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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____ to _____.

Commission file number: 001-36291

DIAMEDICA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

British Columbia	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Two Carlson Parkway, Suite 260 **Minneapolis, Minnesota** (Address of principal executive offices)	**55447** (Zip Code)

Registrant's telephone number, including area code: **(763) 612-6755**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Shares, no par value per share	**DMAC**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act:**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☐ NO ☒

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the registrant's voting common shares held by non-affiliates, computed by reference to the closing sales price at which the voting common shares were last sold as of June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), as reported by The Nasdaq Capital Market on that date, was $78.5 million.

As of March 8, 2021, there were 18,776,157 voting common shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates by reference information (to the extent specific sections are referred to herein) from the registrant's Proxy Statement for its 2021 Annual General Meeting of Shareholders to be held May 25, 2021.

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DIAMEDICA THERAPEUTICS INC.

ANNUAL REPORT ON FORM 10-K

FISCAL YEAR ENDED DECEMBER 31, 2020

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This annual report on Form 10-K contains certain forward-looking statements that are 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, and 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 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 annual report on Form 10-K 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 trials;
- 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 trials, as well as our reliance on collaboration with third parties to conduct our clinical trials;
- our commercialization, marketing and manufacturing capabilities and strategy;
- expectations regarding federal, state, and foreign regulatory requirements and developments, such as potential 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 trials 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 2020 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 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.

INDUSTRY AND MARKET DATA

In addition to the industry, market and competitive position data referenced in this report from our own internal estimates and research, some market data and other statistical information included in this report are based in part upon information obtained from third-party industry publications, research, surveys and studies, none of which we commissioned. Third-party industry publications, research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

We are responsible for all of the disclosure in this report, and while we believe that each of the publications, research, surveys and studies included in this report are prepared by reputable sources, we have not independently verified market and industry data from third-party sources. In addition, while we believe our internal company research and estimates are reliable, such research and estimates have not been verified by independent sources. Assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "*Part I. Item 1A. Risk Factors.*" These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "*Cautionary Note Regarding Forward-Looking Statements*."

PART I

Item 1. Business

Overview

We are a clinical stage biopharmaceutical company developing novel treatments for neurological and kidney diseases. 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 acute ischemic stroke (AIS) and chronic kidney disease (CKD). We plan to advance DM199, our lead drug candidate, through required clinical trials to create shareholder value by establishing its clinical and commercial potential as a therapy for AIS and CKD.

AIS and CKD patients suffer from impaired blood flow in the brain and kidneys, respectively. These patients also tend to exhibit lower than normal levels of endogenous (produced by the body) kallikrein-1 (KLK1), which is a protein produced primarily in the kidneys, pancreas and salivary glands. We believe treatment with DM199 could replenish levels of KLK1, thereby allowing the natural function of kallikrein-kinin system (KKS) to release bradykinin (BK) in the body where and when needed, generating beneficial nitric oxide and prostacyclin, setting in motion metabolic pathways that can improve blood flow (through vasoregulation), dampen inflammation and protect tissues and end-organs from ischemic damage, supporting structural integrity and normal functioning.

In the case of AIS, low KLK1 levels are associated with increased risk of stroke and a predictor of stroke recurrence. Our ReMEDy Phase 2 trial in AIS was completed in the first half of 2020 and, in addition to meeting its primary safety and tolerability endpoints, showed a 13.4% absolute decrease in severe recurrent strokes (p=0.03) over the 90-day treatment period. Related to CKD, we completed a Phase 1b single dose, pharmacokinetic (PK) study of DM199 in subjects with moderate CKD during 2019. Subjects received a single dose in the study, after which short-term improvements in the biomarkers Nitric Oxide (NO) and Prostaglandin E2 (PGE2) of 27.2% and 40.6%, respectively, were observed at approximately 24 hours after DM199 administration. Increases in these biomarkers are consistent with the expected mechanism of action for DM199. We believe DM199 has the potential to treat a variety of diseases where restoring healthy function requires sufficient activity of KLK1 and its system, KKS.

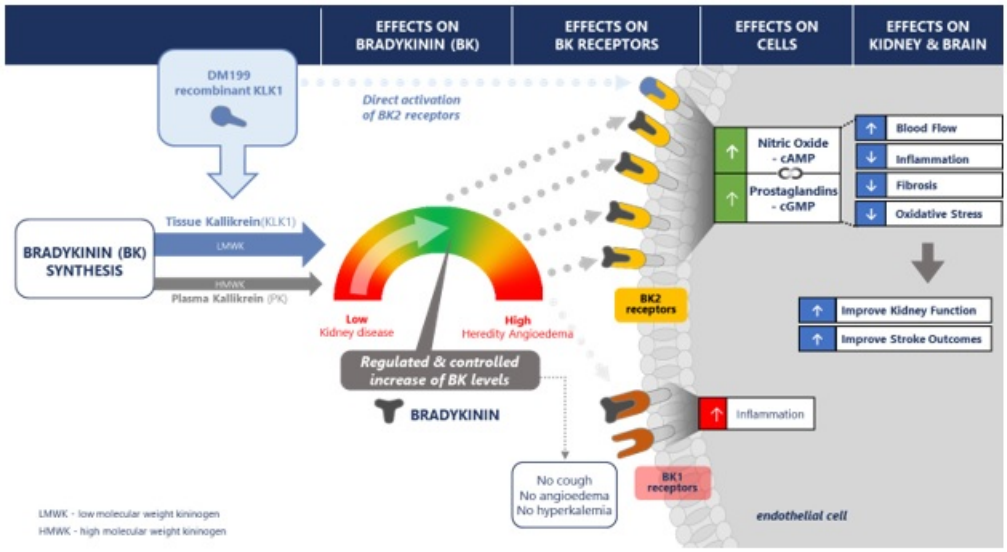
Today, forms of KLK1 derived from human urine and pancreas of a pig (porcine pancreas) are approved and sold in Japan, China and Korea to treat AIS, CKD, retinopathy, hypertension and related vascular diseases. We believe millions of patients have been treated with these KLK1 therapies and the data from more than 200 published papers and studies support their clinical benefit. However, there are numerous regulatory, commercial and clinical drawbacks associated with KLK1 derived from human urine and porcine pancreas which can be overcome by developing a synthetic version of KLK1 such as DM199. We believe higher regulatory standards and antibody reactions are the primary reasons why KLK1 derived from human urine and porcine pancreas are not currently available and used in the United State or Europe. We are not aware of any synthetic version of KLK1 with regulatory approval for human use in any country, nor are we aware of any synthetic version in development other than our drug candidate, DM199.

Kallikrein-Kinin System

KLK1 is a serine protease, or protein, produced primarily in the kidneys, pancreas and salivary glands. KLK1 plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels, which decreases vascular resistance) in the body, as well as an important role in reducing inflammation and oxidative stress (an imbalance between potentially damaging reactive oxygen species, or free radicals, and antioxidants in the body).

KLK1 is involved in multiple biochemical processes. The most well-characterized activity of KLK1 is enzymatic cleavage of low molecular weight kininogen (LMWK) to produce bradykinin (BK)-like peptides, collectively known as kinins, which activate BK receptors (primarily BK2R with some BK1R). Activation of BK receptors by kinins sets in motion metabolic pathways that can improve blood flow (through vasodilation), dampen inflammation, and protect tissues and end-organs from ischemic damage. Scientific literature, including publications in *Circulation Research*, *Immunopharmacology* and *Kidney International*, suggests that lower endogenous KLK1 levels in patients are associated with diseases related to vascular disorders, such as kidney diseases, stroke and hypertension. DM199, as a protein replacement therapy, may replenish KLK1 levels to properly activate the KKS to locally produce nitric oxide, prostaglandin and other anti-inflammatory mediators that protect the brain and kidney from damage. By providing additional supply of the KLK1 protein, DM199 treatment could potentially improve blood flow to and reduce inflammation in damaged end-organs, such as the brain and the kidneys, supporting their structural integrity and normal functioning.

DM199 (KLK1) and Our Therapeutic Hypothesis



We have conducted numerous internal and third-party analyses to demonstrate that DM199 is structurally and functionally equivalent to KLK1 derived from human urine. Specifically, the amino acid structure of DM199 is identical to the human urine form, and the enzymatic and pharmacokinetic profiles are substantially similar to both human urine and porcine derived KLK1. The physiological effects of DM199 on blood pressure, from our completed studies, is similar to that of human urine and porcine-derived forms of KLK1. We believe that the results of this work suggest that the therapeutic action of DM199 will be the same or, potentially, better than that of the forms marketed in Asia.

We believe DM199 may provide new treatment options with significant benefits over the current standards of care by offering a therapeutic treatment option to a greater number of patients with the potential for fewer side effects.

Summary of Clinical Results

To date, clinical trials have been and/or are being conducted in the United States, Europe and Australia. We believe the clinical data generated to date by DM199 supports the continued development of DM199 as a treatment for AIS and CKD.

- Our Phase 2 ReMEDy study of DM199 in the treatment of AIS (n=91) met our primary safety and tolerability end points and further demonstrated a statistically significant reduction in the number of participants with severe recurrent stroke was noted in the active treatment group: 1 (2%) patient treated with DM199 vs. 7 (16%) on placebo (p=0.028), with 4 of the 7 resulting in participant death (p=0.28).

- Additionally, in our Phase 2 ReMEDy study, in a subset of participants (n=46) most closely aligned with the target treatment population for DM199 in our proposed ReMEDy II Phase 2/3 study, participants treated with DM199 (n=25) vs. standard of care supportive therapies and/or tissue plasminogen activator (tPA) (n=21), the results showed that 36% of participants receiving DM199 progressed to a full or nearly full recovery at 90 days (National Institutes of Health Stroke Scale (NIHSS): 0-1), compared to 14% of participants in the placebo group. This represents a 22% absolute increase in the proportion of participants achieving a full or nearly full recovery.

- Our Phase 2 REDUX trial of DM199 in the treatment of CKD caused by rare or significant unmet diseases is ongoing. As of the date of the report 68 participants have been enrolled and no results have been released.

- In July 2019, we completed a Phase 1b clinical trial of DM199 in participants with moderate or severe CKD caused by Type 1 or Type 2 diabetes. The study was performed mainly to assess the pharmacokinetics (PK) of three dose levels of DM199 (3, 5 and 8 μg/kg), administered in a single subcutaneous (SC) dose. In August 2019, we announced the successful completion of this study including positive pharmacodynamic (PD) results which were consistent with the proposed mechanism of action for DM199.

In all studies, DM199 was shown to be safe and well tolerated with no DM199 related serious adverse events or study discontinuations. The primary adverse events noted in our studies include constipation, nausea and headache, all of which resolved without medical intervention.

We are developing DM199 to treat AIS and CKD in the following clinical trials:

Indication	Delivery	Stage	Status	Endpoints
Neurological Diseases				
Acute Ischemic Stroke	Intravenous (IV)/SC	Phase 2/3	Investigational New Drug (IND) Application Submission by end of the first quarter of 2021	Primary endpoint at day 90: ● Modified Rankin Scale score of 0-1 Secondary endpoints at day 90: ● Stroke recurrence ● NIHSS and Barthel index ● Deaths
Kidney Diseases				
IgA Nephropathy (IgAN)	SC	Phase 2	Enrolling	Primary endpoint at day 95: ● Safety & tolerability ● Proteinuria and estimated glomerular filtration rate (eGFR) Secondary endpoints at day 90: ● Change in IgG & IgA biomarkers
African Americans with CKD	SC	Phase 2	Enrolling	Primary endpoint at day 95: ● Safety & tolerability ● Proteinuria and eGFR Secondary endpoints at day 90: ● Change in blood pressure
Diabetic Kidney Disease (DKD)	SC	Phase 2	Enrollment complete	Primary endpoint at day 95: ● Safety & tolerability ● Proteinuria and eGFR Secondary endpoints at day 90: ● Change in blood sugar levels

Supporting Data for Use of DM199 (KLK1):

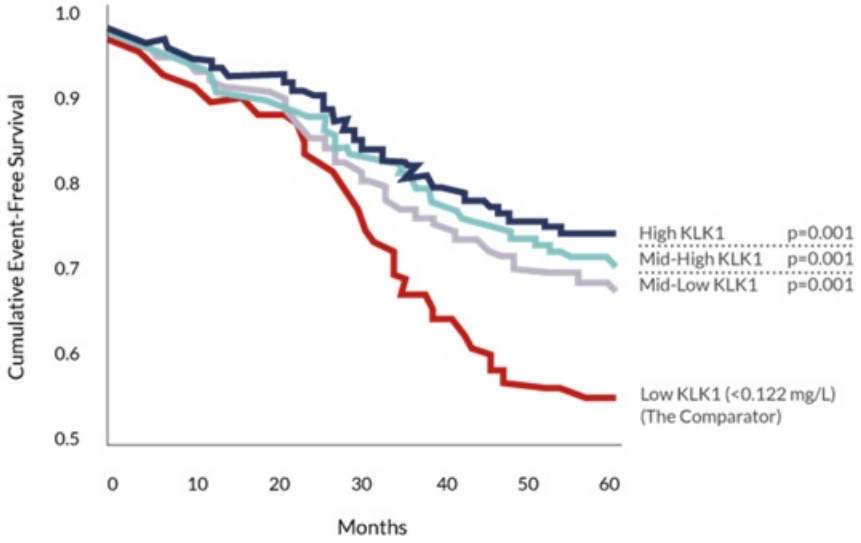
We have identified several hundred papers supporting the clinical use of urinary and porcine derived KLK1 from China, Japan and Korea. We estimate approximately 25 companies are marketing porcine KLK1 and 1 company marketing human urinary KLK1 in these countries.

For patients with chronic kidney disease, studies have shown that KLK1 excretion, or levels of KLK1 in the urine, were significantly decreased. This decrease was more pronounced in patients with severe renal failure requiring dialysis, as illustrated in the graph below.

Low KLK1 Levels Are Associated With Chronic Kidney Disease

Source: Immunopharmacology 44 1999. 183–192

Studies have also shown that lower KLK1 levels are also a predictor of stroke recurrence. As shown in the graph below, the red line represents patients in the lowest KLK1 quartile who are at the highest risk for recurrence of stroke. (2,478 stroke patients and event free survival over 5 years).



Source: Annals of Neurology (2011) 70:265-73

Our Strategy

Our long-term goal is to become a leader in the discovery, development and commercialization of recombinant proteins for the treatment of severe and life-threatening diseases. We seek to identify and select, for development and partnership, recombinant proteins with novel mechanisms that have biological properties with broad applicability. Once we have selected a class of recombinant proteins, we apply their biological properties to clinical settings with unmet needs. We evaluate opportunities based on the estimated development timeline, cost, regulatory pathway and commercial opportunity. After identifying suitable molecules for clinical development, we intend to mitigate development risk by maintaining a diversified and broad clinical pipeline, analyzing data to determine the potential of each program and entering into development collaborations with industry-leading companies.

Our near-term goal is to focus on properly designing and initiating our ReMEDy 2 Phase 2/3 study of DM199 in AIS and to complete our currently ongoing REDUX Phase 2 study of DM199 in CKD.

Currently, our strategy includes the following key components:

- DM199 for CKD - complete our ongoing Phase 2 study;
- DM199 for AIS – initiate and complete our pending Phase 2/3 study;
- Complete manufacturing process development to support applications for commercial approval of DM199;
- Identify a strategic partner(s) to assist with future clinical development and commercialization of DM199; and
- Use our expertise to identify and manufacture other novel recombinant proteins.

AIS Background and Disease Pathology

Acute Ischemic Stroke Background

Stroke is characterized by the rapidly developing loss of brain function due to a blockage of blood flow in the brain. As a result, the affected tissues of the brain becomes inactive and may eventually die. Strokes can be classified into two major categories: AIS and hemorrhagic stroke. AIS is characterized by interruption of the blood supply by a blood clot (ischemia), while a hemorrhagic stroke results from rupture, or bleeding, of a blood vessel in the brain. Risk factors for stroke include, among other things, advanced age, hypertension (high blood pressure), previous stroke or transient ischemic attack (TIA), diabetes, high cholesterol, cigarette smoking, atrial fibrillation, physical inactivity and obesity.

More specifically, with respect to an ischemic stroke, at the site of a blood flow blockage in the brain, there exist two major ischemic zones - the core ischemic zone with nearly complete loss of blood flow (blood flow below 10% to 25%), and the surrounding ischemic penumbra, a rim of mild to moderately ischemic tissue surrounding the core ischemic zone. Within minutes, the significant lack of blood flow in the core ischemic zone deprives these cells of glucose and oxygen which rapidly depletes energy stores and triggers the loss of ion gradients, ultimately leading to neuronal cell death, or apoptosis. The ischemic penumbra zone, however, may remain viable for several hours via collateral arteries that branch from the main occluded artery in the core ischemic zone. Unfortunately, the penumbra is at great risk of delayed tissue damage due to inflammation which may also lead to neuronal cell death. As time goes on, a lack of blood flow in the core ischemic zone (infarct) may lead to fluid buildup (edema) and swelling which creates intracranial pressure. This pressure on the brain leads to tissue compression resulting in additional ischemia. Additional events in AIS include vascular damage to the blood vessel lining or endothelium, loss of structural integrity of brain tissue and blood vessels and inflammation. A stroke can lead to permanent damage with memory loss, speech problems, reading and comprehension difficulties, physical disabilities and emotional/behavioral problems. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation and/or long-term institutional or family care. However, provided the extended window of viability in the penumbra, next generation stroke therapies are being developed to protect valuable brain tissue during the hours to a week after a stroke.

Unmet Medical Need in AIS

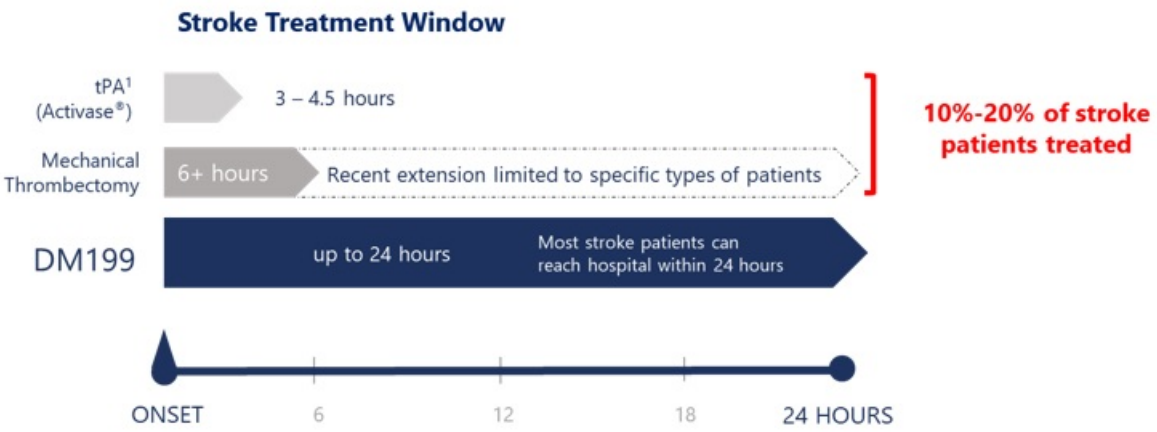
According to the World Health Organization, each year approximately 1.7 million in the U.S., Europe and Japan and approximately 15 million people worldwide suffer a stroke, of which 5.0 million will die and 5.0 million will be permanently disabled. According to the U.S. Center for Disease Control and Prevention (CDC) approximately 87% of all strokes are ischemic in nature, a blockage of blood flow in/to the brain. We believe that stroke represents an area of significant unmet medical need and a KLK1 therapy (such as DM199) could provide a significant patient benefit, in particular given its proposed treatment window of up to 24 hours after the first sign of symptoms. Currently, the only FDA-approved pharmacological intervention for AIS is tPA, which must be given within 4.5 hours of symptom onset. Treating patients with tPA during this time window can be challenging because it is difficult to determine precisely when symptoms began and a patient must undergo complex brain imaging before treatment to rule out a hemorrhagic stroke, a ruptured blood vessel causing bleeding within the brain. Mechanical thrombectomy, a procedure in which the clot is removed using catheter-based tools, is also available to certain patients. Despite the availability of these treatments, we believe they are relevant to approximately 10% of ischemic stroke patients due to the location of the clot, the elapsed time after the stroke occurred or other safety considerations. Thus, we believe DM199 may offer significant advantages over the current treatment options in that it fills a serious, unmet need for patients who cannot receive tPA or mechanical thrombectomy. Additionally, we believe DM199 may also offer a complimentary follow-on treatment for patients who initially receive tPA or mechanical thrombectomy treatments by enabling sustained blood flow improvements to the brain during the critical weeks and months after a stroke, reducing the risk of stroke recurrence.

Specifically with respect to the United States, and according to the CDC:

- Every year in the United States, approximately 795,000 people experience a stroke (ischemic or hemorrhagic). Approximately 610,000 of these are first events and approximately 25%, or 185,000, are recurrent stroke events.
- Approximately one of every 20 deaths in the United States is caused by stroke and is the fifth leading cause of death. On average, someone in the United States has a stroke every 40 seconds and someone dies from a stroke every four minutes.
- Stroke is the leading cause of serious long-term disability and reduces mobility in more than half of stroke survivors age 65 and over.
- Risk of having a first stroke is nearly twice as high for African Americans as for Caucasians, and African Americans have the highest rate of death due to stroke.

Stroke costs in the United States, as reported by the American Heart Association, averaged nearly $46 billion in 2014 and 2015, including the cost of health care services, medications and lost productivity.

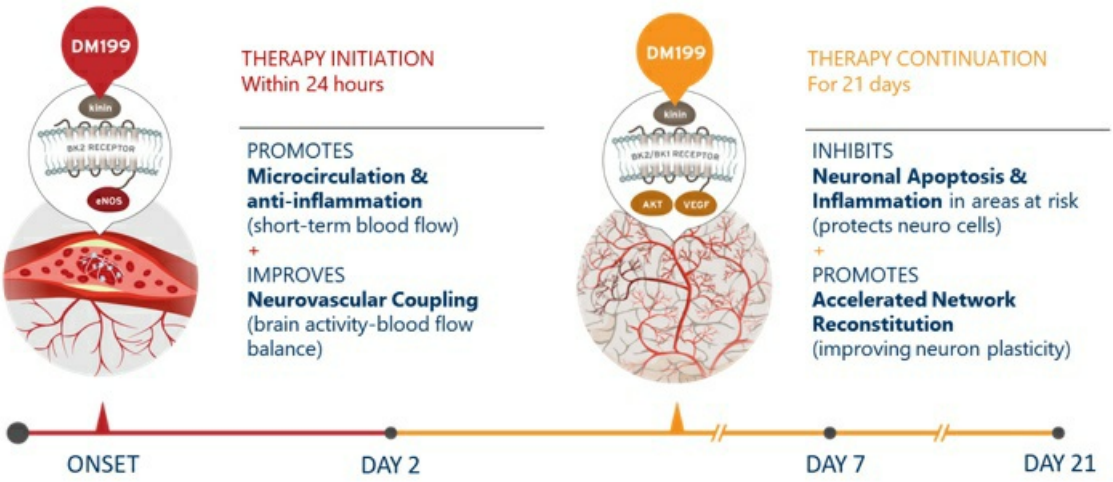
Acute Ischemic Stroke Treatment Options



DM199 – Our Novel Solution for the Treatment of AIS

We believe DM199 has the potential to preserve "at risk" brain tissue by increasing cerebral blood flow, establishing better collateral circulation, decreasing inflammation, reducing cell death, or apoptosis, and facilitating improved blood flow to at-risk brain tissue in the ischemic penumbra. Immediate actions include activation of the KKS to release nitric oxide and improve microcirculation in ischemic tissue along with improvements in the balance between blood flow and brain activity (neurovascular coupling). Longer term (days following the stroke) actions include the restoration of the blood brain barrier through increases in regulatory T cells (Tregs), a subpopulation of regulatory T cells that modulate the immune system and prevent pathologic autoimmune response, and inhibition of neuronal cell death, or apoptosis.

DM199 Acute Ischemic Stroke: Proposed Mechanism

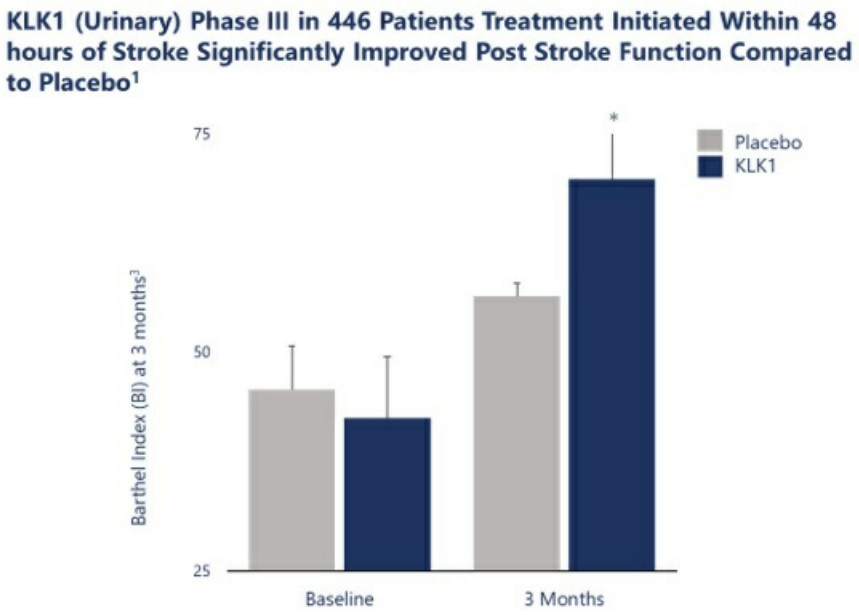


In January 2019, we published a paper titled "Human Tissue Kallikrein in the Treatment of Acute Ischemic Stroke" in the peer reviewed journal, *Therapeutic Advances in Neurological Disorders*. The paper reviews the scientific literature covering the biochemical role of KLK1 and presents the mechanistic rationale for using KLK1 as an additional pharmacological treatment for AIS. In addition to the biochemical mechanism of KLK1, the review highlights supporting results from human genetics and preclinical animal models of brain ischemia. It also reviews published clinical results for treatment of AIS by a form of KLK1 that is isolated from human urine. This form has been approved for post-infarct treatment of AIS in China and data has been published from clinical trials involving over 4,000 patients. The paper offers a series of testable therapeutic hypotheses for demonstrating the long-term beneficial effect of KLK1 treatment in AIS patients and the reasons for this action.

We are developing DM199 to treat AIS patients with a therapeutic window of up to 24 hours after the first sign of symptoms, well beyond the current window of up to 4.5 hours for tPA, thereby filling a large unmet need for those patients who cannot receive tPA under the currently available treatment window of tPA. This important attribute could potentially make therapy available to the millions of patients worldwide who currently have limited treatment options.

Supporting Data from the Use of Urine-derived KLK1 for the Treatment of AIS in China

In China, Kailikang is approved and marketed by Techpool Bio-Pharma Inc., a company controlled by Shanghai Pharmaceuticals Holding Co. Ltd. Kailikang has been approved for the treatment of AIS in China. We believe the initial treatment window is up to 48 hours after stroke symptom onset. Based on IQVIA data, other publications and our own internal analysis, we estimate that over 600,000 stroke patients have been treated with Kailikang in China since its approval in 2005. More than 50 published clinical studies, covering over 4,000 stroke patients, have demonstrated a beneficial effect of Kailikang treatment in AIS including improvements in standard stroke scores, blood flow and biomarkers of inflammation. According to a publication in the *China Journal of Neurology*, in a double-blinded, placebo-controlled trial of 446 patients treated with either Kailikang or a placebo with initial treatment administered up to 48 hours after symptom onset showed significantly better scores on the European Stroke Scale and Activities of Daily Living at three weeks post-treatment and after three months using the Barthel Index:



Additionally, a comprehensive meta-analysis covering 24 clinical studies involving 2,433 patients published in the *Journal of Evidence-Based Medicine* concluded that human urinary KLK1 appears to ameliorate neurological deficits for patients with AIS and improves long-term outcomes, though a few treated patients suffered from transient hypotension.

Furthermore, in a retrospective study covering 300 consecutive AIS patients, published in *Brain and Behavior* March 2018, patients treated with human urinary KLK1 experienced 39% (p=0.009) fewer recurrent strokes within one year.

CKD Background and Disease Pathology

Chronic Kidney Disease Background

CKD is characterized by a progressive decline in overall kidney function as measured by the eGFR, a test used to evaluate blood flow through the kidneys, and albuminuria, a marker for glomerular injury which is a measure of the amount of albumin protein excreted in your urine and an indicator for how well the kidneys are filtering excess fluid and waste products out of your blood. As glomerular filtration decreases, the body's ability to continue to regulate its many functions, including the elimination of metabolic waste, is lost and ultimately, may result in severe physiologic consequences. Among multiple underlying causes, CKD often begins with an increase in blood glucose which leads to the thickening of the glomerular membrane, known as fibrosis. As the kidney function becomes impaired, eGFR decreases and albuminuria increases. Increased albuminuria means that abnormal amounts of protein are released into the urine collecting tubules of the kidney through damaged capillary pores in the glomerular floor. Additionally, increased blood glucose leads to increased blood pressure, elevated reactive oxygen species, advanced glycation end product formation (harmful compounds that are formed when protein or fat combine with sugar in the bloodstream) and inflammation. As these continue, structural components of the kidney begin to collapse, resulting in cell ischemia and cell death. As the renal damage continues, a progressive thickening of the glomerular basement membrane is seen along with continued pathological changes in the cells and inflammation. Early stages of CKD are characterized as microalbuminuria (small amounts of protein leak into the urine). Late stages are characterized as macroalbuminuria (large amounts of protein leak into the urine). The rate of decline depends on a number of factors including the type of diabetes, genetic predisposition, glycemic controls and blood pressure. At the final stages of CKD, the kidneys fail completely and dialysis or a kidney transplant is needed.

Unmet Medical Need in CKD

CKD is a widespread health problem that generates significant economic burden throughout the world:

- According to the National Kidney Foundation, 37 million Americans have CKD and millions of others are at increased risk.
- The primary causes of CKD are diabetes (Type 2 and Type 1) and hypertension. The Medical Clinics of North America estimates that over 40% of those with Type 2 diabetes and 20% of those with Type 1 diabetes will eventually develop CKD, making it one of the more common risks for diabetics.
- Patients with CKD are at greater risk for hypertension and heart disease.

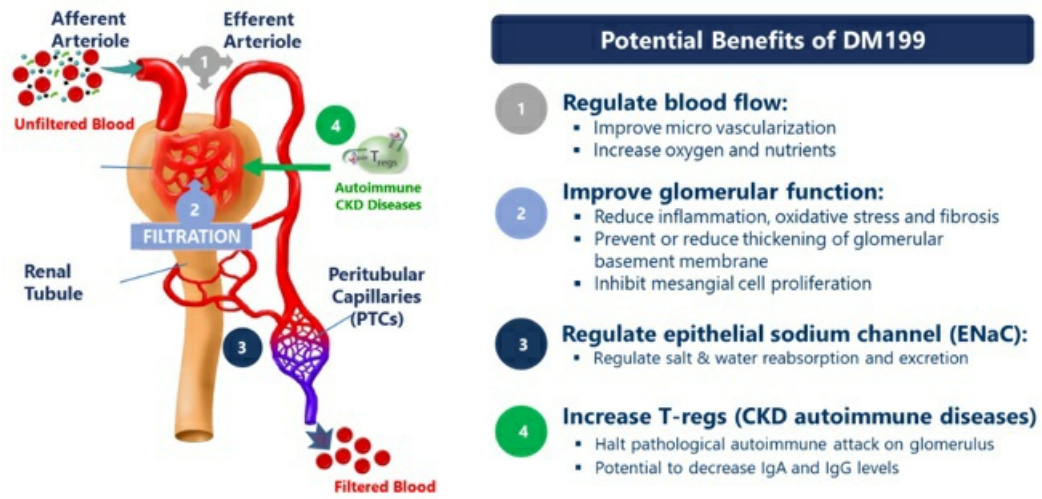
Currently, there is no cure for CKD and treatment primarily involves management of the symptoms of the disease. Blood pressure medications, such as angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB), are often prescribed to control hypertension, and hopefully, slow the progression of CKD. Recently sodium glucose co-transporter 2 inhibitors (SGLT2) have received approval to expand their label to treat diabetic kidney disease to reduce the rate of cardiovascular events. Nevertheless, according to the National Kidney Foundation, many of these patients continue to show declining kidney function and 3.6% of the overall population has a lifetime risk of developing ESRD, where dialysis or a kidney transplant is needed. We believe DM199 offers a potentially novel approach for the treatment of CKD because KLK1 protein plays a vital role in normal kidney function. Since patients with moderate to severe CKD often excrete abnormally low levels of KLK1 in their urine, we believe that DM199 may potentially prevent or reduce further kidney damage by increasing levels of KLK1 and restoring the protective KKS to regulate the production and release of nitric oxide and prostacyclin.

DM199 – Our Novel Solution for the Treatment of CKD

We believe DM199 has the potential to offer meaningful therapeutic benefits for CKD patients. We believe that the KLK1 protein plays a vital role in maintaining normal kidney function, promoting the production of nitric oxide, prostacyclin and other anti-inflammatory mediators which are important for kidney health and integrity. Patients with moderate to severe CKD often excrete abnormally low levels of KLK1 in their urine, leading to the hypothesis that a KLK1 deficit contributes to disease progression. We believe that DM199, as a protein replacement therapy, can potentially replenish KLK1 levels and properly activate the KKS enabling or improving the production of nitric oxide, prostacyclin and other anti-inflammatory mediators which may protect the kidney from damage and possibly restore normal kidney function. In related preclinical testing, DM199 treatment in an animal model of Type 1 diabetes, a known cause of CKD, delayed the onset of the disease, attenuated the degree of insulitis (inflammation in the insulin producing islet cells of the pancreas) and improved pancreatic beta cell mass in a dose-dependent manner by increasing Tregs.

By providing additional KLK1, DM199 has the potential to:

- Improve blood flow through the kidney by restoring proper regulation of blood flow through veins, arteries and especially capillaries (vasoregulation);
- Support the structural integrity of the kidney by reducing scar tissue formation (fibrosis), oxidative stress, and inflammation; and
- Activate mechanisms that upregulate Tregs, improve insulin sensitization, glucose uptake and glycogen synthesis, and lower blood pressure.



Further supporting the hypothesis that an intact KKS is critical for normal kidney function, a series of observational studies published in*Immunopharmacology* showed the amount of KLK1 released into the urine appears to be inversely correlated with the severity of disease in patients with CKD. Urinary KLK1 excretion was decreased in patients with both mild (not requiring dialysis) and severe (kidney failure/hemodialysis) renal disease compared to controls. Decreases in urinary KLK1 activity were seen especially when the reduction was associated with decreased glomerular filtration rate.

DM199 treatment is intended to directly replenish KLK1 levels to maintain, or possibly restore, kidney function. Current treatment options, especially ACEi drugs, primarily slow the rate of decline in kidney function and are associated with side effects. Importantly, it is becoming increasingly clear that part of the beneficial effect of ACEi drugs involves preventing the normal breakdown of BK leading to substantial increases in BK levels throughout the body. However, these effects can be unregulated and ACEi drugs therefore can generate excessive BK where it is not needed, potentially leading to side effects such as persistent cough, angioedema (swelling of skin and tissue) and hyperkalemia (abnormally high potassium levels that can lead to cardiac arrest and sudden death). We believe DM199 treatment could potentially restore normal KLK1 levels allowing the KKS to perform its normal physiological processes and release BK when and where it is needed, avoiding these side effects.

We intend to seek approval for use of DM199 as a novel and ground-breaking therapy for CKD. Protein replacement therapy with DM199, through the activation of the KKS, may complement the renin-angiotensin system, primarily targeted by ACEis and ARBs, and may potentially improve the function of the diseased renal system by improving blood flow and vasodilation, as well as reducing inflammation and oxidative stress.

Supporting Data from the Use of Porcine-Derived KLK1 for the Treatment of CKD in Japan, China and Korea

KLK1 derived from porcine pancreas is currently used to treat CKD in Japan, China and Korea. Specifically, porcine KLK1 is also used to treat hypertension and retinopathy. Based on data published by the data analytics company IQVIA and our own internal analysis, we estimate that millions of patients have been treated with porcine KLK1 for these and other vascular diseases. We have identified 17 clinical papers, published in China and Germany supporting the therapeutic activity of porcine KLK1 in CKD patients, whether given alone or in combination with an ARB or an ACEi. These unblinded studies involve treatment durations ranging from a few weeks up to six months and report improvement in kidney disease based on decreased urinary albumin excretion rates and other clinical endpoints of kidney disease.

Study Details				Δ from Baseline		Publication Details	
Observation	Control	N	Length	UAER % Δ	eGFR (ml/min)	Journal Name	Year
pKLK1 + ARB	ARB	60	1 Month	(57.7%) **	n/m	China Modern Doctor	2011
pKLK1 + ARB	ARB	68	1 Month	(63.2%) **	+21.9 **	Journal of XinXiang Medical College	2012
pKLK1	n/a	13	2 Months	n/m	+27.0 ^	Klinische Wochen-schrift [1] (Germany)	1980
pKLK1	n/a	10	2 Months	n/m	+4.8	Japan Journal of Nephrology	1984
pKLK1	n/a	100	2 Months	(42.6%) ^^	n/m	Medical Information [2]	2014
pKLK1	Antiplatelet	112	2 Months	(56.3%) ^	n/m	Chinese Journal of Medicine (Micro) [3]	2015
pKLK1	Antiplatelet	88	2 Months	(23.5%)	n/m	Chinese Journal of Medicine (Macro) [3]	2015
pKLK1 + ARB	ARB	50	3 Months	(46.4%) *	n/m	Chinese Journal of Gerontology	2005
pKLK1 + ARB	ARB	51	3 Months	(32.7%) *	n/m	Practical Clinical Medicine (Micro) [4]	2006
pKLK1 + ARB	ARB	32	3 Months	(51.0%) *	n/m	Practical Clinical Medicine (Macro) [4]	2006
pKLK1 + ARB	ARB	58	3 Months	(37.5%) *	n/m	Journal of Practical Diagnosis & Treatment [5]	2007
pKLK1 + ARB	ARB	92	3 Months	(64.4%) *	n/m	Contemporary Medicine	2016
pKLK1 + ARB	ARB	62	6 Months	(58.6%) **	n/m	Guide of China Medicine	2010
pKLK1 + ARB	ARB	60	6 Months	(84.3%) **	n/m	Chin J Diabetes [6]	2011
pKLK1 + ARB	ARB	90	6 Months	(57.8%) *	+42.2 *	Chin J Lab Design	2013
pKLK1 + ARB	ARB	100	6 months	(52.7%) **	+41.0 *	Journal of Guangzhao Medical University	2017
pKLK1	Standard Care	86	6 Months	(60.5%) *	n/m	Psychological Monthly	2019
DM199 + ARB	**n/a**	**28**	**@24 hours**	**(18.7%)** UACR	**+ 4.08^^**	**DiaMedica Phase 1b Single Dose Study [7]**	**2019**

Notes

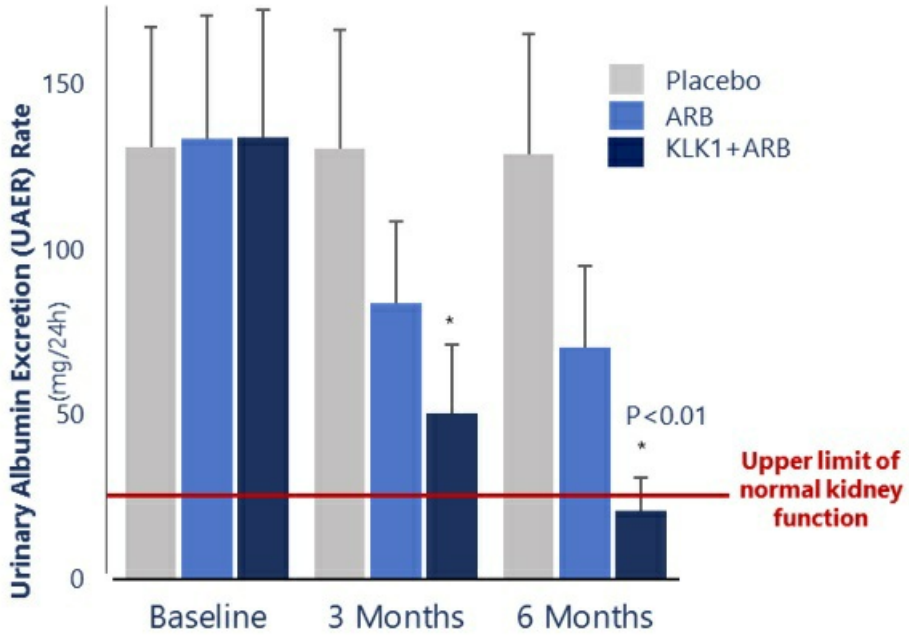
1. Study assessed patients with low and normal urinary KLK1 (uKLK1) levels. Study subjects did not have CKD. The data presented in the table is based on patients with low uKLK1 levels at baseline. No significant GFR change was observed in patients with normal uKLK1 levels at baseline.
2. A significant decrease was observed from baseline ($p < 0.05$), but the actual baseline statistic was unavailable. The study did publish UAER levels at the end of weeks 1 - 8. Data presented in the table measures UAER change from week 1 to week 8.
3. Study analyzed two cohorts: microalbuminuria group (UAE 30 - 300 mg/24h) and clinical albuminuria group (UAE >300 mg/24h).
4. Study analyzed two cohorts: microalbuminuria group (urine protein ≤0.5g/24h) and massive albuminuria group (urine protein >0.5g/24h).
5. Δ in urinary albumin creatininine ratio at 3 months was -87 mg/g (baseline= 175 mg/g, 3 Mo = 88 mg/g, P<0.05 compared to control)
6. At 3 months UAER Δ was -84.5 µg/min (P<0.01 compared to control)
7. Urinary albumin creatinine ratio excludes participants with baseline UACR levles <30 mg/g (normals)

** = p<0.05 (intergroup) | ^ = p<0.05 (Intragroup)*
*** = p<0.01 (intergroup) | ^^ = p<0.01 (Intragroup)*

n/a = not applicable
n/m = not measured

We also identified one 90-patient study in which porcine KLK1 given in combination with an ARB restored normal kidney function.

Kallidinogenase (Porcine-Derived KLK1) Improves Kidney Function in 90 Patients



Our Competition and Current Treatments for Acute Ischemic Stroke and Chronic Kidney Disease

The biopharmaceutical industry is highly competitive and characterized by rapidly advancing technologies that focus on rapid development of proprietary drugs. We believe that our DM199 product candidate, development capabilities, experience and scientific knowledge provide us with certain competitive advantages. However, we face significant potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for competitive products and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize, thus limiting our market share and resulting in a longer period before we can recover the expenses of developing and commercializing our DM199 product candidate.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These activities may lead to consolidated efforts that allow for more rapid development of competitive product candidates.

We also compete for staff, development and clinical resources. These competitors may impair our ability to recruit or retain qualified scientific and management personnel, our ability to work with specific advisors, or our ability to work with clinical contract organizations due to conflicts of interest or capacity constraints, and may also delay recruitment of clinical study sites and study volunteers, impeding progress in our development programs.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government or other third-party payers. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more effective or less expensive than any products that we may develop.

Acute Ischemic Stroke

Currently, there is one approved pharmaceutical treatment for AIS. That treatment is tPA (marketed under the brand name Activase®), and its therapeutic window is limited to up to 4.5 hours after the AIS. There are, however, a number of companies that are actively pursuing a variety of approaches to develop pharmaceutical products for the treatment of AIS including, among others:

- Stem cells (Athersys, Inc.)
- tPA extended treatment window (Genentech)
- Cerebral edema (Biogen Inc.)
- Anti-inflammatory and clot dissolving (Biogen Inc.)
- Cell protection and anti-inflammation (ZZ Biotech LLC)
- Inhibiting platelet aggregation (Acticor Biotech SAS)

There is a large unmet therapeutic need for AIS treatments that can be administered beyond the 4.5-hour time window of tPA. With this large unmet therapeutic need, there is significant competition to develop new therapeutic options. New therapeutic options in development include tissue protection focused therapies (deliverable from hours to days after the stroke) that preserve and protect brain cells beyond the tPA therapeutic window. Currently, the most advanced treatments involve the mechanical removal of blood clots in arteries supplying blood to the brain through sophisticated catheter-based approaches, or mechanical thrombectomy. According to published research, use of mechanical thrombectomy is growing and the window of time after a stroke where the procedure can be used is widening. The goal is to provide treatment options for the vast majority of AIS patients who do not receive hospital care early enough to qualify for tPA therapy. We believe there is a very significant market opportunity for a drug that has a therapeutic window beyond that of tPA and is able to obtain regulatory approval.

Chronic Kidney Disease

CKD is primarily associated with diabetes and hypertension along with other disease states. In the United States, we are aware of only two currently approved treatments for CKD. These treatments include an ACEi (marketed under the brand name Captopril®) which is approved for the treatment of patients with CKD caused by Type 1 diabetes and a sodium glucose co-transporter 2 inhibitor (marketed under the brand name INVOKANA® and Farxiga®) which is approved for the treatment of diabetic kidney disease (DKD), a type of CKD, in adults with mild to moderate Type 2 diabetes and macroalbuminuria.

There are several pharmaceutical products for the treatment of CKD currently in clinical development, some of which include:

- Mineralcorticortisteroid receptor agonist (Bayer HealthCare Pharmaceuticals LLC)
- Chymase inhibitor (Bayer HealthCare Pharmaceuticals LLC)
- Transient receptor potential canonical channel 5 (Goldfinch Bio)
- CCR2 receptor antagonists (ChemoCentryx, Inc., Bristol-Myers Squibb Company)
- Oxidative stress, cyclo-oxygenase 2 inhibitors (Reata Pharmaceuticals, Inc.)

- Glycosylation inhibitors (Glycadia, Inc. aka Glycadia Pharmaceuticals)
- Endothelin A receptor antagonists (Chinook therapeutics, Inc.)
- Cyclin nucleotide phosphodiesterase inhibitor (Pfizer Inc.)
- Aldosterone receptor antagonists (Mitsubishi Tanabe Pharma Corporation)
- Nitric oxide enzyme inhibitor (GenKyoTex SA)
- Nitric oxide (Cyclerion/Ironwood Pharmaceuticals, Inc.)

Additionally, there are several pharmaceutical products specifically for the treatment of IgAN currently in clinical development, some of which include:

- Local corticoid steroid gut immune system (Calliditas Therapeutics AB)
- Dual acting ARB and endothelin receptor antagonist (Travere Therapeutics, Inc.)
- Antibody MASP-2 inhibitor (Omeros Corporation)
- Small-molecule inhibitor of complement factor B (Novartis AG)
- Small-molecule inhibitor Nrf2 activator/NFkB inhibitor (Reata Pharmaceuticals, Inc.)

Current treatment strategies for CKD include the strict control of high blood pressure and high blood sugar. The ACEi drug Captopril® is approved for use in patients with CKD due to Type 1 diabetes and both ACEi and ARBs are widely prescribed to slow the progression of CKD. Furthermore, the treatment with ACEi has been linked to hyperkalemia (elevated blood potassium levels), which increases the risk for abnormal heart rhythms and sudden death. In fact, two clinical trials investigating the use of ACEi and ARB combination therapy in kidney disease were stopped prematurely because participants developed hyperkalemia. The added complication of hyperkalemia results in patients receiving smaller, or suboptimal, doses or patients being untreated because they cannot tolerate the treatment. Additional side effects with ACEi treatment are angioedema (swelling of skin tissue) and persistent cough.

INVOKANA® (canagliflozin) is approved for use in patients to reduce the risk of end-stage renal disease (ESRD), worsening of kidney function, cardiovascular death and hospitalization for heart failure in adults with Type 2 diabetes and DKD with a certain amount of protein in the urine. Potential side effects of INVOKANA include lower limb amputations, dehydration, diabetic ketoacidosis and genital mycotic infections. Farxiga (dapagliflozin) is approved for use in patients to reduce the risk of hospitalization for heart failure in adults with Type 2 diabetes and established cardiovascular disease. Potential side effects of INVOKANA include dehydration, diabetic ketoacidosis and genital mycotic infections.

DM199 treatment is intended to directly replenish KLK1 levels, maintaining or potentially restoring kidney function. Current treatment options, especially ACEi drugs, only partially restore kidney function and are associated with high-risk side effects. ACEi drugs can generate excessive BK where it is not needed, potentially leading to side effects such as cough and angioedema. DM199 treatment may potentially allow KLK1 to follow its normal physiological processes and release BK when and where it is needed, avoiding these side effects.

DM199 Clinical Studies

AIS Phase 2/3 ReMEDy 2 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 Phase 2/3 trial for DM199 in patients with AIS, including plans for an adaptive trial design with a primary endpoint based upon the modified Rankin Scale (mRS) at day 90 and acknowledged that, provided the study results qualify, a single trial may support a Biologics License Application (BLA) submission. Additionally, based upon the clinical and preclinical testing performed to date and currently in process, the FDA did not recommend any additional studies in preparation for an IND submission and initiation of our planned Phase 2/3 trial. We intend to file an IND for this study by the end of the first quarter of 2021.

We believe that the feedback received from the FDA provides us a well-defined regulatory pathway and we are preparing an IND submission to initiate an adaptive Phase 2/3 randomized, double-blind, placebo-controlled study. This study is intended to assess the efficacy, safety and tolerability of DM199 in patients with mild to moderate AIS. The study is expected to enroll approximately 300 to 350 male and female subjects age 18 and over. Enrolled participants must have a diagnosis of mild to moderate AIS (NIHSS scores between 5 and 20), and present within 24 hours of symptom onset. Current plans for the study are to exclude patients with large vessel occlusions, which are eligible for treatment with mechanical thrombectomy, and/or patients eligible for tPA. We believe that our targeted study population represents approximately 80% of all AIS patients. As currently planned, study participants will be dosed with either DM199 or placebo over 21 days with the primary endpoint measured at day 90. In order to increase the probability of a successful outcome, we also intend to propose conducting an interim analysis with the potential to adjust the study sample size to ensure proper statistical powering, if necessary. The primary endpoint for the Phase 2/3 trial will be the modified Rankin Scale. Secondary endpoints are anticipated to include stroke recurrence and standard stroke measures, including National Institutes of Health Stroke Scale (NIHSS) and Barthel Index.

AIS Phase 2 ReMEDy Study

Enrollment in the ReMEDy study began in February 2018 and concluded in October 2019. We enrolled 92 participants to assess DM199 in the treatment of participants who experienced an AIS. The study drug (DM199 or placebo) was administered as an IV infusion within 24 hours of stroke symptom onset, followed by subcutaneous injections later that day and once every 3 days for 21 days. The study was designed to measure safety and tolerability along with multiple tests designed to investigate DM199's therapeutic potential including standard functional stroke measures and stroke recurrence assessed at 90 days post-stroke and certain plasma-based biomarkers. Standard functional stroke measurements include the Modified Rankin Scale, National Institutes of Health Stroke Scale, the Barthel Index and C-reactive protein, a measure of inflammation. Positive top-line results, including the achievement of primary safety and tolerability endpoints and no DM199-related serious adverse events, were announced in May 2020. In addition to meeting its primary safety and tolerability endpoints, a statistically significant 86% (P=0.028) relative reduction in the number of participants with severe recurrent strokes was observed in the active treatment group (N=1, 2.2%) compared to placebo (N=7, 15.6%), a potentially transformative outcome given that approximately 25% of the 795,000 strokes occurring each year in the United States are recurrent strokes.

When participants treated with mechanical thrombectomy are excluded from the study data set, representing the group of participants most closely aligned with the target treatment population for DM199 in our proposed Phase 2/3 ReMEDy II study, a positive therapeutic effect was demonstrated. As shown in the table below, when evaluating the participants treated with DM199 (n=25) vs. standard of care supportive therapies and/or tPA (n=21), the results showed that 36% of participants receiving DM199 progressed to a full or nearly full recovery at 90 days (NIHSS: 0-1), compared to 14% of participants in the placebo group. This represents a 22% absolute increase in the proportion of participants achieving a full or nearly full recovery. Additionally, subject deaths decreased from 24% in the placebo group to 12% in the active therapy group, a 50% relative reduction. Note that the number of subjects in these subsets was insufficient for statistical significance.

DM199 vs. Standard of Care Supportive Therapies and/or tPA

	NIHSS Outcomes at 90 Days			
	0-1	**2-8**	**≥ 9**	**Death**
Placebo (n=21)	14%	57%	5%	24%
DM199 (n=24)	36%	36%	16%	12%

Further, in reviewing evaluable participants (n=91), improvements in the following biomarkers were observed in participants treated with DM199, which we believe are consistent with the DM199 mechanism of action:

- Increased NO (+105%) and PGE2 (+54%) were observed at day 22 vs. baseline ($p<0.05$). Placebo group was not statistically significant vs. baseline ($p>0.05$). These changes noted in the active treatment group did not reach statistical significance compared to placebo.

- Reduction in C-reactive protein (CRP) of (-70%), a blood marker of inflammation, at 90 days. CRP decreased significantly vs. baseline ($p<0.05$), but was not statistically significant vs. placebo. The change in the placebo group was not statistically significant vs. baseline ($p>0.05$).

- Reduction in elevated glucose levels in participants with Type 2 diabetes (n=30), as defined by a blood glucose level >7 mmol/l (n=14), an average decrease of 1.9 mmol/l (p=0.06) in blood glucose levels of participants on active therapy was observed at day 22. In comparison, participants in the placebo group (n=16) showed an average increase of 0.08 mmol/l (p=0.94) at day 22.

Changes in the eGFR, a measure of kidney function, were also analyzed in participants with eGFR <70 mL/Min/1.732 at baseline, which indicates the presence of CKD. Participants receiving DM199 exhibited a marked increase in eGFR at days 22 (last dose) and 56 (34 days post-treatment), as shown in the table below. eGFR at day 22 increased by at least 2 mL/Min in 77% of DM199 participants compared to 20% in placebo (p=0.007).

	eGFR Mean Δ from Baseline (mL/Min/1.73^2)	
	Day 22 (Last Dose)	**Day 56** (Off Treatment)
Placebo	+0.84 (n=15)	-0.24 (n=12)
DM199	+7.5 (n=13)	+5.8 (n=12)
Group Difference	**+6.6**	**+6.1**

We believe these findings from our Phase 2 ReMEDy trial,which are consistent with Chinese data on the urine-derived form of KLK1, provide a signal that DM199 appears safe and well tolerated and may have promise as a new tool for physicians who have limited options for the treatment of patients suffering AIS and may also mitigate the adverse impact of ischemic stroke on kidney function.

CKD Phase 2 REDUX Study

In October 2019, the FDA accepted our Phase 2 clinical trial protocol for the treatment of CKD caused by rare or significant unmet diseases. The trial named REDUX, Latin for restore, is a multi-center, open-label investigation of approximately 90 participants with mild or moderate CKD (Stage II or III) and albuminuria, who are being enrolled in three cohorts (30 participants per cohort). The study is being conducted in the United States at 14 sites and is focused on participants with CKD: Cohort I is focused on non-diabetic, hypertensive African Americans 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 capture the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is focused on participants with IgAN. Cohort III, which was added after the completion of our August 2020 public offering, is focused on 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 will 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 eGFR and albuminuria, as measured by the urinary albumin to creatinine ratio. Participant enrollment and dosing for this study commenced in December 2019.

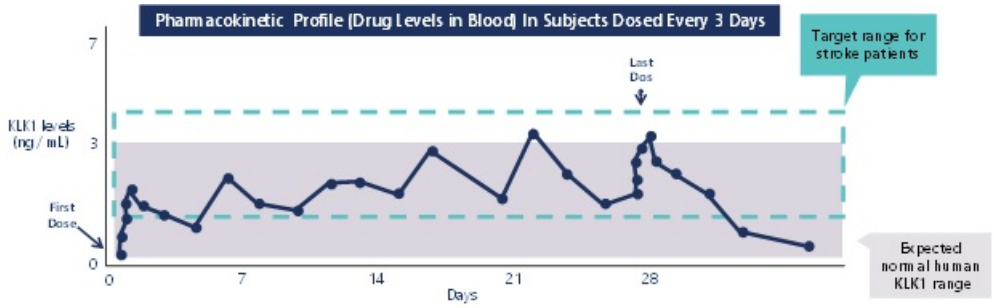
As of March 1, 2021, we had enrolled 68 subjects, including 15 African American subjects into Cohort I, 21 subjects with IgAN into Cohort II and 32 subjects with Type 2 diabetes, hypertension and albuminuria into Cohort III of the REDUX study. Due to actions implemented at our clinical study sites to combat the COVID-19 pandemic, we have continued to experience slower than expected enrollment in the first two cohorts of the REDUX trial. We believe this is due to the reduction or suspension of activities at our clinical study sites as they address staff and patient safety concerns and patient concerns related to visiting clinical study sites in light of the COVID-19 pandemic. However, with the significant declines in new COVID-19 cases and the anticipated availability and effectiveness of vaccines, we currently anticipate completion of Cohort I and Cohort II in the second half of 2021. The enrollment of Cohort III was much more rapid completing in December 2020, which is likely due to the large population of potential subjects. We currently expect topline results from Cohort III to be available in the second quarter of 2021.

CKD Phase 1b

In July 2019, we completed a Phase 1b clinical trial of DM199 in participants with moderate or severe CKD caused by Type 1 or Type 2 diabetes. We initiated dosing patients in this study in February 2019. The study was performed to assess the pharmacokinetics (PK) of three dose levels of DM199 (3, 5 and 8 µg/kg), administered in a single subcutaneous dose, as well as the evaluation of safety, tolerability and secondary pharmacodynamic (PD) endpoints. The study results demonstrated that at the 3µg/kg dose level, the PK profiles were similar between moderate and severe CKD patients, and consistent with healthy subjects (normal kidney function) tested previously. Additionally, DM199 was well tolerated with no dose-limiting tolerability observed. There were no deaths, no discontinuations due to a treatment-related adverse event (AE) and no treatment-related significant adverse events (SAEs). AEs were minor and consistent with standard treatment(s) in the CKD patient population. We announced favorable overall interim PD results from the first 28 subjects that included short-term improvements in NO, average increase of 35.2%, PGE2, average increase of 41.2%, eGFR, average increase of 4.08 mL/min/1732, and the urinary albumin to creatinine ratio (UACR) excluding subjects with normal UACR levels, average decrease of 18.7%. PD results appeared to be drug related in that the greatest improvements occurred approximately 24 hours after DM199 administration and subsequently declined.

Other Clinical Studies

In 2017, we completed and published, in the *International Journal of Clinical Trials*, results from, a Phase 1b study with DM199 designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in healthy volunteers. This study compared multiple dose levels of DM199, administered via IV and SC routes to identify a dose and delivery route that most closely compared to, or improved upon, the pharmacokinetic and pharmacodynamics profile of the approved urinary KLK1 (Kailikang) in China. We found that a dose of DM199 administered via IV infusion mimicked the drug profile of IV-administered Kailikang. This study also identified a dose of DM199, administered via SC injection, which had a superior pharmacokinetic profile and that maintained more normal KLK1 levels throughout the day. Below are results from our clinical trial showing the pharmacokinetic profile of subcutaneously administered DM199 observed in study subjects as compared to what we believe is normal range in healthy subjects.



During 2013 and 2014, five clinical trials were completed with DM199 in over 120 volunteers, including multiple Phase 1 single dose ascending and multiple dose ascending studies in healthy volunteers and patients with Type 2 diabetes. Chronic dosing studies over 16 to 28 days were also conducted in healthy volunteers and patients with Type 2 diabetes (see below). As is generally the case for early phase clinical trials, the primary endpoints for all studies were safety, tolerability, and pharmacokinetics. The Phase 2 (Part D) study also investigated a series of secondary endpoints that included blood glucose concentration, insulin levels, glucose tolerance testing and a variety of experimental biomarkers evaluating the potential efficacy of DM199 in treating Type 2 diabetes patients.

DM199 Trial Design Overview

Trial	Participants (N)	Design	Doses (µg/kg)	Route	Length
Phase-1 Part A	Healthy (32)	Single ascending dose	5, 15, 30, 50	SC	1 week
Phase-1 Part B	Type 2 diabetes (10)	Single ascending dose	0.3, 1.5, 15	SC	1 week
Phase-1 Part C	Healthy (18)	Multiple ascending dose	3, 15, 25	SC	6 doses over 16 days
Phase-2A Part D	Type 2 diabetes (36)	Blinded multiple dose	Placebo, 3, 15	SC	10 doses over 28 days
Phase 1 Bridging	Healthy (36)	Single ascending dose	0.25, 0.50, 0.75 1.0 3.0	IV IV SC	1 week

In combination, these studies showed that DM199 was well tolerated and demonstrated clear physiological activity. After SC injection, DM199 exhibited a favorable pharmacokinetic profile with extended half-life (*i.e.*, the time required to reduce concentration of the drug in the body by one-half), supporting potential dosing intervals of up to one week. The dose-limiting tolerability issue in healthy volunteers was orthostatic hypotension (a condition in which blood pressure falls significantly when a person stands) observed largely at the 50 µg/kg dose level, which is much greater than the dose level anticipated to be efficacious in patients. In each trial, observed treatment emergent side-effects were mild to moderate in severity and resolved. The most common treatment-emergent side effects included headache, dizziness, nausea and injection site pain, the majority of which were observed in the highest dose group of the Phase 1-Part A trial.

Two of these clinical studies focused on patients with Type 2 diabetes. The first study enrolled 10 Type 2 diabetic patients. The patients were dosed with either DM199, at three single ascending dose levels or placebo. DM199 was well-tolerated at all three dose levels by the diabetic patients with no dose limiting side effects. The second study in patients with Type 2 diabetes enrolled 36 patients treated with one of two SC dose levels of DM199 or placebo over 28 days. This study achieved its primary endpoints 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 trial site that were unable to be reconciled. See "*Part I. Item 1. Business—Legal Proceedings*" for more information on this study.

Potential DM199 Commercial Advantages

Several researchers have studied the structural and functional properties of KLK1. This deep body of knowledge has revealed the potential clinical benefits of KLK1 treatments. Today, forms of KLK1 derived from human urine and porcine pancreas are sold in Japan, China and Korea to treat AIS, CKD, retinopathy, hypertension and related diseases. We are not aware of any synthetic version of KLK1 with regulatory approval for human use in any country, nor any synthetic version in development besides our drug candidate DM199 (recombinant human KLK1). We believe at least five companies have attempted, unsuccessfully, to create a synthetic version of KLK1.

The growing understanding of the role of KLK1 in human health and its use in Asia as an approved therapeutic highlight two important potential commercial advantages for DM199:

- **KLK1 treatment is sold in Japan, China and Korea**. Research has shown that patients with low levels of KLK1 are associated with a variety of diseases related to vascular dysfunction, such as CKD, AIS, retinopathy and hypertension. Clinical trial data with human urine and porcine derived KLK1 has demonstrated statistically significant clinical benefits in treating a variety of patients with KLK1 compared to placebo. These efficacy results are further substantiated by established markets in Japan, China and Korea for pharmaceutical sales of KLK1 derived from human urine and porcine pancreas. We estimate that millions of patients have been treated with these forms of KLK1 in Asia. Altogether, we believe this supports a strong market opportunity for a synthetic version of KLK1 such as DM199.

- **KLK1 treatment has had limited side effects and has been well tolerated in studies to date** KLK1 is naturally produced by the human body; and, therefore, the body's own control mechanisms act to limit potential side effects. The only notable side effect observed in our clinical trials was orthostatic hypotension, or a sudden drop in blood pressure, which was only seen at doses 10 to 20 times higher than our anticipated therapeutic dose levels. Moreover, routine clinical use of KLK1 treatment in Asia we understand has been well-tolerated by patients for several decades. In 2017, we completed a clinical trial comparing the pharmacokinetic profile of DM199 to the human urinary form of KLK1 (Kailikang), which showed DM199, when administered in intravenous form, had a similar pharmacokinetic profile. Further, when DM199 was administered subcutaneously, DM199 demonstrated a longer acting pharmacokinetic profile, superior to the intravenously administered Kailikang and DM199.

In addition, we believe that there are also significant formulation, manufacturing, regulatory and other advantages for synthetic human KLK1 drug candidate DM199:

- **Potency and Impurity Considerations**. KLK1 produced from human urine or porcine pancreas presents risks related to preventing impurities, endotoxins, and chemical byproducts due to the inherent variability of the isolation and purification process. We believe that this creates the risk of inconsistencies in potency and impurities from one production run to the next. However, we expect to produce a consistent formulation of KLK1 that is free of endotoxins and other impurities.

- **Cost and Scalability**. Large quantities of human urine and porcine pancreas must be obtained to derive a small amount of KLK1. This creates potential procurement, cost and logistical challenges to source the necessary raw material, particularly for human urine sourced KLK1. Once sourced, the raw material is processed using chemicals and costly capital equipment and produces a significant amount of byproduct waste. Our novel recombinant manufacturing process utilizes widely available raw materials and can be readily scaled for commercial production. Accordingly, we believe our manufacturing process will have significant cost and scalability advantages.

- **Regulatory**. We are not aware of any attempts by manufacturers of the urine or porcine based KLK1 products to pursue regulatory approvals in the United States. We believe that this is related to challenges presented by using inconsistent and potentially hazardous biomaterials, such as human urine and porcine pancreas, and their resulting ability to produce a consistent drug product. Our novel recombinant manufacturing process utilizes widely available raw materials which we believe provides a significant regulatory advantage, particularly in regions such as the United States, Europe and Canada, where safety standards are high. In addition, we believe that DM199 could qualify for 12 years of data exclusivity under the Biologics Price Competition and Innovation Act of 2009, which was enacted as part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010.

From a strategic perspective, we continue to believe that strategic alternatives with respect to our DM199 product candidate, including licenses and business collaborations, with other regional and global pharmaceutical and biotechnology companies can be important in advancing the clinical development of DM199. Therefore, as a matter of course and from time to time, we engage in discussions with third parties regarding these matters.

Regulatory Approval

Securing regulatory approval for the manufacture and sale of human therapeutic products in the United States, Europe, Canada and other commercial territories is a long and costly process that is controlled by that particular territory's national regulatory agency. The national regulatory agency in the United States is the FDA, in Europe it is the European Medicines Agency (EMA), and in Canada it is Health Canada. Other national regulatory agencies have similar regulatory approval processes, but each national regulatory agency has its own approval processes. Approval in the United States, Europe or Canada does not assure approval by other national regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country.

Prior to obtaining regulatory approval to market a drug product, every national regulatory agency has a variety of statutes and regulations which govern the principal development activities. These laws require controlled research and testing of products, governmental review, and approval of a submission containing preclinical and clinical data establishing the safety and efficacy of the product for each use sought, approval of manufacturing facilities including adherence to good manufacturing practices (GMP) during production and storage, and control of marketing activities, including advertising, labeling and pricing approval.

None of our product candidates have been completely developed or tested; and, therefore, we are not yet in a position to seek regulatory approval in any territory to market any of our product candidates.

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export, and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval may subject us to a variety of administrative or judicial sanctions, including refusal by the applicable regulatory authority to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

U.S. Approval Process

In the United States, the FDA is responsible for the drug approval process. The FDA's mission is to ensure that all medications on the market are safe and effective. The FDA's approval process examines and thoroughly reviews potential new drugs; only those that are in compliance with the Code of Regulations, 21 CFR 312 and 21 CFR 314 are approved.

The U.S. food and drug regulations require licensing of manufacturing facilities, carefully controlled research and testing of products, governmental review and approval of test results prior to marketing of therapeutic products, and adherence to GMP, as defined by each licensing jurisdiction, during production.

A description of the different stages in the drug approval process in the United States follows.

Stage 1: Preclinical Research. After an experimental drug is discovered, research is conducted to help determine its potential for treating or curing an illness. This is called preclinical research. Animal and/or bench studies are conducted to determine if there are any harmful effects of the drug and to help understand how the drug works. Information from these experiments is submitted to the FDA as part of an IND application. The FDA reviews the information in the IND and decides if the drug is safe to study in humans.

Stage 2: Clinical Research. The experimental drug is studied in humans. The studies are known as clinical trials. Clinical trials are carefully designed and controlled experiments in which the experimental drug is administered to patients to test its safety and to determine the effectiveness of an experimental drug. The four general phases of clinical research are described below.

- *Phase 1 Clinical Studies*. Phase 1 clinical studies are generally conducted with healthy volunteers who are not taking other medicines; patients with the illness that the drug is intended to treat are not tested at this stage. Ultimately, Phase 1 studies demonstrate how an experimental drug affects the body of a healthy individual. Phase 1 consists of a series of small studies consisting of "tens" of volunteers. Tests are done on each volunteer throughout the study to see how the person's body processes, responds to, and is affected by the drug. Low doses and high doses of the drug are usually studied, resulting in the determination of the safe dosage range in volunteers by the end of Phase 1. This information will determine whether the drug proceeds to Phase 2.

- *Phase 2 Clinical Studies*. Phase 2 clinical studies are conducted in order to determine how an experimental drug affects people who have the disease to be treated. Phase 2 usually consists of a limited number of studies that help determine the drug's short-term safety, side effects, and general effectiveness. The studies in Phase 2 often are controlled investigations involving comparison between the experimental drug and a placebo, or between the experimental drug and an existing drug. Information gathered in Phase 2 studies will determine whether the drug proceeds to Phase 3.

- *Phase 3 Clinical Studies*. Phase 3 clinical studies are expanded controlled and uncontrolled trials that are used to more fully investigate the safety and effectiveness of the drug. These trials differ from Phase 2 trials because a larger number of patients are studied (sometimes in the thousands) and because the studies are usually double blinded, placebo controlled and of longer duration. As well, Phase 3 studies can include patients who have more than one illness and are taking medications in addition to the experimental drug used in the study. Therefore, the patients in Phase 3 studies more closely reflect the general population. The information from Phase 3 forms the basis for most of the drug's initial labeling, which will guide physicians on how to use the drug.

- *Phase 4 Clinical Studies*. Phase 4 clinical studies are conducted after a drug is approved. Phase 4 studies may be required by the FDA or conducted by companies to more fully understand how their drug compares to other drugs. FDA-required Phase 4 studies often investigate the drug in specific types of patients that may not have been included in the Phase 3 studies and can involve very large numbers of patients to further assess the drug's safety.

Stage 3: FDA Review for Approval. Following the completion of Phase 3 clinical studies, the pharmaceutical company prepares an electronic common technical document reporting all clinical nonclinical and chemistry, manufacturing and control studies conducted on the drug that is transmitted to the FDA as a New Drug Application (NDA). The FDA reviews the information in the NDA to determine if the drug is safe and effective for its intended use. An advisory panel meeting is scheduled for a new drug allowing the FDA to gain feedback from experts. If the FDA determines that the drug is safe and effective, the drug will be approved.

Stage 4: Marketing. After the FDA has approved the experimental drug, the pharmaceutical company can make it available to physicians and their patients. A company also may continue to conduct research to discover new uses for the drug. Each time a new use for a drug is discovered, the drug once again is subject to the entire FDA approval process before it can be marketed for that purpose.

Any FDA approved pharmaceutical products are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements is likely to have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

DM199 may qualify for 12 years of data exclusivity under the Biologics Price Competition and Innovation Act of 2009 (the BPCIA), which was enacted as part of the Affordable Care Act (ACA). Under the BPCIA, an application for a biosimilar product (BLA) cannot be submitted to the FDA until four years, or if approved by the FDA, until 12 years, after the original brand product identified as the reference product is approved under a BLA. The BPCIA provides an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. The new law is complex and is only beginning to be interpreted and implemented by the FDA.

European Approval Process

The EMA is roughly parallel to the FDA in terms of the drug approval process and the strict requirements for approval. The EMA was set up in 1995 in an attempt to harmonize, but not replace, the work of existing national medicine regulatory bodies in individual European countries. As with the FDA, the EMA drug review and approval process follows similar stages from preclinical testing through clinical testing in Phase 1, 2, and 3. There are some differences between the FDA and EMA review process, specifically the review process in individual European countries. Such differences may allow certain drug products to be tested in patients at an earlier stage of development.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services and other divisions of the U.S. government, including, the Department of Health and Human Services, the Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, if a drug product is reimbursed by Medicare, Medicaid, or other federal or state healthcare programs, a company, including its sales, marketing and scientific/educational grant programs, must comply with the federal Food, Drug & Cosmetic Act as it relates to advertising and promotion of drugs, the federal False Claims Act, as amended, the federal Anti-Kickback Statute, as amended, the Physician Payments Sunshine Act, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and similar state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 (OBRA), and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Among other things, OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products being lower than the prices we might otherwise obtain. Additionally, the ACA substantially changes the way healthcare is financed by both governmental and private insurers. There may continue to be additional proposals relating to the reform of the U.S. healthcare system, in the future, some of which could further limit coverage and reimbursement of drug products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third-party payers, including government health administrative authorities, managed care providers, private health insurers and other organizations. In the United States, private health insurers and other third-party payers often provide reimbursement for products and services based on the level at which the government (through the Medicare and/or Medicaid programs) provides reimbursement for such treatments. Third-party payers are increasingly examining the medical necessity and cost-effectiveness of medical products and services in addition to their safety and efficacy; and, accordingly, significant uncertainty exists regarding the coverage and reimbursement status of newly approved therapeutics. In particular, in the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. As a result, coverage and adequate third party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment in research and product development.

The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payers' drug formularies or lists of medications for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or may otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product candidate to each third-party payer separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies to demonstrate the cost-effectiveness of our product candidates. This process could delay the market acceptance of any of our product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective. If we are unable to obtain coverage and adequate payment levels for our product candidates from third-party payers, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

Research and Development

We have devoted substantially all of our efforts to research and development (R&D) which therefore comprises the largest component of our operating costs. Our primary focus over the past approximately nine years has been our lead product candidate, DM199, which is currently in clinical development for the treatment of AIS and CKD.

We expect our R&D expenses will continue to increase in the future as we advance our initial product candidate, DM199, through clinical trials in AIS and CKD and seek to expand our product candidate portfolio. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming and we consider the active management and development of our clinical pipeline to be integral to our long-term success. The actual probability of success for each product candidate, clinical indication and preclinical program may be affected by a variety of factors including, among other things, the safety and efficacy data for each product candidate, amounts invested in their respective programs, competition and competitive developments, manufacturing capability and commercial viability.

R&D expenses include:

- expenses incurred under contract research agreements and other agreements with third parties;
- expenses incurred under agreements with clinical trial sites that conduct research and development activities on our behalf;
- employee and consultant-related expenses, which include salaries, benefits, travel and share-based compensation;
- laboratory and vendor expenses related to the execution of clinical trials and non-clinical studies;
- the cost of acquiring, developing, manufacturing, and distributing clinical trial materials; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supply costs.

R&D costs are expensed as incurred. Costs for certain development activities such as clinical trials are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We expect that it will be at least three to five years, if ever, before we have any product candidates ready for commercialization.

Manufacturing

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of DM199 nor do we have plans to develop our own manufacturing operations in the foreseeable future. We rely on Catalent Pharma Solutions, LLC (Catalent), a contract manufacturing organization (CMO) with proven GMP experience in the manufacturing of recombinant proteins for clinical trials, for all of our required raw materials, active pharmaceutical ingredients for our clinical trials. We have licensed certain gene expression technology and we contract with Catalent for the manufacture of DM199. We currently employ internal resources and third-party consultants to manage our manufacturing relationship with Catalent.

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for our initial product candidate, DM199, or any future product candidates, because it is still early in the clinical development stage. We currently expect to partner with a large pharmaceutical company for sales execution. However, our future commercial strategy may include the use of distributors, a contract sales force or the establishment of our own commercial and specialty sales force, as well as similar strategies for regions and territories outside the United States.

Intellectual Property

We view patents and other means of intellectual property protection including trade secrets as an important component of our core business. We focus on translating our innovations into intangible property protecting our proprietary technology from infringement by competitors. To that end, patents are reviewed frequently and continue to be sought in relation to those components or concepts of our preclinical and clinical products to provide protection. Our strategy, where possible, is to file patent applications to protect our product candidates, as well as methods of manufacturing, administering and using a product candidate. Prior art searches of both patent and scientific databases are performed to evaluate novelty, inventiveness and freedom-to-operate. We require all employees, consultants and parties to a collaborative research agreement to execute confidentiality agreements upon the commencement of employment, consulting relationships or a collaboration with us. These agreements require that all confidential information developed or made known during the course of the engagement with us is to be kept confidential. We also maintain agreements with our scientific staff and all parties contracted in a scientific capacity affirming that all inventions resulting from work performed for us, using our property or relating to our business and conceived or completed during the period covered by the agreement are the exclusive property of DiaMedica.

Our DM199 patent portfolio includes three granted U.S. patents, a granted European patent and pending applications in Australia, Canada, China, Europe, India, Japan, Korea and the United States. Granted or pending claims offer various forms of protection for DM199 including claims to compositions of matter, pharmaceutical compositions, specific formulations and dosing levels and methods for treating a variety of diseases, including chronic kidney disease, stroke and related disorders. These U.S. patents and applications, and their foreign equivalents, are described in more detail below.

Issued patents held by us cover the DM199 composition of matter based on an optimized combination of closely-related isoforms that differ in the extent of glycosylation (process by which sugars are chemically attached to proteins). Issued claims in this patent family cover the most pharmacologically active variants of DM199 and methods of using the same for treating ischemic conditions and these patents are due to expire in 2033. A second patent family includes an issued U.S. patent with claims directed to methods of treating subjects by administering a SC formulation of DM199 or related recombinant kallikrein-1 (KLK1) polypeptides and is predicted to expire in 2033. The pending applications are directed to a range of dose levels and dosing regimens of DM199 that are potentially useful for treating a wide range of diseases including, e.g. pulmonary arterial hypertension, cardiac ischemia, chronic kidney disease, diabetes, stroke and vascular dementia which, if granted, are predicted to expire in 2038.

As previously discussed, we do not own or operate manufacturing facilities for the production of clinical or commercial quantities of DM199. We are contracting with Catalent for the manufacture of DM199. We have licensed certain gene expression technology and we contract with Catalent for the manufacture of DM199. Under the terms of this license, certain milestone and royalty payments may become due and are dependent upon, among other factors, performing clinical trials, obtaining regulatory approvals and ultimately the successful commercialization of a new drug, the outcome and timing of which is uncertain. The royalty term is indefinite but the license agreement may be canceled by us on 90 days' prior written notice. The license may not be terminated by Catalent unless we fail to make required milestone and royalty payments.

Methods and reagents required for commercial scale manufacture of DM199 are subject to a series of patents issued to Catalent. We license these patents from Catalent, and such license is exclusive as it relates to the production of DM199 or any human KLK1 protein.

We believe that our proprietary technology along with trade secrets and specialized knowledge of the manufacturing process will provide substantial protection from third-party competitors. We also believe that DM199 cannot be easily reverse engineered for the production of a copycat version.

We believe that the most relevant granted patents and applications with composition of matter or method of use claims covering DM199 are listed below, along with their projected expiration dates exclusive of any patent term extension:

Patent/Application Number	Title	Geography	Predicted Expiration
Issued patents			
US 9,364,521	Human Tissue Kallikrein 1 Glycosylation Isoforms	US	2033
US 9,839,678	Human Tissue Kallikrein 1 Glycosylation Isoforms	US	2033
EP 2 854 841	Human Tissue Kallikrein 1 Glycosylation Isoforms	Europe	2033
US 9,616,015	Formulations for Human Tissue Kallikrein-1 for Parenteral Delivery and Related Methods	US	2033
Pending applications			
AU 2018230478	Dosage Forms of Tissue Kallikrein 1	Australia	2038
CA 3054962	Dosage Forms of Tissue Kallikrein 1	Canada	2038
CN 201880016380.4	Dosage Forms of Tissue Kallikrein 1	China	2038
EP 18763243.5	Dosage Forms of Tissue Kallikrein 1	Europe	2038
IN 201917037712	Dosage Forms of Tissue Kallikrein 1	India	2038
JP 2019-548655	Dosage Forms of Tissue Kallikrein 1	Japan	2038
KR 10-2019-7026369	Dosage Forms of Tissue Kallikrein 1	Korea	2038
US 16/492,059	Dosage Forms of Tissue Kallikrein 1	US	2038

Employees

As of December 31, 2020, we had 11 employees, 10 of which were full-time employees. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements. We believe our employee relations are good.

Information About Our Executive Officers

The following table sets forth information as of December 31, 2020 regarding each of our current executive officers:

Name	Age	Positions
Rick Pauls	49	President and Chief Executive Officer, Director
Scott Kellen	55	Chief Financial Officer and Secretary
Harry Alcorn, Pharm.D.	64	Chief Medical Officer
Sydney Gilman, Ph.D.	68	Vice President, Regulatory Affairs

The present principal occupations and recent employment history of each of our executive officers are set forth below.

Rick Pauls was appointed our President and Chief Executive Officer in January 2010. Mr. Pauls has served as a member of our Board of Directors since April 2005 and the Chairman of the Board from April 2008 to July 2014. Prior to joining DiaMedica, Mr. Pauls was the Co-Founder and Managing Director of CentreStone Ventures Inc., a life sciences venture capital fund, from February 2002 until January 2010. Mr. Pauls was an analyst for Centara Corporation, another early stage venture capital fund, from January 2000 until January 2002. From June 1997 until November 1999, Mr. Pauls worked for General Motors Acceptation Corporation specializing in asset-backed securitization and structured finance. Mr. Pauls previously served as an independent member of the board of directors of LED Medical Diagnostics, Inc. Mr. Pauls received his Bachelor of Arts in Economics from the University of Manitoba and his M.B.A. in Finance from the University of North Dakota.

Scott Kellen joined DiaMedica as our Vice President of Finance in January 2018 and was appointed our Chief Financial Officer and Secretary in April 2018. Prior to joining DiaMedica, Mr. Kellen served as Vice President and Chief Financial Officer of Panbela Therapeutics, Inc., formerly known as Sun BioPharma, Inc., a publicly-traded clinical stage drug development company, from October 2015 until April 2018. From February 2010 to September 2015, Mr. Kellen served as Chief Financial Officer and Secretary of Kips Bay Medical, Inc., a publicly-traded medical device company, and became Chief Operating Officer of Kips Bay in March 2012. From November 2007 to May 2009, Mr. Kellen served as Finance Director of Transoma Medical, Inc. From 2005 to October 2007, Mr. Kellen served as Corporate Controller of ev3 Inc. From March 2003 to April 2005, Mr. Kellen served as Senior Manager, Audit and Advisory Services of Deloitte & Touche, LLP. Altogether, Mr. Kellen has spent more than 25 years in the life sciences industry, focusing on publicly traded early stage and growth companies. Mr. Kellen has a Bachelor of Science degree in Business Administration from the University of South Dakota and is a Certified Public Accountant (inactive).

Harry Alcorn Jr. Pharm.D. was appointed our Chief Medical Officer in August 2018. Prior to joining DiaMedica, Dr. Alcorn served as Chief Scientific Officer at DaVita Clinical Research (DCR), a company that provides clinical research services for Pharmaceutical and Biotech companies, from October 1997 to June 2018. While at DCR, Dr. Alcorn was responsible for clinical research operations, including the formation and management of the early clinical and late phase research services. Dr. Alcorn also founded the U.S. Renal Network, the first network of Phase 1 renal research sites in the United States. Dr. Alcorn developed DCR's site management organization for clinical trials. Dr. Alcorn also served as an Executive Director, a Pharmacist and an Investigator at DCR. During this time, from January 2013 to December 2014, he also served on the Board of Directors for the Association of Clinical Pharmacology Units, an association of Phase 1 clinical trial sites. Dr. Alcorn has over 30 years of clinical research experience working with biotech and pharmaceutical companies, both public and private, in conducting research in renal, hepatic and cardiovascular disease. Dr. Alcorn has written and consulted on the development of several protocols and has served as Principal Investigator or Sub Investigator in numerous studies and, for several of these studies, presented study design and results to the FDA. Currently he holds clinical faculty appointments with the University of Minnesota, Creighton University, University of Nebraska Medical Center, Virginia Commonwealth and the University of Colorado, Denver. Dr. Alcorn graduated from Creighton University with a Bachelor of Pharmacy and went on to earn his Doctor of Pharmacy degree from University of Nebraska Medical Center.

Sydney A. Gilman, Ph.D. was appointed our Vice President, Regulatory Affairs in November 2019. Dr. Gilman is currently the founder and President of Trident Rx Consulting Services LLC, a regulatory consulting firm, a position he has held since January 2004. Dr. Gilman is a former FDA Chemistry reviewer. He spent six years at the FDA in various CDER Therapeutic Drug Divisions of the Center for Drug Evaluation and Research with consulting ties to both Biologics and Devices. Dr. Gilman also has an additional 20 years of experience in the pharmaceutical industry in positions ranging from Senior Scientist to Director to Vice President responsibilities. He earned his Bachelor of Science from Loyola College and a Ph.D. in Organic Chemistry from the University of Pittsburgh.

Available Information

We are a corporation governed under British Columbia's Business Corporations Act (BCBCA). Our company was initially incorporated pursuant to The Corporations Act (Manitoba) by articles of incorporation dated January 21, 2000. Our articles were subsequently amended several times, including on April 11, 2016 to continue the Company from The Corporations Act (Manitoba) to the Canada Business Corporations Act (CBCA) and on May 31, 2019, to continue our existence from a corporation incorporated under the CBCA into British Columbia under the BCBCA.

Our registered office is located at 301-1665 Ellis Street, Kelowna, British Columbia, Canada V1Y 2B3 and our principal executive office is located at our wholly owned subsidiary, DiaMedica USA Inc., located at Two Carlson Parkway, Suite 260, Minneapolis, Minnesota, USA 55447. Our telephone number is 763-496-5454. Our internet website address is http://www.diamedica.com. Information contained on our website does not constitute part of this report.

We make available, free of charge and through our Internet web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). Reports filed with the SEC may be viewed at www.sec.gov.

Implications of Being an Emerging Growth Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act), and we may remain an emerging growth company for up to five years from December 31, 2018. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenue exceeds $1.07 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not emerging growth companies. In particular, in this report, we have provided only two years of audited financial statements and have not included certain other information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity interests. However, we have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards, and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1A. Risk Factors

The following are the material factors known to us that could materially adversely affect our business, operating results or financial condition.

Risk Factors Summary

This summary is not complete and should be read in conjunction with the risk factors that follow.

Risks Related to Our DM199 Product Candidate and Clinical Trials

- Our prospects depend on the clinical and commercial success of DM199, which is in the clinical stage of development.
- We are required to conduct clinical trials and if these trials fail to demonstrate the safety and efficacy of DM199, or any future product candidate, we will not obtain the approvals required to market and commercialize the product.
- The COVID-19 pandemic has resulted and will likely continue to result in enrollment delays in our REDUX trial.
- Our DM199 product candidate may cause or have attributed to it undesirable side effects.
- We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Risks Related to Governmental and Regulatory Compliance and Approvals

- The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future partner or collaborator from obtaining approvals for the commercialization of DM199 or any future product candidate.
- Any product candidate for which we or any future partner or collaborator obtains marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with the product candidate.

Risks Related to Our Reliance on Third Parties

- We rely on contract manufacturers over whom we have limited control.
- We rely on third parties to plan, conduct and/or monitor our clinical trials, and their failure to perform could cause delays in completing our product development.
- Future development collaborations are expected to be important to us.

Risks Related to the Future Commercialization of DM199 or Any Future Product Candidate

- The successful commercialization of DM199 or any future product candidate, if approved, will depend on market acceptance and coverage and adequate reimbursement for the product.
- We face competition in developing our DM199 or any future product candidate and our DM199 product candidate may face competition sooner than expected.

Risks Related to Our International Operations

- Our international operations involve a variety of risks.
- If we lose our ability to operate in Australia and receive the R&D incentive payment, our results of operations could suffer.

Risks Related to Intellectual Property

- We may be unable to adequately protect our technology and enforce our intellectual property rights.
- We may require additional third-party licenses to effectively develop, manufacture and commercialize our DM199 or any future product candidate, and such license might not be available on commercially-acceptable terms, or at all.
- Changes in patent law and its interpretation could diminish the value of our patents.
- Intellectual property litigation may be expensive, time consuming and cause delays in the development, manufacturing and commercialization of our DM199 or any future product candidate.
- We could lose important intellectual property rights that we currently license from a third party if we fail to comply with our obligations under the license agreements or otherwise experience disruptions to our relationships with our licensors.

Risks Related to Pending Litigation and Other Legal Matters

- We face the risk of product liability claims, which could exceed our insurance coverage and lead to clinical trial delays.
- If we are unable to maintain product liability insurance, certain agreements would be subject to termination.
- We have sued a contract research organization to compel it to comply with the terms of a clinical trial research agreement and to date have been unsuccessful in this litigation.

Risks Related to Our Financial Position and Need for Additional Capital

- We have incurred and expect to continue to incur substantial losses and may never become profitable.
- Since we have no revenue from product sales and do not expect any revenue from product sales for at least three to five years, we will need additional funding to continue our R&D activities and other operations, which may not be available to us on acceptable terms, or at all.

Risks Related to Human Capital Management

- We heavily rely on the capabilities and experience of our key executives and scientists and the loss of any of them could affect our ability to develop DM199 or any future product candidate.
- We will likely need to expand our operations and increase the size of our company and we may experience difficulties in managing growth.

Risks Related to Our Common Shares

- Our common share price has been and may continue to be volatile and no assurance can be provided that an active trading market for our shares will continue.
- We may issue additional common shares resulting in share ownership dilution, and if there are substantial sales of our common shares or the perception that such sales may occur, the market price of our common shares could decline.

Risks Related to Our Jurisdiction of Organization

- We are governed by the corporate laws of British Columbia, which in some cases have a different effect on shareholders than the corporate laws in effect in the United States.
- We may be classified as a "passive foreign investment company" in future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders.

Risks Related to Our DM199 Product Candidate

Our prospects depend on the clinical and commercial success of our DM199 product candidate which is in the clinical stage of development.

We are highly dependent on the success of DM199 and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate. To date, we have expended significant time, resources and effort on the development of DM199, including conducting preclinical and clinical trials, for the treatment of AIS and CKD. DM199 requires significant additional clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by ourselves and any potential partner or collaborator to continue to conduct the clinical trials for DM199 will be required to obtain required regulatory approvals and successfully commercialize this product candidate. Although we intend to study the use of DM199 to treat multiple diseases, we have no other product candidates in our current clinical development pipeline. Our ability to generate revenue from product sales and to achieve commercial success of DM199 will depend almost entirely on our ability to demonstrate sufficient safety and efficacy to obtain regulatory approval for DM199. We may fail to complete required clinical trials successfully, obtain regulatory approvals, or commercialize DM199. Competitors may develop alternative products and methodologies to treat the diseases or indications that we are pursuing, thus reducing or eliminating the anticipated competitive advantages of DM199. We do not know whether any of our product development efforts will prove to be effective, meet applicable regulatory standards required to obtain the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. DM199 is not expected to be commercially viable for at least three to five years. In addition, although no significant adverse events have occurred to date in our clinical trials, it is possible that DM199 may be observed to cause undesirable side effects. Results of early preclinical and clinical research may not be indicative of the results that will be obtained in later stages of clinical research. If regulatory authorities do not approve DM199 for the treatment of AIS and/or CKD or any other indications, or if we fail to maintain regulatory compliance, we will likely be unable to commercialize DM199 and our business and results of operations would be harmed. If we do succeed in developing viable products from DM199, we will face many potential future obstacles, such as the need to develop or obtain manufacturing, sales and marketing and distribution capabilities.

The clinical and commercial success of our DM199 product candidate will depend on a number of factors, many of which are beyond our control.

The clinical and commercial success of our DM199 product candidate will depend on a number of factors, many of which are beyond our control, including, among others:

- the timely initiation, continuation and completion of our currently ongoing Phase 2 and future clinical trials for DM199, which will depend substantially upon requirements for such trials imposed by the FDA and other regulatory agencies and bodies;
- our ability to demonstrate the safety and efficacy of DM199 to the satisfaction of the relevant regulatory authorities;
- whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials, and the scope and nature of such clinical trials, prior to approval to market our DM199 product candidate;
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities, as well as pricing and reimbursement determinations;
- the ability to successfully commercialize DM199, if approved by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- our ability and the ability of third-party manufacturers to manufacture the quantities of DM199, with quality attributes necessary to meet regulatory requirements, sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- acceptance of DM199, if approved, as safe and effective by patients and the healthcare providers;
- the achievement and maintenance of compliance with all regulatory requirements applicable to DM199 by us and our third-party manufacturers and supporting vendors;
- the maintenance of an acceptable safety profile of DM199 following any approval;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competitive treatments;
- our ability to provide approved product with a convenient and patient-friendly administration method;
- our ability to successfully enforce our intellectual property rights for DM199 and against the products of potential competitors; and
- our ability to avoid or succeed in defending any third-party patent interference or patent infringement claims.

No assurance can be provided that we will ever be able to achieve profitability through the sale of, or royalties from, our DM199 product candidate. If we or any future partners or collaborators are not successful in obtaining approval for and commercializing DM199, or are delayed in completing those efforts, our business and operations would be substantially harmed.

Risks Related to Our Clinical Trials

If clinical trials of our DM199 or any future product candidate fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results, we would incur additional costs and experience delays in completing, or may ultimately be unable to complete, the development of DM199 or any future product candidate and therefore be unable to commercialize it.

Before obtaining marketing approval from regulatory authorities for the sale of DM199 or any future product candidate, we must conduct preclinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidate. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials we are currently conducting or may conduct in the future will demonstrate adequate efficacy and safety to result in regulatory approval to market DM199 or any future product candidate in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. In addition, the patient populations in our clinical studies for DM199 often have co-morbidities that may cause severe illness or death, which may be attributed to DM199 in a manner that negatively affects the safety profile of our DM199 product candidate. If the results of our ongoing or future clinical trials for DM199 are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may be prevented from or delayed in obtaining marketing approval, and even if we obtain marketing approval, any sales of DM199 may be limited.

If we have difficulty enrolling patients in our clinical trials or*experience other delays in clinical testing, we will be delayed in commercializing DM199 or any future product candidate, and our business may be substantially harmed.*

We cannot predict whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could shorten any periods during which we may have the exclusive right to commercialize our DM199 or any future product candidate or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our DM199 or any future product candidate and may harm our financial condition, results of operations and prospects. The commencement and completion of clinical trials for our DM199 or any future product candidate may be delayed for a number of reasons, including among others:

- patients choosing an alternative treatment for the indications for which we are developing our product candidate or participating in competing clinical trials;
- competing clinical trials and scheduling conflicts with participating clinicians;
- patients failing to enroll or remain in our trials at the rates and within the timelines we expect;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of our contract manufacturers to comply with current Good Manufacturing Practices (cGMP) requirements;
- any changes to our manufacturing process that may be necessary or desired;
- delays or failure to obtain clinical supply from contract manufacturers of our product candidate necessary to conduct clinical trials;
- the product candidate demonstrating a lack of safety or efficacy during clinical trials;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects, or other reasons;
- clinical investigators not performing our clinical trials on their anticipated schedule, dropping out of a trial or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;

- inspections of clinical trial sites by regulatory authorities, Institutional Review Boards (IRBs) or ethics committees finding regulatory violations that require us to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more IRBs or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- public health crises, epidemics and pandemics, such as the COVID- 19 pandemic, which adversely impacted and may continue to adversely impact our ability to recruit or enroll subjects for our clinical trials.

Our product development costs will increase if we experience delays in testing or approval or if we need to perform more or larger clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to regulatory authorities or IRBs or ethics committees for re-examination, which may impact the cost, timing or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on our business, financial condition, and prospects.

The COVID-19 pandemic has resulted in a delay in enrollment in our REDUX trial and will likely continue to result in enrollment delays and could also significantly disrupt in other ways our REDUX trial or other clinical trials which could delay or prevent our receipt of necessary regulatory approvals for DM199.

The COVID-19 pandemic is having a severe effect on the clinical trials of many drug candidates. Some trials have been merely delayed, while others have been cancelled. Due to actions implemented at our clinical study sites to combat the COVID-19 pandemic, we have experienced slower than expected enrollment in the first two cohorts of our REDUX clinical trial. We believe this is due to both the reduction or suspension of activities at our clinical study sites as they address staff and patient safety concerns as well as patient concerns related to their personal risk in visiting clinical study sites in light of the COVID-19 pandemic. However, with the significant declines in new COVID-19 cases and the anticipated availability and effectiveness of vaccines, we currently anticipate completion of Cohort I and Cohort II in the second half of 2021.

The extent to which the pandemic may impact our ongoing and planned clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and severity of the pandemic, and the effectiveness of actions to contain, treat and prevent COVID-19, including the availability and effectiveness of recently authorized vaccines. The continued spread of COVID-19 could cause us to experience continued and/or additional disruptions that could severely impact our business and clinical trials, including:

- continued or additional delays or difficulties in enrolling or retaining participants in our clinical trials;
- delays or difficulties in the initiation of additional clinical sites in the event that the current clinical sites are unable to recruit sufficient participants or at an acceptable rate;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in shipping that may affect the transport of clinical trial materials;

- changes in local regulations as part of a response to the pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- inability of participants to comply with clinical trial protocols, impede participant movement or interrupt healthcare services;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could result in participants dropping out of the trial, missing scheduled doses or follow-up visits or failing to follow protocol or otherwise impact the results of the clinical trial, including by increasing the number of observed adverse events;
- delays in receiving authorizations from local regulatory authorities to initiate our planned clinical trials;
- delays in necessary interactions with local regulatory authorities, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families, required quarantines or the desire of employees to avoid contact with large groups of people.

As a result, the expected timeline for the full data readout of our REDUX clinical trial has been and may continue to be negatively impacted, which has also adversely affected the timing of certain regulatory filings and our ability to initiate required Phase 3 studies, obtain regulatory approval for and to commercialize our DM199 product candidate.

Our DM199 product candidate may cause or have attributed to it undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial scope of its approved uses, or result in significant negative consequences following any marketing approval.

Although no significant adverse events have occurred to date in our clinical trials, undesirable side effects may be identified as related to DM199 by investigators conducting our clinical trials and could cause us or regulatory authorities to interrupt, delay or halt clinical trials and result in the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities, potential product liability claims or a more restrictive label. This may require longer and more extensive clinical development or we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our DM199 product candidate for any or all of our targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial. Any of these occurrences may significantly harm our business, financial condition and prospects.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices (cGCP) requirements, or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethics committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable cGMP. Clinical trials may be suspended by us or by the FDA, other foreign regulatory authorities, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

The design and implementation of clinical trials is a complex process. As a Company, we have limited experience designing and implementing clinical trials. We may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third party payers. Additionally, a trial that is not well-designed could be delayed and more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States, and the FDA may not accept data from such trials.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States. For example, we conducted our ReMEDy Phase 2 clinical trial in Australia. Based upon our recently completed Type B, pre-IND meeting with the FDA, we believe that the FDA will accept this data; however, there can be no assurance that the FDA will accept data from the clinical trial we conducted in Australia when we submit our IND for our planned Phase 2/3 trial of DM199 in stroke patients. Clinical trial conducted outside the United States must be conducted in accordance with cGCP requirements, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such an inspection necessary.

If the FDA does not accept data from the clinical trial we conducted in Australia, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan, including the development and commercial launch of our DM199 product candidate for the treatment of (AIS). In addition, the conduct of clinical trials outside the United States also exposes us to additional risks, including risks associated with the following:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schemes;
- foreign currency exchange rate fluctuations;
- compliance with foreign manufacturing, customs, shipment, and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Future legislation in the United States, Europe or other countries, and/or regulations and policies adopted by the FDA, the EMA or comparable regulatory authorities, may increase the time and cost required for us or any future partners or collaborators to conduct and complete clinical trials of our current or any future product candidates.

The FDA and the EMA have each established regulations to govern the product development and approval process, as have other foreign regulatory authorities. The policies of the FDA, the EMA and other regulatory authorities may change. For example, in December 2016, the 21st Century Cures Act (Cures Act) was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but not all of its provisions have yet been implemented. Additionally, in August 2017, the FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from the FDA or other regulatory authorities will have on the development of DM199 or any future product candidate.

Risks Related to Governmental and Regulatory Compliance and Approvals

We may not be able to obtain FDA acceptance of INDs to commence future clinical trials in the United States or on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.

Prior to commencing additional clinical trials in the United States for future trials of DM199 or any future product candidate, we will be required to have an accepted IND for each product candidate and for each targeted indication. During 2019, we filed and the FDA accepted an IND for the Phase 1b study and a Phase 2 study in patients with CKD. A submission of an IND may not result in the FDA allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to submit or obtain acceptance of INDs may cause the development of DM199 or any future product candidate to be delayed or terminated, which could materially and adversely affect our business and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future partner or collaborator from obtaining approvals for the commercialization of our DM199 or any future product candidate.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Our DM199 or any future product candidate, and the activities associated with their development and commercialization, including design, research, testing, manufacture, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the EMA and other similar foreign regulatory agencies. Failure to obtain marketing approval for DM199 or any future product candidate will prevent us or any future partner or collaborator from commercializing the product candidate. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-parties to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, EMA or other regulatory authorities may determine that DM199 or any future product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit its commercial use. As a result, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Our inability to obtain regulatory approval for DM199 or any future product candidate, or if such approval is limited, could substantially harm our business.

Any product candidate for which we or any future partner or collaborator obtains marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with the product candidate, when and if it is approved.

The FDA and other federal and state agencies, including the U.S. Department of Justice (DOJ), closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws, as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients using our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future partner or collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Current and future legislation may increase the difficulty and cost for us and any future partner or collaborator to obtain marketing approval of and commercialize our DM199 or any future product candidate and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our DM199 or any future product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell DM199 or any future product candidate for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the ACA includes measures to change health care delivery, decrease the number of individuals without insurance, ensure access to certain basic health care services, and contain the rising cost of care. This healthcare reform movement, including the enactment of the ACA, has significantly changed health care financing by both governmental and private insurers in the United States. With respect to pharmaceutical manufacturers, the ACA increased the number of individuals with access to health care coverage, including prescription drug coverage, but it simultaneously imposed, among other things, increased liability for rebates and discounts owed to certain entities and government health care programs, fees for the manufacture or importation of certain branded drugs and transparency reporting requirements under the Physician Payments Sunshine Act. In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we may receive for any product, if approved. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our DM199 or any future product candidate.

Risks Related to Our Reliance on Third Parties

We rely on contract manufacturers over whom we have limited control. If we are subject to quality, cost or delivery issues with the materials supplied by these or future contract manufacturers, we may be unable to produce adequate supplies of DM199 or any future product candidate, and our clinical and business operations could suffer significant harm.

Completion of our clinical trials and commercialization of our DM199 product candidate and any future product candidate require access to, or development of, facilities to manufacture our product candidates at sufficient yields and, ultimately, at commercial scale. Clinical and commercial drug product must be produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We rely on a CMO to manufacture DM199. We rely on CMOs for manufacturing, filling, labeling, packaging, storing and shipping DM199 in compliance applicable cGMP regulations. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations.

As a company, we have no direct experience in manufacturing or managing third parties in manufacturing our DM199 product candidate in the volumes that are expected to be necessary to support commercialization, if DM199 is approved. Our efforts to establish these capabilities may not meet our requirements as to scale-up, timeliness, yield, cost or quality in compliance with applicable cGMP regulations. We or any future partner or collaborator or our CMOs may encounter difficulties in production, which may include the following, among others:

- costs and challenges associated with scale-up and attaining sufficient manufacturing yields;
- supply chain issues, including the timely availability and shelf life requirements of raw materials and supplies and the lack of redundant and backup suppliers;
- quality control and assurance;
- shortages of qualified personnel and capital required to manufacture large quantities of our product candidate;
- competing capacity needs at CMOs supporting product development as quantities for supply increase;
- establishment of commercial supply capacity through binding supply agreements;
- compliance with regulatory requirements that vary in each country where a product might be sold;
- capacity limitations and scheduling availability in contracted facilities; and
- natural disasters, cyberattacks or other force majeure events that affect facilities and possibly limit production or loss of product inventory maintained in third party storage facilities.

There can be no assurances that our current CMOs or any future CMOs will be able to meet our timetable and requirements for our DM199 product candidate or any future product candidate. If we are unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, we may be delayed in the development of DM199 or any future product candidate. Further, CMOs must operate in compliance with cGMP regulations, and failure to do so could result in, among other things, the disruption of product supplies. Our dependence upon our current CMOs and any future third parties for the manufacture of our product candidates may adversely affect our ability to develop our product candidates on a timely and competitive basis and, if we are able to commercialize our product candidates, may adversely affect our revenues from product sales and profit margins.

We rely and will continue to rely on third parties to plan, conduct and monitor our preclinical and clinical trials, and their failure to perform as required could cause delays in completing our product development and substantial harm to our business.

We rely and will continue to rely on third parties to conduct a significant portion of our preclinical and clinical development activities. Preclinical activities include in vivo studies in specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a feasible cost, our development programs may face delays. Further, if any of these third parties fails to perform as we expect or if its work fails to meet regulatory requirements, our testing could be delayed, cancelled or rendered ineffective. This happened to us in the past and resulted in us commencing litigation against Pharmaceutical Research Associates Group B.V. (PRA Netherlands) as a result of its handling of 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, as described later in this report, and could happen again.

Our inability to maintain contractual relationships with physicians could have a negative impact on our research and development.

We maintain contractual relationships with respected physicians in hospitals and universities who assist us in the design of our clinical trials and interpretation of trial results. If we are unable to enter into and maintain these relationships, our ability to develop, obtain required regulatory approvals for, and market our DM199 or any future product candidate could be adversely affected. In addition, it is possible that U.S. federal and state and international laws requiring us to disclose payments or other transfers of value, such as gifts or meals, to surgeons and other healthcare providers could have a chilling effect on the relationships with individuals or entities that may, among other things, want to avoid public scrutiny of their financial relationships with us.

Future development collaborations are expected to be important to us. If we are unable to enter into or maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected.

In the future, we intend to seek to collaborate with pharmaceutical and biotechnology companies for the development and/or commercialization of DM199. We face significant competition in seeking appropriate collaborators or partners. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's or partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's or partner's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators or partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of our DM199 product candidate and take certain actions including, among other things, reducing or delaying its development program, delaying its potential development schedule or reducing the scope of research activities. If we fail to enter into one or more collaborations and do not have sufficient funds or expertise to undertake the necessary development or clinical trial activities, we may not be able to continue or further develop DM199 and our business may be materially and adversely affected.

Future collaborations we may enter into may involve the following risks, among others:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to the collaboration;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay nonclinical or clinical development, provide insufficient funding for product development of targets selected by us, stop or abandon nonclinical or clinical development for a product candidate, or repeat or conduct new nonclinical and clinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our future collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the preclinical or clinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the way we are perceived in the business and financial communities could be adversely affected.

If our collaborations do not result in the successful development of DM199 or any future product candidate, it could be delayed and we may need additional resources to develop product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our future collaborators.

Risks Related to the Future Commercialization of DM199 or Any Future Product Candidate

The successful commercialization of DM199 or any future product candidate, if approved, will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenue.

Even if DM199 or any future product candidate is successfully developed and receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payers such as private insurers or governments and other funding parties. The degree of market acceptance for DM199 or any product candidate we develop will depend on a number of factors including, among others:

- demonstration of sufficient clinical efficacy and safety;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the product's approved labeling;
- cost-effectiveness and availability of acceptable pricing;
- the availability of alternative treatment methods and the superiority of alternative treatment methods;
- the effectiveness of marketing and distribution methods and support for the product; and
- coverage and reimbursement policies of government and third-party payers to the extent that the product could receive regulatory approval but not be approved for coverage by or receive adequate reimbursement from government and quasi-government agencies or other third-party payers.

If we fail to obtain coverage and adequate reimbursement for DM199 or any future product candidate, our revenue-generating ability will be diminished and there is no assurance that the anticipated market for the product will be sustained.

Our ability to successfully commercialize DM199 or any future product candidate will depend, in part, on the extent to which coverage of and adequate reimbursement for such product and related treatments will be available from governmental health payer programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other organizations. No assurance can be given that third-party coverage and adequate reimbursement will be available that will allow us to obtain or maintain price levels sufficient for the realization of an appropriate return on our investment in product development. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private health insurers, managed care plans and other organizations is critical to new product acceptance by healthcare providers. There is no uniform coverage and reimbursement policy among third-party payers in the United States; however, private third-party payers may follow Medicare coverage and reimbursement policy in setting their own coverage policy and reimbursement rates. Additionally, coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for DM199 or any future product candidate, the related reimbursement rates might not be adequate to make the product attractive to providers, or may require patient cost sharing (e.g., copayments/deductibles) that patients find unacceptably high. In addition, healthcare reform and controls on healthcare spending may limit coverage of the product and the price we charge and get paid for the product and the volumes thereof that we can sell. Patients are unlikely to use our DM199 or any future product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of its cost.

Outside of the United States, the successful commercialization of DM199 or any future product candidate will depend largely on obtaining and maintaining government coverage, because in many countries patients are unlikely to use prescription drugs that are not covered by their government healthcare programs. Negotiating coverage and reimbursement with governmental authorities can delay commercialization by 12 months or more. Coverage and reimbursement policies may adversely affect our ability to sell our DM199 or any future product candidate on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and we expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase.

We face competition from other biotechnology and pharmaceutical companies and our financial condition and operations will suffer if we fail to compete effectively.

Technological competition is intense in the industry in which we operate. Development of new, potentially competitive therapies comes from pharmaceutical companies, biotechnology companies and universities, as well as companies that offer non-pharmaceutical solutions. Many of our competitors have substantially greater financial and technical resources; more extensive R&D capabilities; and greater marketing, distribution, production and human resources than we do. Moreover, competitors may develop products more quickly than us and may obtain regulatory approval for such products more rapidly than we do. Products and processes which are more effective than those that we intend to develop may be developed by our competitors. R&D by others may render our product candidates non-competitive or obsolete.

Our DM199 product candidate may face competition sooner than expected.

We believe that DM199 could qualify for 12 years of data exclusivity in the United States under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which was enacted as part of the ACA. Under the BPCIA, an application for a biosimilar product, or BLA, cannot be submitted to the FDA until four years, or if approved by the FDA, until 12 years, after the original brand product identified as the reference product is approved under a BLA. The BPCIA provides an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. This law is complex and is only beginning to be interpreted and implemented by the FDA. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for DM199 or any future product candidate that is a biologic. There is also a risk that the U.S. Congress could repeal or amend the BPCIA to shorten this exclusivity period, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if, as we expect, our DM199 product candidate is considered to be a reference product eligible for 12 years of exclusivity under the BPCIA, another company could market competing products if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the BPCIA could result in a shorter exclusivity period for our DM199 product candidate, which could have a material adverse effect on our business.

Risks Related to Our International Operations

A variety of risks are associated with operating our business internationally which could materially adversely affect our business.

We have conducted R&D operations and/or clinical trials in the United States, Canada and Australia. In the future, we expect to conduct certain clinical trials, and plan to seek regulatory approval of DM199 or any future product candidates, outside of the United States. Accordingly, we are subject to risks related to operating in foreign countries including, among others:

- differing regulatory requirements for drug approvals;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different United States and foreign drug import and export rules;
- reduced protection for intellectual property rights in certain countries;
- withdrawal from or revision to international trade policies or agreements and the imposition or increases in import and export licensing and other compliance requirements, customs duties and tariffs, import and export quotas and other trade restrictions, license obligations, and other non-tariff barriers to trade;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with that country, company, person or entity;
- different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are or will be developed;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- compliance with the Foreign Corrupt Practices Act and other anti-corruption and anti-bribery laws;
- foreign taxes, including withholding of payroll taxes;
- foreign currency exchange rate fluctuations, which could result in increased operating expenses and/or reduced revenue, and other obligations incident to doing business in another country;
- difficulties in managing and staffing international operations and increases in infrastructure costs, including legal, tax, accounting, and information technology;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by foreign partners or collaborators;
- transportation delays and interruptions;

- business interruptions resulting from natural disasters or geopolitical actions, including war and terrorism or systems failure, including cybersecurity breaches; and
- compliance with evolving and expansive international data privacy laws, such as the European Union General Data Protection Regulation.

We have conducted certain R&D operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the R&D incentive payment allowed by Australian regulations, our business and results of operations could suffer.

We maintain a wholly-owned Australian subsidiary, DiaMedica Australia Pty Ltd., and have conducted various clinical activities in Australia. Current Australian tax regulations provide for a refundable R&D incentive payment equal to 43.5% of qualified expenditures. We received incentive payments of approximately USD $205,000 and USD $856,000 during 2020 and 2019, respectively, for research expenditures made during 2020 and 2019. If our subsidiary loses its ability to operate in Australia, or if we are ineligible or unable to receive the R&D incentive payment or the Australian government significantly reduces or eliminates the incentive program, our results of operations may be adversely affected.

Risks Related to Intellectual Property

If we are unable to adequately protect our technology and enforce our intellectual property rights, our competitors may take advantage of our development efforts or acquired technology and compromise our prospects of marketing and selling our DM199 or any future product candidate.

We believe that patents and other proprietary rights are key to our business. Our policy is to file patent applications to protect technology, inventions and improvements that may be important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We plan to enforce our issued patents and our rights to proprietary information and technology. We review third-party patents and patent applications, both to refine our own patent strategy and to monitor the landscape related to our technology.

Our success depends, in part, on our ability to secure and protect our intellectual property rights and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us. We have a number of patents, patent applications and rights to patents related to our compounds, product candidates and technology, but we cannot be certain that they will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

To the extent that development, manufacturing and testing of our product candidates is performed by third party contractors, such work is performed pursuant to fee for service contracts. Under the contracts, all intellectual property, technology know-how and trade secrets arising under such agreements are our exclusive property and must be kept confidential by the contractors. It is not possible for us to be certain that we have obtained from the contractors all necessary rights to such technologies. Disputes may arise as to the scope of the contract or possible breach of contract. No assurance can be given that our contracts would be enforceable or would be upheld by a court.

The patent positions of pharmaceutical and biotechnology firms, ourselves included, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. Therefore, it is not clear whether our pending patent applications will result in the issuance of patents or whether we will develop additional proprietary products which are patentable. Part of our strategy is based on our ability to secure a patent position to protect our technology. There is no assurance that we will be successful in this approach and failure to secure patent protection may have a material adverse effect upon us and our financial condition. Also, we may fail in our attempt to commercialize products using currently patented or licensed technology without having to license additional patents. Moreover, it is not clear whether the patents issued or to be issued will provide us with any competitive advantages or if any such patents will be the target of challenges by third parties, whether the patents of others will interfere with our ability to market our products, or whether third parties will circumvent our patents by means of alternate processes. Furthermore, it is possible for others to develop products that have the same effect as our product candidates or technologies on an independent basis or to design around technologies patented by us. Patent applications relating to or affecting our business may have been filed by pharmaceutical or biotechnology companies or academic institutions. Such applications may conflict with our technologies or patent applications and such conflict could reduce the scope of patent protection that we could otherwise obtain or even lead to the rejection of our patent applications. There is no assurance that we can enter into licensing arrangements on commercially reasonable terms or develop or obtain alternative technology in respect of patents issued to third parties that incidentally cover our products or production technologies. Any inability to secure licenses or alternative technology could result in delays in the introduction of some of our product candidates or even lead to us being prevented from pursuing the development, manufacture or sale of certain products. Moreover, we could potentially incur substantial legal costs in defending legal actions that allege patent infringement, or by initiating patent infringement suits against others. It is not possible for us to be certain that we are the creator of inventions covered by pending patent applications or that we were the first to invent or file patent applications for any such inventions. While we have used commercially reasonable efforts to obtain assignments of intellectual property from all individuals who may have created materials on our behalf (including with respect to inventions covered by our patent and pending patent applications), it is not possible for us to be certain that we have obtained all necessary rights to such materials. No assurance can be given that our patents, if issued, would be upheld by a court, or that a competitor's technology or product would be found to infringe on our patents. Moreover, much of our technology know-how that is not patentable may constitute trade secrets. Therefore, we require our employees, consultants, advisors and collaborators to enter into confidentiality agreements either as stand-alone agreements or as part of their employment or consulting contracts. However, no assurance can be given that such agreements will provide meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of confidential information. Also, while we have used commercially reasonable efforts to obtain executed copies of such agreements from all employees, consultants, advisors and collaborators, no assurance can be given that executed copies of all such agreements have been obtained.

We may require additional third-party licenses to effectively develop, manufacture and commercialize our DM199 or any future product candidate and are currently unable to predict the availability or cost of such licenses.

A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover our product candidates, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these product candidates, and payments under them would reduce our profits from these product candidates. We are currently unable to predict the extent to which we may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights, and whether a license to such patents will be available on acceptable terms, or at all. There may be patents in the United States or in foreign countries or patents issued in the future that are unavailable to license on acceptable terms. Our inability to obtain such licenses may hinder or eliminate our ability to develop, manufacture and market our product candidates.

Changes in patent law and its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our DM199 or any future product candidate.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office (USPTO), the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could, therefore, be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent in USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, and similar legislative, judicial, and administrative bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

Litigation regarding patents, patent applications, and other proprietary rights may be expensive, time consuming and cause delays in the development, manufacturing and commercialization of our DM199 or any future product candidate.

Third parties may claim that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights or otherwise to protect our proprietary information and to prevent its disclosure, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is in our favor. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability (including treble damages and attorneys' fees if we are found to have willfully infringed) and require us or any third-party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be available on commercially acceptable terms or at all. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Moreover, similar challenges may be made by third parties outside the context of litigation, e.g., via administrative proceedings such as post grant or inter partes review in the United States or via oppositions or other similar proceedings in other countries/regions.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation, validity or enforceability, interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation or such other proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of our common shares.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are a party to a license agreement relating to an expression system and cell line for use in the production of DM199 or any human KLK1, and we may need to obtain additional licenses from others to advance our R&D activities or allow the commercialization of DM199 or any other product candidates we may identify and pursue. Future license agreements may impose various development, diligence, commercialization and other obligations on us. If any of our in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain access to technologies that are material to our business, and we may be required to cease our development and commercialization of DM199 or other product candidates that we may identify or to seek alternative manufacturing methods. However, suitable alternatives may not be available or the development of suitable alternatives may result in a significant delay in our commercialization of DM199. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including, among others:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them.

Because we rely on third parties to develop our DM199 product candidate, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, employment or consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint R&D programs which may require us to share trade secrets under the terms of R&D collaboration or similar agreements. However, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. A competitor's discovery of our trade secrets may impair our competitive position and could have a material adverse effect on our business and financial condition.

Patent terms may be inadequate to protect the competitive position of our DM199 or any future product candidate for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Pending Litigation and Other Legal Matters

We have sued a contract research organization to compel them to comply with the terms of a clinical trial research agreement and to date have been unsuccessful in this litigation

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. We believe there were significant execution errors in Part D of the study that were caused by protocol deviations occurring at the clinical trial site that were unable to be reconciled. We believe these included dosing errors and sample mix-ups. These errors undermined our ability to interpret the secondary endpoints. To date, we have been unable to obtain the complete study records from PRA Netherlands for the arm of the study that included 36 patients with Type 2 diabetes and was intended to measure primary endpoints (safety, tolerability) and secondary endpoints (blood glucose concentration, insulin levels, glucose tolerance test and a variety of experimental biomarkers). Without these records, and given our inability to reconcile the protocol deviations, we have been unable to generate a final study report. Due in part to these confounded secondary endpoints, we are not currently continuing the clinical study of DM199 for Type 2 diabetes. We have initiated litigation against PRA Netherlands in the Netherlands to compel them to comply with the terms of the clinical research agreement, including providing full study records, and to recover damages. No assurance can be provided that we will be successful in this litigation or even continue to pursue it, especially in light of the history of this case and our inability to obtain success in commencing litigation against a U.S. subsidiary of PRA Netherlands in the United States. Litigation distracts the attention of our management from our business, is expensive and the outcome is uncertain.

We face the risk of product liability claims, which could exceed our insurance coverage, deplete our cash resources and lead to clinical trial delays.

A risk of product liability claims, and related negative publicity, is inherent in the development of human therapeutics. We are exposed to the risk of product liability claims alleging that use of our DM199 or any future product candidate caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of a product candidate and may be made directly by patients involved in clinical trials of our product candidate, by consumers or healthcare providers, or by individuals, organizations or companies selling our products, if and when approved. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm, and could lead to clinical trial delays and could negatively impact existing or future collaborations.

Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. To protect against potential product liability risks, we have AUD $20 million per occurrence and AUD $20 million aggregate clinical trial insurance for the ReMEDy Phase 2 clinical trial in Australia and US $5.0 million product liability insurance coverage. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available to us at a cost acceptable to us or at all. We may choose or find it necessary under our collaboration agreements to increase our insurance coverage in the future. We may not be able to secure greater or broader product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources, and otherwise have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to maintain product liability insurance required by third parties, certain agreements, such as those with clinical study sites, contract resource organizations and other supporting vendors, would be subject to termination, which could have a material adverse impact on our operations.

Some of our agreements with third parties require, and in the future will likely require, us to maintain product liability insurance in at least certain specified minimum amounts. If we cannot maintain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred substantial losses since our inception and expect to continue to incur substantial losses for at least three to five years and may never become profitable.

We are a clinical stage biopharmaceutical company focused on the development of our DM199 product candidate. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and do not expect to generate any revenue from the sale of products for at least three to five years. We have incurred significant R&D and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the years ended December 31, 2020 and 2019, we incurred a net loss of $12.3 million and $10.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of $68.9 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital. We expect to continue to incur substantial operating losses as we continue our R&D activities, planned clinical trials, regulatory activities and otherwise develop our DM199 or any future product candidate to a point where it receives required regulatory approvals and may be commercially sold and we begin to recognize future product sales, or receive royalty payments, licensing fees and/or milestone payments 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 trials of, and seek regulatory approval for our DM199 or any future product candidate. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Our failure to become and remain profitable may depress the market price of our common shares and could impair our ability to raise capital, continue to develop our DM199 or any future product candidate, expand our business and product offerings or continue our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

Since we currently have no revenue from product sales and do not expect any revenue from product sales for at least three to five years, we will need additional funding to continue our R&D activities and other operations, which may not be available to us on acceptable terms, or at all.

We expect we will need substantial additional capital to further our R&D activities, planned clinical trials and regulatory activities and to otherwise develop our DM199 product candidate to a point where it may be commercially sold. We expect our current cash resources of $27.5 million in cash, cash equivalents and marketable securities as of December 31, 2020 to be sufficient to allow us to complete all three 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 planned operations for at least the next twelve months from the date of issuance of the financial statements included in this report. However, the amount and timing of our future funding requirements will depend on many factors, including, among others:

- the rate of progress in the development of and the conduct of clinical trials with respect to our DM199 or any future product candidates;
- the timing and results of our ongoing development efforts, including in particular our current Phase 2 clinical studies;
- the costs of our development efforts, including the conduct of clinical trials with respect to our DM199 or any future product candidates;
- the costs associated with identifying additional product candidates and the potential expansion of our current development programs or potential new development programs;

- the costs necessary to obtain regulatory approvals for our DM199 or any future product candidates;
- the costs of developing and validating manufacturing processes for our DM199 or any future product candidates;
- the costs associated with being a U.S. public reporting company with shares listed on The Nasdaq Capital Market;
- the costs we incur in the filing, prosecution, maintenance and defense of our intellectual property; and
- the costs related to 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. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable.

Since our inception, we have financed our operations primarily from public and private sales of equity securities, the exercise of warrants and stock options, interest income on funds available for investment, and government grants and tax incentives, 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 and 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.

Although we have previously been successful in obtaining financing through our equity securities offerings, there can be no assurance that we will be able to do so in the future. 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. It is possible that financing will not be available or, if available, may not be on favorable terms. The availability of financing will be affected by the results of our clinical studies and other scientific and clinical research; our ability to obtain regulatory approvals; market acceptance of DM199 or any future 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, we may be required to implement cost reduction strategies; delay, reduce or eliminate one or more of our product development programs; relinquish significant rights to DM199 or any future product candidates or obtain funds on less favorable terms than we would otherwise accept; and/or divest assets or cease operations through a merger, sale or liquidation of our company.

Risks Related to Human Capital Management

We rely heavily on the capabilities and experience of our key executives, clinical personnel and advisors and the loss of any of them could affect our ability to develop our DM199 or any future product candidate.

We depend heavily on members of our management team and certain other key personnel, including in particular our clinical personnel. We also depend on our clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to us. In addition, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial, medical, clinical and regulatory personnel, particularly as we continue to expand our activities and seek regulatory approvals for clinical trials and eventually our DM199 product candidate. We enter into agreements with scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of our business. We also enter into agreements with physicians and institutions that will recruit patients into our clinical trials on our behalf in the ordinary course of our business. Notwithstanding these arrangements, we face significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. We cannot predict our success in hiring or retaining the personnel we require for our continued growth. The loss of the services of any of our key executive officers, clinical personnel and advisors could potentially harm our business, operating results or financial condition.

We will likely need to expand our operations and increase the size of our Company and we may experience difficulties in managing our growth.

As we advance our DM199 product candidate through preclinical testing and clinical studies, or develop any future product candidates, we will need to increase our product development, scientific, clinical, regulatory and compliance and administrative headcount to manage these programs. In addition, to continue to meet our obligations as a U.S. public reporting company, we will likely need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing, distribution and sales infrastructure if we seek to market our products directly; and
- continue to improve our operational, manufacturing, quality assurance, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

Risks Related to Our Common Shares

Our common share price has been volatile and may continue to be volatile.

Our common shares trade on The Nasdaq Capital Market under the trading symbol “DMAC.” During 2020, the sale price of our common shares ranged from $1.87 to $10.43 per share. A number of factors could influence the volatility in the trading price of our common shares, including changes in the economy or in the financial markets, industry related developments and the impact of material events and changes in our operations, such as our clinical results, operating results and financial condition. Each of these factors could lead to increased volatility in the market price of our common shares. In addition, the market prices of the securities of our competitors may also lead to fluctuations in the trading price of our common shares.

We do not have a history of a very active trading market for our common shares.

During 2020, the daily trading volume of our common shares ranged from 1,100 shares to 1.1 million shares. Although we anticipate a more active trading market for our common shares in the future, we can give no assurance that a more active trading market will develop or be sustained. If we do not have an active trading market for our common shares, it may be difficult for you to sell our common shares at a favorable price or at all.

We may issue additional common shares resulting in share ownership dilution.

Future dilution will likely occur due to anticipated future equity issuances by us. 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. In addition, as of December 31, 2020, we had outstanding warrants to purchase 265,000 common shares, options to purchase 1,389,564 common shares, deferred share units representing 47,237 common shares and 1,099,098 common shares reserved for future issuance in connection with future grants under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan. If these or any future outstanding warrants, options or deferred share units are exercised or otherwise converted into our common shares, our shareholders will experience additional dilution.

If there are substantial sales of our common shares or the perception that such sales may occur, the market price of our common shares could decline.

Sales of substantial numbers of our common shares, or the perception that such sales may occur, could cause a decline in the market price of our common shares. Any sales by existing shareholders or holders who exercise their warrants or stock options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common shares.

We are an "emerging growth company" and a "smaller reporting company," and because we have opted to use the reduced disclosure requirements available to us, certain investors may find investing in our common shares less attractive.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We may remain an emerging growth company until December 31, 2023, the last day of the fiscal year following the fifth anniversary of our first sale of common shares pursuant to a registration statement under the Securities Act of 1933, as amended, or until such earlier time as we have more than $1.07 billion in annual revenue, the market value of our common shares held by non-affiliates is more than $700 million or we issue more than $1 billion of non-convertible debt over a three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We are also a "smaller reporting company" under the federal securities laws and, as such, are subject to scaled disclosure requirements afforded to such companies. For example, as a smaller reporting company, we are subject to reduced executive compensation disclosure requirements.

Our shareholders and investors may find our common shares less attractive as a result of our status as an "emerging growth company" and "smaller reporting company" and our reliance on the reduced disclosure requirements afforded to these companies. If some of our shareholders or investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the market price of our common shares may be more volatile.

We have never paid dividends and do not expect to do so in the foreseeable future.

We have not declared or paid any cash dividends on our common shares to date. The payment of dividends in the future will be dependent on our earnings and financial condition and on such other factors as our Board of Directors considers appropriate. Unless and until we pay dividends, shareholders may not receive a return on their common shares. There is no present intention by our Board of Directors to pay dividends on our common shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, appreciation, if any, in the market price of our common shares will be your sole source of gain for the foreseeable future.

Risks Related to Our Jurisdiction of Organization

We are governed by the corporate laws of British Columbia, which in some cases have a different effect on shareholders than the corporate laws in effect in the United States.

We are a British Columbia corporation. Our corporate affairs and the rights of holders of our common shares are governed by British Columbia's Business Corporations Act (BCBCA) and applicable securities laws, which laws may differ from those governing a company formed under the laws of a United States jurisdiction. The provisions under the BCBCA and other relevant laws may affect the rights of shareholders differently than those of a company governed by the laws of a United States jurisdiction and may, together with our Notice of Articles and Articles, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the BCBCA and the Delaware General Corporation Law (DGCL), by way of example, that may be of most interest to shareholders include the following:

- for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our Notice of Articles), the BCBCA, subject to the provisions of our Articles, generally requires two-thirds majority vote by shareholders; whereas, the DGCL generally only requires a majority vote of shareholders;

- under the BCBCA, a holder of 5% or more of our common shares can requisition a special meeting at which any matters that can be voted on at our annual meeting can be considered; whereas, the DGCL does not give this right;

- our Articles require two-thirds majority vote by shareholders to pass a resolution for one or more directors to be removed; whereas, the DGCL only requires the affirmative vote of a majority of the shareholders; and

- our Articles may be amended by resolution of our directors to alter our authorized share structure, including to (a) subdivide or consolidate any of our shares and (b) create additional classes or series of shares; whereas, under the DGCL, a majority vote by shareholders is generally required to amend a corporation's certificate of incorporation and a separate class vote may be required to authorize alternations to a corporation's authorized share structure.

We cannot predict if investors find our common shares less attractive because of these material differences. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

We may be classified as a "passive foreign investment company" in future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders.

General Rule. For any taxable year in which 75% or more of our gross income is passive income, or at least 50% of the value of our assets (where the value of our total assets is determined based upon the market value of our common shares at the end of each quarter) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company (PFIC) for U.S. federal income tax purposes. The percentage of a corporation's assets that produce or are held for the production of passive income generally is determined based upon the average ratio of passive assets to total assets calculated at the end of each fiscal quarter. On December 4, 2020, the Treasury and IRS published a set of final and proposed regulations and guidance on PFICs. Among other changes that were made in the final regulations, a change in the computation of the 50% passive asset test described above will be implemented that will close off any alternative method of calculating assets that was advantageous to taxpayers. Taxpayers must calculate the value of assets at the end of each measuring period, then use the "weighted average" of those values to determine the value of assets for the passive asset test for the taxable year. Under the old rules, the "weighted average" arguably could be calculated based on value, or percentage. Final regulations section 1.1297-1(d)(1)(i) now requires the weighted average to be calculated based on the average value at the end of each measuring period (generally each of the four quarters that make up the company's taxable year, unless an election is made to use an alternative measuring period (such as a week or month)). In addition, in new proposed regulations section 1.1297-1(d)(2), a limited exception to the treatment of working capital to take into account the short-term cash needs of operating companies was provided for purposes of measuring the passive asset test. This new rule provides that an amount of cash held in a non-interest bearing account that is held for the present needs of an active trade or business and is no greater than the amount reasonably expected to cover 90 days of operating expenses incurred in the ordinary course of the trade or business of the foreign corporation (for example, accounts payable for ordinary operating expenses or employee compensation) is not treated as a passive asset. The Treasury Department and the IRS indicated that they continue to study the appropriate treatment of working capital for purposes of the passive asset test.

PFIC Status Determination. The tests for determining PFIC status for any taxable year are dependent upon a number of factors, some of which are beyond our control, including the value of our assets, the market price of our common shares, and the amount and type of our gross income. Based on these tests (i) we believe that we were a PFIC for the taxable year ended December 31, 2016, and (ii) we do not believe that we were a PFIC for any of the taxable years ended thereafter through December 31, 2020. Our status as a PFIC is a fact-intensive determination made for each taxable year, and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, 2021 or for future taxable years. U.S. shareholders who own our common shares for any period during which we are a PFIC (which we believe would currently only be those shareholders holding our common shares in the taxable year ended December 31, 2016) will be required to file IRS Form 8621 for each tax year during which they hold our common shares, unless, after we are no longer a PFIC, any such shareholder makes the "purging election" discussed below.

PFIC Consequences. If we are a PFIC for any year during a non-corporate U.S. shareholder's holding period of our common shares, and the U.S. shareholder does not make a Qualified Electing Fund election (QEF Election) or a "mark-to-market" election, both as described below, then such non-corporate U.S. shareholder generally will be required to treat any gain realized upon a disposition of our common shares, or any so-called "excess distribution" received on our common shares, as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would not be available. This income generally would be allocated over a U.S. shareholder's holding period with respect to our common shares and the amount allocated to prior years will be subject to tax at the highest tax rate in effect for that year and an interest charge would be imposed on the amount of deferred tax on the income allocated to prior taxable years. Pursuant to the specific provisions of the PFIC rules, a taxpayer may realize gain on the disposition of common shares if the securities are disposed of by a holder whose securities are attributed to the U.S. shareholder, if the securities are pledged as security for a loan, transferred by gift or death, or are subject to certain corporate distributions. Additionally, if we are a PFIC, a U.S. shareholder who acquires our common shares from a decedent would be denied normally available step-up in tax basis for our common shares to fair market value at the date of death but instead would have a tax basis equal to the lower of the fair market value of such common shares or the decedent's tax basis in such common shares.

QEF Election. A U.S. shareholder may avoid the adverse tax consequences described above by making a timely and effective QEF election. A U.S. shareholder who makes a QEF election generally must report, on a current basis, its share of our ordinary earnings and net capital gains, whether or not we distribute any amounts to our shareholders, and would be required to comply with specified information reporting requirements. Any gain subsequently recognized upon the sale by that U.S. shareholder of the common shares generally would be taxed as capital gain and the denial of the basis step-up at death described above would not apply. The QEF election is available only if the company characterized as a PFIC provides a U.S. shareholder with certain information regarding its earnings and capital gains, as required under applicable U.S. Treasury regulations. We intend to provide all information and documentation that a U.S. shareholder making a QEF election is required to obtain for U.S. federal income tax purposes (e.g., the U.S. shareholder's pro rata share of ordinary income and net capital gain, and a "PFIC Annual Information Statement" as described in applicable U.S. Treasury regulations).

Mark-to-Market Election. As an alternative to a QEF Election, a U.S. shareholder may also mitigate the adverse tax consequences of PFIC status by timely making a "mark-to-market" election. A U.S. shareholder who makes the mark-to-market election generally must include as ordinary income each year the increase in the fair market value of the common shares and deduct from gross income the decrease in the value of such shares during each of its taxable years. Losses would be allowed only to the extent of the net mark-to-market gain accrued under the election. If a mark-to-market election with respect to our common shares is in effect on the date of a U.S. shareholder's death, the tax basis of the common shares in the hands of a U.S. shareholder who acquired them from a decedent will be the lesser of the decedent's tax basis or the fair market value of the common shares. A mark-to-market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including The Nasdaq Capital Market. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U.S. shareholder might not be eligible to make a mark-to-market election to mitigate the adverse tax consequences if we are characterized as a PFIC.

Election Tax Risks. Certain economic risks are inherent in making either a QEF Election or a mark-to-market election. If a QEF Election is made, it is possible that earned income will be reported to a U.S. shareholder as taxable income and income taxes will be due and payable on such an amount. A U.S. shareholder of our common shares may pay tax on such "phantom" income, i.e., where income is reported to it pursuant to the QEF Election, but no cash is distributed with respect to such income. There is no assurance that any distribution or profitable sale will ever be made regarding our common shares, so the tax liability may result in a net economic loss. A mark-to-market election may result in significant share price gains in one year causing a significant income tax liability. This gain may be offset in another year by significant losses. If a mark-to-market election is made, this highly variable tax gain or loss may result in substantial and unpredictable changes in taxable income. The amount included in income under a mark-to-market election may be substantially greater than the amount included under a QEF election. Both the QEF and mark-to-market elections are binding on the U.S. shareholder for all subsequent years that the U.S. shareholder owns our shares unless permission to revoke the election is granted by the IRS.

Purging Election. Although we generally will continue to be treated as a PFIC as to any U.S. shareholder if we are a PFIC for any year during a U.S. shareholder's holding period, if we cease to satisfy the requirements for PFIC classification, the U.S. shareholder may avoid PFIC classification for subsequent years if the U.S. shareholder elects to make a so-called "purging election," by recognizing income based on the unrealized appreciation in the common shares through the close of the tax year in which we cease to be a PFIC. When a foreign corporation no longer qualifies as a PFIC (due to a change in facts or law), the foreign corporation nonetheless retains its PFIC status with respect to a shareholder unless and until the shareholder makes an election under Code section 1298(b)(1) and regulations section 1.1298–3 (purging election) on IRS Form 8621 attached to the shareholder's tax return (including an amended return), or requests the consent of the IRS Commissioner to make a late election under Code section 1298(b)(1) and regulations section 1.1298–3(e) (late purging election) on Form 8621-A.

RULES RELATING TO A PFIC ARE VERY COMPLEX. YOU SHOULD CONSULT YOUR TAX ADVISER CONCERNING THE RELATIVE MERITS AND THE ECONOMIC AND TAX IMPACT OF THE PFIC RULES TO YOUR INVESTMENT IN OUR COMMON SHARES AS A NON-ELECTING U.S. SHAREHOLDER, A U.S. SHAREHOLDER MAKING A QEF ELECTION, A U.S. SHAREHOLDER MAKING A MARK-TO-MARKET ELECTION, OR A U.S. SHAREHOLDER MAKING ANY AVAILABLE PURGING ELECTION.

Should we be classified as a PFIC during a U.S. shareholder's holding period for our common shares, each such U.S. shareholder should consult their own tax advisors with respect to the possibility of making these elections and the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares. In addition, the possibility of us being classified as a PFIC may deter certain U.S. investors from purchasing our common shares, which could have an adverse impact on the market price of our common shares and our ability to raise additional financing by selling equity securities, including our common shares.

It may be difficult for non-Canadian shareholders or investors to obtain and enforce judgments against us because of our organization as a British Columbia corporation.

We are a corporation existing under the laws of British Columbia, Canada. Two of our directors are residents of Canada, and all or a substantial portion of their assets, and a small portion of our assets, are located outside the United States. Consequently, it may be difficult for holders of our securities who reside in the United States to effect service within the United States upon those directors who are not residents of the United States. It may also be difficult for holders of our securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon our civil liability and the civil liability of our directors, and officers under the United States federal securities laws. Our shareholders and other investors should not assume that British Columbian or Canadian courts (i) would enforce judgments of United States courts obtained in actions against us or such directors, or officers predicated upon the civil liability provisions of the United States federal securities laws or the securities or "blue sky" laws of any state or jurisdiction of the United States, or (ii) would enforce, in original actions, liabilities against us or such directors, or officers predicated upon the United States federal securities laws or any securities or "blue sky" laws of any state or jurisdiction of the United States. In addition, the protections afforded by the securities laws of British Columbia or Canada may not be available to our shareholders or other investors in the United States.

General Risk Factors

We may not achieve our publicly announced milestones according to schedule, or at all.

From time to time, we may announce the timing of certain events we expect to occur, such as the anticipated timing of initiation or completion of or results from our clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ significantly from what has been publicly disclosed. The timing of events such as the initiation or completion of a clinical trial, filing of an application to obtain regulatory approval or an announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a CMO or contract research organization, the COVID-19 pandemic or any other event having the effect of delaying the publicly announced timeline. We undertake no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on our business plan, financial condition or operating results, and the trading price of our common shares.

If securities or industry analysts do not continue to publish research or reports about our business, or publish negative reports about our business, the market price of our common shares and trading volume could decline.

The market price and trading volume for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, the market price of our common shares would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of our common shares or trading volume to decline.

We could be subject to securities class action litigation, which is expensive and could divert management attention.

In the past, securities class action litigation has often been brought against a company following a decline or increase in the market price of its securities or certain significant business transactions. We may become involved in this type of litigation in the future, especially if our clinical trial results are not successful or we enter into an agreement for a significant business transaction. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business. This is particularly true in light of our limited securities litigation insurance coverage.

Fluctuations in insurance cost and availability could adversely affect our operating results or risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, property insurance and workers' compensation insurance. The costs of maintaining adequate insurance coverage, most notably directors' and officers' liability insurance, have increased significantly recently and may continue to do so in the future, thereby adversely affecting our operating results. If such costs continue to increase, we may be forced to accept lower coverage and higher deductibles, which, in the event of a claim, could require significant, unplanned expenditures of cash and inhibit our ability to recruit qualified directors and officers. In addition, if any of our current insurance coverages should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers.

Item 1B. Unresolved Staff Comments

This Item 1B is inapplicable to us as a smaller reporting company.

Item 2. Properties

Our principal executive offices, together with our research and development operations, are at the office of our wholly owned subsidiary, DiaMedica USA Inc., located at Two Carlson Parkway, Suite 260, Minneapolis, Minnesota, USA 55447. We lease these premises, which consist of approximately 3,800 square feet, pursuant to a lease that expires in August 2022. We believe that our facilities are adequate for our current needs and that suitable additional space will be available as and when needed on acceptable terms.

Item 3. 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 trial 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 trials 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 substances defenses, by April 7, 2021. However, before that time, we intend to file 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. If the case is moved to the NCC, the existing deadlines could change.

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 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC" and have been so listed since December 7, 2018, the date of our initial public offering in the United States. Our common shares previously traded in Canada on the TSX Venture Exchange under the trading symbol "DMA" through January 18, 2019. We voluntarily delisted our common shares from the TSX Venture Exchange since we believe that the financial and administrative costs associated with maintaining a dual listing were not justified. Prior to our initial public offering, our common shares traded over-the-counter in the United States on the OTCQB marketplace under the trading symbol "DMCAD" from November 15, 2018 to December 7, 2018 and before November 15, 2018, under the trading symbol "DMCAF."

Number of Record Holders

As of March 1, 2021, we had 39 holders of record of our common shares. This does not include persons whose common shares are in nominee or "street name" accounts through brokers or other nominees.

Dividend Policy

We have never declared or paid cash dividends on our common shares, and currently do not have any plans to do so in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Additionally, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors. As a result, our shareholders will likely need to sell their common shares to realize a return on their investment and may not be able to sell their shares at or above the price paid for them.

Purchases of Equity Securities by the Company

We did not purchase any common shares or other equity securities of our company during the fourth quarter ended December 31, 2020.

Recent Sales of Unregistered Equity Securities

We did not sell any unregistered equity securities of our company during the fourth quarter ended December 31, 2020.

Exchange Controls

There are no governmental laws, decrees or regulations in Canada that restrict the export or import of capital, including foreign exchange controls, or that affect the remittance of dividends, interest or other payments to non-resident holders of the securities of DiaMedica, other than Canadian withholding tax.

Certain Canadian Federal Income Tax Considerations for U.S. Holders

The following is, as of March 1, 2021, a summary of the principal Canadian federal income tax considerations under the *Income Tax Act* (Canada) (Tax Act) generally applicable to a holder of our common shares who, for purposes of the Tax Act and at all relevant times, is neither resident in Canada nor deemed to be resident in Canada for purposes of the Tax Act and any applicable income tax treaty or convention, and who does not use or hold (and is not deemed to use or hold) common shares in the course of carrying on a business in Canada, deals at arm's length with us, is not affiliated with us, is not a "specified shareholder" of us (within the meaning of subsection 18(5) of the Tax Act) and holds our common shares as capital property (Holder). A "specified shareholder" for these purposes generally includes a person who (either alone or together with persons with whom that person is not dealing at arm's length for the purposes of the Tax Act) owns or has the right to acquire or control 25% or more of the common shares determined on a votes or fair market value basis. Generally, common shares will be considered to be capital property to a Holder thereof provided that the Holder does not hold common shares in the course of carrying on a business and such Holder has not acquired them in one or more transactions considered to be an adventure or concern in the nature of trade.

This summary does not apply to a Holder, (i) that is a "financial institution" for purposes of the mark-to-market rules contained in the Tax Act; (ii) that is a "specified financial institution" as defined in the Tax Act; (iii) that holds an interest which is a "tax shelter investment" as defined in the Tax Act; or (iv) that has elected to report its tax results in a functional currency other than Canadian currency. Special rules, which are not discussed in this summary, may apply to a Holder that is an "authorized foreign bank" within the meaning of the Tax Act, a partnership or an insurer carrying on business in Canada and elsewhere. Such Holders should consult their own tax advisors.

This summary is based upon the provisions of the Tax Act (including the regulations (Regulations) thereunder) in force as of March 1, 2021 and our understanding of the current administrative policies and assessing practices of the Canada Revenue Agency (CRA) published in writing by the CRA prior to March 1, 2021. This summary takes into account all specific proposals to amend the Tax Act (and the Regulations) publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (Tax Proposals) and assumes that the Tax Proposals will be enacted in the form proposed, although no assurance can be given that the Tax Proposals will be enacted in their current form or at all. This summary does not otherwise take into account any changes in law or in the administrative policies or assessing practices of the CRA, whether by legislative, governmental or judicial decision or action. This summary is not exhaustive of all possible Canadian federal income tax considerations and does not take into account other federal or any provincial, territorial or foreign income tax legislation or considerations, which may differ materially from those described in this summary.

This summary is of a general nature only and is not, and is not intended to be, and should not be construed to be, legal or tax advice to any particular Holder, and no representations concerning the tax consequences to any particular Holder are made. Holders should consult their own tax advisors regarding the income tax considerations applicable to them having regard to their particular circumstances.

Dividends

Dividends paid or credited (or deemed to be paid or credited) to a Holder by us are subject to Canadian withholding tax at the rate of 25% unless reduced by the terms of an applicable tax treaty or convention. For example, under the Canada-United States Tax Convention (1980), as amended (US Treaty), the dividend withholding tax rate is generally reduced to 15% (or 5% in the case of a Holder that is a company that beneficially owns at least 10% of our voting shares) in respect of a dividend paid or credited to a Holder beneficially entitled to the dividend who is resident in the United States for purposes of the US Treaty and whose entitlement to the benefits of the US Treaty is not limited by the limitation of benefits provisions of the US Treaty. Holders are urged to consult their own tax advisors to determine their entitlement to relief under the US Treaty or any other applicable tax treaty as well as their ability to claim foreign tax credits with respect to any Canadian withholding tax, based on their particular circumstances.

Disposition of Common Shares

A Holder generally will not be subject to tax under the Tax Act in respect of a capital gain realized on the disposition or deemed disposition of a common share, unless the common share constitutes or is deemed to constitute "taxable Canadian property" to the Holder thereof for purposes of the Tax Act, and the gain is not exempt from tax pursuant to the terms of an applicable tax treaty or convention.

In general, provided the common shares are listed on a "designated stock exchange" (which currently includes The Nasdaq Capital Market) at the date of the disposition, the common shares will only constitute "taxable Canadian property" of a Holder if, at any time within the 60-month period preceding the disposition: (i) such Holder, persons with whom the Holder did not deal at arm's length, partnerships in which the Holder or a person with whom the Holder did not deal at arm's length holds a membership interest directly or indirectly through one or more partnerships, or any combination thereof, owned 25% or more of the issued shares of any class or series of the Company's share capital; and (ii) more than 50% of the fair market value of the common shares was derived directly or indirectly from one or any combination of (A) real or immovable property situated in Canada, (B) Canadian resource properties, (C) timber resource properties, and (D) options in respect of, or interests in, or for civil law rights in, property described in any of subparagraphs (ii)(A) to (C), whether or not the property exists. However, and despite the foregoing, in certain circumstances the common shares may be deemed to be "taxable Canadian property" under the Tax Act.

Holders whose common shares may be "taxable Canadian property" should consult their own tax advisers.

Certain U.S. Federal Income Tax Considerations

The following discussion is generally limited to certain material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our common shares by U.S. Holders (as defined below). This discussion applies to U.S. Holders that hold our common shares as capital assets. This summary is for general information purposes only and does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Holder arising from and relating to the acquisition, ownership, and disposition of our common shares. Accordingly, this summary is not intended to be, and should not be construed as, legal or U.S. federal income tax advice with respect to any U.S. Holder. Although this discussion is generally limited to the U.S. federal income tax considerations to U.S. Holders, the U.S. federal income tax treatment of dividends on and gain on sale or exchange of our common shares by certain "Non-U.S. Holders" (as defined below) is included below at "U.S. Federal Income Taxation of Non-U.S. Holders."

No legal opinion from U.S. legal counsel or ruling from the Internal Revenue Service (IRS) has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the acquisition, ownership, and disposition of common shares. This summary is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions presented in this summary. In addition, because the guidance on which this summary is based are subject to various interpretations, the IRS and the U.S. courts could disagree with one or more of the positions described in this summary.

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (Code), U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the United States and Canada (Convention), all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This summary is applicable to U.S. Holders who are residents of the United States for purposes of the Convention and who qualify for the full benefits of the Convention. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation.

This discussion does not address all of the U.S. federal income tax considerations that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, broker-dealers and traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, retirement plans, regulated investment companies, real estate investment trusts, certain former citizens or residents of the United States, persons who hold common shares as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own (or are deemed to own) 10% or more (by voting power or value) of our common shares, persons that acquire their common shares as part of a compensation arrangement, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax considerations or any U.S. federal estate, gift or alternative minimum tax considerations. In addition, except as specifically set forth below, this summary does not discuss applicable tax reporting requirements.

As used in this discussion, the term "U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity treated as a partnership for U.S. federal income tax purposes holds the common shares, the U.S. federal income tax considerations relating to an investment in the common shares will depend in part upon the status and activities of such entity and the particular partner. Any such entity should consult its own tax advisor regarding the U.S. federal income tax considerations applicable to it and its partners of the purchase, ownership and disposition of the common shares.

Persons holding common shares should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of common shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Distributions

Subject to the discussion below under "Passive Foreign Investment Company Considerations," a U.S. Holder that receives a distribution with respect to the common shares generally will be required to include the gross amount of such distribution (before reduction for any Canadian withholding taxes) in gross income as a dividend when actually or constructively received to the extent of the U.S. Holder's pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder's common shares. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's common shares, the remainder will be taxed as capital gain. However, we cannot provide any assurance that we will maintain or provide earnings and profits determinations in accordance with U.S. federal income tax principles. Therefore, U.S. Holders should expect that a distribution will generally be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

The U.S. dollar value of any distribution on the common shares made in Canadian dollars generally should be calculated by reference to the exchange rate between the U.S. dollar and the Canadian dollar in effect on the date of receipt (or deemed receipt) of such distribution by the U.S. Holder regardless of whether the Canadian dollars so received are in fact converted into U.S. dollars at that time. If the Canadian dollars received are converted into U.S. dollars on the date of receipt (or deemed receipt), a U.S. Holder generally should not recognize currency gain or loss on such conversion. If the Canadian dollars received are not converted into U.S. dollars on the date of receipt (or deemed receipt), a U.S. Holder generally will have a basis in such Canadian dollars equal to the U.S. dollar value of such Canadian dollars on the date of receipt (or deemed receipt). Any gain or loss on a subsequent conversion or other disposition of such Canadian dollars by such U.S. Holder generally will be treated as ordinary income or loss and generally will be income or loss from sources within the United States for U.S. foreign tax credit purposes. Different rules apply to U.S. Holders who use the accrual method of tax accounting. Each U.S. Holder should consult its own U.S. tax advisors regarding the U.S. federal income tax consequences of receiving, owning, and disposing of foreign currency.

Distributions on the common shares that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute "passive category income." Because we are not a United States corporation, such dividends will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation" to a U.S. Holder who is an individual, trust or estate will generally be treated as "qualified dividend income" and are eligible for taxation at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. However, if we are a PFIC for the taxable year in which the dividend is paid or the preceding taxable year (see discussion below under "Passive Foreign Investment Company Considerations"), we will not be treated as a qualified foreign corporation, and therefore the reduced capital gains tax rate described above will not apply. Each U.S. Holder is advised to consult its own tax advisors regarding the availability of the reduced tax rate on dividends.

If a U.S. Holder is subject to Canadian withholding tax on dividends paid on the holder's common shares (see discussion above under "Material Canadian Federal Income Tax Considerations—Dividends"), the U.S. Holder may be eligible, subject to a number of complex limitations, to claim a credit against its U.S. federal income tax for the Canadian withholding tax imposed on the dividends. However, if U.S. persons collectively own, directly or indirectly, 50% or more of the voting power or value of our common shares it is possible that a portion of any dividends we pay will be considered U.S. source income in proportion to our U.S. source earnings and profits, which could limit the ability of a U.S. Holder to claim a foreign tax credit for the Canadian withholding taxes imposed in respect of such a dividend, although certain elections may be available under the Code and the Convention to mitigate these effects. A U.S. Holder may claim a deduction for the Canadian withholding tax in lieu of a credit, but only for a year in which the U.S. Holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex. Each U.S. Holder is advised to consult its tax advisor regarding the availability of the foreign tax credit under its particular circumstances.

Sale, Exchange or Other Disposition of Common Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of common shares. The amount of gain recognized will equal the excess of the amount realized (i.e., the amount of cash plus the fair market value of any property received) over the U.S. Holder's adjusted tax basis in the common shares sold or exchanged. The amount of loss recognized will equal the excess of the U.S. Holder's adjusted tax basis in the common shares sold or exchanged over the amount realized. Such capital gain or loss generally will be long-term capital gain or loss if, on the date of sale, exchange or other disposition, the common shares were held by the U.S. Holder for more than one year. Net long-term capital gain derived by a non-corporate U.S. Holder with respect to capital assets is currently subject to tax at reduced rates. The deductibility of a capital loss is subject to limitations. Any gain or loss recognized from the sale, exchange or other disposition of common shares will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes, except as otherwise provided in an applicable income tax treaty and if an election is properly made under the Code.

Passive Foreign Investment Company Considerations

General Rule. In general, a corporation organized outside the United States will be treated as a PFIC in any taxable year in which either (1) at least 75% of its gross income is "passive income" or (2) at least 50% of the average quarterly value of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. The percentage of a corporation's assets that produce or are held for the production of passive income generally is determined based upon the average ratio of passive assets to total assets calculated at the end of each fiscal quarter. On December 4, 2020, the Treasury and IRS published a set of final and proposed regulations and guidance on PFICs. Among other changes that were made in the final regulations, a change in the computation of the 50% passive asset test described above will be implemented that will close off any alternative method of calculating assets that was advantageous to taxpayers. Taxpayers must calculate the value of assets at the end of each measuring period, then use the "weighted average" of those values to determine the value of assets for the passive asset test for the taxable year. Under the old rules, the "weighted average" arguably could be calculated based on value, or percentage. Final regulations section 1.1297-1(d)(1)(i) now requires the weighted average to be calculated based on the average value at the end of each measuring period (generally each of the four quarters that make up the company's taxable year, unless an election is made to use an alternative measuring period (such as a week or month)). In addition, in new proposed regulations section 1.1297-1(d)(2), a limited exception to the treatment of working capital to take into account the short-term cash needs of operating companies was provided for purposes of measuring the passive asset test. This new rule provides that an amount of cash held in a non-interest bearing account that is held for the present needs of an active trade or business and is no greater than the amount reasonably expected to cover 90 days of operating expenses incurred in the ordinary course of the trade or business of the foreign corporation (for example, accounts payable for ordinary operating expenses or employee compensation) is not treated as a passive asset. The Treasury Department and the IRS indicated that they continue to study the appropriate treatment of working capital for purposes of the passive asset test. In determining whether a foreign corporation is a PFIC, a proportionate share of the items of gross income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) are taken into account.

PFIC Status Determination. Although the tests for determining PFIC status are applied as of the end of each taxable year and are dependent upon a number of factors, some of which are beyond our control, including the value of our assets, the market price of our common shares, and the amount and type of our gross income (i) we believe that we were a PFIC for the taxable year ended December 31, 2016, and (ii) we do not believe that we were a PFIC for the taxable years ended December 31, 2017 through 2020. Our status as a PFIC is a fact-intensive determination made on an annual basis, and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, 2021 or for subsequent taxable years. U.S. Holders who own our common shares for any period during which we are a PFIC will be required to file IRS Form 8621 for each tax year during which they hold our common shares. No opinion of legal counsel or ruling from the IRS concerning our status as a PFIC has been obtained or is currently planned to be requested. However, the determination of our PFIC status is made annually after the close of each taxable year and it is difficult to predict before such determination whether we will be a PFIC for any given taxable year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. No assurance can be provided regarding our PFIC status, and neither we nor our United States counsel expresses any opinion with respect to our PFIC status.

PFIC Consequences. If we are a PFIC at any time when a non-corporate U.S. Holder owns common shares, and such U.S. Holder does not make a "qualified electing fund" election (QEF election) or a "mark-to-market" election, both as described below, such U.S. Holder will generally be subject to federal tax under the excess distribution rules (described below). Under such rules, additional taxes and interest charges would apply to certain distributions by us or to gain upon dispositions of our common shares. If neither of such elections are made, the excess distribution rules apply to (1) distributions paid during a taxable year that are greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder's holding period for the common shares, and (2) any gain recognized on a sale, exchange or other disposition (which would include a pledge or transfer by gift or death) of common shares. Under the excess distribution rules, the non-corporate U.S. Holder's tax liability will be determined by allocating such distribution or gain ratably to each day in the U.S. Holder's holding period for the common shares. The amount allocated to the current taxable year (*i.e.*, the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we were a PFIC in the holding period will be taxed as ordinary income earned in the current taxable year and the preferential tax rate applicable to capital gains or dividends received on our common shares would not be available. The amount allocated to other taxable years (*i.e.*, prior years in which we were a PFIC) will be taxed at the highest marginal rate in effect (for individuals or corporations as applicable) for ordinary income in each such taxable year, and an interest charge, generally applicable to the underpayment of tax, will be added to the tax and the preferential tax rate applicable to capital gains or dividends received on our common shares would not be available. These adverse tax consequences would not apply to a pension or profit-sharing trust or other tax-exempt organization that did not borrow funds or otherwise utilize leverage in connection with its acquisition of our common shares. In addition, if a non-electing U.S. Holder who is an individual dies while owning our common shares, such U.S. Holder's successor generally would not receive a step-up in tax basis with respect to such common shares, but instead would have a tax basis equal to the lower of the fair market value of such common shares or the decedent's tax basis in such common shares.

Purging Election. If we are a PFIC at any time when a U.S. Holder holds our common shares, we will generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder holds our common shares even if we cease to meet the PFIC gross income test or asset test in a subsequent year. However, if we cease to meet these tests, a U.S. Holder can avoid the continuing impact of the PFIC rules by making a special election (a Purging Election) to recognize gain by making a "deemed sale" election with respect to all of the U.S. Holder's common shares and have such common shares deemed to be sold at their fair market value on the last day of the last taxable year during which we were a PFIC. The shareholder makes a purging election under Code section 1298(b)(1) and regulations section 1.1298–3 on IRS Form 8621 attached to the shareholder's tax return (including an amended return), or requests the consent of the IRS Commissioner to make a late election under Code section 1298(b)(1) and regulations section 1.1298–3(e) (late purging election) on Form 8621-A. In addition, for a U.S. Holder making such an election, a new holding period would be deemed to begin for our common shares for purposes of the PFIC rules. After the Purging Election, the common shares with respect to which the Purging Election was made will not be treated as shares in a PFIC unless we subsequently again become a PFIC.

QEF Election. The tax considerations that would apply if we were a PFIC would be different from those described above if a U.S. Holder were able to make a valid QEF election. For each year that we meet the PFIC gross income test or asset test, an electing U.S. Holder would be required to include in gross income its pro rata share of our ordinary income and net capital gains, if any, as determined under U.S. federal income tax principles. The U.S. Holder's adjusted tax basis in our common shares would be increased by the amount of such inclusions. An actual distribution to the U.S. Holder out of such income generally would not be treated as a dividend and would decrease the U.S. Holder's adjusted tax basis in our common shares. Gain realized from the sale of our common shares covered by a QEF election would be taxed as a capital gain and the denial of the basis step-up at death described above would not apply. Generally, a QEF election must be made by the U.S. Holder in a timely filed tax return for the first taxable year in which the U.S. Holder held our common shares that includes the close of our taxable year for which we met the PFIC gross income test or asset test. A separate QEF election would need to be made for any of our subsidiaries that are classified as a PFIC. A QEF election is made on IRS Form 8621. U.S. Holders will be eligible to make QEF elections only if we agree to provide U.S. Holders with the information they will need to comply with the QEF rules. In the event we become a PFIC, we intend to provide all information and documentation that a U.S. Holder making a QEF election is required to obtain for U.S. federal income tax purposes (*e.g.,* the U.S. Holder's pro rata share of ordinary income and net capital gain, and a "PFIC Annual Information Statement" as described in applicable U.S. Treasury regulations).

Mark-to-Market Election. As an alternative to a QEF election, a U.S. Holder may also mitigate the adverse tax consequences of PFIC status by timely making a "mark-to-market" election, provided the U.S. Holder completes and files IRS Form 8621 in accordance with the relevant instructions and related Treasury regulations. A U.S. Holder who makes the mark-to-market election generally must include as ordinary income each year the increase in the fair market value of the common shares and deduct from gross income the decrease in the value of such shares during each of its taxable years, but with losses limited to the amount of previously recognized net gains. The U.S. Holder's tax basis in the common shares would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. If a mark-to-market election with respect to our common shares is in effect on the date of a U.S. Holder's death, the tax basis of the common shares in the hands of a U.S. Holder who acquired them from a decedent will be the lesser of the decedent's tax basis or the fair market value of the common shares. Any gain from a sale, exchange or other disposition of the common shares in any taxable year in which we are a PFIC (*i.e.*, when we meet the gross income test or asset test described above) would be treated as ordinary income and any loss from a sale, exchange or other disposition would be treated first as an ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as a capital loss. If we cease to be a PFIC, any gain or loss recognized by a U.S. Holder on the sale or exchange of the common shares would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The common shares should be marketable stock as long as they are listed on The Nasdaq Capital Market and are regularly traded. A mark-to-market election will not apply to the common shares for any taxable year during which we are not a PFIC but will remain in effect with respect to any subsequent taxable year in which we again become a PFIC. Such election will not apply to any subsidiary that we own. Accordingly, a U.S. Holder may continue to be subject to the PFIC rules with respect to any lower-tier PFICs notwithstanding the U.S. Holder's mark-to-market election. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U.S. Holder might not be eligible to make a mark-to-market election to mitigate the adverse tax consequences if we are characterized as a PFIC.

Each U.S. person who is a shareholder of a PFIC generally must file an annual report (on IRS Form 8621) with the IRS containing certain information, and the failure to file such report could result in the imposition of penalties on such U.S. person and in the extension of the statute of limitations with respect to federal income tax returns filed by such U.S. person.

The U.S. federal income tax rules relating to PFICs are very complex. U.S. Holders are urged to consult their own tax advisors with respect to the purchase, ownership and disposition of common shares, the consequences to them of an investment in a PFIC, any elections available with respect to the common shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of common shares in the event we are considered a PFIC.

Additional Tax on Passive Income

Certain U.S. Holders that are individuals, estates or trusts (other than trusts that are exempt from tax) with adjusted income exceeding certain thresholds, will be subject to a 3.8% tax on all or a portion of their "net investment income," which includes dividends on the common shares, and net gains from the disposition of the common shares. Further, excess distributions treated as dividends, gains treated as excess distributions, and mark-to-market inclusions and deductions are all included in the calculation of net investment income.

Treasury regulations provide, subject to the election described in the following paragraph, that solely for purposes of this additional tax, that distributions of previously taxed income will be treated as dividends and included in net investment income subject to the additional 3.8% tax. Additionally, to determine the amount of any capital gain from the sale or other taxable disposition of common shares that will be subject to the additional tax on net investment income, a U.S. Holder who has made a QEF election will be required to recalculate its basis in the common shares excluding any QEF election basis adjustments.

Alternatively, a U.S. Holder may make an election which will be effective with respect to all interests in controlled foreign corporations and PFICs that are subject to a QEF election and that are held in that year or acquired in future years. Under this election, a U.S. Holder pays the additional 3.8% tax on QEF election income inclusions and on gains calculated after giving effect to related tax basis adjustments. U.S. Holders that are individuals, estates or trusts should consult their own tax advisors regarding the applicability of this tax to any of their income or gains in respect of the common shares.

U.S. Federal Income Taxation of Non-U.S. Holders

A beneficial owner of our common shares, other than a partnership or entity treated as a partnership for U.S. Federal income tax purposes, that is not a U.S. Holder is referred to herein as a "Non-U.S. Holder". Non-U.S. Holders generally will not be subject to U.S. federal income tax or withholding tax on dividends received from us with respect to our common shares, unless that income is effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States. In general, if the Non-U.S. Holder is entitled to the benefits of certain U.S. income tax treaties with respect to those dividends, that income is taxable only if it is attributable to a permanent establishment maintained by the Non-U.S. Holder in the United States.

Non-U.S. Holders generally will not be subject to U.S. federal income tax or withholding tax on any gain realized upon the sale, exchange or other disposition of our common shares, unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business in the United States. In general, if the Non-U.S. Holder is entitled to the benefits of certain income tax treaties with respect to that gain, that gain is taxable only if it is attributable to a permanent establishment maintained by the Non-U.S. Holder in the United States; or

- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more during the taxable year of disposition and other conditions are met.

If the Non-U.S. Holder is engaged in a U.S. trade or business for U.S. federal income tax purposes, the income from the common shares, including dividends and the gain from the sale, exchange or other disposition of the stock, that is effectively connected with the conduct of that trade or business will generally be subject to regular U.S. federal income tax in the same manner as discussed above relating to the general taxation of U.S. Holders. In addition, if you are a corporate Non-U.S. Holder, your earnings and profits that are attributable to the effectively connected income, which are subject to certain adjustments, may be subject to an additional branch profits tax at a rate of 30%, or at a lower rate as may be specified by an applicable U.S. income tax treaty.

Information Reporting with Respect to Foreign Financial Assets

U.S. individuals that own "specified foreign financial assets" (as defined in Section 6038D of the Code) with an aggregate fair market value exceeding certain threshold amounts generally are required to file an information report on IRS Form 8938 with respect to such assets with their tax returns. Significant penalties may apply to persons who fail to comply with these rules. Specified foreign financial assets include not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by certain financial institutions, any stock or security issued by a non-U.S. person, such as our common shares. Upon the issuance of future U.S. Treasury regulations, these information reporting requirements may apply to certain U.S. entities that own specified foreign financial assets. The failure to report information required under the current regulations could result in substantial penalties and in the extension of the statute of limitations with respect to federal income tax returns filed by a U.S. Holder. U.S. Holders should consult their own tax advisors regarding the possible implications of these U.S. Treasury regulations for an investment in our common shares.

Special Reporting Requirements for Transfers to Foreign Corporations

A U.S. Holder that acquires common shares generally will be required to file IRS Form 926 with the IRS if (1) immediately after the acquisition such U.S. Holder, directly or indirectly, owns at least 10% of our common shares, or (2) the amount of cash transferred in exchange for common shares during the 12-month period ending on the date of the acquisition exceeds USD $100,000. Significant penalties may apply for failing to satisfy these filing requirements. U.S. Holders are urged to contact their tax advisors regarding these filing requirements.

Information Reporting and Backup Withholding

Dividends on and proceeds from the sale or other disposition of common shares may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if (1) the U.S. holder fails to provide an accurate taxpayer identification number or otherwise establish a basis for exemption, (2) the U.S. Holder is notified by the IRS that backup withholding applies, or (3) the payment is described in certain other categories of persons.

If you sell your common shares through a U.S. office of a broker, the payment of the proceeds is subject to both U.S. backup withholding and information reporting unless you certify that you are a non-U.S. person, under penalties of perjury, or you otherwise establish an exemption. If you sell your common shares through a non-U.S. office of a non-U.S. broker and the sales proceeds are paid to you outside the United States, then information reporting and backup withholding generally will not apply to that payment. However, U.S. information reporting requirements, but not backup withholding, will apply to a payment of sales proceeds, even if that payment is made to you outside the United States, if you sell your common shares through a non-U.S. office of a broker that is a U.S. person or has certain other contacts with the United States, unless you certify that you are a non-U.S. person, under penalty of perjury, or you otherwise establish an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A U.S. HOLDER. EACH U.S. HOLDER IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN COMMON SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Item 6. Selected Financial Data

The following tables present, as of the dates and for the periods indicated, our selected historical financial data as indicated therein. The consolidated statements of operations data for the years ended December 31, 2020 and 2019 and the consolidated balance sheet data as of December 31, 2020 and 2019 are derived from our audited financial statements that are included elsewhere in this annual report on Form 10-K. Our historical results are not indicative of the results to be expected in the future.

This information should be read together with our consolidated financial statements and the related notes, as well as the section entitled "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*" included elsewhere in this report.

	Year Ended December 31,	
	2020	**2019**
Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	$ 8,310	$ 7,900
General and administrative	4,389	3,693
Total operating expenses	12,699	11,593
Operating loss	(12,699)	(11,593)
Other (income) expense:		
Governmental assistance – research incentives	(205)	(856)
Other income, net	(229)	(119)
Total other income, net	(434)	(975)
Loss before income tax expense and other comprehensive income	(12,265)	(10,618)
Income tax expense	27	31
Unrealized loss (gain) on marketable securities	4	(2)
Net loss and comprehensive loss	$ (12,296)	$ (10,647)
Loss per share, basic and diluted	$ (0.78)	$ (0.89)
Weighted average number of shares outstanding: Basic and diluted	15,680,320	11,987,696

	December 31,	
	2020	**2019**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 27,507	$ 7,878
Working capital	25,893	7,518
Total assets	28,095	9,053
Total current liabilities	2,028	1,317
Total shareholders' equity	26,014	7,617

Item 7. 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 subsidiaries for the years ended December 31, 2020 and 2019.

This discussion should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. 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 developing novel treatments for neurological and kidney diseases. 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, our lead drug candidate, through required clinical trials to create shareholder value by establishing its clinical and commercial potential as a therapy for AIS and CKD.

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, 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 (KKS).

Our DM199 product candidate is in clinical development as follows:

Program	Delivery	PRE-CLINICAL	PHASE I	PHASE 2	PHASE 3
Neurological Diseases					
Acute Ischemic Stroke	DM199 IV/SC	**Phase 2/3:** IND Submission Q1 2021			
Kidney Diseases					
IgA Nephropathy (IgAN)	DM199 SC	**Phase 2:** Enrolling			
African Americans with CKD (APOL1)[1]	DM199 SC	**Phase 2:** Enrolling			
Diabetic Kidney Disease (DKD)	DM199 SC	**Phase 2:** Topline H1 2021			

Neurological Diseases

AIS Phase 2/3 ReMEDy 2 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 Phase 2/3 trial for DM199 in patients with AIS, including plans for an adaptive trial design with a primary endpoint based upon the modified Rankin Scale at day 90 and acknowledged that, provided the study results qualify, a single trial may support a Biologics License Application submission. Additionally, based upon the clinical and preclinical testing performed to date and currently in process, the FDA did not recommend any additional studies in preparation for an IND submission and initiation of our planned Phase 2/3 trial. We intend to file an IND for this study by the end of the first quarter of 2021.

AIS Phase 2 ReMEDy Clinical Trial

Enrollment in the ReMEDy study began in February 2018 and concluded in October 2019. We enrolled 92 participants to assess DM199 in the treatment of participants who experienced an AIS. The study drug (DM199 or placebo) was administered as an intravenous infusion within 24 hours of stroke symptom onset, followed by subcutaneous injections later that day and once every 3 days for 21 days. The study was designed to measure safety and tolerability along with multiple tests designed to investigate DM199's therapeutic potential including standard functional stroke measures and stroke recurrence assessed at 90 days post-stroke and certain plasma-based biomarkers. Standard functional stroke measurements include the Modified Rankin Scale, National Institutes of Health Stroke Scale, the Barthel Index and C-reactive protein, a measure of inflammation. Positive top-line results, including the achievement of primary safety and tolerability endpoints and no DM199-related serious adverse events, were announced in May 2020. In addition to meeting its primary safety and tolerability endpoints, a statistically significant 86% (P=0.028) relative reduction in the number of participants with severe recurrent strokes was observed in the active treatment group (N=1, 2.2%) compared to placebo (N=7, 15.6%), a potentially transformative outcome given that approximately 25% of the 795,000 strokes occurring each year in the United States are recurrent strokes.

Kidney Diseases

CKD Phase 2 REDUX Clinical Trial

In October 2019, the FDA accepted our Phase 2 clinical trial protocol for the treatment of CKD caused by rare or significant unmet diseases. The trial 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 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 capture the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is focused on participants with IgA Nephropathy. Cohort III, which was added after the completion of our August 2020 public offering, is focused on 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.

As of March 1, 2021, we had enrolled 68 subjects, including 15 African American subjects into Cohort I, 21 subjects with IgAN into Cohort II and 32 subjects with Type 2 diabetes, hypertension and albuminuria into Cohort III of the REDUX study. Due to actions implemented at our clinical study sites to combat the COVID-19 pandemic, we have continued to experience slower than expected enrollment in the first two cohorts of the REDUX trial. We believe this is due to the reduction or suspension of activities at our clinical study sites as they address staff and patient safety concerns and patient concerns related to visiting clinical study sites in light of the COVID-19 pandemic. However, with the significant declines in new COVID-19 cases and the anticipated availability and effectiveness of vaccines, we currently anticipate completion of Cohort I and Cohort II in the second half of 2021. The enrollment of Cohort III was much more rapid completing in December 2020, which is likely due to the large population of potential subjects. We currently expect topline results from Cohort III to be available in the second quarter of 2021.

CKD Phase 1b Clinical Trial

During 2019, we initiated and completed a Phase 1b clinical trial of DM199 in 32 subjects with moderate or severe CKD caused by Type 1 or Type 2 diabetes mellitus. The study was performed at 3 sites in the U.S. and was designed to assess the pharmacokinetics of three dose levels of DM199 (3, 5 and 8 μg/kg), administered in a single subcutaneous dose, as well as the evaluation of safety, tolerability and secondary pharmacodynamic endpoints. Results from the study were also used to guide the design of Phase 2 CKD studies.

We continue to believe that strategic alternatives with respect to our DM199 product candidate, including licenses and business collaborations, with other regional and global pharmaceutical and biotechnology companies can be important in advancing the clinical development of DM199. Therefore, as a matter of course and from time to time, we engage in discussions with third parties regarding these matters.

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 and tax credits. We have incurred losses in each year since our inception. Our net losses were $12.3 million and $10.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $68.9 million. Substantially all of our operating losses resulted from expenses incurred in connection with our product candidate development programs, our primary 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 Phase 2 study of DM199 for CKD;
- initiate and complete our pending Phase 2/3 study of DM199 for AIS;
- complete manufacturing process development to support applications for commercial approval of DM199;
- 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 resources will be sufficient to allow us to complete all three 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 planned operations for at least the next twelve months from the date of issuance of the 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, including enrollment in our clinical trials, 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.

Components of Our Results of Operations

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 site costs, outside nursing services, laboratory testing, preclinical trials; development of manufacturing processes; costs for production runs of DM199; salaries, benefits and share-based compensation and other personnel costs. We incurred $8.3 million and $7.9 million in R&D expenses for the years ended December 31, 2020 and 2019, respectively. Over the past approximately nine years, our R&D efforts have been primarily focused on developing DM199.

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. We have experienced a delay and expect to continue to expect a delay in the timing of costs incurred in the REDUX trial as a result of the COVID-19 pandemic. We do not, however, expect to experience a significant overall increase in costs. We intend to continue to assess the effect of the pandemic on our REDUX trial by monitoring the spread of the COVID-19 virus and the actions implemented to combat the virus. 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, into advanced 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, 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 of salaries and related benefits, including share-based compensation related to our executive, finance, business development and support functions. Other G&A expenses include professional fees for auditing, tax and legal services, insurance, rent, utilities and travel expenses. We expect our G&A expenses will 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. During the last three quarters of 2020 our office remained closed and our employees worked remotely. In addition, all non-essential travel was on hold. We have encouraged our employees to interact with each other and vendors through audio and video conferencing. We did not incur significant additional expenses during 2020 related to these changes, nor do we expect to incur significant additional expenses going forward. We expect to continue to work remotely and restrict non-essential travel for the foreseeable future.

In 2020, our G&A expenses increased due to increased costs associated with non-cash share-based compensation costs, outside professional services and directors and officers liability insurance. The increase in 2020 was partially offset by reduced travel and meeting costs primarily due to the COVID-19 pandemic.

Other Income, Net

Other income, net consists primarily of governmental assistance comprised of R&D incentives earned by our Australian subsidiary DiaMedica Australia Pty Ltd., foreign currency exchange gains and losses and interest income.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 3 to our consolidated financial statements included elsewhere in this report, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Research and Development Costs

R&D costs include expenses incurred in the conduct of human clinical trials, for third-party service providers performing various treatment, testing and data accumulation and analysis related to these clinical studies; non-clinical research studies; developing the manufacturing process necessary to produce sufficient amounts of the DM199 compound for use in our clinical studies; consulting resources with specialized expertise related to execution of our development plan for our DM199 product candidate; and personnel costs, including salaries, benefits and share-based compensation.

We charge R&D costs, including clinical trial costs, to expense when incurred. Our human clinical trials are performed at clinical trial sites and are generally administered jointly by us with assistance from contract research organizations, and include outside service providers such as outside nursing services, testing laboratories and data coordination and collection. Costs of setting up clinical trial sites are accrued upon execution of the study agreement. Expenses related to the performance of clinical trials are accrued based on contracted amounts and the achievement of agreed upon milestones, such as patient enrollment, patient follow-up, etc. We monitor levels of performance under each significant contract, including the extent of patient enrollment and other activities through communications with the clinical trial sites, CROs and supporting vendors and adjust the estimates, if required, on a quarterly basis so that clinical expenses reflect the actual work performed at each clinical trial site and by each CRO or supporting vendor.

Clinical Trial Costs

Our clinical trials are performed at clinical trial sites and are administered by us with assistance from CROs or outside contractors as necessary. Clinical trial costs are accrued based on estimates of work completed to date by CROs, outside contractors and clinical trial sites that manage and perform the trials. We obtain initial estimates of total costs based on the trial protocol, actual enrollment of subjects, trial duration, project management costs, manufacturing costs, patient treatment costs and other activities as required by the trial protocol. Additional, non-patient related costs may be charged to us and are recognized as the tasks are completed by the clinical trial site. Accrued clinical trial costs may be subject to revisions as clinical trials progress and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Share-based Compensation

We account for all share-based compensation awards using a fair value method. The cost of employee and non-employee services received in exchange for awards of equity instruments is measured and recognized based on the estimated grant date fair value of those awards. Compensation cost is recognized ratably using the straight-line attribution method over the vesting period, which is considered to be the requisite service period. We record forfeitures in the periods in which they occur.

The fair value of share-based awards is estimated using the Black-Scholes option pricing model. The determination of the fair value of share-based awards is affected by our common share price, as well as assumptions regarding a number of complex and subjective variables. Risk-free interest rates are based upon United States Government bond rates appropriate for the expected term of each award. Expected volatility rates are based on the historical volatility equal to the expected life of the option. The assumed dividend yield is zero, as we do not expect to declare any dividends in the foreseeable future. The expected term of options is estimated considering the vesting period at the grant date, the life of the option and the average length of time similar grants have remained outstanding in the past.

The assumptions used in calculating the fair value under the Black-Scholes option valuation model are set forth in the following table for options issued by us for the years ended December 31, 2020 and 2019:

	2020			2019		
Common share fair value	$4.08	–	$6.91	$2.07	–	$4.60
Risk-free interest rate	0.3	–	1.3%	1.5	–	2.4%
Expected dividend yield		0%			0%	
Expected option life (in years)	5.0	–	5.2	4.2	–	5.1
Expected stock price volatility	94.4	–	102.2%	88.7	–	103.5%

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development	$ 8,310	$ 7,900
General and administrative	4,389	3,693
Other income, net	(434)	(975)

Research and Development Expenses

R&D expenses were $8.3 million for the year ended December 31, 2020 compared to $7.9 million for the year ended December 31, 2019, an increase of $0.4 million. The increase was primarily due to a combination of costs incurred for our REDUX Phase 2 CKD study initiated late in 2019, driven in particular by the addition of the third cohort targeting participants with DKD, which fully enrolled during the fourth quarter of 2020, and increased non-cash share-based compensation costs. These increases were partially offset by decreases in clinical study costs incurred for the ReMEDy stroke study, which wound down in the first half of 2020, and non-recurring costs of the Phase 1b CKD study which was started and completed in the prior year period. Additionally, there was a year over year net decrease in drug manufacturing and development costs.

General and Administrative Expenses

G&A expenses were $4.4 million and $3.7 million for the years ended December 31, 2020 and 2019, respectively. This $0.7 million increase was primarily due to increased non-cash share-based compensation costs, outside professional services and directors and officers liability insurance. The increase in 2020 was partially offset by reduced travel and meeting costs primarily due to the COVID-19 pandemic.

Other Income, Net

Other income, net, was $0.4 million for the year ended December 31, 2020 compared to $1.0 million for 2019. This decrease was driven primarily by reduced R&D incentives receivable from the Australian Government, paid for qualifying research work performed by DiaMedica Australia Pty Ltd. during 2020, related to the decreased ReMEDy stroke study costs. This decrease was partially offset by increased foreign currency transaction gains recognized during 2020.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of December 31, 2020 and 2019 and cash flows for each of the years ended December 31, 2020 and 2019, and are intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	**December 31, 2020**	**December 31, 2019**
Cash, cash equivalents and marketable securities	$ 27,507	$ 7,878
Total assets	28,095	9,053
Total current liabilities	2,028	1,318
Total shareholders' equity	26,014	7,617
Working capital	25,893	7,518

	Year Ended December 31,	
Cash Flow Data	**2020**	**2019**
Cash flow provided by (used in):		
Operating activities	$ (9,185)	$ (9,102)
Investing activities	(16,134)	(3,908)
Financing activities	28,845	70
Net increase (decrease) in cash	$ 3,526	$ (12,940)

Working Capital

We had cash, cash equivalents and marketable securities of $27.5 million, current liabilities of $2.0 million and working capital of $25.9 million as of December 31, 2020, compared to $7.9 million in cash, cash equivalents and marketable securities, $1.3 million in current liabilities and $7.5 million in working capital as of December 31, 2019. The increases in our combined cash, cash equivalents and marketable securities and in our working capital were due primarily to our February 2020 and August 2020 public offerings.

On August 10, 2020, we issued and sold an aggregate of 4,600,000 common shares in a public underwritten offering at a public offering price of $5.00 per share, receiving gross proceeds of $23.0 million and net proceeds of approximately $21.1 million, after deducting the underwriting discount and offering expenses.

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, receiving gross proceeds of $8.5 million and net proceeds of approximately $7.7 million, after deducting the underwriting discount and offering expenses.

Cash Flows

Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $9.2 million compared to $9.1 million for the year ended December 31, 2019. This slight increase relates primarily to the combination of the increase in the net loss and partially offset by an increase in non-cash share-based compensation.

Investing Activities

Investing activities consist primarily of purchases of marketable securities and property and equipment. Net cash used in investing activities was $16.1 million for the year ended December 31, 2020 compared to $3.9 million for the year ended December 31, 2019. This increase was due to the investment of a portion of the net proceeds received in the February 2020 and August 2020 public offerings in short-term marketable securities, partially offset by an increase in the maturities of marketable securities during 2020.

Financing Activities

Financing activities consist primarily of net proceeds from the sale of common shares. Net cash provided by financing activities was $28.8 million for the year ended December 31, 2020 compared to $70,000 for the year ended December 31, 2019. This increase was due to our February 2020 and August 2020 public offerings compared to no offerings in 2019.

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 trials 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 trials, 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 all three 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 planned operations for at least the next 12 months from the date of issuance of the 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, the potential expansion of our 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 primarily from public and private sales of equity, the exercise of warrants and stock options, interest income on funds available for investment and government grants and tax incentives. 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 and 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, we may be required to implement cost reduction strategies; delay, reduce, or eliminate one or more of our product development programs; relinquish significant rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us; and/or divest assets or cease operations through a merger, sale, or liquidation of our company.

Commitments and Contingencies

In the normal course of business, we incur obligations to make future payments as we execute our business plan. As of December 31, 2020, we had outstanding commitments, including R&D contracts and other commitments, that are known and committed of approximately $2.2 million over the next 12 months and $0 in the following 12 months. These contracts relate to clinical, and development activities, including the clinical study sites and related professional service providers conducting or supporting the conduct of the REDUX study and the clinical research organization conducting the Phase 2 clinical trial for DM199 related to AIS. These commitments are subject to significant change and the ultimate amounts due may be materially different as these obligations are affected by, among other factors, the number and pace of patients enrolled, the number of clinical study sites, the amount of time to complete study enrollments and the time required to finalize the analysis and reporting of study results. These commitments are generally cancelable upon 30 days' notice, with our obligation then limited to costs incurred up to that date. As of December 31, 2020, we had future operating lease commitments totaling approximately $105,000 over the remainder of the lease, of which $61,000 is due over the next 12 months.

We have entered into a license agreement with Catalent Pharma Solutions, LLC whereby we have licensed certain gene expression technology and we contract with Catalent for the manufacture of DM199. Under the terms of this license, certain milestone and royalty payments may become due under this agreement and are dependent upon, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which is uncertain. As of December 31, 2020, two milestones remain which include $185,000 due upon the initiation of dosing in our first Phase 3 trial and $185,000 upon our first regulatory approval for commercial sale. Following the launch of our first product, we will also incur a royalty of less than 1% on net sales. The royalty term is indefinite but the license agreement may be canceled by us on 90 days' prior written notice. The license may not be terminated by Catalent unless we fail to make required milestone and royalty payments.

Off-Balance Sheet Arrangements

During 2020 and 2019, we did not have any off-balance sheet arrangements (as defined by applicable SEC regulations) 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This Item 7A is inapplicable to DiaMedica as a smaller reporting company and has been omitted pursuant to Item 305(e) of SEC Regulation S-K.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
DiaMedica Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of DiaMedica Therapeutics Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board of the United States of America ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Baker Tilly US, LLP

We have served as the Company's auditors since 2016.
Minneapolis, MN
March 10, 2021

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,409	$ 3,883
Marketable securities	20,098	3,995
Amounts receivable	340	823
Deposits	10	88
Prepaid expenses and other assets	64	47
Total current assets	27,921	8,836
Non-current assets:		
Operating lease right-of-use asset	100	153
Property and equipment, net	74	64
Total non-current assets	174	217
Total assets	$ 28,095	$ 9,053
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,099	$ 182
Accrued liabilities	864	1,076
Finance lease obligation	6	6
Operating lease obligation	59	54
Total current liabilities	2,028	1,318
Non-current liabilities:		
Finance lease obligation, non-current	7	13
Operating lease obligation, non-current	46	105
Total non-current liabilities	53	118
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,746,157 and 12,006,874 shares issued and outstanding, as of December 31, 2020 and 2019, respectively	—	—
Paid-in capital	94,925	64,232
Accumulated other comprehensive (loss) income	(2)	2
Accumulated deficit	(68,909)	(56,617)
Total shareholders' equity	26,014	7,617
	$ 28,095	$ 9,053
Total liabilities and shareholders' equity		

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 8,310	$ 7,900
General and administrative	4,389	3,693
Total operating expenses	12,699	11,593
Operating loss	(12,699)	(11,593)
Other (income) expense:		
Governmental assistance - research incentives	(205)	(856)
Other income, net	(229)	(119)
Total other income, net	(434)	(975)
Loss before income tax expense	(12,265)	(10,618)
Income tax expense	27	31
Net loss	(12,292)	(10,649)
Other comprehensive income (loss)		
Unrealized (gain) loss on marketable securities	4	(2)
Net loss and comprehensive loss	$ (12,296)	$ (10,647)
Basic and diluted net loss per share	$ (0.78)	$ (0.89)
Weighted average shares outstanding – basic and diluted	15,680,320	11,987,696

See accompanying notes to consolidated financial statements.

DiaMedica Therapeutics Inc.
Consolidated Statements of Shareholders' Equity
(In thousands, except share amounts)

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2018	11,956,874	$ 62,993	$ —	$ (45,968)	$ 17,025
Exercise of common stock options	50,000	75	—	—	75
Share-based compensation expense	—	1,164	—	—	1,164
Unrealized gain on marketable securities	—	—	2	—	2
Net loss	—	—	—	(10,649)	(10,649)
Balances at December 31, 2019	12,006,874	$ 64,232	$ 2	$ (56,617)	$ 7,617
Issuance of common shares, net of offering costs of $2,694	6,725,000	28,805	—	—	28,805
Exercise of common stock options	14,283	45	—	—	45
Share-based compensation expense	—	1,843	—	—	1,843
Unrealized loss on marketable securities	—	—	(4)	—	(4)
Net loss	—	—	—	(12,292)	(12,292)
Balances at December 31, 2020	18,746,157	$ 94,925	$ (2)	$ (68,909)	$ 26,014

See accompanying notes to consolidated financial statements.

DiaMedica Therapeutics Inc.
Consolidated Statements of Cash Flows
(In thousands, except share amounts)

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (12,292)	$ (10,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,843	1,164
Amortization of discount on marketable securities	(4)	(74)
Non-cash lease expense	52	49
Depreciation	21	21
Changes in operating assets and liabilities:		
Amounts receivable	483	(43)
Prepaid expenses	(17)	322
Deposits	78	183
Accounts payable	917	(301)
Accrued liabilities	(266)	226
Net cash used in operating activities	(9,185)	(9,102)
Cash flows from investing activities:		
Purchase of marketable securities	(39,746)	(12,919)
Maturities of marketable securities	23,643	9,000
Purchase of property and equipment	(47)	(2)
Disposition of property and equipment, net	16	13
Net cash used in investing activities	(16,134)	(3,908)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	28,805	—
Proceeds from exercise of stock options	45	75
Principal payments on finance lease obligations	(5)	(5)
Net cash provided by financing activities	28,845	70
Net increase (decrease) in cash and cash equivalents	3,526	(12,940)
Cash and cash equivalents at beginning of period	3,883	16,823
Cash and cash equivalents at end of period	$ 7,409	$ 3,883
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 36	$ 26
Cash paid for interest	$ 2	$ 2

See accompanying notes to consolidated financial statements.

1. Business

DiaMedica Therapeutics Inc. and its wholly-owned subsidiaries, DiaMedica USA, Inc. and DiaMedica Australia Pty Ltd. (collectively we, us, our, DiaMedica and the Company), exist for the primary purpose of advancing the clinical and commercial development of a proprietary recombinant KLK1 protein for the treatment of neurological and kidney diseases. Currently, our primary focus is on 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 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 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 DM199 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 December 31, 2020, we have incurred losses of $68.9 million since our inception in 2000. For the year ended December 31, 2020, we incurred a net loss of $12.3 million and negative cash flows from operating activities of $9.2 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 are sufficient to generate revenue to fund our continuing operations. Further, we expect our operating losses to continue as we pursue the research, development and clinical trials of, and to seek regulatory approval for, our DM199 product candidate. In addition, we expect our operating expenses to increase in 2021 compared to 2020 to support our ongoing clinical and organizational development. As of December 31, 2020, we had cash, cash equivalents and short-term investments of $27.5 million, working capital of $25.9 million and shareholders' equity of $26.0 million.

Our principal sources of cash have included net proceeds from the issuance of equity securities. See Note 12 titled "Shareholders' Equity" for additional information. 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 trials, regulatory activities and otherwise develop our DM199 product candidate 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 planned operations for at least the next twelve months from the date of issuance of these financial statements. However, 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 additional capital are favorable.

3. Summary of Significant Accounting Policies

Basis of consolidation

The accompanying consolidated financial statements include the assets, liabilities and expenses of DiaMedica Therapeutics Inc., and our wholly-owned subsidiaries, DiaMedica USA, Inc. and DiaMedica Australia Pty Ltd. All significant intercompany transactions and balances have been eliminated in consolidation.

Functional currency

The United States dollar is our functional currency as it represents the economic effects of the underlying transactions, events and conditions and various other factors including the currency of historical and future expenditures and the currency in which funds from financing activities are mostly generated by the Company. A change in the functional currency occurs only when there is a material change in the underlying transactions, events and condition. A change in functional currency could result in material differences in the amounts recorded in the consolidated statements of operations and comprehensive loss for foreign exchange gains and losses. All amounts in the accompanying consolidated financial statements are in U.S. dollars unless otherwise indicated.

Use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

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.

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 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 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 December 31, 2020.

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 December 31, 2020, 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.

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.

Long-lived assets

Property and equipment are stated at purchased cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of three to ten years for office equipment and four years for computer equipment. Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations. Repairs and maintenance are expensed as incurred.

Long-lived assets are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the asset or related group of assets may not be recoverable. If the expected future undiscounted cash flows are less than the carrying amount of the asset, an impairment loss is recognized at that time. Measurement of impairment may be based upon appraisal, market value of similar assets or discounted cash flows.

Research and development costs

Research and development costs include expenses incurred in the conduct of human clinical trials, for third-party service providers performing various treatment, testing and data accumulation and for analysis related to clinical studies; sponsored non-clinical research agreements; developing the manufacturing process necessary to produce sufficient amounts of the DM199 compound for use in our clinical studies; consulting resources with specialized expertise related to execution of our development plan for our DM199 product candidate; and personnel costs, including salaries, benefits and share-based compensation.

We charge research and development costs, including clinical trial costs, to expense when incurred. Our human clinical trials are performed at clinical trial sites and are administered jointly by us with assistance from contract research organizations. Costs of setting up clinical trial sites are accrued upon execution of the study agreement. Expenses related to the performance of clinical trials are accrued based on estimates of work completed to date by contract research organizations, outside contractors and clinical trial sites that manage and perform the trials, and those that manufacture the investigational product. We obtain initial estimates of total costs based on the trial protocol, extent of enrollment of subjects, trial duration, project management costs, manufacturing costs, patient treatment costs and other activities as required by the trial protocol. Additionally, actual costs may be charged to us and are recognized as the tasks are completed by the clinical trial site. Accrued clinical trial costs may be subject to revisions as clinical trials progress and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

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 research and development costs and were $105,000 and $87,000 for the years ended December 31, 2020 and 2019, respectively.

Share-based compensation

The cost of employee and non-employee services received in exchange for awards of equity instruments is measured and recognized based on the estimated grant date fair value of those awards. Compensation cost is recognized ratably using the straight-line attribution method over the vesting period, which is considered to be the requisite service period. We record forfeitures in the periods in which they occur.

The fair value of share-based awards is estimated at the date of grant using the Black-Scholes option pricing model. The determination of the fair value of share-based awards is affected by our share price, as well as assumptions regarding a number of complex and subjective variables. Risk free interest rates are based upon United States Government bond rates appropriate for the expected term of each award. Expected volatility rates are based on the historical volatility over a term equal to the expected life of the option. The assumed dividend yield is zero, as we do not expect to declare any dividends in the foreseeable future. The expected term of options is estimated considering the vesting period at the grant date, the life of the option and the average length of time similar grants have remained outstanding in the past.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted rates, for each of the jurisdictions in which the Company operates, expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized. The Company has provided a full valuation allowance against the gross deferred tax assets as of December 31, 2020 and 2019. See Note 14, “Income Taxes” for additional information. The Company’s policy is to classify interest and penalties related to income taxes as income tax expense.

Government assistance

Government assistance relating to research and development performed by DiaMedica Australia Pty Ltd. is recorded as a component of other (income) expense. Government assistance is recognized when the related expenditures are incurred. We recognized $205,000 and $856,000 of other income related to research activities performed in 2020 and 2019, respectively.

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 the exclusion of common share equivalents as their effect would be anti-dilutive.

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

	Year Ended December 31,	
	2020	**2019**
Net loss	$ (12,292)	$ (10,649)
Weighted average shares outstanding—basic and diluted	15,680,320	11,987,696
Basic and diluted net loss per share	$ (0.78)	$ (0.89)

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

	Year Ended December 31,	
	2020	2019
Employee and non-employee stock options	1,389,564	1,220,359
Common shares issuable under common share purchase warrants	265,000	971,953
Common shares issuable upon settlement of deferred share units	47,237	21,183
	1,701,801	2,213,495

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:

		Fair Value Measurements as of December 31, 2020 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 10,678	$ —	$ 10,678	$ —
Bank certificate of deposit	496	—	496	—
Government securities	8,924	—	8,924	—
Total marketable securities	$ 20,098	$ —	$ 20,098	$ —

		Fair Value Measurements as of December 31, 2019 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 1,997	$ —	$ 1,997	$ —
Government securities	1,998	—	1,998	—
Total marketable securities	$ 3,995	$ —	$ 3,995	$ —

Accrued interest receivable on available-for-sale securities was $34,000 and $25,000 for the years ended December 31, 2020 and 2019, respectively, and is included in amounts receivable.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the year ended December 31, 2020.

Under the terms of the Company's investment policy, purchases of marketable securities are limited to investment grade governmental and corporate obligations 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 December 31, 2020.

5. Amounts Receivable

Amounts receivable consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Research and development incentives	$ 289	$ 793
Sales-based taxes receivable	2	13
Other	49	17
Total amounts receivable	$ 340	$ 823

6. Deposits

Deposits consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Advances to vendors, current	$ 10	$ 88

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

7. Property and Equipment

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

	December 31, 2020	December 31, 2019
Furniture and equipment	$ 69	$ 51
Computer equipment	62	56
	131	107
Less accumulated depreciation	(57)	(43)
Property and equipment, net	$ 74	$ 64

Depreciation expense was $21,000 for each of the years ended December 31, 2020 and 2019. During 2020 and 2019, we disposed of $23,000 and $14,000 of equipment, respectively.

8. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Trade and other payables	$ 1,099	$ 182
Accrued compensation	483	419
Accrued research and other professional fees	360	172
Accrued clinical study costs	13	433
Accrued taxes and other liabilities	8	52
Total accrued liabilities	$ 1,963	$ 1,258

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.

This lease does not provide an implicit rate and, due to the lack of a commercially salable product, we are generally considered unable to obtain commercial credit. Therefore, considering the quoted rates for the lowest investment-grade debt and the interest rates implicit in recent financing leases, we estimated our incremental borrowing rate to be 9%. We used our estimated incremental borrowing rate and other information available at the lease commencement date in determining the present value of the lease payments.

Our operating lease cost and variable lease costs were $66,000 and $53,000, respectively, for the year ended December 31, 2020. 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 December 31, 2020 (in thousands):

2021	$ 68
2022	46
Total lease payments	$ 114
Less interest portion	(9)
Present value of lease obligation	$ 105

10. Commitments and Contingencies

Clinical trials and product development

In the normal course of business, the Company incurs obligations to make future payments as it executes its business plan. These contracts may relate to preclinical or clinical studies, manufacturing or manufacturing process development and other product development activities. Currently, these contracts include clinical study sites in our Phase 2 CKD study, home nursing services and various vendors supporting the performance of the study. These commitments are subject to significant change and the ultimate amounts due may be materially different as these obligations are affected by, among other factors, the number and pace of patients enrolled, the number of clinical study sites enrolling subjects, the amount of time to complete study enrollments and the time required to finalize, analyze and report of study results. Clinical research agreements are generally cancelable upon 30 days' notice, with the Company's obligation limited to costs incurred up to that date, including any non-cancelable costs. Cancelation terms for product manufacturing and process development contracts vary and are generally dependent upon timelines for sourcing research materials and reserving laboratory time. As of December 31, 2020, the Company estimates that its outstanding commitments, including such cancellable contracts, are approximately $2.2 million over the next 12 months and $0 in the following 12 months.

On December 17, 2019, we announced the enrollment of the first subject in REDUX, a multi-center, open-label, Phase 2 clinical trial investigating 90 participants with Stage II or III CKD, who will be 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 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 capture 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 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 (eGFR) and albuminuria, as measured by the urinary albumin to creatinine ratio.

Additional clinical trials will be subsequently required if the results of the Phase 2 REDUX study are positive. In addition, we are preparing an Investigational New Drug submission to initiate an adaptive Phase 2/3 randomized, double-blind, placebo-controlled study. This study is intended to assess the efficacy, safety and tolerability of DM199 in patients with mild to moderate AIS. The study is expected to enroll approximately 300 to 350 subjects age 18 and over. At this time, we are unable to reasonably estimate the total costs of future trials. Such costs are contingent on and subject to change depending on the results of current and future clinical trials as well as developments in the regulatory requirements.

Technology license

The Company has entered into a license agreement with Catalent Pharma Solutions, LLC (Catalent) whereby we have licensed certain gene expression technology and we contract with Catalent for the manufacture of DM199. Under the terms of this license, certain milestone and royalty payments may become due under this agreement and are dependent upon, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which is uncertain. As of December 31, 2020, two milestones remain which include $185,000 due upon the initiation of dosing in our first Phase 3 trial and $185,000 upon our first regulatory approval for commercial sale. Following the launch of our first product, we will also incur a royalty of less than 1% on net sales. The royalty term is indefinite but the license agreement may be canceled by us on 90 days' prior written notice. The license may not be terminated by Catalent unless we fail to make required milestone and royalty payments. There were no amounts due or payable under this agreement during 2020 and 2019.

Indemnification of directors and officers

The Company, as permitted under laws of British Columbia and in accordance with the Company's articles and indemnification agreements, will indemnify and advance expenses to its directors and officers to the fullest extent permitted by law and may choose to indemnify other employees or agents from time to time. The Company has secured insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to the Company. As of December 31, 2020, there was no pending litigation or proceeding involving any director or officer of the Company as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification. Insofar as indemnification for liabilities arising under the United States Securities Act of 1933, as amended (Securities Act) may be permitted to directors, officers and controlling persons of the Company, the Company has been advised that, in the opinion of the United States Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company had not recorded any liabilities for these obligations as of December 31, 2020 or 2019.

11. Shareholders' Equity

Authorized capital stock

DiaMedica has authorized share capital of an unlimited number of common voting 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 extraordinary general meeting.

Equity issued during the year ended December 31, 2020

On August 10, 2020, the Company issued and sold an aggregate of 4,600,000 common shares in an initial public offering at a price to the public of $5.00 per share. As a result of the offering, the Company received gross proceeds of $23.0 million, which resulted in net proceeds to the Company of approximately $21.1 million, after deducting the underwriting discount and offering expenses.

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

During the year ended December 31, 2020, 14,283 common shares were issued upon the exercise of options for gross proceeds of $45,161 and no warrants were exercised.

Equity issued during the year ended December 31, 2019

During the year ended December 31, 2019, 50,000 common shares were issued upon the exercise of options for gross proceeds of $75,000 and no warrants were exercised.

Shares reserved

Common shares reserved for future issuance are as follows:

	December 31, 2020
Employee and non-employee stock options	1,389,564
Common shares issuable upon settlement of deferred share units	47,237
Shares available for grant under the 2019 Omnibus Incentive Plan	1,099,098
Common shares issuable under common share purchase warrants	265,000
Total	2,800,899

12. Share-Based Compensation

2019 Omnibus Incentive Plan

The DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan (2019 Plan) was adopted by the Board ofDirectors (Board) 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 December 31, 2020, there were options to purchase 873,182 common shares were outstanding and 26,054 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 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 December 31, 2020, options to purchase 516,384 common shares were outstanding under the Prior Plan.

Prior Deferred share unit plan

The DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan (Prior DSU Plan) was terminated by the Board 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 December 31, 2020, there were 21,183 common shares reserved for issuance upon settlement of DSUs outstanding.

The aggregate number of common shares reserved for issuance for awards granted under the 2019 Plan, the Prior Plan and the Prior DSU Plan as of December 31, 2020 was 1,436,803.

Prior to December 31, 2018, all options granted under the Prior Plan were priced in Canadian dollars. Options granted after December 31, 2018 under the 2019 Plan and the Prior Plan have been priced in United States dollars.

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

	December 31, 2020	December 31, 2019
Research and development	$ 534	$ 370
General and administrative	1,309	794
Total share-based compensation	$ 1,843	$ 1,164

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	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balances at December 31, 2018	639,359	$ 6.07	$ —
Granted	725,825	4.52	
Exercised	(50,000)	1.50	
Expired/cancelled	(7,353)	5.49	
Forfeited	(87,472)	5.22	
Balances at December 31, 2019	1,220,359	$ 5.33	$ 678
Granted	302,332	4.73	
Exercised	(14,283)	3.21	
Expired/cancelled	(78,147)	5.29	
Forfeited	(40,697)	4.86	
Balances at December 31, 2020	1,389,564	$ 5.24	$ 7,109

A summary of the status of our unvested shares underlying options during the year ended and as of December 31, 2020 is as follows:

	Shares Underlying Options	Weighted Grant Date Fair Value Per Share
Unvested at December 31, 2019	578,747	$ 3.73
Granted	302,332	4.73
Vested	(449,556)	5.09
Forfeited	(40,697)	4.86
Unvested at December 31, 2020	390,826	$ 4.83

Information about stock options outstanding, vested and expected to vest as of December 31, 2020, is as follows:

	Outstanding, Vested and Expected to Vest			Options Vested and Exercisable	
Per Share Exercise Price	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Exercisable	Weighted Average Remaining Contractual Life (Years)
$2.00 - $2.99	125,700	5.0	$ 2.29	125,700	5.0
$3.00 - $3.99	15,000	6.2	3.90	15,000	6.2
$4.00 - $4.99	950,546	8.4	4.55	596,401	8.1
$5.00 - $10.00	248,168	6.7	8.33	211,487	6.7
$10.01 - $34.00	50,150	1.9	18.22	50,150	1.9
	1,389,564	7.5	$ 5.33	998,738	7.1

The cumulative grant date fair value of employee options vested during the years ended December 31, 2020 and 2019 was $1.4 million and $918,000, respectively. Total proceeds received for options exercised during the years ended December 31, 2020 and 2019 were $45,161 and $75,000, respectively.

As of December 31, 2020, total compensation expense related to unvested employee stock options not yet recognized was $1.1 million, which is expected to be allocated to expenses over a weighted-average period of 1.4 years.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020 and 2019 was $41,000 and $75,000, respectively.

The assumptions used in calculating the fair value under the Black-Scholes option valuation model are set forth in the following table for options issued by the Company for the years ended December 31, 2020 and 2019:

	2020			2019		
Common share fair value	$4.08	–	$6.91	$2.07	–	$4.60
Risk-free interest rate	0.3	–	1.3%	1.5	–	2.4%
Expected dividend yield		0%			0%	
Expected option life (years)	5.0	–	5.2	4.2	–	5.1
Expected stock price volatility	94.4	–	102.2%	88.7	–	103.5%

13. Related Party Transaction

During 2020, 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 $235,000 during the year ended December 31, 2020, and are recorded as research and development expenses, of which approximately $33,000 was outstanding and included in accounts payable as of December 31, 2020.

14. Employee Benefit Plan

We maintain an employee 401(k) retirement savings plan (401(k) Plan). The 401(k) Plan provides eligible employees with an opportunity to make tax-deferred contributions into a long-term investment and savings program. All employees over the age of 21 may elect to participate in the 401(k) Plan beginning on their hire date. The 401(k) Plan allows eligible employees to contribute a portion of their annual compensation, subject only to maximum limits required by law. We contribute an amount up to 4% of each employees' compensation under the safe harbor provisions provided by the Internal Revenue Service rules governing 401(k) plans. Employee and employer safe harbor contributions vest immediately.

We have recorded contribution expenses of $62,000 for each of the years ended December 31, 2020 and 2019.

15. Income Taxes

The Company has incurred net operating losses since inception. The Company has not reflected the benefit of net operating loss carryforwards in the accompanying consolidated financial statements and has established a full valuation allowance against its deferred tax assets.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as operating losses and tax credit carryforwards.

The significant components of our deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets (liabilities):		
Non-capital losses carried forward	$ 14,321	$ 11,211
Research and development expenditures	817	817
Share issue costs	837	395
Patents and other	300	294
Accruals	6	13
Property and equipment	(14)	3
Total deferred tax asset, net	16,267	12,733
Valuation allowance	(16,267)	(12,733)
Net deferred tax asset	$ —	$ —

Realization of the future tax benefits is dependent on our ability to generate sufficient taxable income within the carryforward period. Because of our history of operating losses, management believes that the deferred tax assets arising from the above-mentioned future tax benefits are currently not likely to be realized and, accordingly, we have provided a full valuation allowance.

The reconciliation of the Canadian statutory income tax rate applied to the net loss for the year to the income tax expense is as follows:

	December 31,	
	2020	2019
Statutory income tax rate	27.0%	27.0%
Income tax recovery based on statutory rate	$ (3,274)	$ (2,841)
Share issuance costs	(728)	—
Share-based compensation	498	315
Australian research and development incentive	(102)	137
Prior-year true-ups	84	—
Other	15	(9)
Change in valuation allowance	3,534	2,429
Income tax expense	$ 27	$ 31

Net operating losses and tax credit carryforwards as of December 31, 2020, are as follows:

	Amount (In thousands)	Expiration Years
Non-capital income tax losses, net	$ 48,815	Beginning 2026
Research and development expense carry forwards	3,027	Indefinitely
Tax credits	484	Beginning 2020

The Company is subject to taxation in Canada, the United States and Australia. Tax returns, since the inception of DiaMedica Therapeutics Inc., are subject to examinations by Canadian tax authorities and may change upon examination. Tax returns of DiaMedica USA, Inc., since its inception in 2012 and thereafter, are subject to examination by the U.S. federal and state tax authorities. Tax returns of DiaMedica Therapeutics Australia Pty Ltd., since its inception in 2016 and thereafter, are subject to examination by the Australian tax authorities.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. 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 its Chief Executive Officer and its 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.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the fourth quarter ended December 31, 2020 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

The information in the "Voting Proposal One – Election of Directors" section of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

Executive Officers

Information concerning our executive officers is included in this annual report on Form 10-K under Item 1 of Part I under "Information About Our Executive Officers."

Code of Ethics

We have adopted a code of business conduct and ethics applicable to all of our directors, officers and employees, in accordance with Section 406 of the Sarbanes-Oxley Act, the rules of the SEC promulgated thereunder, and the Nasdaq Listing Rules. In the event that any changes are made or any waivers from the provisions of the code of business conduct and ethics are made, these events would be disclosed on our website or in a report on Form 8-K within four business days of such event. The code of business conduct and ethics is posted on our website at www.diamedica.com. Copies of the code of business conduct and ethics will be provided free of charge upon written request directed to Investor Relations, DiaMedica Therapeutics Inc., Two Carlson Parkway, Suite 260, Minneapolis, Minnesota 55447.

Changes to Nomination Procedures

During the fourth quarter of fiscal 2020, we made no material changes to the procedures by which shareholders may recommend nominees to our Board of Directors.

Audit Committee Matters

The information in the "Corporate Governance—Audit Committee" section of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

Item 11. Executive Compensation

The information in the "Director Compensation" and "Executive Compensation" sections of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Stock Ownership

The information in the "Stock Ownership—Security Ownership of Significant Beneficial Owners" and "Stock Ownership—Security Ownership of Management" sections of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes outstanding options and other awards under our equity compensation plans as of December 31, 2020. Our equity compensation plans as of December 31, 2020 were the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan (2019 Plan), the DiaMedica Therapeutics Inc. Stock Option Plan, Amended and Restated November 6, 2018 (Prior Plan) and the DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan (DSU Plan).

Equity Compensation Plan Information

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,436,803(1)	$ 5.24(2)	1,099,098(3)
Equity compensation plans not approved by security holders	—	$ —	—
Total	1,436,803(1)	$ 5.24(2)	1,099,098(3)

(1) Amount includes 873,182 common shares issuable upon the exercise of stock options and 26,054 common shares issuable upon the settlement of DSU awards outstanding under the 2019 Plan, 516,384 common shares issuable upon the exercise of stock options under the Prior Plan and 21,183 common shares issuable under the DSU Plan.

(2) Not included in the weighted-average exercise price calculation are 26,054 deferred share unit awards under the 2019 Plan and 21,183 deferred share unit awards under the DSU Plan.

(3) Amount includes 1,099,098 shares remaining available for future issuance under the 2019 Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information in the "Related Person Relationships and Transactions" and "Corporate Governance—Director Independence" sections of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services

The information in the "Voting Proposal Two—Appointment of Baker Tilly US, LLP as our Independent Registered Public Accounting Firm and Authorization to Fix Remuneration" section of our definitive proxy statement to be filed with the SEC with respect to our next annual general meeting of shareholders, which involves the election of directors, is incorporated in this annual report on Form 10-K by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

Our consolidated financial statements are included in "*Part II, Item 8. Financial Statements and Supplementary Data*."

Financial Statement Schedules

All financial statement schedules are omitted because they are inapplicable since we are a smaller reporting company.

Exhibits

The exhibits being filed or furnished with this report are listed below, along with an indication as to each management contract or compensatory plan or arrangement.

A copy of any of the exhibits listed or referred to herein will be furnished at a reasonable cost to any person who is a shareholder upon receipt from any such person of a written request for any such exhibit. Such request should be sent to: Mr. Scott Kellen, Chief Financial Officer and Corporate Secretary, DiaMedica Therapeutics Inc., Two Carlson Parkway, Suite 260, Minneapolis, Minnesota 55447, Attn: Shareholder Information.

Item No.	Item	Method 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)
4.1	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Filed herewith
4.2	Specimen Certificate representing Voting Common Shares of DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 4.2 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)
4.3	Warrant dated December 11, 2018 issued by DiaMedica Therapeutics Inc. to Craig-Hallum Capital Group LLC	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 December 11, 2018 (File No. 001-36291)

Item No.	Item	Method of Filing
4.4	Warrant dated October 1, 2019 issued by DiaMedica Therapeutics Inc. to Craig-Hallum Capital Group LLC	Incorporated by reference to Exhibit 4.8 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2019 (File No. 001-36291)
4.5	Warrant dated September 11, 2020 issued by DiaMedica Therapeutics Inc. to Craig-Hallum Capital Group LLC	Incorporated by reference to Exhibit 4.1 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 (File No. 001-36291)
10.1#	DiaMedica Therapeutics Inc. 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 23, 2019 (File No. 001-36291)
10.2#	Form of Option Award Agreement under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan	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 21, 2019 (File No. 001-36291)
10.3#	Form of Restricted Stock Unit Award Agreement under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan	Incorporated by reference to Exhibit 10.3 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2019 (File No. 001-36291)
10.4#	Form of Deferred Stock Unit Award Agreement under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan	Incorporated by reference to Exhibit 10.1 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 (File No. 001-36291)
10.5#	DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018	Incorporated by reference to Exhibit 10.1 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.6#	Form of Option Agreement under the DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018	Incorporated by reference to Exhibit 10.3 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)

Item No.	Item	Method of Filing
10.7#	Form of Option Agreement under the DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated December 21, 2017	Incorporated by reference to Exhibit 10.2 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.8#	DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan	Incorporated by reference to Exhibit 10.4 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.9#	DiaMedica Therapeutics Inc. Short-Term 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 June 21, 2019 (File No. 001-36291)
10.10#	Form of Indemnification Agreement between DiaMedica Therapeutics Inc. and Each Director and Officer	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 4, 2019 (File No. 001-36291)
10.11#	Employment Agreement effective as of September 12, 2018 between DiaMedica USA, Inc. and Rick Pauls	Incorporated by reference to Exhibit 10.6 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.12#	Employment Agreement effective as of September 12, 2018 between DiaMedica USA, Inc. and Scott Kellen	Incorporated by reference to Exhibit 10.7 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2018 (File No. 001-36291)
10.13#	Employment Agreement effective as of September 12, 2018 between DiaMedica USA, Inc. and Harry Alcorn, Ph.D.	Incorporated by reference to Exhibit 10.9 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2018 (File No. 001-36291)

Item No.	Item	Method of Filing
10.14	Two Carlson Parkway Office Lease dated September 18, 2015 between One Two Holding LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.8 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.15	Supplemental to Lease Agreement dated December 16, 2015 between One Two Holding LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.9 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.16	First Amendment to Lease dated May 3, 2017 between One Two Holding LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.10 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.17	Second Amendment to Lease dated September 5, 2017 between One Two Holding LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.11 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.18(1)	GPEx®- Derived Cell Line Sale Agreement dated February 2, 2012 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.12 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.19	First Amendment to GPEx® Development and Manufacturing Agreement dated April 10, 2017 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.13 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.20	Second Amendment to GPEx® Development and Manufacturing Agreement dated as of October 22, 2018 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.19 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2019 (File No. 001-36291)

Item No.	Item	Method of Filing
21.1	Subsidiaries of DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 21.1 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2019 (File No. 001-36291)
23.1	Consent of Baker Tilly US, LLP	Filed herewith
31.1	Certification of President and Chief Executive Officer Pursuant to SEC Rule 13a-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 SEC Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of President and Chief Executive Officer Pursuant to Rule 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 Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from DiaMedica Therapeutics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income (Loss), (iv) the Consolidated Statements of Equity, (v) the Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements	Filed herewith

# Indicates a management contract or compensatory plan or arrangement.

(1) Portions of this exhibit have been redacted and are subject to an order granting confidential treatment under Rule 406 of the United States Securities Act of 1933, as amended (File No. 333-228313, CF #36833). The redacted material was filed separately with the Securities and Exchange Commission.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 10, 2021

By: /s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Rick Pauls Rick Pauls	President, Chief Executive Officer and Director (principal executive officer)	March 10, 2021
/s/ Scott Kellen Scott Kellen	Chief Financial Officer and Secretary (principal financial and accounting officer)	March 10, 2021
/s/ Richard Pilnik Richard Pilnik	Chairman of the Board	March 10, 2021
/s/ Michael Giuffre, M.D. Michael Giuffre, M.D.	Director	March 10, 2021
/s/ James Parsons James Parsons	Director	March 10, 2021

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Exhibit 4.1

DIAMEDICA THERAPEUTICS INC.

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

DiaMedica Therapeutics Inc., a corporation existing under the laws of British Columbia (DiaMedica, we, us, and our), has only one class of securities registered under Section 12 of the U.S. Securities Exchange Act of 1934, as amended: our voting common shares, no par value per share (common shares).

The following description of our common shares is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the provisions of our Notice of Articles and Articles, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Notice of Articles and Articles and the applicable provisions of the British Columbia Business Corporations Act (BCBCA) for additional information.

Authorized Share Capital

Pursuant to our Notice of Articles, we have an authorized share capital consisting of an unlimited number of common shares.

Voting Rights

Each shareholder entitled to vote on a matter has one vote per common share entitled to be voted on the matter and held by that shareholder. Shareholders may exercise their vote either in person or by proxy. Subject to applicable law, holders of our common shares are entitled to vote on all matters on which shareholders generally are entitled to vote. Our common shares do not have cumulative voting rights.

Under our Articles, the presence at a meeting of shareholders, in person or represented by proxy, of any number of shareholders holding not less than 33 1/3% of the issued common shares shall constitute a quorum for the purpose of transacting business at the meeting of shareholders. The affirmative vote of a simple majority of the votes cast is required to pass an ordinary resolution at a meeting of shareholders. The affirmative vote of two-thirds of the votes cast is required to pass a special resolution at a meeting of shareholders.

Dividend Rights

Subject to applicable law and the rights, if any, of shareholders holding shares with special rights as to dividends, holders of our common shares are entitled to receive, pro rata, non-cumulative dividends, as may be declared by our Board of Directors. Pursuant to the provisions of the BCBCA, we may not declare or pay a dividend if there are reasonable grounds for believing that we are, or after the payment would be, unable to pay our liabilities as they become due in the ordinary course of business. We may pay a dividend wholly or partly by the distribution of specific assets, including money or property, or by issuing fully paid shares, or in any one or more of those ways.

Liquidation Rights

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company or any other distribution of our assets among our shareholders for the purpose of winding-up our affairs, holders of common shares are entitled to share pro rata in our assets available for distribution after we pay our creditors.

Other Rights and Preferences

Existing holders of our common shares have no rights of preemption or first refusal under our Articles or the BCBCA with respect to future issuances of our common shares. The common shares do not have conversion rights or other subscription rights, are not subject to redemption and do not have the benefit of any sinking fund provisions. Subject to the rules and policies of The Nasdaq Stock Market and applicable corporate and securities laws, our Board of Directors has the authority to issue additional common shares. Our Notice of Articles and Articles do not restrict the ability of a holder of our common shares to transfer his, her or its common shares. All currently outstanding common shares are fully paid and non-assessable.

Transfer Agent and Registrar

The transfer agent and registrar for our common shares is Computershare Investor Services.

Exchange Listing

Our common shares are listed and trade in the United States on The Nasdaq Capital Market under the trading symbol "DMAC."

Anti-Takeover Effects of Certain Provisions of our Notice of Articles and Articles and Shareholder Rights Plan and the BCBCA

Our Notice of Articles and Articles and Shareholder Rights Plan and the BCBCA contain provisions that may have the anti-takeover effect of delaying, deferring or preventing a change in control of DiaMedica.

Anti-Takeover Provisions in our Notice of Articles and Articles

Our Notice of Articles and Articles contain the following anti-takeover provisions that may have the anti-takeover effect of delaying, deferring or preventing a change in control of DiaMedica:

- Subject to the BCBCA and the rights, if any, of the holders of our issued common shares, we have an unlimited number of common shares available for future issuance without shareholder approval. The existence of unissued and unreserved common shares may enable the Board to issue common shares to persons friendly to current management, thereby protecting the continuity of our management.

- Subject to the BCBCA, unless an alteration of our Notice of Articles would be required, our directors can authorize the alteration of our Articles to, among other things, create additional classes or series of shares or, if none of the shares of a class or series are allotted or issued, eliminate that class or series of shares.

- Subject to the BCBCA, our shareholders can authorize the alteration of our Articles and Notice of Articles to create or vary the rights or restrictions attached to any class of our shares by passing an ordinary resolution at a duly convened meeting of shareholders.

- Only the chairman of the Board of Directors, the chief executive officer, or president in the absence of a chief executive officer, or a majority of the directors, by resolution, may, at any time, call a meeting of the shareholders. Subject to the BCBCA, shareholders holding no less than 5% of our issued common shares that carry the right to vote may request a meeting of the shareholders.

- The affirmative vote of at least two-thirds (2/3) of the votes cast is required to pass a special resolution at a meeting of shareholders, which includes any business brought before a special meeting of shareholders and certain business brought before an annual general meeting of shareholders.

- Our Board of Directors may fill vacancies on the Board of Directors. Our directors may also, between annual general meetings of our shareholders, appoint one or more additional directors to serve until the next annual general meeting of shareholders; provided, however, that the number of additional directors shall not at any time exceed one-third (1/3) of the number of directors who held office at the expiration of the last meeting of shareholders.

- Directors may be removed by a special resolution of shareholders if approved by holders of at least two-thirds (2/3) our outstanding common shares represented in person or by proxy at a duly convened meeting of our shareholders.

- We will indemnify our directors, former directors, his or her heirs and legal personal representatives and other individuals as we may determine against all eligible penalties to which such person is or may be liable to the fullest extent permitted by British Columbia law. We will pay all expenses actually and reasonably incurred by such person, either as such expenses are incurred in advance of the final disposition of an eligible proceeding or after the final disposition of an eligible proceeding.

Anti-takeover Laws of Canada and the BCBCA

We are a corporation organized under the laws of British Columbia. As such, we are subject to federal and provincial corporate and securities laws of Canada as well as the laws of British Columbia. The following laws of Canada and provisions of the BCBCA may have the anti-takeover effect of delaying, deferring or preventing a change in control of DiaMedica.

In Canada, takeover bids are governed by provincial corporate and securities laws and the rules of applicable stock exchanges. The following description of the rules relating to acquisitions of securities and takeover bids to which Canadian corporate and securities laws apply does not purport to be complete and is subject, and qualified in its entirety by reference, to applicable corporate and securities laws, which may vary from province to province.

A party (acquiror) who acquires beneficial ownership of, or control or direction over, more than 10% of the voting or equity securities of any class of a reporting issuer (or securities convertible into voting or equity securities of any class of a reporting issuer) will generally be required to file with applicable provincial regulatory authorities both a news release and a report containing the information prescribed by applicable securities laws. Subject to the below, the acquiror (including any party acting jointly or in concert with the acquiror) will be prohibited from purchasing any additional securities of the class of the target company previously acquired for a period commencing on the occurrence of an event triggering the aforementioned filing requirement and ending on the expiry of one business day following the filing of the report. This filing process and the associated restriction on further purchases also apply in respect of subsequent acquisitions of 2% or more of the securities of the same class (or securities convertible into voting or equity securities of any class of a reporting issuer). The restriction on further purchases does not apply to an acquiror that beneficially owns, or controls or directs, 20% or more of the outstanding securities of that class.

In addition to the foregoing, certain other Canadian legislation may limit a Canadian or non-Canadian entity's ability to acquire control over or a significant interest in us, including the Competition Act (Canada) and the Investment Canada Act (Canada). Issuers may also approve and adopt shareholder rights plans or other defensive tactics designed to be triggered upon the commencement of an unsolicited bid and make the company a less desirable takeover target.

Pursuant to the BCBCA, we may not effect any of the following fundamental changes without the affirmative vote of the holders of at least two-thirds (2/3) of our outstanding common shares represented in person or by proxy at a duly convened meeting of our shareholders:

- Any proposed amalgamation involving DiaMedica in respect of which the BCBCA requires that the approval of our shareholders be obtained;
- Any proposed plan of arrangement pursuant to the BCBCA involving DiaMedica in respect of which the BCBCA or any order issued by an applicable court requires that the approval of our shareholders be obtained;
- Any proposed sale, lease or exchange of all or substantially all of our undertaking; and
- Any voluntary liquidation of our company.

Tax Considerations for U.S. Holders

See "Exchange Controls," "Certain Canadian Federal Income Tax Considerations for U.S. Holders" and "Certain U.S. Federal Income Tax Considerations" in our Annual Report on Form 10-K under Part II. Item 5. Market For Registrant's Common Equity, Related Stockholder Matters And Issuer Purchases of Equity Securities.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-235775) and Form S-8 (File Nos. 333-228821 and 333-231717) of DiaMedica Therapeutics Inc. of our report dated March 10, 2021, relating to the consolidated financial statements of DiaMedica Therapeutics Inc., which appears in this annual report on Form 10-K for the fiscal year ended December 31, 2020.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 10, 2021

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002

I, Rick Pauls, certify that:

1. I have reviewed this annual report on Form 10-K 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.

Date: March 10, 2021

/s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302(A) OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Kellen, certify that:

1. I have reviewed this annual report on Form 10-K 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.

Date: March 10, 2021

/s/ Scott Kellen
Scott Kellen
Chief Financial Officer and Corporate Secretary
(principal financial officer)

Exhibit 32.1

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

In connection with the Annual Report of DiaMedica Therapeutics Inc. (the Company) on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Rick Pauls, President and Chief Executive Officer of the Company, 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 and belief:

(1) 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 the Company.

/s/ Rick Pauls
Rick Pauls
President and Chief Executive Officer
(principal executive officer)

Minneapolis, Minnesota
March 10, 2021

Exhibit 32.2

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

In connection with the Annual Report of DiaMedica Therapeutics Inc. (the Company) on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Scott Kellen, Chief Financial Officer of the Company, 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 and belief:

(1) 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 the Company.

/s/ Scott Kellen
Scott Kellen
Chief Financial Officer and Corporate Secretary
(principal financial officer)

Minneapolis, Minnesota
March 10, 2021