

**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, 2021**

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:

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
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, 2021, there were 18,786,157 voting common shares of the registrant outstanding.

**DiaMedica Therapeutics Inc.**  
**FORM 10-Q**  
**June 30, 2021**

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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.*

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## 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 include, among other things, statements about:

- 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 certain anticipated dates with respect to our pending and anticipated clinical studies;
- our ability to obtain required regulatory approvals of our DM199 product candidate for AIS and CKD;
- 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 and our ability to serve those markets;
- the rate and degree of market acceptance, both in the United States and internationally, of our DM199 product candidate for AIS and CKD;
- 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 novel strain of coronavirus, or COVID-19, pandemic on our business, including in particular the conduct of our clinical studies and the timing thereof;
- our commercialization, marketing and manufacturing capabilities and strategy;
- expectations regarding federal, state, and foreign regulatory requirements and developments, such as potential United States Food and Drug Administration (FDA) regulation of our DM199 product candidate for AIS and CKD;
- 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 studies and obtain regulatory approvals for 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; and
- our anticipated use of the net proceeds from our underwritten public offerings.

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, 2020 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, 2021</u>	<u>December 31, 2020</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,228	\$ 7,409
Marketable securities	19,067	20,098
Amounts receivable	16	340
Prepaid expenses and other assets	318	74
Total current assets	<u>21,629</u>	<u>27,921</u>
Non-current assets:		
Operating lease right-of-use asset	72	100
Property and equipment, net	73	74
Total non-current assets	<u>145</u>	<u>174</u>
Total assets	<u>\$ 21,774</u>	<u>\$ 28,095</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 239	\$ 1,099
Accrued liabilities	1,132	864
Finance lease obligation	5	6
Operating lease obligation	64	59
Total current liabilities	<u>1,440</u>	<u>2,028</u>
Non-current liabilities:		
Finance lease obligation, non-current	5	7
Operating lease obligation, non-current	11	46
Total non-current liabilities	<u>16</u>	<u>53</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,786,157 and 18,746,157 shares issued and outstanding, as of June 30, 2021 and December 31, 2020, respectively	—	—
Paid-in capital	96,126	94,925
Accumulated other comprehensive loss	(3)	(2)
Accumulated deficit	(75,805)	(68,909)
Total shareholders' equity	<u>20,318</u>	<u>26,014</u>
Total liabilities and shareholders' equity	<u>\$ 21,774</u>	<u>\$ 28,095</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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 2,156	\$ 1,600	\$ 4,562	\$ 2,949
General and administrative	1,209	1,108	2,422	2,163
Operating loss	(3,365)	(2,708)	(6,984)	(5,112)
Other income:				
Governmental assistance - research incentives	-	(65)	-	(180)
Other income, net	(98)	(178)	(102)	(51)
Total other income	(98)	(243)	(102)	(231)
Loss before income tax expense	(3,267)	(2,465)	(6,882)	(4,881)
Income tax expense	7	9	14	18
Net loss	(3,274)	(2,474)	(6,896)	(4,899)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	—	(13)	1	27
Net loss and comprehensive loss	<u>\$ (3,274)</u>	<u>\$ (2,487)</u>	<u>\$ (6,895)</u>	<u>\$ (4,872)</u>
Basic and diluted net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.17)</u>	<u>\$ (0.37)</u>	<u>\$ (0.36)</u>
Weighted average shares outstanding – basic and diluted	<u>18,786,157</u>	<u>14,139,074</u>	<u>18,776,461</u>	<u>13,623,400</u>

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, 2021 and 2020**  
(In thousands, except share and per share amounts)  
(Unaudited)

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
<b>Balances at December 31, 2020</b>	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)
<b>Balances at March 31, 2021</b>	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)
<b>Balances at June 30, 2021</b>	18,786,157	\$ 96,126	\$ (3)	\$ (75,805)	\$ 20,318

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
<b>Balances at December 31, 2019</b>	12,006,874	\$ 64,232	\$ 2	\$ (56,617)	\$ 7,617
Issuance of common shares net of offering costs of \$819	2,125,000	7,682	—	—	7,682
Exercise of common stock options	7,200	16	—	—	16
Share-based compensation expense	—	393	—	—	393
Unrealized gain on marketable securities	—	—	40	—	40
Net loss	—	—	—	(2,425)	(2,425)
<b>Balances at March 31, 2020</b>	14,139,074	\$ 72,323	\$ 42	\$ (59,042)	\$ 13,323
Share-based compensation expense	—	436	—	—	436
Unrealized loss on marketable securities	—	—	(13)	—	(13)
Net loss	—	—	—	(2,474)	(2,474)
<b>Balances at June 30, 2020</b>	14,139,074	\$ 72,759	\$ 29	\$ (61,516)	\$ 11,272

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,896)	\$ (4,899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	957	829
Amortization of premium (discount) on marketable securities	38	(23)
Non-cash lease expense	28	26
Depreciation	12	11
Changes in operating assets and liabilities:		
Amounts receivable	324	504
Prepaid expenses and other assets	(244)	(146)
Accounts payable	(860)	370
Accrued liabilities	239	(494)
Net cash used in operating activities	<u>(6,402)</u>	<u>(3,822)</u>
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(25,244)	(8,799)
Maturities of marketable securities	26,235	6,000
Purchases of property and equipment	(13)	(2)
Proceeds from disposition of property and equipment	2	—
Net cash provided by (used in) investing activities	<u>980</u>	<u>(2,801)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common shares, net of offering costs	—	7,682
Proceeds from the exercise of stock options	244	16
Principal payments on finance lease obligations	(3)	(3)
Net cash provided by financing activities	<u>241</u>	<u>7,695</u>
Net increase (decrease) in cash and cash equivalents	(5,181)	1,072
Cash and cash equivalents at beginning of period	7,409	3,883
Cash and cash equivalents at end of period	<u>\$ 2,228</u>	<u>\$ 4,955</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), are focused on developing novel treatments for neurological disorders and kidney diseases. Currently, our primary focus is on developing DM 199, a proprietary recombinant 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 the British Columbia Business Corporations Act, and our common shares are publicly traded on The Nasdaq Capital Market under the symbol “DMAC.”

**2. Risks, Uncertainties and Going Concern**

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, accordingly, has not begun to commercialize any product candidate or 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 five years, if at all. 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, 2021, we have incurred losses of \$75.8 million since our inception in 2000. For the six months ended June 30, 2021, 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, 2021, DiaMedica had cash and cash equivalents of \$2.2 million, marketable securities of \$19.1 million, working capital of \$20.2 million and shareholders’ equity of \$20.3 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 our clinical data is not positive or economic and market conditions deteriorate.

We expect that we will need substantial additional capital to further our research and development activities, complete the required clinical studies and regulatory activities and otherwise develop our product candidate, DM199, or any future product candidates, to a point where they may be commercially sold. We expect our current cash, cash equivalents and marketable securities, to be sufficient to allow us to complete our currently ongoing Phase 2 study in patients with CKD and to otherwise fund our currently planned operations into the third quarter of 2022, but not at least 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 ongoing development efforts, the potential expansion of current development programs, potential new development programs and related general and administrative 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 capital are favorable.

The accompanying interim condensed consolidated financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business and do not include any adjustments relating to the recoverability or classification of assets or the amounts of liabilities that might result from the outcome of these uncertainties. Our ability to continue as a going concern, realize the carrying value of our assets and discharge our liabilities in the ordinary course of business is dependent upon a number of factors, including our ability to obtain additional financing, the success of our development efforts, our ability to obtain marketing approval for our initial product candidate, DM199, in the United States, the European Union or other markets, and ultimately our ability to license and/or market and sell our initial product candidate. These factors, among others, raise substantial doubt about our ability to continue operations as a going concern. See Note 3 titled “Liquidity and Management Plans.”



### 3. Liquidity and Management Plans

As of December 31, 2020 and June 30, 2021, the Company had an accumulated deficit of \$68.9 million and \$75.8 million, respectively, and the Company has not generated positive cash flow from operations since its inception.

Additional funding will be required to continue the Company's research and development and other operating activities. In the next 12 months, we will likely 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 on terms acceptable to us or sufficient to meet our needs. This risk would increase if our clinical data is not positive or economic and market conditions deteriorate.

There can be no assurances that we will be able to obtain additional financing on commercially reasonable terms, or at all. 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 or making capital expenditures. 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 may be affected by our clinical data and other results of scientific and clinical research; our ability to obtain regulatory approvals; market acceptance of our product candidates; the state of the capital markets generally with particular reference to pharmaceutical and biotechnology companies; the status of any then 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.

### 4. 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, 2020 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 one financial institution. 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, investment grade corporate obligations and bank certificates of deposit, 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 income (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 income (loss). There were no other-than-temporary unrealized losses as of June 30, 2021.

### ***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, 2021, 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 \$68,000 and \$60,000 for the six months ended June 30, 2021 and 2020, respectively.

#### **5. 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, 2021				December 31, 2020			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Government securities	\$ 4,247	\$ —	\$ 4,247	\$ —	\$ 8,924	\$ —	\$ 8,924	\$ —
Bank certificates of deposit	—	—	—	—	496	—	496	—
Commercial paper and corporate bonds	14,820	—	14,820	—	10,678	—	10,678	—
Total	<u>\$ 19,067</u>	<u>\$ —</u>	<u>\$ 19,067</u>	<u>\$ —</u>	<u>\$ 20,098</u>	<u>\$ —</u>	<u>\$ 20,098</u>	<u>\$ —</u>

Accrued interest receivable on available-for-sale securities is included in amounts receivable and was \$9,000 and \$34,000 as of June 30, 2021 and December 31, 2020, 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, 2021.

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, 2021 and December 31, 2020.

#### **6. Amounts Receivable**

Amounts receivable consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Research and development incentives	\$ —	\$ 289
Sales-based taxes receivable	—	2
Other	16	49
Total amounts receivable	<u>\$ 16</u>	<u>\$ 340</u>

## 7. Property and Equipment

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

	June 30, 2021	December 31, 2020
Furniture and equipment	\$ 64	\$ 69
Computer equipment	63	62
	<u>127</u>	<u>131</u>
Less accumulated depreciation	(54)	(57)
Property and equipment, net	<u>\$ 73</u>	<u>\$ 74</u>

## 8. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued clinical study costs	\$ 638	\$ 13
Accrued research and other professional fees	296	360
Accrued compensation	191	483
Accrued taxes and other liabilities	7	8
Total accrued liabilities	<u>\$ 1,132</u>	<u>\$ 864</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 \$34,000 and \$28,000, respectively, for the six months ended June 30, 2021. 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, 2021 (in thousands):

2021	33
2022	46
Total lease payments	\$ 79
Less interest portion	(4)
Present value of lease obligation	<u>\$ 75</u>

## 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, 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.

### Equity issued during the six months ended June 30, 2020

On February 13, 2020, we issued and sold an aggregate of 2,125,000 common shares in a public, underwritten offering at a public offering price of \$4.00 per share. As a result of the offering, we received gross proceeds of \$8.5 million, which resulted in net proceeds to us of approximately \$7.7 million, after deducting the underwriting discount and offering expenses.

During the six months ended June 30, 2020, 7,200 common shares were issued upon the exercise of options for gross proceeds of \$6,000 and no warrants were exercised.

### Shares reserved

Common shares reserved for future issuance are as follows:

	<b>June 30, 2021</b>
Stock options outstanding	1,421,092
Deferred share units outstanding	72,142
Shares available for grant under the DiaMedica Therapeutics Inc. Omnibus Incentive Plan	995,026
Common shares issuable under common share purchase warrants	265,000
<b>Total</b>	<b>2,753,260</b>

## 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):

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Net loss	\$ (3,274)	\$ (2,474)	\$ (6,896)	\$ (4,899)
Weighted average shares outstanding—basic and diluted	18,786,157	14,139,074	18,776,461	13,623,400
Basic and diluted net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.17)</u>	<u>\$ (0.37)</u>	<u>\$ (0.36)</u>

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Employee and non-employee stock options	1,421,092	1,413,988	1,421,092	1,413,988
Common shares issuable under common share purchase warrants	265,000	255,000	265,000	255,000
Common shares issuable under deferred unit plan	72,142	47,237	72,142	47,237

## 12. Share-Based Compensation

### 2019 Omnibus Incentive Plan

The DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan (2019 Plan) was adopted by the Board of Directors in March 2019 and approved by our shareholders at our annual general and special meeting of shareholders held on May 22, 2019. The 2019 Plan permits the Board, or a committee or subcommittee thereof, to grant to the Company's eligible employees, non-employee directors and consultants non-statutory and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, deferred stock units, 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 in approximately equal quarterly installments over one to three years. Options granted to non-employees have a maximum term of five years and generally vest in approximately equal quarterly installments 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 2,000,000 shares. As of June 30, 2021, options to purchase 930,682 common shares were outstanding and 50,959 common shares were reserved for issuance upon settlement of deferred share units (DSUs) under the 2019 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, 2021, options to purchase 490,410 common shares were outstanding under the Prior Plan.

### Prior deferred share unit plan

The DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan (DSU Plan) was terminated by the Board of Directors in conjunction with the shareholder approval of the 2019 Plan. Awards outstanding under the DSU Plan remain outstanding in accordance with and pursuant to the terms thereof. As of June 30, 2021, there were 21,183 common shares reserved for DSUs outstanding.

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	
	2021	2020	2021	2020
Research and development	\$ 140	\$ 131	\$ 271	\$ 238
General and administrative	306	305	686	591
Total share-based compensation	<u>\$ 446</u>	<u>\$ 436</u>	<u>\$ 957</u>	<u>\$ 829</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, 2020	1,389,568	\$ 5.38	\$ 7,109
Granted	85,000	9.69	
Exercised	(40,000)	6.11	132
Expired/cancelled	(13,476)	6.54	
Balances at June 30, 2021	<u>1,421,092</u>	<u>\$ 5.63</u>	<u>\$ -</u>

Information about stock options outstanding, vested and expected to vest as of June 30, 2021, is as follows:

Outstanding, Vested and Expected to Vest					Options Vested and Exercisable		
Per Share Exercise Price		Weighted Average Remaining Contractual Life (Years)		Weighted Average Exercise Price	Options Exercisable		Weighted Average Remaining Contractual Life (Years)
	Shares						
\$2.00 - \$2.99	120,500	4.5	\$ 2.44	120,500	4.5		
\$3.00 - \$3.99	2,500	5.8	3.06	2,500	5.8		
\$4.00 - \$4.99	953,567	7.9	4.51	792,526	7.7		
\$5.00 - \$9.99	274,525	7.1	8.10	216,088	6.5		
\$10.00 - \$27.06	70,000	3.7	16.80	51,667	1.6		
	<u>1,421,092</u>	<u>7.2</u>	<u>\$ 5.63</u>	<u>1,183,281</u>	<u>6.9</u>		

### 13. Related Party Transaction

During 2021, we have engaged a consulting firm owned by our Vice President of Regulatory Affairs to perform certain tasks supporting our quality and regulatory activities. The work is performed as required by us and all services are invoiced on an hourly basis with no minimum commitment. Total charges invoiced were approximately \$149,000 during the six-months ended June 30, 2021, and are recorded as research and development expenses, of which approximately \$8,500 was outstanding and included in accounts payable as of June 30, 2021.

## 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, 2021 and 2020.

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, 2020, which includes additional information about our critical accounting policies and practices and risk factors. 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 primarily focused on developing novel treatments for neurological disorders and kidney diseases. Currently, our primary focus is on developing DM199, a proprietary recombinant KLK1 protein for the treatment of acute ischemic stroke (AIS) and chronic kidney disease (CKD). Our goal is to use our patented and licensed technologies to establish our Company as a leader in the development and commercialization of therapeutic treatments from novel recombinant proteins. We plan to advance DM199, our lead drug candidate, through required clinical studies to create shareholder value by establishing its clinical and commercial potential as a therapy for AIS and CKD.

DM199 is a recombinant form of human tissue kallikrein-1 (KLK1). KLK1 is a serine protease (protein) produced primarily in the kidneys, pancreas and salivary glands, that plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels which decreases blood pressure) 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 the body). We believe DM199 has the potential to treat a variety of diseases where healthy functioning requires sufficient activity of KLK1 and its system, the kallikrein-kinin system.

Our DM199 product candidate is in clinical development as follows:

	Program	Product	Preclinical	Phase I	Phase 2	Pivotal	Milestones
Neuro	Acute Ischemic Stroke	DM199 IV/SC	ReMEDy2 Pivotal Phase 2/3 at day 90				FDA clearance May 2021; initiation Summer 2021
	Stroke Recurrence	DM199 IV/SC	ReMEDy2 Recurrence at day 30				
Cardio-Renal	IgA Nephropathy (IgAN)	DM199 SC	REDUX Phase 2				Topline results H2 2021
	Hypertensive African Americans with CKD / APOL1	DM199 SC	REDUX Phase 2				Topline results H2 2021
Other	Acute Pancreatitis	DM300	Preclinical				Ongoing development

#### *AIS Phase 2/3 ReMEDy2 Study*

In December 2020, we received written responses from the FDA following a Type B Pre-IND meeting request that we submitted in October 2020 regarding our development plan for DM199 in the treatment of AIS. In the FDA’s written responses to the questions we provided, the FDA agreed with our proposals regarding key elements of a pivotal Phase 2/3 study for DM199 in patients with AIS, including plans for an adaptive study design with a primary endpoint based upon the modified Rankin Scale at day 90 and acknowledged that, provided the study results qualify, a single study may support a Biologics License Application submission.



In April 2021, we submitted an Investigational New Drug (IND) application to the FDA detailing a proposed protocol for this clinical study. The FDA accepted our IND in May 2021, allowing us to proceed with this pivotal Phase 2/3 study which we have named ReMEDy2. This clinical study follows our Phase 2 study in AIS patients that demonstrated an improvement in stroke outcomes and reduction in severe stroke recurrence. The upcoming pivotal ReMEDy2 study will evaluate whether DM199, a recombinant investigational agent, can improve three-month outcomes in AIS patients who have no treatment option other than supportive care. Initial preparations are underway and initiation of the study is expected later this summer.

#### *REDUX Clinical Study*

In October 2019, the U.S. Food and Drug Administration (FDA) accepted our Phase 2 clinical study protocol for the treatment of CKD caused by rare or significant unmet diseases. The study named REDUX, Latin for restore, is a multi-center, open-label investigation targeting enrollment of approximately 90 participants with mild or moderate CKD (Stage II or III) and albuminuria, who are being enrolled in three equal cohorts. The study is being conducted in the United States at 13 sites and is focused on participants with CKD: Cohort I is focused on non-diabetic, hypertensive African Americans (AA) with Stage II or III CKD. African Americans are at greater risk for CKD than Caucasians, and those African Americans who have the APOL1 gene mutation are at an even higher risk. The study is designed to evaluate the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is focused on participants with IgA Nephropathy (IgAN). Cohort III, which was added after the completion of our August 2020 public offering, is focused on diabetic kidney disease (DKD) participants with Type 2 diabetes mellitus with CKD, hypertension and albuminuria. The study will evaluate two dose levels of DM199 within each cohort. Study participants receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure, albuminuria and kidney function, which will be evaluated by changes from baseline in estimated glomerular filtration rate and albuminuria, as measured by the urinary albumin to creatinine ratio. Participant enrollment and dosing for this study commenced in December 2019.

In June 2021, we announced interim results indicating that DM199 is demonstrating clinically meaningful improvements in kidney function in Cohorts I and II, as measured by simultaneously stabilizing estimated glomerular filtration rate (eGFR) and decreasing urine albumin-to-creatinine ratio (UACR). In participants who were hypertensive (Cohorts I and III), DM199 also reduced blood pressure by clinically significant levels and importantly, there was no effect on participants who were not hypertensive (Cohort II). We reported the following preliminary data:

- AA: Decrease in UACR -27% in moderate to severe albuminuria (baseline UACR >500) (n=6), Increase in eGFR +2 ml/min (n=12) and decrease in blood pressure -8/-3 mmHg;
- IgAN: UACR decreased by -33% (P=0.002) (baseline UACR>500) (n=11) and eGFR and blood pressure were stable (n=16); and
- DKD: eGFR and UACR levels were stable and blood pressure decreased significantly by -5/1 mmHg (n=28)

DM199 was safe and well tolerated across all cohorts, with no DM199 related severe adverse events (SAEs) or discontinuations due to drug-related adverse events (AEs). AEs were generally mild to moderate in severity, with the most common being local injection site irritation that resolved.

As of July 31, 2021, we had enrolled 75 subjects, including 20 African American subjects into Cohort I, 22 subjects with IgAN into Cohort II and completed enrollment with 33 subjects with Type 2 diabetes, hypertension and albuminuria into Cohort III. We have continued to experience slower than expected enrollment in the first two cohorts of the REDUX study. We believe this is due to continued concerns of potential study subjects related to visiting clinical study sites. We are evaluating the effects of the recent surge in COVID-19 infections related to the Delta variant and we will provide an update on the anticipated completion of Cohort I and Cohort II when we are able to reasonably estimate.

## 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 and \$4.9 million for the six months ended June, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$75.8 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. In the near term, we anticipate that our expenses will increase as we:

- complete our ongoing REDUX Phase 2 study of DM199 for CKD;
- initiate and complete our pivotal ReMEDy2 Phase 2/3 study of DM199 for AIS;
- complete manufacturing process development to support applications for commercial approval of DM199;
- complete preliminary development of a second proprietary recombinant protein named DM300;
- provide G&A support for our operations; and
- maintain, expand and protect our intellectual property portfolio.

While we expect our rate of future negative cash flow per month will vary due to the timing of expenses incurred, we expect our current cash and marketable securities resources will be sufficient to allow us to complete the remaining two cohorts in our REDUX Phase 2 study in patients with CKD, initiate our pending Phase 2/3 study in patients with AIS and to otherwise fund our currently planned operations into the third quarter of 2022, but not at least twelve months from the date of issuance of these condensed consolidated financial statements. However, the amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, including 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. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable.

## Overview of Expense Components

### *Research and Development 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 studies; 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, 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. Although as previously discussed, we have experienced a delay and expect to continue to experience a delay in the timing of costs incurred in the REDUX study as a result of the COVID-19 pandemic, we do not expect to experience a significant overall increase in costs. We intend to continue to assess the effect of the pandemic on our REDUX study and our future studies by monitoring the continued spread of the COVID-19 virus, actions implemented to combat the virus, the availability and effectiveness of vaccines and the number of people vaccinated. Our R&D expenses have increased beginning with the second quarter of 2021 as compared to prior year periods as we commenced preparation for our ReMEDy2 clinical study. We expect that our R&D expenses will continue to increase in the future as we initiate the ReMEDy2 clinical study and if we are successful in advancing DM199, or any of our preclinical programs, into advanced stages of clinical development. The process of conducting clinical studies necessary to obtain regulatory approval and manufacturing scale-up to support expanded development and potential future commercialization is costly and time consuming. Any failure by us or delay in completing clinical studies, manufacturing scale-up or in obtaining regulatory approvals could lead to increased R&D expenses and, in turn, have a material adverse effect on our results of operations.

### General and Administrative Expenses

G&A expenses consist primarily of salaries and related benefits, including share-based compensation related to our executive, finance, business development and support functions. G&A expenses also include insurance, rent and utilities, travel expenses, patent costs and professional fees for auditing, tax and legal services. We expect our G&A expenses will continue to increase in the future as we expand our development and operating activities.

We have instituted a number of procedural changes related to protecting the health and safety of our employees in response to the COVID-19 pandemic. Our office was closed in the second quarter of 2020 and remained closed during the first quarter of 2021 and our employees worked remotely. In the second quarter of 2021, we opened our office and allowed, but did not require, employees to work in the office two days of each week. Non-essential travel continues to be on hold and we encourage our employees to interact with each other and vendors through audio and video conferencing. We did not incur significant additional G&A expenses during the three and six months ended June 30, 2021 related to these changes, or the COVID-19 pandemic, nor do we expect to incur significant additional G&A expenses related to the COVID-19 pandemic going forward. Provided conditions related to COVID-19 do not deteriorate, we expect to continue to work on a modified in-person/remote schedule and restrict non-essential travel for the foreseeable future.

### Other (Income) Expense

Other (income) expense consists primarily of interest income and foreign currency exchange gains and losses. In past years, governmental assistance – research incentives, which were associated with the ReMEDy Phase 2 stroke study, were a significant component of this line item.

## Results of Operations

### Comparison of the Three and Six Months ended June 30, 2021 and 2020

The following table summarizes our unaudited results of operations for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 2,156	\$ 1,600	\$ 4,562	\$ 2,949
General and administrative	1,209	1,108	2,422	2,163
Total other income, net	98	243	102	231

### Research and Development Expenses

R&D expenses increased to \$2.2 million for the three months ended June 30, 2021, up from \$1.6 million for the three months ended June 30, 2020, an increase of \$0.6 million. R&D expenses increased to \$4.6 million for the six months ended June 30, 2021, compared to \$2.9 million for the six months ended June 30, 2020, an increase of \$1.7 million. The increase for the six month comparison was primarily due to a number of factors including costs incurred for our pivotal ReMEDy2 clinical study, increased year-over-year costs related to manufacturing process development and our REDUX Phase 2 CKD study, as well as increased personnel costs associated with additional staff added to support R&D operations. These increases were partially offset by decreased costs incurred for our ReMEDy Phase 2 stroke study which completed in the prior year.

### General and Administrative Expenses

G&A expenses were \$1.2 million for the three months ended June 30, 2021, up from \$1.1 million for the three months ended June 30, 2020. G&A expenses increased to \$2.4 million for the six months ended June 30, 2021, up \$0.2 million from \$2.2 million for the six months ended June 30, 2020. The increase for the six-month comparison was primarily due to increased professional services costs and increased personnel costs to support our expanding clinical programs.

## Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of June 30, 2021 and December 31, 2020, and our sources and uses of cash for each of the six month periods ended June 30, 2021 and 2020, and is intended to supplement the more detailed discussion that follows (in thousands):

<b>Liquidity and Capital Resources</b>	<b>June 30, 2021</b>	<b>December 31, 2020</b>
Cash, cash equivalents and marketable securities	\$ 21,295	\$ 27,507
Total assets	21,774	28,095
Total current liabilities	1,440	2,028
Total shareholders' equity	20,318	26,014
Working capital	20,189	25,893

<b>Cash Flow Data</b>	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
Cash flow provided by (used in):		
Operating activities	\$ (6,402)	\$ (3,822)
Investing activities	980	(2,801)
Financing activities	241	7,695
Net increase (decrease) in cash and cash equivalents	\$ (5,181)	\$ 1,072

## Working Capital

We had cash and cash equivalents of \$2.2 million, marketable securities of \$19.1 million, current liabilities of \$1.4 million and working capital of \$20.2 million as of June 30, 2021, compared to \$7.4 million in cash and cash equivalents, marketable securities of \$20.1 million, \$2.0 million in current liabilities and \$25.9 million in working capital as of December 31, 2020. The decreases in our combined cash, cash equivalents and marketable securities and in our working capital are due primarily to our increased clinical study costs associated with preparing for our ReMEDy2 Phase 2/3 stroke study, costs related to our REDUX Phase 2 CKD study and increased costs related manufacturing development.

## Cash Flows

### *Operating Activities*

Net cash used in operating activities for the six months ended June 30, 2021 was \$6.4 million compared to \$3.8 million for the six months ended June 30, 2020. This increase relates primarily to the increase in the 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 \$1.0 million for the six months ended June 30, 2021 compared to net cash used in investing activities of \$2.8 million for the six months ended June 30, 2020.

### *Financing Activities*

Financing activities consist primarily of net proceeds from the exercise of stock options and in the prior year period from the sale of common shares in our February 2020 underwritten public offering. Net cash provided by financing activities was \$0.2 million for the six months ended June 30, 2021 compared to \$7.7 million for the six months ended June 30, 2020.

## 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 expect to do so for at least three to five years. We 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 do not expect to generate any revenue from product sales unless and until we obtain regulatory approval. 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 we continue the research, development and clinical studies of, and seek regulatory approval for, our DM199 product candidate. In the long-term, subject to obtaining regulatory approval of our DM199 product candidate or any future product candidate and in the absence of the assistance of a strategic partner, we expect 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 candidates, to a point where they may be commercially sold. Although we are striving to achieve these plans, there is no assurance these and other strategies will be achieved or that additional funding will be obtained on favorable terms or at all. While our rate of future negative cash flow per month will vary due to the timing of expenses incurred, we expect our current cash resources will be sufficient to allow us to complete the remaining two cohorts in our REDUX Phase 2 study in patients with CKD, initiate our pending Phase 2/3 study in patients with AIS and to otherwise fund our currently planned operations into the third quarter of 2022, but not at least twelve months from the date of issuance of these condensed consolidated financial statements. However, the amount and timing of future funding requirements will depend on many factors, including the timing and results of our ongoing development efforts, including our clinical studies, the potential expansion of current development programs, potential new development programs 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.

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 incentive grants, 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.

## Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (as defined by applicable SEC regulations) that could have a current material effect or that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

## 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, 2020.

### **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, 2021 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**

In March 2013, we entered into a clinical research agreement with PRA Netherlands to perform a double-blinded, placebo-controlled, single-dose and multiple-dose study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and proof of concept of DM199 in healthy subjects and in patients with Type 2 diabetes mellitus. In one arm of this study, we enrolled 36 patients with Type 2 diabetes who were treated with two subcutaneous dose levels of DM199 over a 28-day period. This study achieved its primary endpoint and demonstrated that DM199 was well-tolerated. The secondary endpoints for this study, however, were not met. The secondary efficacy endpoints were confounded due to what we believe were significant execution errors caused by protocol deviations occurring at the clinical study site that were unable to be reconciled. To date, we have been unable to obtain the complete study records from PRA Netherlands and generate a final study report. On November 14, 2017, we initiated litigation with PRA Netherlands in the United States District Court, Southern District of New York, to compel PRA Netherlands to comply with the terms of the clinical research agreement, including providing full study records and to recover damages. After PRA Netherlands objected to personal jurisdiction and venue, on August 24, 2018, we re-filed our complaint against both PRA Netherlands and its U.S. parent, PRA Health Sciences, Inc. (PRA USA and collectively with PRA Netherlands, PRA), in the United States District Court, District of Delaware. PRA again objected to the venue and personal jurisdiction. The complaint alleges, among other things, that PRA failed to conduct the study in accordance with the study protocol and with generally accepted standards for conducting such clinical studies and that PRA further refused to provide us with all data, records and documentation, and/or access thereto, related to the study in accordance with the clinical trial study agreement. The complaint sought to compel PRA to comply with the terms of the clinical trial study agreement, including providing full study records and to recover damages. On November 19, 2018, PRA Netherlands and PRA USA filed motions to dismiss the lawsuit. On February 20, 2019, we filed a motion seeking to transfer the Delaware action to the United States District Court, District of Minnesota. PRA Netherlands and PRA USA filed an opposition to our motion. On September 21, 2020, the District Court judge issued a ruling denying our motion to transfer indicating that DiaMedica had not met the required standards to support a venue transfer. We believe that, based upon the rationale utilized in the opinion, that the case will likely be dismissed for lack of personal jurisdiction over PRA Netherlands. On November 2, 2020, a final dismissal order was issued by the District Court judge. Due to the uncertainty inherent in appealing this ruling, we have chosen to cease action in the United States and file our claims against PRA Netherlands directly in a Dutch Court. On November 13, 2020, PRA Netherlands was served with our complaint. PRA Netherlands and PRA USA filed their initial appearances with the Dutch Court on February 24, 2021, and are due to submit their defense, bringing forward all procedural and substance defenses. We have filed a motion to move the case to the Netherlands Commercial Court (NCC), which specializes in handling international commercial disputes and provides more flexibility to accommodate the specific needs of an individual case and PRA has agreed to move to the NCC. We are currently waiting for the NCC to assign judges to this matter, after which they will evaluate the adequacy of the documentation submitted in support of our claims and PRA's response in order to determine the activities or additional information required and determine a schedule accordingly.

From time to time, we may be subject to other 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. Other than the PRA matter noted above, we are not currently engaged in or aware of any threatened legal actions.

### **ITEM 1A. RISK FACTORS**

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

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

Not applicable

**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	<a href="#">Notice of Articles of DiaMedica Therapeutics Inc. dated May 31, 2019</a>	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	<a href="#">Articles of DiaMedica Therapeutics Inc. dated May 31, 2019</a>	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	<a href="#">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</a>	Filed herewith
31.2	<a href="#">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</a>	Filed herewith
32.1	<a href="#">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</a>	Furnished herewith
32.2	<a href="#">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</a>	Furnished herewith
101	Financial statements from the quarterly report on Form 10-Q of DiaMedica Therapeutics Inc. for the quarter ended June 30, 2021, 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 (formatted as Inline XBRL and contained in Exhibit 101)	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: August 11, 2021

/s/ Rick Pauls

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

Date: August 11, 2021

/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 11, 2021

/s/ Rick Pauls

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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 11, 2021

/s/ Scott Kellen  
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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:

- (1) the Quarterly Report on Form 10-Q of DiaMedica Therapeutics Inc. for the quarter ended June 30, 2021 (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 11, 2021

/s/ Rick Pauls

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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:

- (1) the Quarterly Report on Form 10-Q of DiaMedica Therapeutics Inc. for the quarter ended June 30, 2021 (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 11, 2021

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