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

FORM 10-Q

(Mark one)
☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934-**

For the transition period from _____ to _____

Commission File Number: 001-36291

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒

As of May 12, 2023, there were26,933,727 voting common shares of the registrant outstanding.

DiaMedica Therapeutics Inc.
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This quarterly report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended, that are subject to the safe harbor created by those sections. For more information, see "*Cautionary Note Regarding Forward-Looking Statements.*"

As used in this report, references to "*DiaMedica,*" *the* "*Company,*" "*we,*" "*our*" *or* "*us,*" *unless the context otherwise requires, refer to DiaMedica Therapeutics Inc. and its subsidiaries, all of which are consolidated in DiaMedica's condensed consolidated financial statements. References in this report to* "*common shares*" *mean our voting common shares, no par value per share.*

We own various unregistered trademarks and service marks, including our corporate logo. Solely for convenience, the trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the owner of such trademarks and trade names will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this report that are not descriptions of historical facts are forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 that are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and share price. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," "would," the negative of these terms or other comparable terminology and the use of future dates.

The forward-looking statements in this report are subject to risks and uncertainties and include, among other things:

- our plans to develop, obtain regulatory approval for and commercialize our DM199 product candidate for the treatment of acute ischemic stroke (AIS) and chronic kidney disease (CKD) and our expectations regarding the benefits of our DM199 product candidate;
- the clinical hold by the United States Food and Drug Administration (FDA) on the investigational new drug application (IND) for our ReMEDy2 trial and risks associated therewith, including that we may not be able to provide objective evidence acceptable to the FDA substantiating our belief as to the cause of the hypotension events that occurred and led to the clinical hold; our plan to resolve the issues and prevent future events may not be successful or may be more costly than anticipated; we may not be able to address sufficiently the concerns identified by the FDA or we may be required to collect additional data or information or conduct additional clinical testing beyond what the FDA has currently requested and what we currently expect; our ability to successfully engage with the FDA and satisfactorily respond to its requests for further information and data regarding the ReMEDy2 trial and the timing and outcome of our planned interactions with the FDA concerning the clinical hold; and the FDA may not remove the clinical hold on the IND for our ReMEDy2 trial in a timely manner or at all;
- our ability to conduct successful clinical testing of our DM199 product candidate for AIS or CKD and meet certain anticipated or target dates with respect to our clinical studies, including in particular our ReMEDy2 trial and especially in the light of the effects of novel strains of the coronavirus, or COVID-19, on site activations and enrollment, hospital and medical facility staffing shortages, and concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility, and the clinical hold noted above;
- uncertainties relating to regulatory applications and related filing and approval timelines and the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial;
- the adaptive design of our ReMEDy2 trial, which is intended to enroll approximately 350 participants at up to 75 sites in the United States, and the possibility that these numbers and other aspects of the study could increase depending upon certain factors, including additional input from the FDA and results of the interim analysis as determined by the independent data safety monitoring board;
- the perceived benefits of our DM199 product candidate over existing treatment options for AIS and CKD;
- the potential size of the markets for our DM199 product candidate for AIS and CKD and our ability to serve those markets and the rate and degree of market acceptance of, and our ability to obtain coverage and adequate reimbursement for, our DM199 product candidate for AIS and CKD both in the United States and internationally;
- our ability to partner with and generate revenue from biopharmaceutical or pharmaceutical partners to develop, obtain regulatory approval for and commercialize our DM199 product candidate for AIS and CKD;
- the success, cost and timing of our ReMEDy2 clinical trial, as well as our reliance on third parties to conduct our clinical trials;
- our commercialization, marketing and manufacturing capabilities and strategy;
- expectations regarding federal, state and foreign regulatory requirements and developments, such as potential FDA regulation of our DM199 product candidate for AIS and CKD;
- our estimates regarding expenses, future revenue, capital requirements, how long our current cash resources will last and need for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our DM199 product candidate;
- expectations regarding competition and our ability to obtain data exclusivity for our DM199 product candidate for AIS and CKD; and
- our ability to obtain funding for our operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for our DM199 product candidate for AIS and CKD.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under "*Part I. Item 1A. Risk Factors*" in our annual report on Form 10-K for the fiscal year ended December 31, 2022 and those described above and elsewhere in this report. Moreover, we operate in a very competitive and rapidly-changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements should not be relied upon as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, including the securities laws of the United States, we do not intend to update any forward-looking statements to conform these statements to actual results or to changes in our expectations.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,147	$ 4,728
Marketable securities	26,508	28,774
Prepaid expenses and other assets	962	251
Amounts receivable	57	82
Total current assets	29,674	33,835
Non-current assets:		
Operating lease right-of-use asset	407	424
Property and equipment, net	136	136
Total non-current assets	543	560
Total assets	$ 30,217	$ 34,395
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,780	$ 734
Accrued liabilities	956	1,365
Operating lease obligation	73	63
Financing lease obligation	5	6
Total current liabilities	2,814	2,168
Non-current liabilities:		
Operating lease obligation, non-current	377	396
Finance lease obligation, non-current	4	4
Total non-current liabilities	381	400
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,464,977 and 26,443,067 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Paid-in capital	128,500	128,078
Accumulated other comprehensive loss	(29)	(74)
Accumulated deficit	(101,449)	(96,177)
Total shareholders' equity	27,022	31,827
Total liabilities and shareholders' equity	$ 30,217	$ 34,395

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,618	$ 1,974
General and administrative	1,903	1,562
Operating loss	(5,521)	(3,536)
Other income:		
Other income, net	256	35
Total other income, net	256	35
Loss before income tax expense	(5,265)	(3,501)
Income tax expense	(7)	(7)
Net loss	(5,272)	(3,508)
Other comprehensive loss		
Unrealized gain (loss) on marketable securities	45	(56)
Net loss and comprehensive loss	$ (5,227)	$ (3,564)
Basic and diluted net loss per share	$ (0.20)	$ (0.13)
Weighted average shares outstanding – basic and diluted	26,448,941	26,443,067

See accompanying notes to the condensed consolidated financial statements.

DiaMedica Therapeutics Inc.
Condensed Consolidated Statements of Shareholders' Equity
For the Three Months Ended March 31, 2023 and 2022
(In thousands, except share amounts)
(Unaudited)

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2022	26,443,067	$ 128,078	$ (74)	$ (96,177)	$ 31,827
Issuance of common shares in settlement of deferred stock units	17,621	—	—	—	—
Issuance of common shares upon the vesting of restricted stock units	4,289	—	—	—	—
Share-based compensation expense	—	422	—	—	422
Unrealized gain on marketable securities	—	—	45	—	45
Net loss	—	—	—	(5,272)	(5,272)
Balances at March 31, 2023	26,464,977	$ 128,500	$ (29)	$ (101,449)	$ 27,022

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2021	26,443,067	$ 126,576	$ (51)	$ (82,501)	$ 44,024
Share-based compensation expense	—	308	—	—	308
Unrealized loss on marketable securities	—	—	(56)	—	(56)
Net loss	—	—	—	(3,508)	(3,508)
Balances at March 31, 2022	26,443,067	$ 126,884	$ (107)	$ (86,009)	$ 40,768

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (5,272)	$ (3,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	422	308
Amortization of (discount) premium on marketable securities	(205)	120
Non-cash lease expense	17	15
Depreciation	7	6
Changes in operating assets and liabilities:		
Amounts receivable	25	(38)
Prepaid expenses and other assets	(711)	(699)
Accounts payable	1,046	(76)
Accrued liabilities	(418)	(16)
Net cash used in operating activities	(5,089)	(3,888)
Cash flows from investing activities:		
Purchase of marketable securities	(9,824)	(13,379)
Maturities of marketable securities	12,340	15,593
Purchases of property and equipment	(7)	—
Net cash provided by investing activities	2,509	2,214
Cash flows from financing activities:		
Principal payments on finance lease obligations	(1)	(1)
Net cash provided by (used in) financing activities	(1)	(1)
Net decrease in cash and cash equivalents	(2,581)	(1,675)
Cash and cash equivalents at beginning of period	4,728	4,707
Cash and cash equivalents at end of period	$ 2,147	$ 3,032
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	$ —	$ 10
Cash paid for income taxes	$ 14	$ 7

See accompanying notes to the condensed consolidated financial statements.

1. Business

DiaMedica Therapeutics Inc. and its wholly owned subsidiaries, DiaMedica USA, Inc. and DiaMedica Australia Pty Ltd. (collectively, we, us, our, DiaMedica and the Company), exist for the primary purpose of advancing the clinical and commercial development of our proprietary recombinant KLK1 protein called DM199, for the treatment of neurological and kidney diseases. Currently, our primary focus is on developing DM199, a recombinant form of the human tissue kallikrein-1 (KLK1) protein, for the treatment of acute ischemic stroke (AIS) and chronic kidney disease (CKD). Our parent company is governed under British Columbia's Business Corporations Act, and our common shares are publicly traded on The Nasdaq Capital Market under the symbol "DMAC."

2. Risks and Uncertainties

DiaMedica operates in a highly regulated and competitive environment. The development, manufacturing and marketing of pharmaceutical products require approval from, and are subject to ongoing oversight by, the United States Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in the European Union and comparable agencies in other countries. We are in the clinical stage of development of our initial product candidate, DM199, for the treatment of AIS and CKD. The Company has not completed the development of any product candidate and does not generate any revenues from the commercial sale of any product candidate. DM199 requires significant additional clinical testing and investment prior to seeking marketing approval and is not expected to be commercially available for at least three years, if at all.

On July 6, 2022, we announced that the FDA placed a clinical hold on the investigational new drug application (IND) for our Phase 2/3 ReMEDy2 trial. The clinical hold was issued following us voluntarily pausing participant enrollment in the trial to investigate three unexpected instances of clinically significant hypotension (low blood pressure) occurring shortly after initiation of the intravenous (IV) dose of DM199. In September 2022 we submitted our analysis of the events leading to and causing the hypotensive events, and proposed protocol modifications to address the mitigation of these events for future trial participants. Following review of this analysis, the FDA informed us that they were continuing the clinical hold and requesting, among other items, an additional in-use in vitro stability study of the IV administration of DM199, which includes testing the combination of the IV bag, IV tubing and mechanical infusion pump, to further rule out any other cause of the hypotension events. The requested in-use study has been completed at an independent laboratory and the results were substantially consistent with our earlier testing of the IV bags. These additional supporting data will be submitted to the FDA to provide further evidence to potentially enable lifting of the clinical hold as outlined in the prior FDA complete response letter.

However, there can be no assurance that the FDA will lift the clinical hold on a timely basis or at all. It is also possible that the FDA may make additional requests that we would need to fulfill prior to the lifting of the clinical hold, such as requiring us to complete additional clinical testing or imposing stricter approval conditions than we proposed for our DM199 product candidate. We may not enroll any additional participants in the ReMEDy2 trial until the FDA notifies us that the FDA has lifted the clinical hold and we may resume enrollment in the clinical trial.

Prior to voluntarily halting enrollment, we had experienced slower than expected site activations and enrollment in our ReMEDy2 trial and may continue to experience these conditions if and when we are able to resume enrollment. We believe this was due to a number of factors, including the reduction or suspension of research activities at our current and targeted clinical study sites, as well as staffing shortages, due to COVID-19 and concerns managing logistics and protocol compliance for participants discharged from the hospital into an intermediate care facility. We intend to continue to take certain actions, including bringing certain site engagement responsibilities in-house and engaging a clinical services consulting firm to provide staff support to study sites as needed, to assist study sites in overcoming these issues, if and when we resume enrollment in the ReMEDy2 trial, however no assurances can be provided as to if and when these issues will resolve.

Our future success is dependent upon the success of our development efforts, our ability to demonstrate clinical progress for our DM199 product candidate in the United States or other markets, our ability, or the ability of any future partner, to obtain required governmental approvals of our product candidate, our ability to license or market and sell our DM199 product candidate and our ability to obtain additional financing to fund these efforts.

As of March 31, 2023, we have incurred losses of $101.4 million since our inception in 2000. For the three months ended March 31, 2023, we incurred a net loss of $5.3 million and negative cash flows from operating activities of $5.1 million. We expect to continue to incur operating losses until such time as any future product sales, licensing fees, milestone payments and/or royalty payments generate revenue sufficient to fund our continuing operations. For the foreseeable future, we expect to incur significant operating losses as we continue the development and clinical study of, and to seek regulatory approval for, our DM199 product candidate. As of March 31, 2023, we had combined cash, cash equivalents and marketable securities of $28.7 million, working capital of $26.9 million and shareholders' equity of $27.0 million. Our principal source of cash has been net proceeds from the issuance of equity securities. Although the Company has previously been successful in obtaining financing through equity securities offerings, there is no assurance that we will be able to do so in the future. This is particularly true if we are unable to resolve the clinical hold on the IND for our ReMEDy2 trial, if our clinical data is not positive, or if economic and market conditions do not improve or further deteriorate.

We expect that we will need substantial additional capital to further our research and development activities, complete the required clinical studies, regulatory activities and manufacturing development for our product candidate, DM199, or any future product candidates, to a point where they may be licensed or commercially sold. We expect our current cash, cash equivalents and marketable securities to fund our planned operations for at least the next 12 months from the date of issuance of these condensed consolidated financial statements. The amount and timing of our future funding requirements will depend on many factors, including our ability and timing to release the clinical hold on the IND for our ReMEDy2 trial, the timing and results of our ongoing development efforts, including the duration of the current clinical hold, the rate of site activation and enrollment in our clinical study, the potential expansion of our current development programs, potential new development programs, the effects of COVID-19, staffing shortages and other factors on our clinical trials and our operating expenses. We may require significant additional funds earlier than we currently expect and there is no assurance that we will not need or seek additional funding prior to such time, especially if market conditions for raising capital are favorable.

3. Summary of Significant Accounting Policies

Interim financial statements

We have prepared the accompanying condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States (US GAAP) for interim financial information and with the instructions to Form 10-Q and Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. These condensed consolidated financial statements reflect all adjustments consisting of normal recurring accruals which, in the opinion of management, are necessary to present fairly our consolidated financial position, consolidated results of operations, consolidated statement of shareholders' equity and consolidated cash flows for the periods and as of the dates presented. Our fiscal year ends on December 31. The condensed consolidated balance sheet as of December 31, 2022 was derived from our audited consolidated financial statements. Certain prior year amounts have been reclassified to conform to the current year presentation. These condensed consolidated financial statements should be read in conjunction with our annual consolidated financial statements and the notes thereto. The nature of our business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

Cash and cash equivalents

The Company considers all bank deposits, including money market funds and other investments, purchased with an original maturity to the Company of three months or less, to be cash and cash equivalents. The carrying amount of our cash equivalents approximates fair value due to the short maturity of the investments.

Concentration of credit risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains its cash balances primarily with two financial institutions. These balances generally exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. The Company believes that the credit risk related to marketable securities is limited due to the adherence to an investment policy focused on the preservation of principal.

Marketable securities

The Company's marketable securities typically consist of obligations of the United States government and its agencies, bank certificates of deposit and/or investment grade corporate obligations, which are classified as available-for-sale and included in current assets. All marketable securities mature within 12 months from their date of purchase and generally are intended to fund current operations. Securities are valued based on market prices for similar assets using third party certified pricing sources. Available-for-sale securities are carried at fair value. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income. Realized gains and losses, if any, are calculated on the specific identification method and are included in other income in the condensed consolidated statements of operations.

We conduct periodic reviews to identify and evaluate each available-for-sale debt securities that are in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Declines in fair value considered to be temporary and caused by noncredit-related factors, are recorded in accumulated other comprehensive loss, which is a separate component of shareholders' equity. Declines in fair value that are other than temporary or caused by credit-related factors, are recorded within earnings as an impairment loss. There were no other-than-temporary unrealized losses as of March 31, 2023.

Fair value measurements

Under the authoritative guidance for fair value measurements, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The authoritative guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The hierarchy is broken down into three levels defined as follows:

Level 1 Inputs — quoted prices in active markets for identical assets and liabilities
Level 2 Inputs — observable inputs other than quoted prices in active markets for identical assets and liabilities
Level 3 Inputs — unobservable inputs

As of March 31, 2023, the Company believes that the carrying amounts of its other financial instruments, including amounts receivable, accounts payable and accrued liabilities, approximate their fair value due to the short-term maturities of these instruments. See Note 4, titled "*Marketable Securities*" for additional information.

Patent costs

Costs associated with applying for, prosecuting and maintaining patents are expensed as incurred given the uncertainty of patent approval and, if approved, the resulting probable future economic benefit to the Company. Patent-related costs, consisting primarily of legal expenses and filing/maintenance fees, are included in general and administrative costs and were $38,000 and $64,000 for the three months ended March 31, 2023 and 2022, respectively.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13,*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. The standard was effective for smaller reporting companies in fiscal years beginning after December 15, 2022 with early adoption permitted for all periods beginning after December 15, 2018. We adopted ASU No. 2016-13 on January 1, 2023, which did not have an impact on our condensed consolidated financial statements.

4. Marketable Securities

The available-for-sale marketable securities are primarily comprised of investments in commercial paper, corporate bonds and government securities and consist of the following, measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements Using Inputs Considered as of:							
	March 31, 2023				December 31, 2022			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 12,892	$ —	$ 12,892	$ —	$ 14,209	$ —	$ 14,209	$ —
Government securities	13,616	—	13,616	—	14,565	—	14,565	—
Total	$ 26,508	$ —	$ 26,508	$ —	$ 28,774	$ —	$ 28,774	$ —

Accrued interest receivable on available-for-sale securities is included in amounts receivable and was $55,000 and $80,000 as of March 31, 2023 and December 31, 2022, respectively.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the three months ended March 31, 2023.

Under the terms of the Company's investment policy, purchases of marketable securities are limited to investment grade governmental and corporate obligations and bank certificates of deposit with a primary objective of principal preservation. Maturities of individual securities are less than one year and the amortized cost of all securities approximated fair value as of March 31, 2023 and December 31, 2022.

5. Amounts Receivable

Amounts receivable consisted primarily of accrued interest receivable on marketable securities of $55,000 and $80,000 as of March 31, 2023 and December 31, 2022, respectively.

6. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Prepaid expenses	$ 870	$ 209
Advances to vendors	92	42
Total prepaid expenses and other assets	$ 962	$ 251

We periodically advance funds to vendors engaged to support the performance of our clinical trials and related supporting activities. The funds advanced are held, interest free, for varying periods of time and may be recovered by DiaMedica through partial reductions of ongoing invoices, application against final study/project invoices or refunded upon completion of services to be provided. Deposits are classified as current or non-current based upon their expected recovery time.

7. Property and Equipment

Property and equipment consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Furniture and equipment	$ 124	$ 124
Computer equipment	79	76
Leasehold Improvements	16	16
	219	216
Less accumulated depreciation	(83)	(80)
Property and equipment, net	$ 136	$ 136

8. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued compensation	$ 161	$ 667
Accrued clinical trial costs	376	472
Accrued research and other professional fees	414	215
Accrued other liabilities	5	11
Total accrued liabilities	$ 956	$ 1,365

9. Operating Lease

Office lease

Our operating lease costs were $26,000 and $16,000 for the three months ended March 31, 2023 and 2022, respectively. Our variable lease costs were $15,000 and $11,000 for the three months ended March 31, 2023 and 2022, respectively. Variable lease costs consist primarily of common area maintenance costs, insurance and taxes which are paid based upon actual costs incurred by the lessor.

Maturities of our operating lease obligation are as follows as of March 31, 2023 (in thousands):

2023	80
2024	109
2025	113
2026	116
2027	119
2028	10
Total lease payments	$ 547
Less interest portion	(97)
Present value of lease obligation	$ 450

10. Shareholders' Equity

Authorized capital stock

The Company has authorized share capital of an unlimited number of voting common shares, and the shares do not have a stated par value. Common shareholders are entitled to receive dividends as declared by the Company, if any, and are entitled to one vote per share at the Company's annual general meeting and any special meeting.

Equity issued during the three months ended March 31, 2023

During the three months ended March 31, 2023, 17,621 common shares were issued in settlement of deferred share units and 4,289 common shares were issued upon the vesting of restricted stock units.

Equity issued during the three months ended March 31, 2022

During the three months ended March 31, 2022, we did not issue any common shares

Shares reserved

Common shares reserved for future issuance are as follows:

	March 31, 2023
Common shares issuable upon exercise of employee and non-employee stock options	2,773,498
Common shares issuable upon settlement of deferred stock units	213,905
Common shares issuable upon vesting of restricted stock units	12,867
Common shares issuable upon exercise of common share purchase warrants	265,000
Shares available for grant under the 2019 Omnibus Incentive Plan	1,899,730
Shares available for grant under the 2021 Employment Inducement Incentive Plan	535,000
Total	5,700,000

11. Net Loss Per Share

We compute net loss per share by dividing our net loss (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period, if any, are weighted for the portion of the period that they were outstanding. The computation of diluted earnings per share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued. Our diluted EPS is the same as basic EPS due to common equivalent shares being excluded from the calculation, as their effect is anti-dilutive.

The following table summarizes our calculation of net loss per common share for the periods presented (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (5,272)	$ (3,508)
Weighted average shares outstanding—basic and diluted	26,448,941	26,443,067
Basic and diluted net loss per share	$ (0.20)	$ (0.13)

The following outstanding potential common shares were not included in the diluted net loss per share calculations as their effects were not dilutive:

	Three Months Ended March 31,	
	2023	2022
Employee and non-employee stock options	2,773,498	2,159,413
Common shares issuable under common share purchase warrants	265,000	265,000
Common shares issuable under deferred stock units	213,905	134,402
Common shares issuable upon vesting of restricted stock units	12,867	—

12. Share-Based Compensation

Amended and Restated 2019 Omnibus Incentive Plan

The DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan (the 2019 Plan) was adopted by the Board of Directors (Board) on March 10, 2022 and approved by our shareholders at our 2022 Annual General Meeting of Shareholders held on May 18, 2022.

The 2019 Plan permits the Board, or a committee or subcommittee thereof, to grant to the Company's eligible employees, non-employee directors and certain consultants non-statutory and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, deferred stock units (DSUs), performance awards, non-employee director awards and other stock-based awards. We grant options to purchase common shares under the 2019 Plan at no less than the fair market value of the underlying common shares as of the date of grant. Options granted to employees and non-employee directors have a maximum term of ten years and generally vest over one to four years. Options granted to non-employees have a maximum term of five years and generally vest over one year. Subject to adjustment as provided in the 2019 Plan, the maximum number of the Company's common shares authorized for issuance under the 2019 Plan is 4,000,000 shares. As of March 31, 2023, options to purchase an aggregate of 2,773,498 common shares were outstanding, 196,572 common shares were reserved for issuance upon settlement of DSUs and 12,867 shares were reserved for issuance upon the vesting of restricted stock units under the 2019 Plan.

2021 Employment Inducement Incentive Plan

On December 3, 2021, the Board adopted the DiaMedica Therapeutics Inc. 2021 Employment Inducement Incentive Plan (Inducement Plan) to facilitate the granting of equity awards as an inducement material to new employees joining the Company. The Inducement Plan is administered by the Compensation Committee of the Board of Directors. The Board reserved 1,000,000 common shares of the Company for issuance under the Inducement Plan. The only persons eligible to receive awards under the Inducement Plan are individuals who are new employees and satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4) or 5635(c)(3), as applicable. As of March 31, 2023, options to purchase an aggregate of 465,000 common shares were outstanding under the Inducement Plan.

Prior Stock Option Plan

The DiaMedica Therapeutics Inc. Stock Option Plan, Amended and Restated November 6, 2018 (Prior Plan), was terminated by the Board of Directors in conjunction with the shareholder approval of the 2019 Plan. Awards outstanding under the Prior Plan remain outstanding in accordance with and pursuant to the terms thereof. Options granted under the Prior Plan have terms similar to those used under the 2019 Plan. As of March 31, 2023, options to purchase an aggregate of 462,910 common shares were outstanding under the Prior Plan.

Prior Deferred Stock Unit Plan

The DiaMedica Therapeutics Inc. Amended and Restated Deferred Stock Unit Plan (Prior DSU Plan) was terminated by the Board of Directors in conjunction with the shareholder approval of the 2019 Plan. Awards outstanding under the Prior DSU Plan remain outstanding in accordance with and pursuant to the terms thereof. As of March 31, 2023, there were 17,333 common shares reserved for issuance upon settlement of DSUs outstanding under the Prior DSU Plan.

Share-based compensation expense for each of the periods presented is as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 132	$ 91
General and administrative	290	217
Total share-based compensation	$ 422	$ 308

We recognize share-based compensation based on the fair value of each award as estimated using the Black-Scholes option valuation model. Ultimately, the total expense recognized over the vesting period will only be for those shares that actually vest.

A summary of option activity is as follows (in thousands, except share and per share amounts):

	Shares Underlying Options Outstanding	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balances at December 31, 2022	2,782,248	$ 4.12	$ 17
Granted	—	—	
Expired/cancelled	—	—	
Forfeited	(8,750)	10.04	
Balances at March 31, 2023	2,773,498	$ 4.10	$ —

Information about stock options outstanding, vested and expected to vest as of March 31, 2023, is as follows:

	Outstanding, Vested and Expected to Vest			Options Vested and Exercisable	
Per Share Exercise Price	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Exercisable	Weighted Average Remaining Contractual Life (Years)
$1.00 - $1.99	177,000	9.5	$ 1.50	—	—
$2.00 - $2.99	790,398	7.7	2.51	283,711	5.5
$3.00 - $3.99	409,393	6.8	3.82	259,918	5.7
$4.00 - $4.99	862,182	6.3	4.58	836,014	6.2
$5.00 - $16.00	534,525	6.9	6.74	330,150	6.1
	2,773,498	7.1	$ 4.10	1,709,793	6.0

13. Subsequent Events

On April 10, 2023, Mr. David Wambeke was appointed Chief Business Officer of DiaMedica. In conjunction with his appointment, Mr. Wambeke purchased 468,750 of DiaMedica's common shares at an aggregate purchase price of $750,000 or $1.60 per share.

Additionally, the Company granted Mr. Wambeke an inducement stock option to purchase 140,000 common shares of DiaMedica pursuant to the DiaMedica Therapeutics, Inc. 2021 Employment Inducement Incentive Plan. The stock option has an exercise price of $1.57 per share, which is equal to the closing price of DiaMedica's common shares on the grant date, and a 10-year term. The option will vest over four years, with 25 percent of the shares underlying the option vesting on the one-year anniversary of the grant date, and the remaining shares vesting in equal quarterly installments over the remaining three years.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon accounting principles generally accepted in the United States of America and discusses the financial condition and results of operations for DiaMedica Therapeutics Inc. and our subsidiaries for the three months ended March 31, 2023 and 2022.

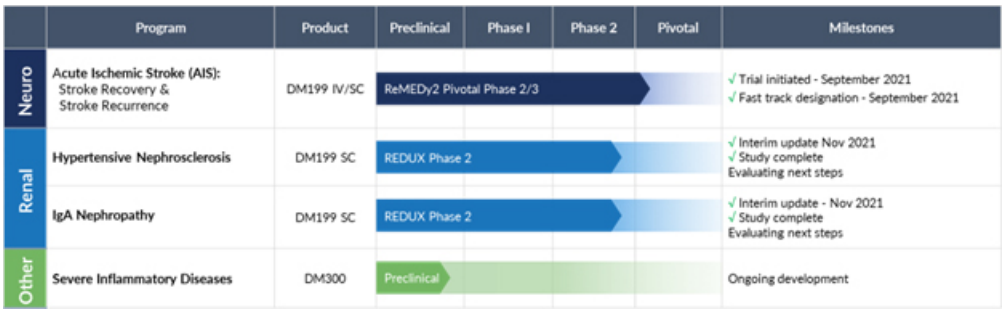
This discussion should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this report and our annual report on Form 10-K for the year ended December 31, 2022. The following discussion contains forward-looking statements that involve numerous risks and uncertainties. Our actual results could differ materially from the forward-looking statements as a result of these risks and uncertainties. See "*Cautionary Note Regarding Forward-Looking Statements*" for additional cautionary information.

Business Overview

We are a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases. Our lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the human tissue kallikrein-1 (KLK1) protein to be clinically studied in patients. KLK1 is an established therapeutic modality in Asia for the treatment of acute ischemic stroke (AIS) and chronic kidney disease (CKD), including hypertensive nephrosclerosis (hypertension). Our long-term goal is to use our patented and in-licensed technologies to establish our Company as a leader in the development and commercialization of therapeutic treatments from novel recombinant proteins. Our current focus is on the treatment of AIS and CKD. We plan to advance DM199, our lead drug candidate, through required clinical trials to create shareholder value by establishing its clinical and commercial potential as a therapy for AIS and CKD.

KLK1 is a serine protease (protein), produced primarily in the kidneys, pancreas and salivary glands, which plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels which decreases vascular resistance) in the body, as well as an important role in reducing inflammation and oxidative stress (an imbalance between potentially damaging reactive oxygen species, or free radicals and antioxidants in the body). We believe DM199 has the potential to treat a variety of diseases where healthy functioning requires sufficient activity of KLK1 and its system, the kallikrein-kinin system (KKS).

Our product development pipeline is as follows:



Neuro: AIS Phase 2/3 ReMEDy2 Study of DM199

Our ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial intended to enroll approximately 350 patients at 75 sites in the United States. Patients enrolled in the trial will be treated with either DM199 or placebo within 24 hours of the onset of AIS symptoms. The trial excludes patients treated with tissue plasminogen activator (tPA) and those with large vessel occlusions. The study population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA or mechanical thrombectomy. We believe that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

On July 6, 2022, we announced that the FDA placed a clinical hold on the investigational new drug application (IND) for our Phase 2/3 ReMEDy2 trial. The clinical hold was issued following us voluntarily pausing participant enrollment in the trial to investigate three unexpected instances of clinically significant hypotension (low blood pressure) occurring shortly after initiation of the intravenous (IV) dose of DM199. In September 2022 we submitted our analysis of the events leading to and causing the hypotensive events, and proposed protocol modifications to address the mitigation of these events for future trial participants. Following review of this analysis, the FDA informed us that they were continuing the clinical hold and requesting, among other items, an additional in-use in vitro stability study of the IV administration of DM199, which includes testing the combination of the IV bag, IV tubing and mechanical infusion pump, to further rule out any other cause of the hypotension events. The requested in-use study has been completed at an independent laboratory and the results were substantially consistent with our earlier testing of the IV bags. These additional supporting data will be submitted to the FDA to provide further evidence to potentially enable lifting of the clinical hold as outlined in the prior FDA complete response letter.

We have also provided responses to FDA inquiries on a potential trypsin impurity contributing to hypotension and methods assays to be used to measure results in the in-use study. The FDA responded to us indicating that the assays developed for the in-use study appeared appropriate and our assessment of the potential trypsin impurity was also acceptable.

However, there can be no assurance that the FDA will lift the clinical hold on a timely basis or at all. It is also possible that the FDA may make additional requests that we would need to fulfill prior to the lifting of the clinical hold, such as requiring us to complete additional clinical testing or imposing stricter approval conditions than we proposed for our DM199 product candidate. We may not enroll any additional participants in the ReMEDy2 trial until the FDA notifies us that the FDA has lifted the clinical hold and we may resume enrollment in the clinical trial.

We also have proactively initiated a Phase 1C open label, single ascending dose (SAD) study of DM199 administered with the PVC IV bags used in the ReMEDy2 trial. The purpose of the study is to confirm, with human data, the DM199 blood concentration level achieved with the IV dose and further evaluate safety and tolerability. In the event that the FDA does not agree that the results of the in-use study support the proposed dose revision, the data from this Phase 1C study can be used to support the rationale for the DM199 IV dose selected for the ReMEDy2 trial. This study is being conducted in Australia and enrollment commenced in March 2023. The third cohort, which received the 0.50 µg/kg dose level proposed for the ReMEDy2 trial, was dosed in April 2023 with no significant adverse events related to DM199. The pharmacokinetic data, including the DM199 blood concentration levels, for all three cohorts will be included as supplemental information in our clinical hold response letter.

Prior to voluntarily halting enrollment, we had experienced slower than expected site activations and enrollment in our ReMEDy2 trial and may continue to experience these conditions if and when we are able to resume enrollment. We believe this was due to a number of factors, including the reduction or suspension of research activities at our current and targeted clinical study sites, as well as staffing shortages, due to COVID-19 and concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility. We intend to continue to take certain actions, including bringing certain site engagement responsibilities in-house and engaging a clinical services consulting firm to provide staff support to study sites as needed, to assist study sites in overcoming these issues, if and when we resume enrollment in the ReMEDy2 trial, however no assurances can be provided as to if and when these issues will resolve.

Renal: CKD Phase 2 REDUX Clinical Trial of DM199

We continue to work towards finalizing the clinical data and related analyses as we evaluate next steps for our CKD program.

Financial Overview

We have not generated any revenues from product sales. We have financed our operations from public and private sales of equity, the exercise of warrants and stock options, interest income on funds available for investment and government grants and tax credits. We have incurred losses in each year since our inception. Our net losses were $5.3 million and $3.5 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $101.4 million. Substantially all of our operating losses resulted from expenses incurred in connection with our product candidate development programs, our primary research and development (R&D) activities, and general and administrative (G&A) support costs associated with our operations and status as a publicly listed company.

While we expect our rate of future negative cash flow per month will vary due to the timing of site activations and patient enrollment expenses if or when we resume our ReMEDy2 trial, we expect our current cash resources will be sufficient to allow us to continue to work with the FDA to lift the clinical hold and continue our Phase 2/3 ReMEDy2 trial in patients with AIS, complete the data analysis from our REDUX Phase 2 trial and evaluate next steps for our CKD program and otherwise fund our planned operations for at least the next 12 months from the date of issuance of the condensed consolidated financial statements included in this report. However, the amount and timing of future funding requirements will depend on many factors, including our ability and timing to obtain a release of the clinical hold on the IND for our ReMEDy2 trial, the timing and results of our ongoing development efforts, including site activations and enrollment in our current or any future clinical studies, the potential expansion of our current development programs, potential new development programs, related G&A support and the effects of COVID-19. We may require significant additional funds earlier than we currently expect and there is no assurance that we will not need or seek additional funding prior to such time. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable.

Overview of Expense Components

Research and Development (R&D) Expenses

R&D expenses consist primarily of fees paid to external service providers such as contract research organizations; contractual obligations for clinical development including clinical sites; outside nursing services and laboratory testing and preclinical trials; development of manufacturing processes; costs for production runs of DM199; salaries, benefits and share-based compensation; and other personnel costs.

At this time, due to the risks inherent in the clinical development process and the clinical stage of our product development programs, including our ability to continue working with the FDA to address the FDA-imposed clinical hold on our ReMEDy2 trial, we are unable to estimate with any certainty the costs we will incur in developing DM199 through marketing approval or any of our preclinical development programs. The process of conducting clinical studies necessary to obtain regulatory approval and manufacturing scale-up to support expanded development and potential future commercialization is costly and time consuming. Any failure by us or delay in completing clinical studies, manufacturing scale-up or in obtaining regulatory approvals could lead to increased R&D expenses and, in turn, have a material adverse effect on our results of operations

We expect that our R&D expenses will increase in the future if we are successful in advancing DM199, or any of our preclinical programs, through the required stages of clinical development. The process of conducting clinical trials necessary to obtain regulatory approval and manufacturing scale-up to support expanded development and potential future commercialization is costly and time consuming. Any failure by us or delay in completing clinical trials, including as a result of the clinical hold remaining in place on our Phase 2/3 ReMEDy2 trial, manufacturing scale-up or in obtaining regulatory approvals, could lead to increased R&D expenses and, in turn, have a material adverse effect on our results of operations.

General and Administrative (G&A) Expenses

G&A expenses consist primarily of salaries and employee benefits, including share-based compensation related to our executive, finance, business development and support functions. G&A expenses also include insurance, including directors and officers liability coverage, rent and utilities, travel expenses, patent costs, and professional fees, including for auditing, tax and legal services.

Other Income, Net

Other income, net consists primarily of interest income earned on marketable securities.

Results of Operations

Comparison of the Three Months ended March 31, 2023 and 2022

The following table summarizes our unaudited results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,618	$ 1,974
General and administrative	1,903	1,562
Other income, net	256	35

Research and Development Expenses

R&D expenses increased to $3.6 million for the three months ended March 31, 2023, up $1.6 million from $2.0 million for the three months ended March 31, 2022. The increased costs were driven by a number of factors, including primarily increased manufacturing and process development costs, the costs for the in-use study performed to address the clinical hold on the IND for our ReMEDy2 AIS trial, costs incurred for the Phase 1C healthy volunteer study and increased personnel costs associated with expanding our clinical team. These increases were partially offset by decreased costs incurred for our Phase 2/3 ReMEDy2 AIS trial due to the clinical hold.

General and Administrative Expenses

G&A expenses were $1.9 million for the three months ended March 31, 2023, up from $1.6 million for the three months ended March 31, 2022. The increase was primarily due to recruiting costs incurred in conjunction with expanding our team and increased legal fees incurred in connection with our lawsuit against PRA Netherlands.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of March 31, 2023 and December 31, 2022, and our sources and uses of cash for each of the three month periods ended March 31, 2023 and 2022, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	**March 31, 2023**	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 28,655	$ 33,502
Total assets	30,217	34,395
Total current liabilities	2,814	2,168
Total shareholders' equity	27,022	31,827
Working capital	26,860	31,667

	Three Months Ended March 31,	
Cash Flow Data	**2023**	**2022**
Cash flow provided by (used in):		
Operating activities	$ (5,089)	$ (3,888)
Investing activities	2,509	2,214
Financing activities	(1)	(1)
Net decrease in cash	$ (2,581)	$ (1,675)

Working Capital

We had aggregate cash, cash equivalents and marketable securities of $28.7 million, current liabilities of $2.8 million and working capital of $26.9 million as of March 31, 2023, compared to aggregate cash, cash equivalents and marketable securities of $33.5 million, $2.2 million in current liabilities and $31.7 million in working capital as of December 31, 2022. The decreases in our combined cash, cash equivalents and marketable securities and in our working capital are due primarily to cash used to fund our operating activities during the three months ended March 31, 2023.

Cash Flows

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2023 was $5.1 million compared to $3.9 million for the three months ended March 31, 2022. Cash used in operating activities is driven primarily by our net loss, partially offset by non-cash share-based compensation and the effects of the changes in operating assets and liabilities.

Investing Activities

Investing activities consist primarily of purchases and maturities of marketable securities. Net cash provided by investing activities was $2.5 million for the three months ended March 31, 2023 compared to net cash provided by investing activities of $2.2 million for the three months ended March 31, 2022. This change resulted primarily from the timing of maturities and investments of the proceeds from our September 2021 private placement.

Capital Requirements

Since our inception, we have incurred losses while advancing the R&D of our DM199 product candidate. We have not generated any revenues from product sales and do not know when or if, we will generate any revenues from product sales of our DM199 product candidate or any future product candidate. We expect to continue to incur substantial operating losses until such time as any future product sales, royalty payments, licensing fees and/or milestone payments are sufficient to generate revenues to fund our continuing operations. We expect our operating losses to increase in the near term as compared to prior periods as we continue the research, development and clinical studies of our DM199 product candidate. In the long-term, subject to obtaining regulatory approval of our DM199 product candidate, or any future product candidate, the absence of the assistance of a strategic partner, would further require us to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

Accordingly, we expect we will need substantial additional capital to further our R&D activities, current and anticipated future clinical studies, regulatory activities and otherwise develop our product candidate, DM199, or any future product candidate, to a point where the product candidate may be licensed or commercially sold. Although we are striving to achieve these plans, there is no assurance that these and other strategies will be achieved, that additional funding will be required after licensing or that additional funding will be obtained on favorable terms or at all. We expect our rate of future negative cash flow per month will vary depending on our clinical activities and the timing of expenses incurred and will increase if and when the clinical hold is lifted and we resume our ReMEDy2 trial. We expect our current cash resources will be sufficient to allow us to continue to work with the FDA to lift the clinical hold and, once lifted, continue our Phase 2/3 ReMEDy2 trial in patients with AIS, complete patient follow-up in our REDUX Phase 2 trial in patients with CKD and otherwise fund our planned operations for at least the next twelve months from the date of issuance of the condensed consolidated financial statements included in this report. However, the amount and timing of our future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, and specifically the resumption of our ReMEDy2 trial, the initiation of new sites and enrollment in such trial, the potential expansion of our current development programs, potential new development programs, the effects of COVID-19, staffing shortages and other factors on our clinical programs and operations and related G&A support. We may require significant additional funds earlier than we currently expect and there is no assurance that we will not need or seek additional funding prior to such time, especially if market conditions for raising additional capital are favorable.

Historically we have financed our operations primarily from sales of equity securities and the exercise of warrants and stock options, and we expect to continue this practice for the foreseeable future. We do not have any existing credit facilities under which we could borrow funds. We may seek to raise additional funds through various sources, such as equity or debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if our clinical data is not positive or economic and market conditions deteriorate.

To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted. Debt financing, if available, may involve agreements that include conversion discounts or covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, or strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. The availability of financing will be affected by our clinical data and other results of scientific and clinical research; the ability to attain regulatory approvals; market acceptance of our product candidates; the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies; the status of strategic alliance agreements; and other relevant commercial considerations.

If adequate funding is not available when needed, we may be required to scale back our operations by taking actions that may include, among other things, implementing cost reduction strategies, such as reducing use of outside professional service providers, reducing the number of our employees or employee compensation, modifying or delaying the development of our DM199 product candidate; licensing to third parties the rights to commercialize our DM199 product candidate for AIS, CKD or other indications that we would otherwise seek to pursue, or otherwise relinquishing significant rights to our technologies, future revenue streams, research programs or product candidates or granting licenses on terms that may not be favorable to us; and/or divesting assets or ceasing operations through a merger, sale, or liquidation of our company.

Critical Accounting Policies and Estimates

There have been no material changes to our critical accounting policies and estimates from the information provided in "*Part II. Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies*," included in our annual report on Form 10-K for the fiscal year ended December 31, 2022.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the United States Securities Exchange Act of 1934, as amended (Exchange Act)) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended March 31, 2023 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation with Pharmaceutical Research Associates Group B.V., acquired by ICON plc as of July 1, 2021, (ICON/PRA Netherlands)

On November 23, 2022, we filed a petition requesting leave for a prejudgment attachment of all relevant documents in possession of Pharmaceutical Research Associates Group B.V., acquired by ICON plc as of July 1, 2021, (ICON/PRA Netherlands), which was granted on November 28, 2022, by the District Court of Northern Netherlands. A representative of the District Court served ICON/PRA Netherlands with the prejudgment attachment on or about December 7 and 8, 2022. The case was formally introduced to the Netherlands Commercial Court (NCC) on December 28, 2022 and a hearing by the NCC to determine whether we are entitled to take possession of the records seized was scheduled and held on March 16, 2023.

On April 21, 2023, the NCC issued a judgement affirming our ownership of the physical documents, including 51 hardcopy folders and certain digital files, related to the clinical studies performed by ICON/PRA Netherlands and seized by the Dutch courts in December 2022. The NCC further ordered ICON/PRA Netherlands to allow and tolerate the surrender of the documents, including digital and source data. Additionally, the NCC found that we are not in breach of any obligation under the clinical study agreement and PRA Netherlands had no basis to suspend the fulfillment of its obligations under the clinical study agreement to provide us all clinical data and access to perform an audit of the study. ICON/PRA Netherlands has three months to file an appeal of this decision.

In addition to the foregoing, from time to time, we may be subject to various ongoing or threatened legal actions and proceedings, including those that arise in the ordinary course of business, which may include employment matters and breach of contract disputes. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We are not currently engaged in or aware of any threatened legal actions which we believe could have a material adverse effect on our condensed consolidated result of operations or financial position.

ITEM 1A. RISK FACTORS

Although Item 1A. is inapplicable to us as a smaller reporting company, we hereby disclose the following new risk factor in addition to those disclosed in our annual report on Form 10-K for the fiscal year ended December 31, 2022:

Adverse developments with respect to the stability of financial institutions we do business with, or unstable banking, credit and/or capital market conditions generally, or the perception thereof, could adversely affect our ability to access our cash on deposit with financial institutions, obtain additional financing, or meet our liquidity requirements.

The recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure, could materially and adversely affect our liquidity, our business, financial condition and stock price. The recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank and their placement into receivership with the Federal Deposit Insurance Corporation ("FDIC") created bank-specific and broader financial institution liquidity risk and concerns. Although the depositors at these financial institutions have continued to have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. Although we did not have deposits at Silicon Valley Bank, Signature Bank or First Republic Bank, the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. In addition, the ability of our suppliers, vendors, and others in which we do business to access their cash and cash equivalents and investments or to obtain any necessary financing to continue their respective businesses could be threatened, which in turn, could harm our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

We did not sell any unregistered equity securities of our Company during the quarter ended March 31, 2023.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

The following exhibits are being filed or furnished with this quarterly report on Form 10-Q:

Exhibit No.	Description	Manner of Filing
3.1	Notice of Articles of DiaMedica Therapeutics Inc. dated May 31, 2019	Incorporated by reference to Exhibit 3.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 4, 2019 (File No. 001-36291)
3.2	Articles of DiaMedica Therapeutics Inc. dated May 31, 2019	Incorporated by reference to Exhibit 3.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 4, 2019 (File No. 001-36291)
31.1	Certification of Chief Executive Officer Pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Exchange Act Rules 13a-14(a)/15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	Financial statements from the quarterly report on Form 10-Q of DiaMedica Therapeutics Inc. for the quarter ended March 31, 2023, formatted in Inline XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statements of Shareholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements.	Filed herewith
104	Cover Page Interactive Data File	Embedded within the Inline XBRL document

SIGNATURES

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 thereunto duly authorized.

DIAMEDICA THERAPEUTICS INC.

Date: May 15, 2023

/s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2023

/s/ Scott Kellen
Scott Kellen
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick Pauls, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of DiaMedica Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2023

/s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Kellen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of DiaMedica Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 15, 2023

/s/ Scott Kellen
Scott Kellen
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick Pauls, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 of DiaMedica Therapeutics Inc. (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of DiaMedica Therapeutics Inc.

Dated: May 15, 2023

/s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Kellen, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 of DiaMedica Therapeutics Inc. (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of DiaMedica Therapeutics Inc.

Dated: May 15, 2023

/s/ Scott Kellen
Scott Kellen
Chief Financial Officer
(Principal Financial Officer)