flow to infarction (blood clot) site and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the infarction and inhibition of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as stroke, chronic kidney disease, retinopathy, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed and clinically studied rKLK1. Non-recombinant, tissue extracted KLK1 protein, produced from the pancreas of pigs and human urine, has been approved for decades outside the U.S. and Europe for patients in Japan, China and South Korea with a variety of ischemic conditions such as AIS, chronic renal disease, retinopathy and hypertension. DM199 is currently being studied in patients with AIS. In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of AIS.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases with a focus on acute ischemic stroke. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality in Asia for the treatment of acute ischemic stroke and other vascular diseases. For more information visit the Company's website at www.diamedica.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and forward-looking information that are based on the beliefs of management and reflect management's current expectations. When used in this press release, the words "anticipates," "believes," "look forward," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "hope," "should," or "will," 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 Company's expectations regarding the effect of the protocol amendments to increase the probability of clinical success of DM199 for the treatment of AIS in the ReMEDy2 trial and streamline the site selection and activation process, timing for site activations and geographic locations thereof and enrollment in the ReMEDy2 trial, anticipated clinical benefits and success of DM199, and cash runway to 2026. 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, uncertainties relating to the effects of the protocol amendments, timing of site activations and enrollment, regulatory applications and related filing and approval timelines; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of acute ischemic stroke and cardio-renal disease and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, enrollment numbers, costs and timeframes; the adaptive design of the ReMEDy2 trial and the possibility that the targeted enrollment and other aspects of the trial could change depending upon certain factors, including additional input from the FDA and the blinded interim analysis; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of COVID-19, hospital and medical facility staffing shortages, and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including its ability to meet its site activation and enrollment goals; DiaMedica's reliance on collaboration with third parties to conduct clinical trials; DiaMedica's ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for acute ischemic stroke and cardio-renal disease, 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, 2023 and subsequent U.S. Securities and Exchange Commission filings. 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
Corporate Communications
Phone: (508) 444-6790
ppapi@diamedica.com

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

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 13,110	$ 7,839
General and administrative	8,157	6,162
Total operating expenses	21,267	14,001
Operating loss	(21,267)	(14,001)
Other income:		
Other income, net	1,929	353
Total other income, net	1,929	353
Loss before income tax expense	(19,338)	(13,648)
Income tax expense	(43)	(28)
Net loss	(19,381)	(13,676)
Other comprehensive income (loss)		
Unrealized gain (loss) on marketable securities	80	(23)
Net loss and comprehensive loss	$ (19,301)	$ (13,699)
Basic and diluted net loss per share	$ (0.60)	$ (0.52)
Weighted average shares outstanding – basic and diluted	32,566,723	26,443,067

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,543	$ 4,728
Marketable securities	48,352	28,774
Prepaid expenses and other assets	411	251
Amounts receivable	369	82
Total current assets	53,675	33,835
Non-current assets:		
Operating lease right-of-use asset	354	424
Property and equipment, net	131	136
Total non-current assets	485	560
Total assets	$ 54,160	$ 34,395
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 926	$ 734
Accrued liabilities	1,777	1,365
Finance lease obligation	3	6
Operating lease obligation	80	63
Total current liabilities	2,786	2,168
Non-current liabilities:		
Finance lease obligation, non-current	1	4
Operating lease obligation, non-current	316	396
Total non-current liabilities	317	400
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 37,958,000 and 26,443,067 shares issued and outstanding, as of December 31, 2023 and 2022, respectively	—	—
Paid-in capital	166,609	128,078
Accumulated other comprehensive income (loss)	6	(74)
Accumulated deficit	(115,558)	(96,177)
Total shareholders' equity	51,057	31,827
Total liabilities and shareholders' equity	$ 54,160	$ 34,395

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (19,381)	$ (13,676)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,683	1,502
Amortization of discounts on marketable securities	(1,223)	(11)
Non-cash lease expense	70	64
Depreciation	30	25
Changes in operating assets and liabilities:		
Amounts receivable	(287)	48
Prepaid expenses and other assets	(160)	(54)
Accounts payable	192	225
Accrued liabilities	348	366
Net cash used in operating activities	(18,728)	(11,511)
Cash flows from investing activities:		
Purchase of marketable securities	(69,410)	(45,684)
Maturities of marketable securities	51,135	57,303
Purchase of property and equipment	(24)	(81)
Net cash provided by (used in) investing activities	(18,299)	11,538
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	36,848	—
Principal payments on finance lease obligations	(6)	(6)
Net cash provided by (used in) financing activities	36,842	(6)
Net increase (decrease) in cash and cash equivalents	(185)	21
Cash and cash equivalents at beginning of period	4,728	4,707
Cash and cash equivalents at end of period	$ 4,543	$ 4,728
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 33	$ 27
Assets acquired under operating lease	$ —	$ 446