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 September 30, 2022

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
Minnetonka, Minnesota 55305
(Address of principal executive offices) (Zip Code)
(763) 312-6755

(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 ☐
Non-accelerated filer ☒

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 November 7, 2022, there were 26,443,067 voting common shares of the registrant outstanding.

DiaMedica Therapeutics Inc.
FORM 10-Q
September 30, 2022

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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 our ReMEDy2 trial and risks associated therewith, including we may not know or have correctly identified 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 ReMEDy2 trial in a timely manner or at all;
- our ability to conduct successful clinical testing of our DM199 product candidate for AIS and 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 on site activations and enrollment of novel strains of the coronavirus, or COVID-19, hospital and medical facility staffing shortages, and concerns managing logistics and protocol compliance for patients 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 patients at 75 sites in the United States, and the possibility that these numbers and other aspects of the study could change depending upon certain factors, including additional input from the FDA and the blinded interim analysis;
- our expectations regarding the final results of our REDUX trial and timing of the release thereof;
- 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 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 current clinical study, as well as our reliance on third parties to conduct our clinical study;
- 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 and needs 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, 2021 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)

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,771	$ 4,707
Marketable securities	33,313	40,405
Prepaid expenses and other assets	322	84
Amounts receivable	75	130
Deposits	9	113
Total current assets	36,490	45,439
Non-current assets:		
Operating lease right-of-use asset	441	42
Property and equipment, net	110	70
Total non-current assets	551	112
Total assets	$ 37,041	$ 45,551
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 864	$ 509
Accrued liabilities	637	966
Operating lease obligation	34	45
Financing lease obligation	7	4
Total current liabilities	1,542	1,524
Non-current liabilities:		
Operating lease obligation, non-current	415	—
Finance lease obligation, non-current	5	3
Total non-current liabilities	420	3
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Paid-in capital	127,667	126,576
Accumulated other comprehensive loss	(162)	(51)
Accumulated deficit	(92,426)	(82,501)
Total shareholders' equity	35,079	44,024
Total liabilities and shareholders' equity	$ 37,041	$ 45,551

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 1,640	$ 2,332	$ 5,569	$ 6,894
General and administrative	1,488	1,084	4,459	3,506
Operating loss	(3,128)	(3,416)	(10,028)	(10,400)
Other income:				
Other income (loss), net	76	(27)	124	75
Loss before income tax expense	(3,052)	(3,443)	(9,904)	(10,325)
Income tax expense	(7)	(7)	(21)	(21)
Net loss	(3,059)	(3,450)	(9,925)	(10,346)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	5	(2)	(111)	(3)
Net loss and comprehensive loss	$ (3,054)	$ (3,452)	$ (10,036)	$ (10,349)
Basic and diluted net loss per share	$ (0.12)	$ (0.18)	$ (0.38)	$ (0.55)
Weighted average shares outstanding – basic and diluted	26,443,067	19,035,713	26,443,067	18,863,829

See accompanying notes to the condensed consolidated financial statements.

DiaMedica Therapeutics Inc.
Condensed Consolidated Statements of Shareholders' Equity
For the Nine Months Ended September 30, 2022 and 2021
(In thousands, except share amounts)
(Unaudited)

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income (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
Share-based compensation expense	—	365	—	—	365
Unrealized loss on marketable securities	—	—	(60)	—	(60)
Net loss	—	—	—	(3,358)	(3,358)
Balances at June 30, 2022	26,443,067	$ 127,249	$ (167)	$ (89,367)	$ 37,715
Share-based compensation expense	—	418	—	—	418
Unrealized gain on marketable securities	—	—	5	—	5
Net loss	—	—	—	(3,059)	(3,059)
Balances at September 30, 2022	26,443,067	$ 127,667	$ (162)	$ (92,426)	$ 35,079

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2020	18,746,157	$ 94,925	$ (2)	$ (68,909)	$ 26,014
Exercise of common stock options	40,000	244	—	—	244
Share-based compensation expense	—	511	—	—	511
Unrealized loss on marketable securities	—	—	(2)	—	(2)
Net loss	—	—	—	(3,622)	(3,622)
Balances at March 31, 2021	18,786,157	$ 95,680	$ (4)	$ (72,531)	$ 23,145
Share-based compensation expense	—	446	—	—	446
Unrealized gain on marketable securities	—	—	1	—	1
Net loss	—	—	—	(3,274)	(3,274)
Balances at June 30, 2021	18,786,157	$ 96,126	$ (3)	$ (75,805)	$ 20,318
Issuance of common shares net of offering costs of $0.1 million	7,653,060	29,867	—	—	29,867
Share-based compensation expense	—	303	—	—	303
Unrealized loss on marketable securities	—	—	(2)	—	(2)
Net loss	—	—	—	(3,450)	(3,450)
Balances at September 30, 2021	26,439,217	$ 126,296	$ (5)	$ (79,255)	$ 47,036

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (9,925)	$ (10,346)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,091	1,260
Amortization of premium on marketable securities	118	51
Non-cash lease expense	47	43
Depreciation	19	18
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(238)	(129)
Amounts receivable	55	236
Deposits	104	(133)
Accounts payable	355	(400)
Accrued liabilities	(371)	(48)
Net cash used in operating activities	(8,745)	(9,448)
Cash flows from investing activities:		
Purchase of marketable securities	(35,895)	(47,740)
Maturities of marketable securities	42,758	35,905
Purchases of property and equipment	(49)	(15)
Proceeds from disposition of property and equipment	—	2
Net cash provided by (used in) investing activities	6,814	(11,848)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	—	29,867
Proceeds from the exercise of stock options	—	244
Principal payments on finance lease obligations	(5)	(5)
Net cash (used in) provided by financing activities	(5)	30,106
Net (decrease) increase in cash and cash equivalents	(1,936)	8,810
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	$ 2,771	$ 16,219
Supplemental disclosure of non-cash transactions:		
Assets acquired under operating lease	$ 446	$ —
Assets acquired under financing lease	$ 10	$ —

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 Company's Phase 2/3 ReMEDy2 trial. The clinical hold was issued following the Company voluntarily pausing patient 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. The acutely low blood pressure levels in the three patients recovered back to their baseline blood pressure within minutes after the IV infusion was stopped, and the patients suffered no injuries. In response to the FDA's clinical hold letter, on September 16, 2022, we submitted to the FDA supporting in-vitro data that the etiology (cause) of the hypotensive events is likely related to switching the type of IV bag used in the prior ReMEDy 1 trial, where no hypotensive episodes were reported, versus the current ReMEDy 2 trial. We observed significant differences in DM199 binding between the two types of IV bags used in the studies that we believe altered, and unintentionally elevated, the total amount of DM199 being administered to patients in the ReMEDy2 trial triggering the hypotensive events. In addition to our analysis of the events leading to and causing the hypotensive events, we also included in this FDA submission, proposed protocol modifications to address the mitigation of these events, including a reduction in the DM199 dose level for the initial IV dose to effectively match the well tolerated IV dose administered in the ReMEDy1 trial. Following review of this data, the FDA responded to our submission, indicating that the FDA was 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 the IV tubing and mechanical infusion pump, to further rule out any other cause of the hypotension events. There can be no assurance that our belief as to the cause of the hypotension events or our response to prevent future events is correct, or that we will be able to fully respond to the FDA's latest questions sufficiently for the FDA to lift the clinical hold on a timely basis or at all. It is also possible that the FDA may subsequently 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 recently proposed for our DM199 product candidate. We may not enroll any additional patients in the ReMEDy2 trial until we provide the FDA with the requested data and 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 patients discharged from the hospital to an intermediate care facility. While we have taken and intend to continue to take certain actions to assist study sites in overcoming these issues, if and when we resume enrollment in the ReMEDy2 trial, 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 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 September 30, 2022, we have incurred losses of $92.4 million since our inception in 2000. For the nine months ended September 30, 2022, we incurred a net loss of $9.9 million and negative cash flows from operating activities of $8.7 million. We expect to continue to incur operating losses until such time as any future product sales, royalty payments, licensing fees and/or milestone 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 September 30, 2022, DiaMedica had combined cash, cash equivalents and marketable securities of $36.1 million, working capital of $35.0 million and shareholders' equity of $35.1 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 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 twelve 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 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 the COVID-19 pandemic, 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, 2021 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 and investment grade corporate obligations, which are classified as available-for-sale and included in current assets as they 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 with unrealized gains and losses reported as a component of shareholders' equity in accumulated other comprehensive loss. 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.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported in earnings. Subsequent increases or decreases in fair value are reported as a component of shareholders' equity in accumulated other comprehensive loss. There were no other-than-temporary unrealized losses as of September 30, 2022.

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 September 30, 2022, 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 $109,000 and $89,000 for the nine months ended September 30, 2022 and 2021, respectively.

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:							
	September 30, 2022				December 31, 2021			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 18,779	$ —	$ 18,779	$ —	$ 29,421	$ —	$ 29,421	$ —
Government securities	14,534	—	14,534	—	10,984	—	10,984	—
Total	$ 33,313	$ —	$ 33,313	$ —	$ 40,405	$ —	$ 40,405	$ —

Accrued interest receivable on available-for-sale securities is included in amounts receivable and was $73,000 and $130,000 as of September 30, 2022 and December 31, 2021, respectively.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the nine months ended September 30, 2022.

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 September 30, 2022 and December 31, 2021.

5. Amounts Receivable

Amounts receivable consisted of accrued interest receivable on marketable securities of $73,000 and $130,000 as of September 30, 2022 and December 31, 2021, respectively.

6. Deposits

Deposits consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Advances to vendors, current	$ 9	$ 113

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 full or 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 based upon their expected recovery time.

7. Property and Equipment

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

	September 30, 2022	December 31, 2021
Furniture and equipment	$ 111	$ 70
Computer equipment	72	67
	183	137
Less accumulated depreciation	(73)	(67)
Property and equipment, net	$ 110	$ 70

8. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued compensation	$ 303	$ 484
Accrued clinical trial costs	230	284
Accrued research and other professional fees	97	191
Other	7	7
Total accrued liabilities	$ 637	$ 966

9. Operating Lease

New office lease

In June 2022, we entered into an agreement to lease approximately6,000 square feet of office space in Minneapolis, MN, near our former office space. The lease commencement date was September 1, 2022, has a term of 65 months expiring on January 31, 2028 and includes an incentive of five months of full rent abatement. This incentive is subject to repayment if we default in performance of any material obligations under the lease prior to the 48th month of the lease and the landlord terminates the lease. This lease includes both lease (e.g., fixed rent) and variable non-lease components (e.g., common-area and other maintenance costs). Non-lease components are deemed to be executory costs and are therefore excluded from the minimum lease payments used to determine the present value of the operating lease obligation and related right-of-use asset. The lease does not provide an implicit rate and, due to the lack of a commercially salable product, we are generally considered unable to obtain commercial credit. Therefore, considering the quoted rates for the lowest investment-grade debt and the interest rates implicit in recent financing leases, we estimated our incremental borrowing rate to be 8%. We used our estimated incremental borrowing rate and other information available at the lease commencement date in determining the present value of the lease payments. Upon lease commencement, the Company recognized an operating lease right-of-use asset and a corresponding operating lease obligation of $446,000, respectively.

Our operating lease cost and variable lease costs were $52,000 and $25,000, respectively, for the nine months ended September 30, 2022. 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 September 30, 2022 (in thousands):

2022	—
2023	97
2024	109
2025	113
2026	116
2027	119
2028	10
Total lease payments	$ 564
Less interest portion	(115)
Present value of lease obligation	$ 449

Former office lease

We leased certain office space under a non-cancelable operating lease that terminated on August 31, 2022, and we did not renew it. This lease included lease (e.g., fixed rent) and non-lease components (e.g., common-area and other maintenance costs). The right-of-use asset for this lease was fully amortized as of August 31, 2022.

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 nine months ended September 30, 2022

During the nine months ended September 30, 2022, we did not issue any common shares or other equity securities other than stock options and deferred stock units.

Equity issued during the nine months ended September 30, 2021

On September 26, 2021, we issued and sold an aggregate 7,653,060 common shares in a securities purchase agreement at a purchase price of $3.92 per share in a private placement to ten accredited investors. As a result of the offering, we received gross proceeds of $30.0 million, which resulted in net proceeds to us of approximately $29.9 million, after deducting the offering expenses.

In connection with the September 2021 private placement, we entered into a registration rights agreement (Registration Rights Agreement) with the investors pursuant to which we agreed to file with the United States Securities and Exchange Commission (SEC) a registration statement registering the resale of the shares sold in the private placement (Resale Registration Statement). The Resale Registration Statement was filed with the SEC on October 5, 2021 and declared effective by the SEC on October 14, 2021. Under the terms of the Registration Rights Agreement, we agreed to keep the Resale Registration Statement effective at all times until the shares are no longer considered "Registrable Securities" under the Registration Rights Agreement and if we fail to keep the Resale Registration Statement effective, subject to certain permitted exceptions, we will be required to pay liquidated damages to the investors in an amount of up to 10% of the invested capital, excluding interest. We also agreed, among other things, to indemnify the selling holders under the Resale Registration Statement from certain liabilities and to pay all fees and expenses incident to our performance of or compliance with the Registration Rights Agreement.

During the nine months ended September 30, 2021,40,000 common shares were issued upon the exercise of options for gross proceeds of $44,000, with an aggregate intrinsic value of $132,000, and no warrants were exercised.

Shares reserved

Common shares reserved for future issuance are as follows:

	September 30, 2022
Common shares issuable upon exercise of employee and non-employee stock options	2,775,998
Common shares issuable upon settlement of deferred stock units	134,402
Common shares issuable upon exercise of common share purchase warrants	265,000
Shares available for grant under the 2019 Omnibus Incentive Plan	2,014,010
Shares available for grant under the 2021 Employment Inducement Incentive Plan	535,000
Total	5,724,410

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 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (3,059)	$ (3,450)	$ (9,925)	$ (10,346)
Weighted average shares outstanding—basic and diluted	26,443,067	19,035,713	26,443,067	18,863,829
Basic and diluted net loss per share	$ (0.12)	$ (0.18)	$ (0.38)	$ (0.55)

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Employee and non-employee stock options	2,775,998	1,959,100	2,775,998	1,959,100
Common shares issuable under common share purchase warrants	265,000	265,000	265,000	265,000
Common shares issuable under deferred stock units	134,402	71,509	134,402	71,509

12. Share-Based Compensation

Amended and Restated 2019 Omnibus Incentive Plan

At the 2022 Annual General Meeting of Shareholders on May 18, 2022, our shareholders, upon recommendation of our Board of Directors (Board), approved the DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan (the 2019 Plan). The Board approved the 2019 Plan, subject to approval by our shareholders, on March 10, 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 September 30, 2022, options to purchase an aggregate of 1,845,588 common shares were outstanding and 117,069 common shares were reserved for issuance upon settlement of DSUs 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 September 30, 2022, 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 September 30, 2022, options to purchase an aggregate of 465,410 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 September 30, 2022, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 126	$ 100	$ 325	$ 371
General and administrative	292	203	766	889
Total share-based compensation	$ 418	$ 303	$ 1,091	$ 1,260

We recognize share-based compensation based on the fair value of each award as estimated using the Black-Scholes option valuation model. Ultimately, the actual 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, 2021	1,896,600	$ 5.22	$ 169
Granted	989,398	2.61	
Expired/cancelled	(57,813)	8.78	
Forfeited	(52,187)	4.94	
Balances at September 30, 2022	2,775,998	$ 4.15	$ —

Information about stock options outstanding, vested and expected to vest as of September 30, 2022, 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	152,000	9.9	$ 1.50	—	—
$2.00 - $2.99	800,398	8.3	2.50	170,852	4.7
$3.00 - $3.99	409,393	7.5	3.80	193,766	5.8
$4.00 - $4.99	862,182	6.7	4.57	805,349	6.6
$5.00 - $24.00	552,025	7.4	6.85	294,525	6.2
	2,775,998	7.6	$ 4.15	1,464,492	6.2

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 its subsidiaries for the three and nine months ended September 30, 2022 and 2021.

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, 2021. 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. DiaMedica's lead candidate, DM199, is the first pharmaceutically active recombinant (synthetic) form of the human tissue kallikrein-1 (KLK1) protein to be studied in patients. KLK1 is an established therapeutic modality for the treatment of acute ischemic stroke (AIS) and chronic kidney disease (CKD). Our long-term goal is to use our patented and in-licensed technologies to establish our Company as a leader in the development of therapeutic treatments from novel recombinant proteins. Our current focus is on the treatment of AIS and CKD. We plan to advance DM199 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 your 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.

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. DiaMedica believes 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 Company's Phase 2/3 ReMEDy2 trial. The clinical hold was issued following the Company voluntarily pausing patient 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. The acutely low blood pressure levels in the three patients recovered back to their baseline blood pressure within minutes after the IV infusion was stopped, and the patients suffered no injuries. In response to the FDA's clinical hold letter, on September 16, 2022, we submitted to the FDA supporting in-vitro data that the etiology (cause) of the hypotensive events is likely related to switching the type of IV bag used in the prior ReMEDy 1 trial, where no hypotensive episodes were reported, versus the current ReMEDy 2 trial. We observed significant differences in DM199 binding between the two types of IV bags used in the studies that we believe altered, and unintentionally elevated, the total amount of DM199 being administered to patients in the ReMEDY2 trial triggering the hypotensive events. In addition to our analysis of the events leading to and causing the hypotensive events, we also included in this FDA submission, proposed protocol modifications to address the mitigation of these events, including a reduction in the DM199 dose level for the initial IV dose to effectively match the well tolerated IV dose administered in the ReMEDy1 trial. Following review of this data, the FDA responded to our submission, indicating that the FDA was 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 the IV tubing and mechanical infusion pump, to further rule out any other cause of the hypotension events. There can be no assurance that our belief as to the cause of the hypotension events or our response to prevent future events is correct, or that we will be able to fully respond to the FDA's latest questions sufficiently for the FDA to lift the clinical hold on a timely basis or at all. It is also possible that the FDA may subsequently 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 recently proposed for our DM199 product candidate. We may not enroll any additional patients in the ReMEDy2 trial until we provide the FDA with the requested data and 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 patients discharged from the hospital to an intermediate care facility. While we have taken and intend to continue to take certain actions to assist study sites in overcoming these issues, if and when we resume enrollment in the ReMEDy2 trial, no assurances can be provided as to if and when these issues will resolve.

Renal: CKD Phase 2 REDUX Clinical Trial of DM199

As of December 31, 2021, we completed patient enrollment in our REDUX clinical trial for the treatment of CKD with a total of 79 patients enrolled and initiating treatment, including 21 African American patients into Cohort 1, 25 patients with IgAN into Cohort 2 and 33 patients with Type 2 diabetes in Cohort 3. As of March 31, 2022, all patients had completed their treatment periods. We are currently working towards finalizing the data and related analyses and evaluating next steps for our CKD program.

Other: DM300

We have identified a potential novel new treatment for inflammatory diseases, named DM300, which is currently in the preclinical stage of development.

Financial Overview

Since our inception, 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. We have incurred losses in each year since our inception. Our net losses were $9.9 million and $10.3 million for the nine months ended September, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $92.4 million. Substantially all of our operating losses resulted from expenses incurred in connection with the development of our DM199 product candidate, our primary research and development (R&D) activities and general and administrative (G&A) support costs associated with our operations.

We expect to continue to incur significant expenses and increased operating losses for at least the next several years as we advance our clinical programs. In the near term, we anticipate that our expenses will increase as compared to prior periods as we resume enrollment in our pivotal Phase 2/3 ReMEDy2 trial, if and when the clinical hold is lifted, and continue site activations.

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, 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 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 future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, site activations and enrollment in our clinical study, the potential expansion of our current development programs, potential new development programs, related G&A support and the effects of the COVID-19 pandemic. 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.

Overview of Expense Components

Research and Development 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 the total costs we will incur in the continued development of DM199 or any of our preclinical development programs. Prior to voluntarily halting enrollment in the ReMEDy2 trial, we had experienced slower than expected site activations and 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 due to COVID-19, as well as staffing shortages and concerns managing logistics and protocol compliance for patients discharged from the hospital to an intermediate care facility. While we are encouraged that COVID-19 related hospitalizations are down compared to prior periods and while we are taking certain actions to assist study sites in overcoming these issues when enrollment resumes, no assurances can be provided as to if and when these issues will resolve.

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 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, professional fees, including for auditing, tax and legal services, and milestone payments under our technology license agreement with Catalent Pharma Solutions, LLC.

Other Income

Other income, net, consists primarily of interest income and foreign currency exchange gains and/or losses.

Results of Operations

Comparison of the Three and Nine Months ended September 30, 2022 and 2021

The following table summarizes our unaudited results of operations for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 1,640	$ 2,332	$ 5,569	$ 6,894
General and administrative	1,488	1,084	4,459	3,506

Research and Development Expenses

R&D expenses decreased to $1.6 million for the three months ended September 30, 2022, down $0.7 million from $2.3 million for the three months ended September 30, 2021. R&D expenses decreased to $5.6 million for the nine months ended September 30, 2022, down $1.3 million from $6.9 million for the nine months ended September 30, 2021. The decrease for the nine-month comparison was driven primarily by reduced costs incurred during the wrap-up of our REDUX Phase 2 CKD trial and decreased non-clinical testing and manufacturing process development costs which were incurred during 2021 in preparation for initiating our Phase 2/3 ReMEDy2 trial. These decreases were partially offset by increased costs incurred in performing our Phase 2/3 ReMEDy2 trial, inclusive of costs incurred during the clinical hold, and increased personnel costs associated with expanding our R&D operations.

General and Administrative Expenses

G&A expenses were $1.5 million for the three months ended September 30, 2022, up from $1.1 million for the three months ended September 30, 2021. G&A expenses were $4.5 million for the nine months ended September 30, 2022, up from $3.5 million for the nine months ended September 30, 2021. The increase for the nine-month comparison was primarily due to increased directors' and officers' liability insurance, and personnel and professional services costs to support our expanding clinical programs. These increases were partially offset by a reduction in non-cash share-based compensation.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of September 30, 2022 and December 31, 2021, and our sources and uses of cash for each of the nine month periods ended September 30, 2022 and 2021, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 36,084	$ 45,112
Total assets	37,041	45,551
Total current liabilities	1,542	1,524
Total shareholders' equity	35,079	44,024
Working capital	34,948	43,915

Cash Flow Data	Nine Months Ended September 30, 2022	2021
Cash flow provided by (used in):		
Operating activities	$ (8,745)	$ (9,448)
Investing activities	6,814	(11,848)
Financing activities	(5)	30,106
Net increase (decrease) in cash and cash equivalents	$ (1,936)	$ 8,810

Working Capital

We had aggregate cash, cash equivalents and marketable securities of $36.1 million, current liabilities of $1.5 million and working capital of $34.9 million as of September 30, 2022, compared to aggregate cash, cash equivalents and marketable securities of $45.1 million, $1.5 million in current liabilities and $43.9 million in working capital as of December 31, 2021. 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 nine months ended September 30, 2022.

Cash Flows

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was $8.7 million compared to $9.4 million for the nine months ended September 30, 2021. 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 $6.8 million for the nine months ended September 30, 2022 compared to net cash used in investing activities of $11.8 million for the nine months ended September 30, 2021. This change resulted primarily from the investment of the proceeds from our September 2021 private placement in the prior year period.

Financing Activities

Net cash used in financing activities was $5,000 for the nine months ended September 30, 2022 and consisted of principal payments on finance lease obligations. Net cash provided by financing activities was $30.1 million for the nine months ended September 30, 2021 and consisted primarily from net proceeds received from the 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 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. 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 initiation of new sites and enrollment in our clinical study, the potential expansion of our current development programs, potential new development programs, the effects of the COVID-19 pandemic, 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, 2021.

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 September 30, 2022 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

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 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 revised risk factor.

It may take considerable time and expense to respond to the clinical hold that has been placed on our Phase 2/3 ReMEDy2 trial by the FDA, and no assurance can be given that the FDA will remove the clinical hold, in which case our business and prospects will likely suffer material adverse consequences.

On July 6, 2022, we announced that the FDA placed a clinical hold on our Phase 2/3 ReMEDy2 trial studying the use of DM199 to treat AIS patients. The clinical hold was issued following the Company voluntarily pausing patient 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. On September 16, 2022, we submitted to the FDA our analysis of the events leading to and causing the hypotension, proposed protocol modifications to address the mitigation of these events, our rationale and supporting non-clinical data that the cause is likely related to switching the type of IV bag used in the prior ReMEDy1 trial, where no hypotensive episodes were reported, versus the current ReMEDy2 trial. Following review of this data, the FDA responded to our submission, indicating that it was continuing the clinical hold at this time and requesting an additional in-use in vitro stability study of the IV administration of DM199, which includes the IV tubing and mechanical infusion pump, to further rule out any other cause. Although we have begun preparations for these in vitro studies and plan to request a Type A FDA meeting to confirm the study design and obtain additional guidance towards lifting the clinical hold and resuming the ReMEDy2 trial, it may take a considerable period of time, the length of which is not certain at this time, and expense for us to fully address the FDA's concerns. Although we believe that these adverse hypotension events likely resulted from a changing to a new formulation of IV bag in the ReMEDy2 trial, as compared to the IV bag used in the ReMEDy1 trial, it is possible that our belief may be incorrect. In addition, the results of the additional in-use in vitro stability study of the IV administration of DM199 may not indicate a sufficient mitigation of the risk of future hypotension events or resolve the issues raised in the FDA's correspondence with us. Therefore, there is no assurance that our belief as to the cause of the hypotension events or our response to prevent future events is correct, or that we will be able to fully respond to the FDA's latest questions sufficiently for the FDA to lift the clinical hold. Even if our belief as to the cause of the hypotension events or our response to prevent future events is correct and we are able to fully respond to the FDA's questions, the FDA may subsequently 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 recently proposed for our DM199 product candidate. It is possible that we will be unable to fully address the FDA's questions and as a result, the clinical hold may never be lifted and we may never be able to resume enrollment in our Phase 2/3 ReMEDy2 trial. At this time, the full extent of the hypotension events on our Phase 2/3 ReMEDy2 trial is unclear.

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 September 30, 2022.

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 September 30, 2022, 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: November 9, 2022

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

Date: November 9, 2022

/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: November 9, 2022

/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: November 9, 2022

/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 September 30, 2022 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: November 9, 2022

/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 September 30, 2022 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: November 9, 2022

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