

**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 **June 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
(State or other jurisdiction of incorporation or organization)

Not Applicable
(I.R.S. Employer Identification No.)

Two Carlson Parkway, Suite 260
Minneapolis, Minnesota 55447
(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 August 9, 2022, there were 26,443,067 voting common shares of the registrant outstanding.

DiaMedica Therapeutics Inc.
FORM 10-Q
June 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;
- our ability to conduct successful clinical testing of our DM199 product candidate for AIS and CKD and meet certain anticipated or target dates, site activations and enrollment numbers with respect to our clinical studies, especially in the light of the effects 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 on site activations and enrollment in our ReMEDy2 clinical trial of DM199 in AIS patients, and the clinical hold noted below;
- our belief as to the cause of the hypotension events that led to the clinical hold by the United States Food and Drug Administration (FDA) on our ReMEDy2 trial and our response to prevent future events and the risk that we may not correctly identify the cause of the hypotension events or that our plan to resolve the issues and mitigate future events may not be successful or may be more costly than anticipated; our timing with respect to and our ability to successfully engage with the FDA and satisfactorily respond to their requests in connection with the clinical hold and the risk that we may not be able to address successfully their concerns identified in the clinical hold letter or that the FDA may require us to collect additional data or information beyond what we currently expect; the risk that the FDA may not remove the clinical hold on the ReMEDy2 trial in a timely manner or at all; and other risks and uncertainties relating to clinical testing and regulatory applications and related filing and approval timelines, including 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 planned clinical studies, as well as our reliance on collaboration with third parties to conduct our clinical studies;
- our expectations regarding the impact of the COVID-19 pandemic on our business, including in particular our progress with site activation and patient enrollment in our clinical studies and our ability to hire additional personnel;
- 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;
- 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; and
- our anticipated use of the net proceeds from our underwritten public offerings and September 2021 private placement.

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)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,062	\$ 4,707
Marketable securities	35,381	40,405
Amounts receivable	88	130
Deposits	108	113
Prepaid expenses and other assets	534	84
Total current assets	<u>39,173</u>	<u>45,439</u>
Non-current assets:		
Property and equipment, net	74	70
Operating lease right-of-use asset	11	42
Total non-current assets	<u>85</u>	<u>112</u>
Total assets	<u>\$ 39,258</u>	<u>\$ 45,551</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 624	\$ 509
Accrued liabilities	894	966
Finance lease obligation	7	4
Operating lease obligation	11	45
Total current liabilities	<u>1,536</u>	<u>1,524</u>
Non-current liabilities:		
Finance lease obligation, non-current	7	3
Total non-current liabilities	<u>7</u>	<u>3</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Paid-in capital	127,249	126,576
Accumulated other comprehensive loss	(167)	(51)
Accumulated deficit	(89,367)	(82,501)
Total shareholders' equity	<u>37,715</u>	<u>44,024</u>
Total liabilities and shareholders' equity	<u>\$ 39,258</u>	<u>\$ 45,551</u>

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 1,955	\$ 2,156	\$ 3,929	\$ 4,562
General and administrative	1,409	1,209	2,971	2,422
Operating loss	(3,364)	(3,365)	(6,900)	(6,984)
Other income:				
Other income, net	13	98	48	102
Loss before income tax expense	(3,351)	(3,267)	(6,852)	(6,882)
Income tax expense	(7)	(7)	(14)	(14)
Net loss	(3,358)	(3,274)	(6,866)	(6,896)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(60)	1	(116)	(1)
Net loss and comprehensive loss	\$ (3,418)	\$ (3,273)	\$ (6,982)	\$ (6,897)
Basic and diluted net loss per share	\$ (0.13)	\$ (0.17)	\$ (0.26)	\$ (0.37)
Weighted average shares outstanding – basic and diluted	26,443,067	18,786,157	26,443,067	18,776,461

See accompanying notes to the condensed consolidated financial statements.

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

	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
Share-based compensation expense	—	365	—	—	365
Unrealized gain 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

	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

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (6,866)	\$ (6,896)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	673	957
Amortization of premium on marketable securities	160	38
Non-cash lease expense	31	28
Depreciation	12	12
Changes in operating assets and liabilities:		
Amounts receivable	42	324
Deposits	5	6
Prepaid expenses and other assets	(450)	(250)
Accounts payable	115	(860)
Accrued liabilities	(106)	239
Net cash used in operating activities	<u>(6,384)</u>	<u>(6,402)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(27,510)	(25,244)
Maturities of marketable securities	32,258	26,235
Purchases of property and equipment	(6)	(13)
Proceeds from disposition of property and equipment	—	2
Net cash provided by investing activities	<u>4,742</u>	<u>980</u>
Cash flows from financing activities:		
Proceeds from the exercise of stock options	—	244
Principal payments on finance lease obligations	(3)	(3)
Net cash provided by (used in) financing activities	<u>(3)</u>	<u>241</u>
Net decrease in cash and cash equivalents	(1,645)	(5,181)
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	<u>\$ 3,062</u>	<u>\$ 2,228</u>
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	<u>\$ 10</u>	<u>\$ —</u>

See accompanying notes to the condensed consolidated financial statements.

DiaMedica Therapeutics Inc.
Notes to the Condensed Consolidated Financial Statements
(Unaudited)

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), exists for the primary purpose of advancing the clinical and commercial development of our proprietary recombinant KLK1 protein, DM199, for the treatment of neurological and kidney diseases. Currently, our primary focus is on developing DM199, a proprietary 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 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 to four years, if at all.

On July 6, 2022, the Company announced that the FDA placed a clinical hold on the Company's Phase 2/3 ReMEDy2 trial, which is an adaptive design, randomized, double-blind, placebo-controlled 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. The blood pressure levels of the three patients recovered back to their baseline blood pressure within minutes after IV infusion was stopped and the patients suffered no further adverse events. The Company may not enroll any additional patients in the ReMEDy2 trial until the Company provides the FDA with the Company's analysis of the events leading to or causing the hypotension, its protocol modifications to address the mitigation of these events, its rationale and supporting data for the protocol modifications, and the FDA notifies the Company that it may resume enrollment in the clinical trial. Based on information received to date, the Company believes that the use of IV administration bags made from a different type of plastic in the ReMEDy2 study is responsible for the unexpected hypotension and that a proportionate reduction in the DM199 dose level for the initial IV dose will effectively mitigate the hypotension issue in future ReMEDy2 patients. The Company plans to submit a revised ReMEDy2 trial protocol with the supporting rationale and data to the FDA in September 2022. However, 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 questions sufficiently for the FDA to lift the clinical hold. 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 trials or imposing stricter approval conditions than we currently expect for our DM199 product candidate.

Prior to voluntarily halting enrollment, our Phase 2/3 ReMEDy2 trial has been adversely impacted by the COVID-19 pandemic and other factors. Specifically, we have experienced, and when we resume enrollment we may continue to experience, slower than expected site activations and enrollment in our ReMEDy2 trial. We believe this may be 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 during the three-week treatment period. While we are encouraged that COVID-19 related hospitalizations are down compared to prior periods and while we have taken and will continue to take certain actions to assist study sites in overcoming these issues, no assurances can be provided as to if and when these issues will resolve.

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

As of June 30, 2022, we have incurred losses of \$89.4 million since our inception in 2000. For the six months ended June 30, 2022, we incurred a net loss of \$6.9 million and negative cash flows from operating activities of \$6.4 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 studies of, and to seek regulatory approval for, our DM199 product candidate. As of June 30, 2022, DiaMedica had combined cash, cash equivalents and marketable securities of \$38.4 million, working capital of \$37.6 million and shareholders' equity of \$37.7 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 studies, 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 June 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 June 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 \$90,000 and \$68,000 for the six months ended June 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:							
	June 30, 2022				December 31, 2021			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Government securities	\$ 24,286	\$ —	\$ 24,286	\$ —	\$ 29,421	\$ —	\$ 29,421	\$ —
Commercial paper and corporate bonds	11,095	—	11,095	—	10,984	—	10,984	—
Total	<u>\$ 35,381</u>	<u>\$ —</u>	<u>\$ 35,381</u>	<u>\$ —</u>	<u>\$ 40,405</u>	<u>\$ —</u>	<u>\$ 40,405</u>	<u>\$ —</u>

Accrued interest receivable on available-for-sale securities is included in amounts receivable and was \$8,000 and \$130,000 as of June 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 six months ended June 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 June 30, 2022 and December 31, 2021.

5. Amounts Receivable

Amounts receivable consisted of accrued interest receivable on marketable securities of \$8,000 and \$130,000 as of June 30, 2022 and December 31, 2021, respectively.

6. Deposits

Deposits consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Advances to vendors, current	<u>\$ 108</u>	<u>\$ 113</u>

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):

	June 30, 2022	December 31, 2021
Furniture and equipment	\$ 71	\$ 70
Computer equipment	70	67
	<u>141</u>	<u>137</u>
Less accumulated depreciation	(67)	(67)
Property and equipment, net	<u>\$ 74</u>	<u>\$ 70</u>

8. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued clinical trial costs	\$ 529	\$ 284
Accrued compensation	207	484
Accrued research and other professional fees	151	191
Other liabilities	7	7
Total accrued liabilities	<u>\$ 894</u>	<u>\$ 966</u>

9. Operating Lease

We lease certain office space under a non-cancelable operating lease. This lease does not have significant rent escalation holidays, concessions, leasehold improvement incentives or other build-out clauses. Further this lease does not contain contingent rent provisions. This lease terminates on August 31, 2022 and we do not have an option to renew. This lease does include both lease (e.g., fixed rent) and non-lease components (e.g., common-area and other maintenance costs). The 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.

Our operating lease cost and variable lease costs were \$32,000 and \$26,000, respectively, for the six months ended June 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 June 30, 2022 (in thousands):

2022		11
Total lease payments	\$	11
Less interest portion		—
Present value of lease obligation	\$	<u>11</u>

New office lease

In June 2022, we entered into an agreement to lease approximately 6,000 square feet of office space in Minneapolis, MN, near our current office space. The lease commencement date is expected to coincide with the initiation of the lease term on September 1, 2022. The lease term is 65 months, expiring on January 31, 2028. The aggregate base rent due over the initial term under the terms of the lease agreement is approximately \$608,000, without giving effect to certain rent abatement terms. We will also be responsible for the payment of variable lease costs covering certain common area maintenance costs, insurance and taxes. The lease includes a one-time 5-year renewal option at the market rate following the initial lease term. We intend to relocate our principal executive officers, together with our research and development operations, to this office space on September 1, 2022 following the expiration of the lease described above.

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 six months ended June 30, 2022

During the six months ended June 30, 2022, we did not issue any common shares.

Equity issued during the six months ended June 30, 2021

During the six months ended June 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:

	June 30, 2022
Common shares issuable upon exercise of employee and non-employee stock options	2,623,998
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	2,026,010
Shares available for grant under the 2021 Employment Inducement Incentive Plan	675,000
Total	<u>5,724,410</u>

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		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Net loss	\$ (3,358)	\$ (3,274)	\$ (6,866)	\$ (6,896)
Weighted average shares outstanding—basic and diluted	26,443,067	18,786,157	26,443,067	18,776,461
Basic and diluted net loss per share	<u>\$ (0.13)</u>	<u>\$ (0.17)</u>	<u>\$ (0.26)</u>	<u>\$ (0.37)</u>

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		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Employee and non-employee stock options	2,623,998	1,421,092	2,623,998	1,421,092
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	72,142	134,402	72,142

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 June 30, 2022, options to purchase an aggregate of 1,833,588 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 June 30, 2022, options to purchase an aggregate of 325,000 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 June 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 June 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		Six Months Ended	
	June 30		June 30	
	2022	2021	2022	2021
Research and development	\$ 108	\$ 140	\$ 199	\$ 271
General and administrative	257	306	474	686
Total share-based compensation	<u>\$ 365</u>	<u>\$ 446</u>	<u>\$ 673</u>	<u>\$ 957</u>

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	837,398	2.81	
Exercised	—	—	
Expired/cancelled	(57,813)	8.46	
Forfeited	(52,187)	3.90	
Balances at June 30, 2022	<u>2,623,998</u>	\$ 4.37	\$ —

Information about stock options outstanding, vested and expected to vest as of June 30, 2022, is as follows:

Per Share Exercise Price	Outstanding, Vested and Expected to Vest			Options Vested and Exercisable		
	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Exercisable	Weighted Average Remaining Contractual Life (Years)	
\$2.00 - \$2.99	800,398	8.6	\$ 2.53	133,000	4.0	
\$3.00 - \$3.99	328,008	8.6	3.82	85,472	6.9	
\$4.00 - \$4.99	943,567	6.8	4.55	871,399	6.7	
\$5.00 - \$9.99	512,025	8.0	7.96	237,338	6.7	
\$10.00 - \$27.06	40,000	4.0	13.42	31,250	2.7	
	<u>2,623,998</u>	<u>7.8</u>	<u>\$ 4.37</u>	<u>1,358,459</u>	<u>6.3</u>	

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 six months ended June 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 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 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 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:

	Program	Product	Preclinical	Phase I	Phase 2	Pivotal	Milestones
Neuro	Acute Ischemic Stroke (AIS): Stroke Recovery & Recurrence Reduction	DM199 IV/SC	ReMEDy2 Pivotal Phase 2/3				<ul style="list-style-type: none"> ✓ Trial initiated - September 2021 ✓ Fast track designation - September 2021 Interim analysis 2023 (subject to timely resolution of the clinical hold)
Renal	IgA Nephropathy	DM199 SC	REDUX Phase 2				<ul style="list-style-type: none"> ✓ Interim update Nov 2021
	Hypertensive African Americans with CKD	DM199 SC	REDUX Phase 2				<ul style="list-style-type: none"> ✓ Interim update Nov 2021
Other	Inflammatory Diseases	DM300	Preclinical				Ongoing development

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 has 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. The blood pressure levels of the three patients recovered back to their baseline blood pressure within minutes after IV infusion was stopped and the patients suffered no further adverse events. We may not enroll any additional patients in the ReMEDy2 trial until we provide the FDA with our analysis of the events leading to or causing the hypotension, our protocol modifications to address the mitigation of these events, our rationale and supporting data for the protocol modifications, and the FDA notifies us that we may resume enrollment in the clinical trial. Based on information received to date, we believe that the use of IV administration bags made from a different type of plastic in the ReMEDy2 study is responsible for the unexpected hypotension and that a proportionate reduction in the DM199 dose level for the initial IV dose will effectively mitigate the hypotension issue in future ReMEDy2 patients. We plan to submit a revised ReMEDy2 trial protocol with the supporting rationale and data to the FDA in September 2022. However, 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 questions sufficiently for the FDA to lift the clinical hold. 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 trials or imposing stricter approval conditions than we currently expect for our DM199 product candidate.

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 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 the clinical hold is lifted and enrollment resumes, 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 evaluating next steps for our CKD program.

Other: DM300

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

Financial Overview

We have not generated any revenues from product sales. Since our inception, 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 \$6.9 million for each of the six month periods ended June, 2022 and 2021. As of June 30, 2022, we had an accumulated deficit of \$89.4 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:

- complete patient follow-up in our REDUX Phase 2 trial of DM199 for CKD;
- expand our team to provide support for our operations;

- maintain, expand and protect our intellectual property portfolio; and
- provided the FDA lifts the clinical hold, continue site activations and enrollment of patients in our pivotal Phase 2/3 ReMEDy2 trial of DM199 for AIS.

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 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 studies, 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 address the FDA imposed clinical hold on our ReMEDy2 trial, we are unable to estimate with any certainty the 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, such as the clinical hold currently imposed 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.

Results of Operations

Comparison of the Three and Six Months ended June 30, 2022 and 2021

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 1,955	\$ 2,156	\$ 3,929	\$ 4,562
General and administrative	1,409	1,209	2,971	2,422

Research and Development Expenses

R&D expenses decreased to \$2.0 million for the three months ended June 30, 2022, down \$0.2 million from \$2.2 million for the three months ended June 30, 2021. R&D expenses decreased to \$3.9 million for the six months ended June 30, 2022, down \$0.7 million from \$4.6 million for the six months ended June 30, 2021. The decrease for the six-month comparison was due to a number of factors, including reduced costs incurred during the wrap-up of our REDUX Phase 2 CKD trial, decreased non-clinical testing costs which were incurred in preparation for our Phase 2/3 ReMEDy2 trial which initiated during 2021 and decreased manufacturing process development costs. These decreases were partially offset by increased costs incurred in performing our Phase 2/3 ReMEDy2 trial and increased personnel costs associated with R&D operations.

General and Administrative Expenses

G&A expenses were \$1.4 million for the three months ended June 30, 2022, up from \$1.2 million for the three months ended June 30, 2021. G&A expenses were \$3.0 million for the six months ended June 30, 2022, up from \$2.4 million for the six months ended June 30, 2021. The increase for the six-month comparison was primarily due to increased directors' and officers' liability insurance, personnel and professional services costs to support our expanding clinical programs. The increases for the six-month comparison 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 June 30, 2022 and December 31, 2021, and our sources and uses of cash for each of the six month periods ended June 30, 2022 and 2021, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	\$ 38,443	\$ 45,112
Total assets	39,258	45,551
Total current liabilities	1,536	1,524
Total shareholders' equity	37,715	44,024
Working capital	37,637	43,915

Cash Flow Data	Six Months Ended June 30,	
	2022	2021
Cash flow provided by (used in):		
Operating activities	\$ (6,384)	\$ (6,402)
Investing activities	4,742	980
Financing activities	(3)	241
Net decrease in cash and cash equivalents	\$ (1,645)	\$ (5,181)

Working Capital

We had aggregate cash, cash equivalents and marketable securities of \$38.4 million, current liabilities of \$1.5 million and working capital of \$37.6 million as of June 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 six months ended June 30, 2022.

Cash Flows

Operating Activities

Net cash used in operating activities for each of the six months ended June 30, 2022 and June 30, 2021 was \$6.4 million. 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 \$4.7 million and \$1.0 million for the six months ended June 30, 2022 and 2021, respectively. The current year increase relates primarily to the timing of maturities of marketable securities.

Financing Activities

Net cash used in financing activities was \$3,000 for the six months ended June 30, 2022 and consisted of principal payments on finance lease obligations, and net cash provided by financing activities was \$241,000 for the six months ended June 30, 2021 and consisted of net proceeds from the exercise of stock options.

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, planned 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 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 studies, 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 June 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 new risk factor and 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. 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, our intent to propose modifications to the protocol for our ReMEDy2 trial to decrease the dose to be comparable to the dose that was well tolerated in the 46 patients in the previous ReMEDy1 trial may not sufficiently mitigate the risk of future hypotension events or resolve the issues raised in our clinical hold letter from the FDA. 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, such that we would be able to convince the FDA to lift the clinical hold. There is also no assurance that we will be able to fully respond to the FDA's questions. 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 initial 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 trials or imposing stricter approval conditions than we currently expect 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 this event 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 June 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)
10.1	DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 19, 2022 (File No. 001-36291)
10.2	Separation Agreement and Release dated as of May 23, 2022 by and between Harry Alcorn, Jr. Pharm.D. and DiaMedica USA, Inc.	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 25, 2022 (File No. 001-36291)
10.3	Consulting Services Agreement dated as of May 23, 2022 by and between Harry Alcorn, Jr. Pharm.D. and DiaMedica USA, Inc.	Incorporated by reference to Exhibit 10.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 25, 2022 (File No. 001-36291)
10.4	301 Carlson Parkway Office Lease dated June 22, 2022 between Medica Services Company, LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2022 (File No. 001-36291)
10.5	Lease Guaranty Agreement dated June 22, 2022 by DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 10.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2022 (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 June 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 and contained in Exhibit 101

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: August 10, 2022

/s/ Rick Pauls

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

Date: August 10, 2022

/s/ Scott Kellen

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

**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: August 10, 2022

/s/ Rick Pauls

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

**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: August 10, 2022

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

**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 June 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: August 10, 2022

/s/ Rick Pauls

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

**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 June 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: August 10, 2022

/s/ Scott Kellen

Scott Kellen
Chief Financial Officer
(Principal Financial Officer)