

**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, 2018

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)

Canada

(State or other jurisdiction of incorporation or organization)

Not Applicable

(I.R.S. Employer Identification No.)

2 Carlson Parkway, Suite 260

Minneapolis, Minnesota

(Address of principal executive offices)

55447

(Zip Code)

Registrant's telephone number, including area code: **(763) 496-5454**

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

Title of each class

Voting Common Shares, no par value per share

Name of each exchange on which registered

**The Nasdaq Capital Market
The Nasdaq Stock Market LLC**

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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 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 was last sold as of June 30, 2018 (the last business day of the registrant's most recently

completed second fiscal quarter) as reported by TSX Venture Exchange on that date was \$59.8 million.

As of March 14, 2019, there were 11,956,874 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 2019 Annual General and Special Meeting of Shareholders to be held May 22, 2019.

DIAMEDICA THERAPEUTICS INC.
ANNUAL REPORT ON FORM 10-K
FISCAL YEAR ENDED DECEMBER 31, 2018

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This annual report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended, 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” means 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 and chronic kidney disease and our expectations regarding the benefits of our DM199 product candidate;
- our ability to conduct successful clinical testing of our DM199 product candidate for acute ischemic stroke and chronic kidney disease;
- our ability to obtain required regulatory approvals of our DM199 product candidate for acute ischemic stroke and chronic kidney disease;
- the perceived benefits of our DM199 product candidate over existing treatment options for acute ischemic stroke and chronic kidney disease;
- 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 acute ischemic stroke and chronic kidney disease;
- our ability to partner with and generate revenue from biopharmaceutical and pharmaceutical partners to develop, obtain regulatory approval for and commercialize our DM199 product candidate for acute ischemic stroke and chronic kidney disease;
- 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 FDA regulation of our DM199 product candidate for acute ischemic stroke and chronic kidney disease;
- expectations regarding competition and our ability to obtain data exclusivity for our DM199 product candidate for acute ischemic stroke and chronic kidney disease;
- 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 acute ischemic stroke and chronic kidney disease;
- 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;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- the requirements of being a U.S. public reporting company; and
- our anticipated use of the net proceeds from our recent initial public offering.

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. You should not rely upon forward-looking statements 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 primarily focused on the development of novel recombinant (synthetic) proteins. Our goal is to use our patented and licensed technologies to establish our company as a leader in the development and commercialization of novel recombinant proteins to treat kidney and neurological diseases. Our primary focus is on chronic kidney disease (“CKD”) and acute ischemic stroke (“AIS”). We plan to advance our lead drug candidate, DM199, through clinical trials, as appropriate, to create shareholder value by establishing its clinical and commercial potential as a therapy for CKD and AIS.

DM199 is a recombinant form of human tissue kallikrein-1 (“KLK1”). KLK1 is a serine protease (protein) produced in the pancreas, kidneys and salivary glands, which plays a critical role in the regulation of local blood flow and vasodilation (the widening of blood vessels which decreases blood pressure) in the body, as well as an important role in inflammation and oxidative stress (an imbalance between potentially damaging reactive oxygen species, or free radicals, and antioxidants in 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 current product candidates in preclinical and clinical development are as follows:

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KLK1 is involved in multiple biochemical processes. The most well-characterized activity of KLK1 is its enzymatic cleavage of low molecular weight kininogen (“LMWK”) to produce bradykinin (“BK”)-like peptides, collectively known as kinins, which activate BK receptors (BK1R, BK2R). 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. We believe DM199 could replenish KLK1 levels to properly activate the BK system that protects the kidney and brain from damage. By providing this additional supply of KLK1, DM199 treatment could improve blood flow to damaged end-organs, such as kidneys and brain, supporting the structural integrity and normal functioning.

DM199 (KLK1): Increasing Blood Flow in Brain and Kidneys

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We believe DM199 may provide new treatment options with significant benefits over the current standards of care by offering potentially fewer side effects and a therapeutic treatment option to a greater number of patients. There are no approved therapies in the United States or the European Union, of which we are aware, to address low KLK1 levels. We are positioning DM199 for worldwide use. We have conducted and are conducting clinical trials in Europe and Australia to support regulatory filings in the United States, Europe and around the world; with an initial focus on the United States. In December 2018, the FDA accepted our Investigational New Drug application (“IND”) for the initiation of a Phase Ib clinical trial of DM199 in patients with moderate or severe CKD caused by Type I or Type II diabetes and in February 2019, we initiated dosing patients in this study. The results from this Phase Ib study will assist us in the design of upcoming Phase II studies in patients suffering from rare diseases and CKD. The DM199 drug levels from this Phase Ib study will also help determine the optimal dose levels for testing in the Phase II studies.

Lower KLK1 levels are associated with initial stroke events and are also a predictor of stroke recurrence after an initial stroke. 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).

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For patients suffering from kidney disease, studies have shown that KLK1 excretion, or levels of KLK1 in the urine, significantly decreased in patients with mild kidney disease and was further reduced in patients with severe renal failure requiring dialysis as compared to healthy subjects, as illustrated in the graph below.

Low KLK1 Levels Associated With Kidney Disease

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Our Strategy

Our 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, and we evaluate opportunities based on estimated development timelines and costs, regulatory pathway, and commercial opportunities. 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.

Currently, our strategy includes the following key components:

- DM199 for CKD - advance Phase Ib and Phase II studies
- DM199 for AIS - complete our ongoing Phase II study
- DM199 for other vascular diseases - initiate Phase II studies, with sufficient resources
- Leverage our technologies to expand our development pipeline
- Use our expertise to identify and manufacture other novel recombinant proteins

Targeted Indications and Markets for DM199

Chronic Kidney Disease

CKD is characterized by a progressive decline in overall kidney function as measured by glomerular filtration rate (“GFR”) (a test used to check how well the kidneys are filtering excess fluid and waste products out of your blood), and albuminuria (the amount of albumin protein excreted in your urine). When GFR gets too low, patients develop end stage renal disease (“ESRD”) and require dialysis or a kidney transplant to survive. 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, GFR decreases and abnormal amounts of protein are released into the urine collecting tubules of the kidney through damaged capillary pores. Additionally, increased blood glucose leads to increased blood pressure, 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 this continues, structural components of the kidney (the nephron) begin to collapse, resulting in cell ischemia and cell death. As the renal damage continues, a progressive thickening of the basement membrane is seen along with continued pathological changes in the cell 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 amount of protein in the urine). The rate of decline depends on 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.

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

- 30 million Americans and 120 million Chinese suffer from this debilitating and potentially life-threatening condition according to the National Kidney Foundation.
- 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 involves management 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. Nevertheless, according to the National Kidney Foundation, many patients continue to show declining kidney function, with the overall population having a lifetime risk of 3.6% of developing ESRD, where dialysis or a kidney transplant are needed. We believe DM199 offers a potentially novel approach for the treatment CKD since KLLK1 protein plays a vital role in normal kidney function, and BK and BK receptors are critical for kidney health and integrity. Since patients with moderate to severe CKD often excrete abnormally low levels of KLLK1 in their urine, we believe that DM199 may prevent or reduce further kidney damage by replenishing KLLK1 levels and restoring the protective BK system.

Acute Ischemic Stroke

Stroke is characterized by the rapidly developing loss of brain function due to disturbance in the blood. As a result, the affected area of the brain becomes inactive and eventually dies. 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 or an abnormal vascular structure. According to the U.S. Center for Disease Control and Prevention (“CDC”), about 87% of strokes are ischemic in nature with the remainder classified as hemorrhagic. According to the CDC, worldwide, stroke is an important cause of adult disability and the second leading cause of death in developed countries. Risk factors for stroke include advanced age, hypertension (high blood pressure), previous stroke or transient ischemic attack (“TIA”), diabetes, high cholesterol, cigarette smoking and atrial fibrillation. According to the World Health Organization, each year approximately 15 million people worldwide suffer a stroke, of which 5.5 million will die and 5.0 million will be permanently disabled. According to the CDC:

- Every year in the United States, approximately 795,000 people experience a new or recurrent stroke each year (ischemic or hemorrhagic). Approximately 610,000 of these are first events and 185,000 are recurrent stroke events.
- Stroke caused approximately one of every 20 deaths in the United States. On average, someone in the United States has a stroke every 40 seconds, and someone dies from a stroke every four minutes.
- Stroke costs the United States \$34 billion annually, including the cost of health care services, medications and lost productivity.

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, and the surrounding ischemic penumbra having partially reduced blood flow. Within minutes, the significant lack of blood flow in the core (*i.e.*, glucose and oxygen deprivation) rapidly depletes energy stores and triggers the loss of ion gradients, ultimately leading to neuronal cell death. The ischemic penumbra zone, however, may remain viable for several hours via collateral arteries that branch from the main occluded artery in the core zone. Unfortunately, the penumbra is at great risk of delayed tissue damage due to inflammation and cell death, or apoptosis. As time goes on, a lack of blood flow in the ischemic zone (infarct) leads 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.

Acute Ischemic Stroke Treatment Options

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We believe that stroke represents an area of significant unmet medical need, and a KLK1 treatment (such as DM199) could provide a treatment option and a significant patient benefit with its proposed therapeutic window of up to 24 hours after the first sign of symptoms. Currently, the only pharmacological intervention for AIS is the use of tissue plasminogen activator (“tPA”), which must be given within 4.5 hours of symptom onset. Mechanical thrombectomy, in which the clot is removed using catheter-based tools, is also available to some patients. Despite the availability of these treatments, many patients are not eligible due to the location of the clot, the elapsed time after the stroke occurred, or safety considerations. Thus, we believe DM199 offers significant advantages over the current treatment options and fills an unmet need for patients who cannot receive tPA. Additionally, DM199 may also offer a complimentary follow-on treatment for patients who initially receive tPA or mechanical thrombectomy treatments. Based on the number of strokes each year (approximately 1.7 million in the United States, Europe and Japan and 15 million worldwide) and the \$8,500 estimated cost per patient for the current standard of care, tPA, we believe the annual market opportunity for DM199 could be significant.

DM199 Acute Ischemic Stroke: Proposed Mechanism

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KLK1 in China (marketed under the brand name Kailikang®) is widely used for the treatment of AIS, making therapy available to hundreds of thousands of patients who currently have no options. Kailikang® is a human urine-extracted KLK1 protein. We believe that the proprietary DM199 protein could result in an improved efficacy with optimized pharmacokinetics (drug level exposure) and avoid the side effects of risk of endotoxins, impurities and antibody formation in comparison to Kailikang® that is isolated from human urine. We also believe that DM199 addresses potential supply constraints that makes Kailikang® difficult and expensive to produce given the limited source of human urine. We believe these factors make the recombinant protein DM199 a product candidate that is better positioned for regulatory approval worldwide than a urine-derived protein since we believe it can meet the rigorous required manufacturing standards.

Potential Treatments with DM199

Chronic Kidney Disease

We also believe DM199 has the potential to offer therapeutic benefits for CKD patients. The KLK1 protein plays a vital role in normal kidney function, and BK and BK receptors are critical 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 this KLK1 deficit contributes to disease progression. We believe that DM199 may replenish KLK1 levels and activate the BK system that protects the kidney from damage. In fact, DM199 treatment in an animal model of Type 1 diabetes delayed the onset of the disease, attenuated the degree of insulinitis (inflammation in the insulin producing islet cells of the pancreas) and improved pancreatic beta cell mass in a dose-dependent manner by increasing T-regs. By providing additional KLK1, DM199 has the following potentially beneficial actions:

- Improve blood flow to 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 T-regs, 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. The severity of the disease was negatively correlated with KLK1 excretion. Decreases in urinary KLK1 activity was seen especially when the reduction was associated with decreased glomerular filtration rate. We believe DM199 may potentially have advantages over ACEi because it restores already depleted KLK1 levels.

DM199 treatment is intended to directly replenish KLK1 levels, normalizing kidney function. Current treatment options, especially ACEi drugs, only partially restore kidney function and are associated with high-risk 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. While higher BK levels benefit the kidney, ACEi drugs 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 allow KLK1 to follow its normal physiological processes and release BK when and where it is needed, avoiding these side effects. Importantly, we believe successful treatment with ACEi in kidney disease requires a fully functional kallikrein kinin system, KLK1 and bradykinin systems, potentially making ACEi drugs less effective in patients with a pre-existing KLK1 deficit.

KLK1 derived from the pancreas of a pig, or porcine KLK1, is currently used to treat CKD in China and Japan. Porcine KLK1 is also used to treat hypertension and retinopathy in Japan, China and Korea. Based on IQVIA data and our estimates, we estimate millions of patients have been treated with porcine KLK1 for CKD, retinopathy and other vascular diseases in Asia. Over 20 clinical papers have been published in the Chinese literature supporting the therapeutic activity in CKD patients of porcine KLK1 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.

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There is a significant need for new and alternative treatment strategies for CKD and we believe that the combined results of these studies, which are consistent with our proposed mechanism of action for and preclinical studies of DM199, provide a good rationale for formal clinical development of DM199. We intend to seek approval for use of DM199 as a novel and ground-breaking therapy for CKD. We believe DM199 could potentially complement the use of ACEi or ARBs to improve kidney functions without increasing the risk for hyperkalemia, chronic cough, angioedema or other related side effects. Less than 30% of patients with CKD are believed to be on optimal dose of ACEi or ARB due in part to risk of hyperkalemia which can lead to cardiac arrest and sudden death. We believe DM199, through the activation of the BK system, may complement the renin-angiotensin system, primarily targeted by ACEi and ARBs. Activation of the BK system may improve the function of the diseased renal system by improving vasodilation and insulin sensitization, as well as blocking fibrosis, inflammation, thrombosis and oxidative stress. A significant potential advantage of DM199 over ACEi/ARB treatments is that hyperkalemia may be less likely with DM199. We anticipate that DM199 will boost KLK1 levels to release physiological levels of BK when and where needed, generating beneficial nitric oxide and prostacyclin while increasing regulatory T cells (T-regs or TREGS) to reduce inflammation.

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Acute Ischemic Stroke

We believe treatment of AIS with DM199 could have both immediate and long-term benefits for patients that could significantly improve outcomes following AIS. 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). Long-term (days following the stroke) actions include the restoration of the blood brain barrier through increases in T regulatory cells (“T-regs” – a subpopulation of T cells that modulate the immune system and prevent autoimmune disease) and inhibition of apoptotic cell death.

In China, a human urine-extracted KLK1 protein (Kailikang®) is approved and marketed by Techpool Bio-Pharma Inc., a company controlled by Shanghai Pharmaceuticals Holding Co. Ltd. We believe Kailikang® has been approved for the treatment of AIS in China with a treatment window of up to 48 hours post-stroke. Based on IQVIA data, other publications and internal estimates, we believe over 500,000 stroke patients have been treated with Kailikang® for acute ischemic stroke in Asia. More than 50 published clinical studies, covering over 4,000 stroke patients, have demonstrated a beneficial effect of Kailikang® treatment in AIS. According to a publication in the *China Journal of Neurology*, in a double-blinded, placebo-controlled trial of 446 patients treated with either KLK1 or a placebo administered up to 48 hours after a stroke 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.

Furthermore, a comprehensive meta-analysis covering 24 clinical studies involving 2,433 patients published in the *Journal of Evidenced 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.

As DM199 is a recombinant form of human KLK1, we believe it 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 ischemic penumbra brain tissue. We believe DM199 offers the potential for an improved recombinant product for worldwide use. We are developing DM199 to treat AIS patients with therapy beyond the current window of 3 to 4.5 hours for tPA to up to 24 hours after the first sign of symptoms, thereby filling a large unmet need of patients who cannot receive tPA under the currently available treatment window of tPA. We believe this could potentially make therapy available to the millions of patients worldwide who currently have limited options.

Other Potential Programs

We are also currently developing a diagnostic tool, DMDx, to measure KLK1 levels. Several published studies indicate KLK1 insufficiency is associated with multiple disease states including hypertension, CKD and AIS. Levels of endogenous KLK1 in both urine and plasma are inversely correlated with disease severity. Importantly, the decrease in urinary protein occurs in a disease state (e.g. CKD), where a primary hallmark is increased secretion of many other proteins. In this way, we believe KLK1 is a potentially unique diagnostic tool for such diseases.

We believe DM199 may also offer a potentially novel treatment for vascular dementia patients. Vascular dementia is caused by chronic impaired blood supply within the brain, often associated with TIA or prior stroke. According to the Alzheimer’s Society, one third of all stroke survivors could develop dementia within five years. According to the U.S. National Institute of Neurological Disorders and Stroke, there are over 6 million stroke survivors in the United States alone. In a clinical study, KLK1 isolated from human urine demonstrated the ability to improve cognitive function in vascular dementia patients and increase cerebral blood flow. We have drafted a protocol synopsis for a Phase II study in vascular dementia. Our decision to commence this study will be dependent upon our cash resources.

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

The biopharmaceutical industry is highly competitive and characterized by rapidly advancing technologies that focus on rapid development of proprietary drugs. We believe that our product candidates, development capabilities, experience and scientific knowledge provide us with 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 U.S. Food and Drug Administration (“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 product candidates.

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, 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.

Chronic Kidney Disease

In the United States, we are aware of only one currently approved treatment for CKD. That treatment is an ACEi (marketed under the brand name Captopril®) which is approved for the treatment of patients with CKD caused by Type 1 diabetes. There are several pharmaceutical products for the treatment of CKD currently in clinical development, some of which include:

- Mineralcorticosteroid receptor agonist (Bayer HealthCare Pharmaceuticals LLC)
- 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 (AbbVie 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.)

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. However, according to the National Kidney Foundation, 3.6% of the U.S. population over their lifetime will develop ESRD requiring dialysis or kidney transplantation. Furthermore, the treatment with ACEi and ARBs 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 suboptimal dosing 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.

DM199 treatment is intended to directly replenish KLK1 levels, normalizing kidney function. Current treatment options, especially ACEi drugs, only partially restore kidney function and the association with high-risk side effects. ACEi drugs can generate excessive BK where it is not needed, potentially leading to related side effects such as cough and angioedema (swelling of skin and tissue). We believe DM199 treatment would potentially allow KLK1 to follow its normal physiological processes and release BK when and where it is needed, avoiding these side effects. Importantly, successful treatment with ACEi in kidney disease requires a fully functional KLK1 system, potentially making ACEi drugs less effective in patients with a pre-existing KLK1 deficit.

Acute Ischemic Stroke

Currently, there is one approved pharmaceutical treatment for acute ischemic stroke. That treatment is tPA (marketed under the brand name Activase®), and its therapeutic window is limited to 3 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.)
- Cerebral edema (Biogen Inc.)
- Anti-inflammatory and clot dissolving (Biogen Inc.)
- Cell protection and anti-inflammation (ZZ Biotech LLC)
- Inhibits platelet aggregation (Acticor Biotech SAS)

We believe that there is a large unmet therapeutic need for AIS treatments that can be administered beyond the 3 to 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 brain arteries through sophisticated catheter-based approaches. 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. These therapies are especially targeted toward preserving viable cells in the ischemic penumbra hours after a stroke. 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.

In January 2019, we announced the publication of a paper titled “Human Tissue Kallikrein In The Treatment Of Acute Ischemic Stroke” in the peer reviewed journal, *Therapeutic Advances in Neurological Disorders (“TAND”)*. 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 on 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.

DM199 Clinical Studies

We have completed five clinical trials with DM199 in over 120 volunteers, including multiple Phase I 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 Table 1 below). As is generally the case for early phase clinical trials, the primary endpoints for all studies were safety, tolerability, and pharmacokinetics. The Phase II (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 of evaluating the potential efficacy of DM199 in treating Type 2 diabetes patients.

Table 1 DM199 Trial Design Overview

Trial	Participants (N)	Design	Doses ($\mu\text{g}/\text{kg}$)	Route	Length
Phase-I Part A	Healthy (32)	Single ascending dose	5, 15, 30, 50	SC	1 week
Phase-I Part B	Type 2 diabetes (10)	Single ascending dose	0.3, 1.5, 15	SC	1 week
Phase-I Part C	Healthy (18)	Multiple ascending dose	3, 15, 25	SC	6 doses over 16 days
Phase-IIA Part D	Type 2 diabetes (36)	Blinded multiple dose	Placebo, 3, 15	SC	10 doses over 28 days
Phase I 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 subcutaneous (“SC”) injection (under the skin), 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 $\mu\text{g}/\text{kg}$ dose level, which is much greater than those 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 I-Part A trial.

Two of our clinical studies have 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.

In February 2018, we initiated treatment on the first patient in our Phase II REMEDY trial assessing the safety, tolerability and markers of therapeutic efficacy of DM199 in patients suffering from AIS. Our REMEDY trial is expected to enroll up to 100 patients to evaluate DM199 in patients with AIS. The study drug (DM199 or placebo) will be administered as an intravenous (“IV”) infusion within 24 hours of stroke symptom onset, followed by SC injections later that day and once every 3 days for 21 days. The study is designed to measure safety and tolerability along with multiple tests designed to investigate DM199’s therapeutic potential including plasma-based biomarkers and standard functional stroke measures assessed at 90 days post-stroke. 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.

In February 2019, we began enrolling patients in a Phase Ib clinical study evaluating DM199 in CKD patients. This study is being conducted at 3 sites in the U.S. and all sites are actively enrolling patients. The open label clinical trial is evaluating three dose levels of DM199, administered by a single subcutaneous (“SC”) dose, in 32 patients with moderate or severe CKD. Primary endpoints include safety, tolerability pharmacokinetics, change in KLK1 levels, albumin to creatine ratios and kidney biomarkers measured over a 12-day period. This study is intended to assist in identifying dose levels for use in subsequent Phase II trials.

In 2017, we completed and published in the *International Journal of Clinical Trials* the results from a Phase Ib study with DM199 designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in healthy volunteers. Specifically, this study compared multiple doses levels of DM199, administered via IV and SC routes to identify a dose and delivery route that most closely compared to or improves upon the pharmacokinetic and pharmacodynamics profile of the approved urinary KLK1 in China. We found that a dose of DM199 administered via IV infusion mimicked the drug profile of IV-administered urinary derived KLK1 (Kailikang®). We believe that 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 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.

□

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 acute ischemic stroke, chronic kidney disease, 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 are we aware of any synthetic version in development besides our drug candidate DM199 (recombinant human KLK1). We believe at least five companies have attempted to create a synthetic version of KLK1.

The growing understanding of KLK1's role 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 chronic kidney disease, acute ischemic strokes, retinopathy and hypertension. Clinical trial data with human urine and porcine KLK1 has demonstrated statistically significant clinical benefits of 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.
- **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 sudden drop in blood pressure, which was only seen at doses significantly higher than our anticipated therapeutic dose levels. Routine clinical use of KLK1 treatment in Asia has been well-tolerated by patients. In 2017, we completed a clinical trial comparing the pharmacokinetic profile of DM199 to Kailikang® for acute ischemic stroke, which showed DM199, when administered in intravenous form, to have a profile similar to Kailikang®. Further, when DM199 was administered subcutaneously, DM199 demonstrated a superior, longer acting, pharmacokinetic profile to Kailikang®.

We have conducted numerous internal and third-party analyses to demonstrate that DM199 is structurally and functionally equivalent to KLK1 derived from human urine. 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 urinary and porcine derived KLK1. The physiological effects of DM199 on blood pressure, from our completed studies, mirror that of human urinary 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 better than that of the forms marketed in Asia. In addition, we believe that there are also significant formulation, manufacturing, regulatory and other advantages for our synthetic human KLK1 drug candidate DM199:

- **Potency and Impurity Considerations.** KLK1 derived from human urine or porcine pancreas may contain 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, which we believe will provide therapeutic benefits.
- **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 organic material, particularly for human urine sourced KLK1. Once sourced, the raw organic 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 has 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 ACA.

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 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, a federal government agency, 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 potential drugs; and only those that meet strict requirements 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.

The drug approval process begins with the discovery of a potential drug. Pharmaceutical companies then test the drug extensively. 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 in an IND. The FDA reviews the information in the IND and decides if the drug is safe to study in humans.

Stage 2: Clinical Research. In Stage 2, 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 I Clinical Studies. Phase I 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 I studies demonstrate how an experimental drug affects the body of a healthy individual. Phase I 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 I. This information will determine whether the drug proceeds to Phase II.

Phase II Clinical Studies. Phase II clinical studies are conducted in order to determine how an experimental drug affects people who have the disease to be treated. Phase II 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 II 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 II studies will determine whether the drug proceeds to Phase III.

Phase III Clinical Studies. Phase III 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 II trials because a larger number of patients are studied (sometimes in the thousands) and because the studies are usually of longer duration. As well, Phase III 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 III studies more closely reflect the general population. The information from Phase III forms the basis for most of the drug’s initial labeling, which will guide physicians on how to use the drug.

Phase IV Clinical Studies. Phase IV clinical studies are conducted after a drug is approved. Companies often conduct Phase IV studies to more fully understand how their drug compares to other drugs. Also, the FDA may require additional studies after the drug is approved. FDA-required Phase IV studies often investigate the drug in specific types of patients that may not have been included in the Phase III studies and can involve very large numbers of patients to further assess the drug’s safety.

Stage 3: FDA Review for Approval. Following Phase III, the pharmaceutical company prepares reports of all studies conducted on the drug and a complete dossier on the manufacturing of the product and submits the reports to the FDA in 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. Occasionally, the FDA will ask experts for their opinion of the drug. 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 pharmaceutical products for which FDA approvals are obtained 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 can 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 IV 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.

We believe that DM199 could 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 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 U.S. 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 different stages from preclinical testing through clinical testing in Phase I, II, and III. 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 U.S. 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, our company, including our sales, marketing and scientific/educational grant programs, must comply with the federal False Claims Act, as amended, the federal Anti-Kickback Statute, as amended, 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 that will likely be 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 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 as to 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 in order 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 eight years has been our lead product candidate, DM199, which is currently in clinical development for AIS and CKD.

We expect our R&D expenses will continue to increase in the future as we advance our initial product candidate 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 product candidates, amounts invested in the program, competition and competitive developments, manufacturing capability and commercial viability.

Research and development 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.

Research and development 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 several 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”) for all of our required raw materials, active pharmaceutical ingredients and finished DM199 product candidate for our clinical trials. We have licensed certain gene expression technology and we contract with Catalent for the manufacture of DM199. The royalty term is indefinite but 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. 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, 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 sign a collaborative research agreement and 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 our company.

Our patent portfolio includes patents and pending applications that are owned by us, which include claims for composition of matter and methods of use. For our DM199 program, this includes two patent families that are directed to composition of matter, and methods of use.

The DM199 patents protect composition of matter including compositions of glycoforms, formulations, methods of administration and a variety of therapeutic approaches pertaining to current and potential future indications. We currently have additional patent applications for DM199. Additionally, for the manufacture of DM199, we have licensed an expression system and cell line with proven GMP and regulatory support and are contracting with a contract manufacturing organization (“CMO”) with proven GMP experience in manufacturing of recombinant proteins for clinical trials.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of DM199. We intend to rely on 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 development of a new drug, the outcome and timing of which is uncertain. The royalty term is indefinite but 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.

Our DM199 patent portfolio includes granted U.S. patents, a granted European patent, one pending U.S. patent application and a worldwide pending application filed under the Patent Cooperation Treaty (“PCT”). 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 stroke, chronic kidney disease, 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 polypeptides. The PCT patent application is 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.

Methods and reagents required for commercial scale manufacture of DM199 are subject to a series of patents issued to our manufacturing partner. As noted above, we exclusively license these patents from our manufacturing partner for the production of DM199 or any human KLK1 protein. We believe that our proprietary technology along with trade secrets will provide substantial protection from third-party competitors. We believe DM199 cannot be reversed engineered for a copycat version to be made. In addition, DiaMedica has specialized knowledge of the manufacturing process.

We believe that the most relevant granted patents 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 Number	Title	Geography	Expiration
<i>Issued patents</i>			
US 9,364,521	Composition of Matter – Human Tissue Kallikrein 1 Glycosylation Isoforms	US	2033
EP 2 854 841	Composition of Matter – 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
<i>Pending applications</i>			
PCT/US2018/021749	Dosage Forms of Tissue Kallikrein 1	US/Worldwide	2038

License Agreement

In September 2018, we entered into a license and collaboration agreement with Ahon Pharmaceutical Co Ltd. (“Ahon Pharma”), which grants Ahon Pharma exclusive rights to develop and commercialize DM199 for acute ischemic stroke in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, we received an upfront payment of \$500,000 on signing and are entitled to receive an additional payment of \$4.5 million upon regulatory clearance to initiate a clinical trial in China. We also have the potential to receive up to an additional \$27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories will be the sole responsibility of Ahon Pharma. This agreement may be terminated at any time by Ahon Pharma by providing 120 days written notice. Fosun Pharma, through its partnership with SK Group, a South Korea based company is an investor in DiaMedica through its equity investment in 2016.

Employees

As of December 31, 2018, we had 9 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.

Executive Officers

The following table sets forth information as of December 31, 2018 regarding each of our current executive officers:

Name	Age	Positions
Rick Pauls	47	President and Chief Executive Officer, Director
Scott Kellen	53	Chief Financial Officer and Secretary
Todd Verdoorn, Ph.D.	57	Chief Scientific Officer
Harry Alcorn, Pharm.D.	62	Chief Medical Officer

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.

We believe that Mr. Pauls' experience in the biopharmaceutical industry as an executive and investor and his extensive knowledge of all aspects of our company, business, industry, and day-to-day operations as a result of his role as our President and Chief Executive Officer enable him to make valuable contributions to our Board of Directors. In addition, as a result of his role as President and Chief Executive Officer, Mr. Pauls provides unique insight into our future strategies, opportunities and challenges, and serves as the unifying element between the leadership and strategic direction provided by our Board of Directors and the implementation of our business strategies by management.

Scott Kellen 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 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).

Todd Verdoorn, Ph.D. was appointed our Chief Scientific Officer in May 2016. From January 2016 to April 2016, Dr. Verdoorn served as our Vice President, Neuroscience. Prior to joining DiaMedica, Dr. Verdoorn served as Chief Scientist at Intuitive Quantitation, LLC, a company that provides strategic and tactical leadership for companies creating new treatments, from May 2013 to December 2016. From September 2011 to May 2013, Dr. Verdoorn served as Vice President, Neurobiology at NeuroTherapeutics Pharma, Inc., a company that develops and markets therapeutics. From January 2008 to August 2011, Dr. Verdoorn served as Chief Scientist for Orasi Medical, Inc., a medical device company. From June 2007 to January 2008, Dr. Verdoorn served as Chief Scientific Officer for Smart Bioscience SAS, a company that discovers and develops small-molecule therapeutics. Prior to joining Smart Bioscience, Dr. Verdoorn served as Chief Scientific Officer at Algos Preclinical Services, Inc., a research and consulting company, from January 2003 to June 2007. Dr. Verdoorn has more than 26 years of experience working with both public and private companies to develop new treatments for neurological diseases, including five years working with Bristol-Myers Squibb's stroke group. Dr. Verdoorn has a Bachelor of Arts degree in Chemistry from Central College and he earned his Ph.D. in Neurobiology from the University of North Carolina, conducting his post-doctoral research at the Max Planck Institute with Nobel Laureate Dr. Bert Sakmann and served as Associate Professor of Pharmacology at Vanderbilt University School of Medicine.

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 I 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 Jan 2013 to December 2014, he also served on the Board of Directors for the Association of Clinical Pharmacology Units, an association of Phase I 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.

Enforceability of Civil Liabilities Against Foreign Persons

We are organized under and governed by the federal laws of Canada, and, accordingly, are governed by the applicable laws of Canada. There is doubt as to the enforceability, in original actions in Canadian courts, of liabilities based upon the U.S. federal securities laws or the securities laws or "blue sky" laws of any state within the United States and as to the enforceability in Canadian courts of judgments of U.S. courts obtained in actions based upon the civil liability provisions of the U.S. federal securities laws or any such state securities laws or blue sky laws. Accordingly, it may not be possible to enforce judgments obtained in the United States against us.

Available Information

We are a corporation organized under Canada Business Corporations Act (“CBCA”). Our company was initially incorporated under the name Diabex Inc. pursuant to The Corporations Act (Manitoba) by articles of incorporation dated January 21, 2000. Our articles were amended (i) on February 26, 2001 to change our corporate name to DiaMedica Inc., (ii) on April 11, 2016 to continue the Company from The Corporations Act (Manitoba) to the CBCA, (iii) on December 28, 2016 to change our corporate name to DiaMedica Therapeutics Inc., (iv) on September 24, 2018 to permit us to hold shareholder meetings in the United States and to permit our directors, between annual meetings of our shareholders, to appoint one or more additional directors to serve until the next annual meeting of shareholders; provided, however, that the number of additional directors shall not at any time exceed one-third of the number of directors who held office at the expiration of the last meeting of shareholders, and (v) on November 15, 2018 to effect a 1-for-20 consolidation of our common shares.

Our registered office is located at 301-1665 Ellis Street, Kelowna, British Columbia, V1Y 2B3 and our principal executive office is located at our wholly owned subsidiary, DiaMedica USA Inc., located at 2 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 furnishes 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

As a company with less than \$1.07 billion of revenue during our last fiscal year, 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 most significant factors known to us that could materially adversely affect our business, operating results or financial condition.

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 future substantial losses and may never become profitable.

We are a clinical stage biopharmaceutical company focused on the development of novel recombinant proteins. 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 sales revenue for several years. We have incurred significant research, development 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 year ended December 31, 2018 and 2017, we incurred a net loss of \$5.7 million and \$4.3 million, respectively. As of December 31, 2018, we had an accumulated deficit of \$46.0 million. 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 product candidates. In addition, we expect our operating expenses to increase in 2019 compared to 2018 as a result of our recently obtained Nasdaq-listed U.S. public reporting company status. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We currently have no sales revenue and do not expect any sales revenue for several years. Accordingly, we will need additional funding to continue our research and development activities and other operations, which may not be available to us on acceptable terms, or at all.

Our future operations will be dependent upon our ability to develop our product candidates, obtain research grant funding, obtain required regulatory approvals, generate product sales, negotiate collaboration or license agreements or other strategic alternatives, and/or secure additional funds. Despite our recent initial public offering, we expect we will need substantial additional capital to further our research and development (“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. While we are striving to achieve these plans, there is no assurance these and other strategies will be achieved or that additional financing will be obtained on favorable terms or at all. We expect our current cash, which includes the net proceeds of our recent initial public offering, to be sufficient to allow us to complete our current Phase II Remedy trial in patients with acute ischemic stroke and our current Phase Ib study in patients with chronic kidney disease and a Phase II study in patients with chronic kidney disease and to otherwise fund our planned operations through 2020. 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 general and administrative (“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. 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 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 credit, 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 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 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.

We are exposed to the financial risk related to the fluctuation of foreign exchange rates and the degrees of volatility of those rates.

We may be adversely affected by foreign currency fluctuations. To date, we have been primarily funded through issuances of equity and proceeds from the exercise of warrants and stock options, which are denominated both in Canadian and U.S. dollars. Currently, the majority of our expenditures are in U.S. dollars, however, significant costs are also incurred in Canadian dollars, British pounds, and Australian dollars; and, therefore, we are subject to foreign currency fluctuations which may, from time to time, impact our financial position and results of operations.

Risks Related to our Business and our Industry

We are an early stage company with no approved products and no revenue from commercialization of our products.

We are at an early stage of development of our product candidate, DM199, for the treatment of AIS and CKD. We have not completed the development of any product candidate and, accordingly, have not begun to commercialize, any product candidate or generate any sales revenues from any product candidate. DM199 requires significant additional clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by ourselves and potential partners to continue to conduct clinical trials for DM199 will be required to meet applicable regulatory standards, obtain required regulatory approvals, and successfully commercialize this product candidate. DM199 is not expected to be commercially available for several years, if at all.

Our prospects depend on the success of our product candidate, DM199, which is at an early stage of development, and we may not generate sales revenue for several years, if at all, from this product candidate or any future product candidates.

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 acute ischemic stroke and chronic kidney disease. 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 sales revenues and to achieve commercial success in the near term will initially depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize DM199. Prior to commercialization of any potential product, significant additional investments will be necessary to complete the development of DM199 or any future product candidates. Preclinical and clinical trial work must be completed before DM199 or any future product candidate could be ready for use within the markets that we have identified. We may fail to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. Competitors may develop alternative products and methodologies to diagnose and treat the disease indications we are pursuing, thus reducing our competitive advantages. We do not know whether any of our product development efforts will prove to be effective, meet applicable regulatory standards, obtain the requisite regulatory approvals, be capable of being manufactured at a reasonable cost, or successfully marketed. The product candidate we are currently developing is not expected to be commercially viable for several years. In addition, our product candidate may cause undesirable side effects. Results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research. If regulatory authorities do not approve our product candidate or any future product candidates or if we fail to maintain regulatory compliance, we would have limited ability to commercialize our product candidate or any future product candidates, and our business and results of operations would be harmed. If we do succeed in developing viable products from our product candidates, we will face many potential obstacles such as the need to develop or obtain manufacturing, marketing, and distribution capabilities.

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 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 providing access to 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 active development programs may face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory requirements, our testing could be delayed, cancelled, or rendered ineffective.

We rely on a contract manufacturer over whom we have limited control. If we are subject to quality, cost, or delivery issues with the preclinical and clinical grade materials supplied by this or future contract manufacturers, our business operations could suffer significant harm.

We rely on a contract manufacturing organization (“CMO”) to manufacture our product candidate, DM199, for our preclinical studies and clinical trials. We rely on this CMO for manufacturing, filling, packaging, storing, and shipping of drug product in compliance with current good manufacturing practices (“GMP”) regulations applicable to our product candidate. The U.S. Food and Drug Administration (“FDA”) ensures the quality of drug products by carefully monitoring drug manufacturers’ compliance with “GMP” regulations. The “GMP” regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product.

There can be no assurances that this CMO will be able to meet our timetable and requirements. 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 and any future product candidates. Further, CMOs must operate in compliance with GMP regulations and failure to do so could result in, among other things, the disruption of product supplies. Our dependence upon this CMO 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 profit margins.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of our product candidates. 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 may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that neither our current or future product candidates will successfully gain market approval from the FDA or other regulatory authorities, resulting in us being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, 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 product candidates or allow our competitors to bring products to market before us, which would impair our ability to successfully commercialize our product candidates and may harm our financial condition, results of operations and prospects. The commencement and completion of clinical trials for our product candidates may be delayed for a number of reasons, including delays related, but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing the clinical trial on hold;

- patients failing to enroll or remain in our trials at the rate 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 GMP 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 candidates necessary to conduct clinical trials;
- product candidates demonstrating a lack of safety or efficacy during clinical trials;
- patients choosing an alternative treatment for the indications for which we are developing any of our product candidates or participating in competing clinical trials;
- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects, or other reasons;
- reports of clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- competing clinical trials and scheduling conflicts with participating clinicians;
- 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;
- failure of our contract research organizations (“CROs”) to satisfy their contractual duties or meet expected deadlines;
- 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
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

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.

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 collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a 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 candidates involved.

Our current product candidate and the activities associated with its development and commercialization, including design, research, testing, manufacture, safety, efficacy, 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 European Medicines Agency (“EMA”) and other foreign regulatory agencies. Failure to obtain marketing approval for a product candidate will prevent us 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 our product candidates 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 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.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

We are in litigation with Pharmaceutical Research Associates Group B.V., a contract research organization, seeking to compel them to comply with the terms of a clinical trial research agreement and their failure to perform as required could adversely affect our ability to obtain regulatory approval for DM199.

In March 2013, we entered into a clinical research agreement with Pharmaceutical Research Associates Group B.V. (“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 SC 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 which 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 with PRA Netherlands to compel them to comply with the terms of the clinical research agreement, including providing full study records, and to recover damages. Litigation distracts the attention of our management from our business, is expensive and the outcome is uncertain.

We may not be able to obtain FDA acceptance of INDs to commence clinical trials in the United States 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 clinical trials in the United States for our current or any future product candidates, we will likely be required to have an accepted IND for each product candidate and for each targeted indication. During the fourth quarter of 2018, we filed and the FDA accepted an IND for a Phase Ib clinical trial of DM199 in patients with moderate or severe CKD caused by Type I or Type II diabetes. We have not filed any other INDs to initiate a clinical trial for DM199 in the United States. 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 have effective INDs and commence clinical programs will significantly limit our opportunity to generate revenue.

If we have difficulty enrolling patients in clinical trials, the completion of the trials may be delayed or not completed at all.

As DM199 and any future product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, we will need to enroll an increasing number of patients that meet our eligibility criteria. There is significant competition for recruiting patients in clinical trials, and we may be unable to enroll the patients we need to complete clinical trials on a timely basis or at all. The factors that affect our ability to enroll patients are largely uncontrollable and include, but are not limited to, the following:

- size and nature of the patient population;
- eligibility and exclusion criteria for the trial;
- design of the study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians; and
- the number, availability, location, and accessibility of clinical trial sites.

We may not be able to reproduce the results of previously conducted clinical studies and/or comparisons to other forms of KLK1, including Kailikang®, thereby displacing other forms of KLK1, including Kailikang®.

While there have been numerous studies demonstrating the efficacy of Kailikang®, we rely on the scientific and clinical knowledge and experience of other biotechnology and pharmaceutical companies and organizations in conducting those clinical studies. No assurance can be given that in our clinical trials involving DM199 we will be able to reproduce results of previously conducted studies or displace other forms of KLK1 in the market.

Negative results from clinical trials or studies of others and adverse safety events involving the targets of our product candidates may have an adverse impact on our future commercialization efforts.

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors, or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to our product candidates, or the therapeutic areas in which our product candidates compete, could adversely affect our share price and our ability to finance future development of our product candidates, and our business and financial results could be materially and adversely affected.

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 requirements, or cGCPs, 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 current Good Manufacturing Practices. Clinical trials may be suspended by us or by the FDA, other foreign regulatory authorities, or by an IRB or ethic 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, and failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs. 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 inefficient or 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.

Regulatory approval processes are lengthy, expensive, and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

Our shareholders and other investors should be aware of the risks, problems, delays, expenses, and difficulties which we may encounter in light of the extensive regulatory environment within which our business is carried out. Numerous statutes and regulations govern the preclinical and clinical development, manufacture and sale, and post-marketing responsibilities for non-therapeutic and human therapeutic products in the United States, European Union, Canada, Australia and other countries that are the intended markets for our current and future product candidates. Such legislation and regulation governs the approval of manufacturing facilities, the testing procedures, and controlled research that must be carried out, and the preclinical and clinical data that must be collected prior to marketing approval. Our R&D efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to and restricted by such extensive regulation.

The process of obtaining necessary regulatory approvals is lengthy, expensive, and uncertain. We may fail to obtain the necessary approvals to commence or continue clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, governmental authorities in the United States or other countries may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

Completing clinical testing and obtaining required approvals is expected to take several years and to require the expenditure of substantial resources. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials may be delayed or suspended at any time by us or by the various regulatory authorities if it is determined at any time that the subjects or patients are being exposed to unacceptable risks.

Any failure or delay in obtaining regulatory approvals would adversely affect our ability to utilize our technology and would therefore adversely affect our operations. Furthermore, no assurance can be given that our current or future product candidates will prove to be safe and effective in clinical trials or that they will receive the requisite regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may be granted with specific limitations on the indicated uses for which that drug may be marketed. Furthermore, product approvals may be withdrawn if problems occur following initial marketing or if compliance with regulatory standards is not maintained.

Any product candidate for which we obtain 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 our product candidates, when and if any of them are 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 GMP 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 Food, Drug and Cosmetic Act 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 taking 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 collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, 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.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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 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 CRO 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.

Future development collaborations may 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.

We may in the future determine to seek to collaborate with pharmaceutical and biotechnology companies for development or commercialization of our current or future product candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery, nonclinical or clinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to continue or further develop our current or future product candidates and our business may be materially and adversely affected.

Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- 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 discovery, nonclinical or clinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery, nonclinical or clinical development for a product candidate, or repeat or conduct new discovery, and 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 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 discovery, 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.

Additionally, subject to its contractual obligations to us, if a collaborator is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If our collaborations do not result in the successful development of products or product candidates, product candidates 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 collaborators.

We recently entered into a license and collaboration agreement with Ahon Pharma which allows the licensee to have exclusive rights to develop and commercialize DM199 for AIS in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. in exchange for an upfront cash payment, potential future milestone payments and sales royalties. As a result, we are dependent upon this licensee for such development and commercialization and are not guaranteed of receipt of the potential future milestone payments and sales royalties.

We recently entered into a license and collaboration agreement with Ahon Pharma, a subsidiary of Fosun Pharma, which grants Ahon Pharma exclusive rights to develop and commercialize DM199 for AIS in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, we received an upfront payment of \$500,000 on signing and are entitled to receive an additional payment of \$4.5 million upon regulatory clearance to initiate a clinical trial in China. We also have the potential to receive an additional \$27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories will be the sole responsibility of Ahon Pharma. As a result, we are dependent upon Ahon Pharma for such development and commercialization. There can be no assurance that we will receive the potential future milestone payments and sales royalties. This agreement may be terminated at any time by Ahon Pharma by providing 120 days written notice.

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

Even if our product candidates are successfully developed and receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payers such as private insurers or governments and other funding parties, and the medical community. The degree of market acceptance for any products we develop will depend on a number of factors, including:

- demonstration of the 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;
- competitive product profile versus alternative treatment methods and the superiority of alternative treatment or therapeutics;
- the effectiveness of marketing and distribution methods and support for the products; and
- coverage and reimbursement policies of government and third-party payers to the extent that our products 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.

Disease indications may be small subsets of a disease that could be parsed into smaller and smaller indications as different subsets of diseases are defined. This increasingly fine characterization of diseases could have negative consequences; including creating an approved indication that is so small as not to have a viable market for us. If future technology allows characterization of a disease in a way that is different from the characterization used for large pivotal studies, it may make those studies invalid or reduce their usefulness, and may require repeating all or a portion of the studies. Future technology may supply better prognostic ability which could reduce the portion of patients projected to need a new therapy. Even after being cleared by regulatory authorities, a product may later be shown to be unsafe or not to have its purported effect, thereby preventing its widespread use or requiring withdrawal from the market.

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

We believe that there may be many different applications for products successfully derived from our technologies and that the anticipated market for products under development will continue to expand. However, due to competition from existing or new products and the yet-to-be established commercial viability of our products, no assurance can be given that these beliefs will prove to be correct. Physicians, patients, formularies, payers or the medical community in general may not accept or utilize any products that we may develop. Other drugs may be approved during our clinical testing which could change the accepted treatments for the disease targeted and make our product candidates obsolete.

Our ability to commercialize our future products, if any, successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such products 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 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. There is no uniform coverage and reimbursement policy among third-party payers in the United States; however, private third-party payers often follow Medicare coverage policy and payment limitations in setting their own 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 our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. In addition, healthcare reform and controls on healthcare spending may limit the price we charge for any products and the amounts thereof that we can sell. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

Outside of the United States, the successful commercialization of our products 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 products 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 will not be able to successfully commercialize our current or future product candidates without establishing sales and marketing capabilities internally or through collaborators.

We currently have no sales and marketing staff. We may not be able to find suitable sales and marketing staff and collaborators for our product candidates. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any collaborators may not be adequate or successful or could terminate or materially reduce the effort they direct to our products. The development of a marketing and sales capability will require significant expenditures, management resources and time. The cost of establishing such a sales force may exceed any potential product revenue, or our marketing and sales efforts may be unsuccessful. If we are unable to develop an internal marketing and sales capability in a timely fashion, or at all, or if we are unable to enter into a marketing and sales arrangement with a third party on acceptable terms, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell approved products, if any.

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

Technological competition is intense in the industry in which we operate. Competition comes from pharmaceutical companies, biotechnology companies, and universities, as well as companies that offer non-pharmaceutical solutions in the markets we may attempt to address with our products. 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 product candidates 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, 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. The new 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 any of our product candidates that are biologics. 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 current or future product candidates are considered to be reference products 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 product candidates, which could have a material adverse effect on our business.

Our relationships with customers and third-party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will likely play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute the products for which we receive marketing approval. Currently, restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. This statute may apply to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The government also may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the ACA, require manufacturers of covered drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures;
- the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA") and its implementation regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market; and
- the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We are unable to predict what additional federal or state legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal or state governments may impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions and in those jurisdictions we face the same issues as in the United State regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

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 our products.

We depend on our management personnel. We also depend on our scientific and 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 expand our activities and seek regulatory approvals for clinical trials. 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 who 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 continued growth. The loss of the services of any of our executive officers or other key personnel 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 growth.

As we advance DM199 and any future product candidates through preclinical testing and clinical studies, and develop our current or future product candidates, we will need to increase our product development, scientific, regulatory and compliance and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will 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.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing and reporting standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a substantial impact on our business and results of operations, including the imposition of substantial fines or other sanctions.

We may expand our business through the acquisition of companies or businesses or by entering into collaborations or by in-licensing product candidates, each of which could disrupt our business and harm our financial condition.

We have in the past and may in the future seek to expand our pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations, or in-licensing one or more product candidates. Acquisitions, collaborations and in-licenses involve numerous risks, including, but not limited to:

- substantial cash expenditures;
- technology development risks;
- potentially dilutive issuances of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- difficulties in assimilating the operations of the acquired companies;
- potential disputes regarding contingent consideration;
- diverting our management's attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

We cannot provide assurance that any acquisition, collaboration, or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success would depend in part on our ability to manage the growth associated with some of these acquisitions, collaborations and in-licenses. We cannot provide assurance that we would be able to successfully combine our business with that of acquired businesses, manage a collaboration or integrate in-licensed product candidates. Furthermore, the development or expansion of our business may require a substantial capital investment by us.

Our current or future product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval, limit the commercial scope of their approved uses, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal unacceptable side effects or unexpected characteristics. In such an event, 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 product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;

- regulatory authorities may require additional warnings on the label or otherwise seek to limit the scope of the approved uses reflected in the label of such product;
- the FDA may require the use of or modification of a Risk Evaluation and Mitigation Strategy (“REMS”) or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose other implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We face the risk of product liability claims, which could exceed our insurance coverage and produce recalls, each of which could deplete our cash resources.

We are exposed to the risk of product liability claims alleging that use of our product candidates caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing, or sale of our product candidates and may be made directly by patients involved in clinical trials of our product candidates, by consumers or healthcare providers, or by individuals, organizations, or companies selling our products. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm.

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 II 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 have a material adverse effect on our business, financial condition, and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about our products and business, inhibit or prevent commercialization of other products and product candidates, or negatively impact existing or future collaborations.

If we are unable to maintain product liability insurance required by our third parties, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.

Some of our license, clinical trials and other agreements with third parties require, and in the future may require, us to maintain product liability insurance. 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.

A risk of product liability claims, and related negative publicity, is inherent in the development of human therapeutics and other products. Product liability insurance is expensive, its availability is limited, and it may not be offered on terms acceptable to us, or at all. The commercialization of our potential products could be inhibited or prevented by an inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect upon us and our financial condition.

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

We conduct certain R&D operations in Australia. In addition, we may conduct certain future clinical trials and plan to seek regulatory approval of our product candidates outside of the United States. Accordingly, we are subject to risks related to operating in foreign countries, including:

- different regulatory requirements for drug approvals in foreign countries;
- 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;
- unexpected changes in tariffs, trade barriers, and regulatory requirements;
- different reimbursement systems and different competitive drugs indicated to treat the indications for which our product candidates are being 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 fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- 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;
- 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.

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 our collaborator to conduct and complete clinical trials of our current or 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 our product candidates.

Recently enacted and future legislation may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our product candidates 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 product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates 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, which was enacted in the United States in March 2010, 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, new fees for the manufacture or importation of certain branded drugs, and new transparency reporting requirements under the Physician Payments Sunshine Act.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current administration to repeal or replace certain aspects of the ACA. Since January 2017, two U.S. Presidential Executive Orders have been signed and other directives designed to delay the implementation of any certain provisions of the ACA or otherwise remove some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the “BBA,” among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.”

In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. For example, legislation has been enacted to reduce the level of reimbursement paid to providers under the Medicare program over time, as well as phase in alternative payment models for provider services under the Medicare program with the goal of incentivizing the attainment of pre-defined quality measures. As these measures are not fully in effect, and since the U.S. Congress could intervene to prevent their full implementation, it is unclear how payment reductions or the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. It is also unclear if changes in Medicare payments to providers would impact such providers’ willingness to prescribe and administer our products, if approved. Further, there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and patient programs, and reform government program reimbursement methodologies for drug products.

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 drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our current or future product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We conduct certain research and development 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 research and development incentive payment allowed by Australian regulations, our business and results of operations could suffer.

In July 2016, we formed a wholly-owned Australian subsidiary, DiaMedica Australia Pty Ltd., to conduct various clinical activities for our product and development candidate in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead product candidate in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidate in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, 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 AUD\$ 306,000 and AUD\$ 777,000 during 2017 and 2018, respectively, for research expenditures made during 2016 and 2017. 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 business and results of operation may be adversely affected.

Risks Related to Intellectual Property

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

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 identify useful licensing opportunities.

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 which 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 which 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 which 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 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 and manufacture our key products 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 product candidates.

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 by 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 and manufacturing of our key product candidates.

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 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 conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- 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 conditions, 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 products, 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, 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 our competitive position on our product candidates 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 employee's 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 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 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.” 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. Our quarterly losses may vary because of expenses we incur related to future research including the timing of costs for manufacturing and initiating and completing preclinical and clinical trials. 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 very active trading market for our common shares and one may never develop.

Our common shares trade on The Nasdaq Capital Market under the trading symbol “DMAC.” We do not have a very active trading market for our common shares and one may never develop. Although we anticipate a more active trading market for our common shares will develop in the future, we can give no assurance that this will occur or that an active trading market will be sustained. If an active market for our common shares does not develop, it may be difficult for you to sell shares at a favorable price or at all.

Our recent share consolidation may not increase the market price for our common shares on a sustained basis.

On November 15, 2018, we implemented a share consolidation of our common shares, which was previously approved by our shareholders, pursuant to which each 20 common shares outstanding on the record date for the share consolidation was combined into one common share. We cannot predict whether the share consolidation will increase the market price for our common shares on a sustained basis. The history of similar share consolidations for companies in similar circumstances is varied, and we cannot predict whether:

- the share consolidation will result in a sustained price per share that will attract brokers and investors who do not trade in lower priced stocks;
- the share consolidation will result in a price per share that will increase our ability to attract and retain employees and other service providers;
- the market price per share will remain at a level in excess of the minimum bid price as required for continued listing on The Nasdaq Capital Market; or
- even if the share consolidation does increase the market price of our common shares on a sustained basis, we will otherwise meet the requirements of The Nasdaq Capital Market and be able to maintain our listing.

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 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.

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

Future dilution may occur due to additional future equity financing events by us. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted. In addition, if outstanding options, warrants, or deferred share units are exercised or otherwise converted into our common shares, our shareholders will experience additional dilution.

It may be difficult for non-Canadian shareholders or other investors to obtain and enforce judgments against us because of our Canadian incorporation and presence.

We are a corporation existing under the federal laws of Canada. Two of our directors and several of the experts we utilize are residents of Canada, and all or a substantial portion of their assets, and a 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 and the experts 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, officers, and experts under the United States federal securities laws. Our shareholders and other investors should not assume that Canadian courts (i) would enforce judgments of United States courts obtained in actions against us or such directors, officers, or experts 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, officers, or experts 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 Canadian securities laws may not be available to our shareholders or other investors in the United States.

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

Sales of substantial numbers of our common shares or the perception that such sales could occur, especially after the expiration of the 180-day period lock-up period to which our directors, officers and their affiliated entities are subject, 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 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. 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.

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

The trading market for our common shares in the United States 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 cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price 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 are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common shares less attractive to our shareholders and other investors.

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 (the "Securities Act") 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. Our shareholders and other investors may find our common shares less attractive as a result of our reliance on these exemptions. If some of our shareholders or other investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the trading price of our common shares may be more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised financial accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have determined to opt out of such extended transition period and, as a result, we will comply with new or revised financial accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised financial accounting standards is irrevocable.

Our shareholders and other investors may find our common shares less attractive as a result of our reliance on these exemptions. If some of our shareholders or other investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the trading price of our common shares may be more volatile.

As a result of our recent initial public offering and listing on The Nasdaq Capital Market, we expect to incur increased costs as a result of operating as a Nasdaq-listed U.S. public reporting company, and we anticipate that our management will be required to devote substantial time to new compliance initiatives.

As a Nasdaq-listed U.S. public reporting company, we anticipate that we will incur, particularly after we are no longer an “emerging growth company,” significant legal, accounting and other expenses that we did not incur as a company with shares solely listed on the TSX Venture Exchange. In addition, the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley”) and rules subsequently implemented by the SEC and Nasdaq impose various requirements on U.S. public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with U.S. public company reporting and Sarbanes-Oxley requirements and we may have to hire additional accounting, finance, and other personnel to assist us with our efforts to comply with these requirements.

We have no operating experience as a Nasdaq-listed publicly traded company in the United States.

We have no operating experience as a Nasdaq-listed publicly traded company in the United States. Although the individuals who now constitute our management team have experience managing a Nasdaq-listed publicly-traded company, there is no assurance that the past experience of our management team will be sufficient to operate the Company as a publicly traded company in the United States, including timely compliance with the disclosure requirements of the SEC. We are required to develop and implement internal control systems and procedures in order to satisfy the periodic and current reporting requirements under applicable SEC regulations and comply with the Nasdaq listing standards. These requirements will place significant strain on our management team, infrastructure and other resources. In addition, our management team may not be able to successfully or efficiently manage the Company as a U.S. public reporting company that is subject to significant regulatory oversight and reporting obligations.

Our inability to comply with Nasdaq’s continued listing requirements could result in our common shares being delisted, which could affect the market price and liquidity of our common shares and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our common shares on The Nasdaq Capital Market. If we do not maintain compliance with Nasdaq’s continued listing requirements within specified periods and subject to permitted extensions, our common shares may be recommended for delisting (subject to any appeal we would file). No assurance can be provided that we will comply with these continued listing requirements. If our common shares were delisted, it could be more difficult to buy or sell our common shares and to obtain accurate quotations, and the price of our common shares could suffer a material decline. Delisting would also impair our ability to raise additional capital.

Our shareholder rights plan may delay or prevent an acquisition of us that shareholders may consider favorable or may prevent efforts by our shareholders to change our directors or our management, which could decrease the value of your common shares.

Our shareholders approved the adoption of a shareholder rights plan agreement on December 21, 2017. The shareholder rights plan is designed to provide adequate time for our Board of Directors and shareholders to assess an unsolicited takeover bid for our company, to provide our Board of Directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, and to provide shareholders with an equal opportunity to participate in a takeover bid and receive full and fair value for their common shares. The shareholder rights plan is set to expire at the close of our annual meeting of shareholders in 2020. The rights will become exercisable only when a person, including any party related to it, acquires or attempts to acquire 20% or more of our outstanding common shares without complying with the “permitted bid” provisions of the plan or without approval of our Board of Directors. Should such an acquisition occur or be announced, each right would, upon exercise, entitle a rights holder, other than the acquiring person and related persons, to purchase common shares at a 50% discount to the market price at the time. Under the plan, a “permitted bid” is a bid made to all holders of our common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties have been tendered, the offeror may take up and pay for the common shares but must extend the bid for a further 10 days to allow other shareholders to tender.

While we believe our rights plan enables our Board of Directors to help ensure that our shareholders are not deprived of the opportunity to realize the full and fair value of their investments, the rights plan may inhibit a change in control of our company by a third party in a transaction not approved by our Board of Directors. If a change in control is inhibited or delayed in this manner, it may adversely affect the market price of our common shares.

Any failure to maintain an effective system of internal controls may result in material misstatements of our consolidated financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud; and in that case, our shareholders or other investors could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common shares.

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we fail to maintain an effective system of internal controls, we might not be able to report our financial results accurately or prevent fraud; and in that case, our shareholders or other investors could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common shares. As a result of our limited administrative staffing levels, internal controls which rely on segregation of duties in many cases are not possible. Due to resource constraints and the present stage of our development, we do not have sufficient size and scale to warrant the hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this, we are highly reliant on the performance of compensating procedures and senior management’s review and approval. Even if we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles in the United States, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our results of operations or cause us to fail to meet our future reporting obligations.

If we fail to timely achieve and maintain the adequacy of our internal control over financial reporting, we may not be able to produce reliable financial reports or help prevent fraud. Our failure to achieve and maintain effective internal control over financial reporting could prevent us from complying with our reporting obligations on a timely basis, which could result in the loss of shareholder or other investor confidence in the reliability of our consolidated financial statements, harm our business and negatively impact the trading price of our common shares.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our annual report on Form 10-K next year, and after we are no longer an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will have to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Canadian laws differ from the laws in effect in the United States and may afford less protection to holders of our securities.

We are a Canadian corporation and are subject to the CBCA and applicable Canadian securities laws as a Canadian reporting issuer, which laws may differ from those governing a company formed under the laws of a United States jurisdiction. The provisions under the CBCA 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 articles and by-laws, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price another party would be willing to offer in such an instance.

We may be classified as a “passive foreign investment company,” which may have adverse U.S. federal income tax consequences for U.S. shareholders.

Generally, for any taxable year in which 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our common shares, which is subject to change) 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. Based on the price of our common shares and the composition of our gross assets (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, 2018 and 2017. 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, 2019 or for future taxable years.

If we are a PFIC for any year during a non-corporate U.S. shareholder’s holding period of our common shares, 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. Interest charges would also be added to the taxes on gains and distributions realized by all U.S. holders.

A U.S. shareholder may avoid these adverse tax consequences by making a timely and effective “qualified electing fund” election (“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. 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. In the event we become a PFIC, 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).

A U.S. shareholder may also mitigate the adverse tax consequences 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. A mark-to-market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including Nasdaq. 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.

Each 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, our PFIC status 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.

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 2 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 SC 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 them to comply with the terms of the clinical research agreement, including providing full study records and to recover damages. After PRA Netherlands objected to the venue, on August 24, 2018, we re-filed our complaint against both PRA Netherlands and its U.S. subsidiary, 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, we intend to re-file our complaint against PRA in the United States District Court, District of Minnesota. 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 seeks 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. We subsequently requested, and PRA Netherlands and PRA USA agreed, that we be permitted to file a motion seeking to transfer the Delaware action to the United States District Court, District of Minnesota. On February 20, 2019, we filed this motion to transfer venue.

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 are 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 14, 2019, we had 50 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. Moreover, 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, you will likely need to sell your common shares to realize a return on your investment, and you may not be able to sell your shares at or above the price you paid for them.

Use of Proceeds

On December 11, 2018, the SEC declared effective our registration statement on Form S-1 (File No. 333- 228313), as amended, filed in connection with our initial public offering. Pursuant to the registration statement, we issued and sold an aggregate of 4,100,000 common shares in the initial public offering at a price to the public of \$4.00 per share. As a result of the offering, we received gross proceeds of approximately \$16.4 million, resulting in net proceeds to us of approximately \$14.7 million, after deduction of underwriters' discounts and commissions and offering expenses. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Craig-Hallum Capital Group LLC acted as the sole managing underwriter for the offering.

We intend to use the net proceeds from the offering to fund clinical development of DM199, to conduct research activities and for working capital and general corporate purposes. We expect the net proceeds of the offering to be sufficient to allow us to complete our current Phase II Remedy trial in patients with acute ischemic stroke and our current Phase Ib trial in patients with chronic kidney disease and a Phase II study in patients with chronic kidney disease. We do not expect the net proceeds of the offering to be sufficient to fund, and we expect to require additional funding to complete, the development of DM199 through regulatory approval and commercialization, which we may seek through public or private equity or debt financings or through collaborations with other biotechnology companies or other sources. The expected use of the net proceeds from our initial public offering represents our intentions based upon our current plans and business conditions. As of the date of this report, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of product development and commercialization may vary significantly depending on numerous factors, including the status, results and timing of our planned clinical trials, as well as any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the offering.

Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the final prospectus, dated December 6, 2018, filed with the SEC on December 10, 2018 pursuant to Rule 424(b)(4) under the Securities Act.

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, 2018.

Recent Sales of Unregistered Equity Securities

As referred above under “Use of Proceeds,” upon the closing of our initial public offering on December 11, 2018, as additional underwriting compensation and in exchange for cash consideration of \$50, we granted the underwriter a warrant to purchase 205,000 common shares (equal to 5.0% of the common shares sold in the initial public offering) at an exercise price of \$4.80 per share (equal to 120% of the initial public offering price per common share in the initial public offering), subject to customary anti-dilution provisions. The warrant is exercisable for a term of five years. The warrant includes a cashless exercise provision entitling the underwriter to surrender a portion of the underlying common shares that has a value equal to the aggregate exercise price in lieu of paying cash upon exercise. The warrant was issued to the underwriter in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act since the issuance did not involve a public offering, the recipient took the securities for investment and not resale, and we took appropriate measures to restrict transfer. We did not pay underwriter discounts or commissions in connection with the issuance of the warrant to the underwriter.

We did not sell any other unregistered equity securities of our company during the fourth quarter ended December 31, 2018.

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, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2018 and 2017 are derived from our audited financial statements that are included elsewhere in this annual report on Form 10-K. The consolidated statements of operations data for the year ended December 31, 2016 and the consolidated balance sheet data as of December 31, 2016 are derived from our audited financial statements that are not included in this annual report on Form 10-K. Our historical results are not indicative of the results to be expected in the future.

You should read this information together with our financial statements and the related notes, as well as the section entitled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” included elsewhere in this report.

	Fiscal Year Ended December 31,	
	2018	2017
	(in thousands, except share and per share data)	
Consolidated Statements of Operations Data:		
Operating revenues:		
License revenue	\$ 500	\$ —
Operating expenses:		
Research and development	4,522	3,206
General and administrative	2,739	1,313
Total operating expenses	<u>7,261</u>	<u>4,519</u>
Loss from operations	(6,761)	(4,519)
Other (income) expense		
Governmental assistance – research incentives	(1,214)	(244)
Other (income) expense	68	(6)
Change in fair value of warrant liability	39	(9)
Total other (income) expense	<u>(1,107)</u>	<u>(259)</u>
Loss before income tax	(5,564)	(4,260)
Income tax	80	—
Net loss and comprehensive loss	<u>\$ (5,734)</u>	<u>\$ (4,260)</u>
Loss per share, basic and diluted	<u>\$ (0.74)</u>	<u>\$ (0.72)</u>
Weighted average number of shares outstanding:		
Basic and diluted	<u>7,743,520</u>	<u>5,935,790</u>
	December 31,	
	2018	2017
Consolidated Balance Sheet:		
Cash	\$ 16,823	\$ 1,353
Working capital	16,676	491
Total assets	18,339	1,802
Total current liabilities	1,296	1,003
Total shareholders’ equity	17,025	799

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, 2018 and 2017.

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.

Overview

We are a clinical stage biopharmaceutical company primarily focused on the development of novel recombinant proteins. Our goal is to use our patented and licensed technologies to establish our company as a leader in the development and commercialization of therapeutic treatments for novel recombinant proteins to treat kidney and neurological diseases. Our current primary focus is on 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.

In February 2018, we initiated treatment on the first patient in our Phase II REMEDY trial assessing the safety, tolerability and markers of therapeutic efficacy of DM199 in patients suffering from AIS. Our REMEDY trial is expected to enroll up to 100 patients to evaluate DM199 in patients with AIS. In December 2018, the FDA accepted our Investigational New Drug application for the initiation of a Phase Ib clinical trial of DM199 in patients with moderate or severe CKD caused by Type I or Type II diabetes and in February 2019, we initiated dosing patients in this study. The results from this Phase Ib study will assist us in the design of upcoming Phase II studies in patients suffering from rare diseases and CKD. The DM199 drug levels from this Phase Ib study will also help determine the optimal dose levels for testing in the Phase II studies.

In September 2018, we entered into a license and collaboration agreement with Ahon Pharmaceutical Co Ltd. (“Ahon Pharma”), which grants Ahon Pharma exclusive rights to develop and commercialize DM199 for acute ischemic stroke in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, we received an upfront payment of \$500,000 on signing and are entitled to receive an additional payment of \$4.5 million upon regulatory clearance to initiate a clinical trial in China. We also have the potential to receive up to an additional \$27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories will be the sole responsibility of Ahon Pharma. This agreement may be terminated at any time by Ahon Pharma by providing 120 days written notice. Fosun Pharma, through its partnership with SK Group, a South Korea based company is an investor in DiaMedica through its equity investment in 2016.

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 \$5.7 million and \$4.3 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of \$46.0 million. Substantially all of our operating losses resulted from expenses incurred in connection with product candidate development programs, our R&D activities and G&A support costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. In the near term, we anticipate that our expenses will increase as we:

- advance the ongoing clinical development of DM199;
- maintain, expand and protect our intellectual property portfolio; and
- provide G&A support for our operations.

In addition, we expect our operating expenses to increase in 2019 compared to 2018 as a result of our recently obtained Nasdaq-listed U.S. public reporting company status.

In December 2018, we completed an initial public offering of our common shares in the United States, by issuing 4,100,000 common shares at an offering price of \$4.00 per share, for net proceeds to us of approximately \$14.7 million, after deducting underwriting discounts and commissions and offering expenses.

While we expect our rate of future negative cash flow per month to vary due to the timing of expenses incurred, we expect our current cash, which includes the net proceeds of our initial public offering, to be sufficient to allow us to complete our current ongoing Phase II Remedy trial in patients with AIS and our current Phase Ib trial in patients with CKD and a Phase II study in patients with CKD and to otherwise fund our planned operations through the end of 2020.

Financial Overview

Revenues

Since our inception, we have incurred losses while advancing the R&D of our therapeutic product candidates. We have not generated any revenues from product sales and do not expect to do so for a number of years. We may never generate sales revenues from our current DM199 product candidate as we may never succeed in obtaining regulatory approval or commercial sale of this product candidate.

In September 2018, we entered into a license and collaboration agreement with Ahon Pharma under the terms of which we granted exclusive rights to develop and commercialize DM199 for acute ischemic stroke in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, we received a non-refundable upfront payment of \$500,000, due upon signing the agreement, and we are entitled to an additional non-refundable payment of \$4.5 million upon regulatory clearance to initiate a clinical trial in China. We also have the potential to receive up to an additional \$27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories will be the sole responsibility of Ahon Pharma. This agreement may be terminated at any time by Ahon Pharma by providing 120 days written notice.

Research and Development Expenses

R&D expenses consist primarily of fees paid to external service providers such as contract research organizations and contract manufacturing organizations related to clinical trials, contractual obligations for clinical development, clinical sites, laboratory testing, preclinical trials, development of DM199 and the related manufacturing processes, salaries, benefits, share-based compensation and other personnel costs. We incurred \$4.5 million and \$3.2 million in R&D expenses for the years ended December 31, 2018 and 2017, respectively. Over the past approximately eight 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 early 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 expect that our R&D expenses may increase 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 primarily of salaries and related benefits, including share-based compensation related to our executive, finance, business development and support functions. Other G&A expenses include rent and utilities, travel expenses and professional fees for auditing, tax and legal services. We expect that G&A expenses will increase in the future as we expand our operating activities. In addition, G&A expenses are expected to reflect increased costs associated with our listing on The Nasdaq Capital Market and U.S. public reporting company status, which commenced in December 2018. We incurred one-time costs of approximately \$360,000 in 2018, associated with the Nasdaq listing process and related legal and accounting fees.

Other (Income) Expense

Other (income) expense consists primarily of governmental assistance – research incentives, change in the fair value of our warrants that are accounted for as derivative liabilities, interest income, and foreign currency exchange gains and losses.

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.

Revenue Recognition

We followed Accounting Standards Codification (“ASC”) 606, “*Revenue from Contracts with Customers*” in accounting for our license and collaboration agreement with Ahon Pharma. Accordingly, the Company recognizes revenue upon transfer of control of the product to our customer in an amount that reflects the consideration we expect to receive in exchange.

We intend to enter into arrangements for the research and development and/or manufacture of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including (i) intellectual property rights or licenses, (ii) R&D services or (iii) manufacturing services. The underlying terms of these arrangements generally would provide for consideration to DiaMedica in the form of nonrefundable, up-front license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We intend to utilize the sales and usage-based royalty exception in arrangements that result from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

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 Canadian 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, 2018 and 2017:

	2018	2017
Common share fair value	\$8.84 - \$9.33	\$5.20 - \$8.40
Risk-free interest rate	2.1 - 2.2%	1.1%
Expected dividend yield	0%	0%
Expected option life	4.8 - 5.0	4.5
Expected common share price volatility	123.5 - 135.7%	84.7 - 156.8%

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018, but the adoption as of this date had no impact on our financial statements as we had no revenue until the third quarter of 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases*. The guidance in ASU 2016-02 supersedes the lease recognition requirements in the Accounting Standards Codification Topic 840, *Leases*. ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The new standard requires the immediate recognition of all excess tax benefits and deficiencies in the income statement and requires classification of excess tax benefits as an operating activity as opposed to a financing activity in the statements of cash flows. This standard became effective for us on January 1, 2019.

The FASB has subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019, and which we collectively refer to as the new leasing standards:

- ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*, which permits an entity to elect an optional transition practical expedient to not evaluate under Topic 842 land easements that exist or expired prior to adoption of Topic 842 and that were not previously accounted for as leases under the prior standard, ASC 840, *Leases*.
- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02.
- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.
- ASU No. 2018-20, *Narrow-Scope Improvements for Lessors*, which contains certain narrow scope improvements to the guidance issued in ASU 2016-02.

We adopted the new leasing standards on January 1, 2019, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019; and consequently, financial information will not be updated and the disclosures required under Topic 842 will not be provided for dates and periods prior to January 1, 2019. We have reviewed our existing lease contracts and the impact of the new leasing standards on our consolidated results of operations, financial position and disclosures. Upon adoption of the new leasing standards, we expect to recognize a lease liability and related right-of-use asset on our consolidated balance sheet of approximately \$200,000. The impact of adoption of the new leasing standards will not have a material impact to our consolidated statements of operations.

In June 2018, the FASB issued ASU No. 2018-07, “*Improvements to Nonemployee Share-Based Payment Accounting*,” to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. This ASU is effective for public entities for fiscal years beginning after December 15, 2018, with early adoption permitted. Prior to the adoption of this ASU, stock-based compensation awarded to non-employees was subject to revaluation over its vesting terms. Subsequent to the adoption of this ASU, non-employee share-based payment awards are measured on the date of grant, similar to share-based payment awards granted to employees. We do not expect that the adoption of this ASU will impact our financial position or our consolidated statements of operations.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
License revenue	\$ 500	\$ —
Research and development	4,522	3,206
General and administrative	2,739	1,313
Other (income) expense	(1,107)	(259)

License Revenue

License revenue for 2018 was comprised of the initial \$500,000 license payment we were entitled to receive upon signing of the September 27, 2018 license and collaboration agreement with Ahon Pharma.

Research and Development Expenses

R&D expenses were \$4.5 million for the year ended December 31, 2018 compared to \$3.2 million for the year ended December 31, 2017, an increase of \$1.3 million. The increase was primarily due to the additional preclinical testing and related costs required to support an application for an investigational new drug application in the United States, higher study costs for the REMEDY Phase 2 stroke study as compared with the DM199 bridging study which was substantially completed in 2017, and increased personnel and non-cash stock-based compensation costs.

General and Administrative Expenses

G&A expenses were \$2.7 million for the year ended December 31, 2018 compared to \$1.3 million for the year ended December 31, 2017. General and administrative costs increased due to one-time costs incurred associated with our planned public offering in the United States, primarily the Nasdaq listing process and related legal and accounting fees. Higher salaries, fees and short-term benefits due to the addition of staff and higher share-based compensation also contributed to the increase during 2018.

Other (Income) Expense

Other income, net, was \$1.1 million for the year ended December 31, 2018 compared to \$259,000 for 2017. The increase resulted primarily from the recognition of the R&D incentive from the Australian Government paid for qualifying research work performed by DiaMedica Australia. This increase was partially offset by increased foreign currency transaction losses.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of December 31, 2018 and 2017 and for each of years ended December 31, 2018 and 2017, and is intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	December 31,	
	2018	2017
Cash	\$ 16,823	\$ 1,353
Total assets	18,339	1,802
Total current liabilities	1,296	1,003
Total shareholders' equity	17,025	799
Working capital	16,676	491

Cash Flow Data	Year Ended December 31,	
	2018	2017
Cash flow provided by (used in):		
Operating activities	\$ (5,696)	\$ (3,900)
Investing activities	(50)	(22)
Financing activities	21,216	3,539
Net increase (decrease) in cash	\$ 15,470	\$ (383)

Working Capital

We had cash of \$16.8 million, current liabilities of \$1.3 million and working capital of \$15.5 million as of December 31, 2018, compared \$1.4 million in cash, \$1.0 million in current liabilities and \$491,000 in working capital as of December 31, 2017. The increases in cash and working capital are due to our December 2018 initial public offering in the United States and March 2018 private placement.

Cash Flows

Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was \$5.7 million compared to \$3.9 million for the year ended December 31, 2017. This increase relates primarily to an increase in the net loss, in addition to the effects of the changes in operating assets and liabilities.

Investing Activities

Investing activities consist primarily of purchases of property and equipment. Net cash used in investing activities was \$50,000 for the year ended December 31, 2018 compared to \$22,000 for the year ended December 31, 2017. This increase relates primarily to the expansion of our office space and staff.

Financing Activities

Financing activities consist primarily of net proceeds from the sale of common shares and warrants and proceeds from the exercise of stock options and warrants. Net cash provided by financing activities was \$21.2 million for the year ended December 31, 2018 compared to \$3.5 million for the year ended December 31, 2017. Cash flows from financing activities for 2018 included net proceeds from our December 2018 initial public offering and private placements of our common shares and warrants to purchase common shares in March 2018.

In December 2018, we completed an initial public offering of our common shares in the United States by issuing 4,100,000 common shares at an offering price of \$4.00 per share, resulting in net proceeds to us of approximately \$14.7 million, after deducting underwriting discounts and commissions and offering expenses.

On March 29, 2018, we completed, in two tranches, a brokered and non-brokered private placement of 1,322,965 units at a price of \$4.90 per unit for aggregate gross proceeds of approximately \$6.3 million. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$7.00 at any time prior to expiration on March 19, 2020 and March 29, 2020 for tranche 1 and tranche 2, respectively. The warrants are subject to early expiration under certain conditions. In connection with the offering, we paid an aggregate cash fee of approximately \$384,000 to brokers and issued an aggregate of 80,510 compensation options. Each compensation option entitles the holder to purchase one common share at \$4.90, the offering price, for a period of two years from the closing of the offering, subject to acceleration on the same terms as the warrants issued to the investors.

On December 18, 2017, we completed a non-brokered private placement of 181,220 units at a price of \$5.20 per unit for aggregate gross proceeds of approximately \$944,000. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$7.00 at any time prior to expiration on December 19, 2019, subject to early expiration under certain conditions. On April 17, 2017, we completed a non-brokered private placement of 526,316 units at a price of \$3.80 per unit for aggregate proceeds of approximately \$2,000,000. Each unit consists of one common share and one-half common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$4.60 at any time prior to expiration on April 17, 2019. The warrant expiration date can be accelerated at our option in the event that the volume-weighted average trading price of our common shares exceeds \$6.00 per common share for any 10 consecutive trading days.

Capital Requirements

Since our inception, we have incurred losses while advancing the R&D of our product candidates. We have not generated any revenues from product sales and do not expect to do so for a number of years. We do not know when, or if, we will generate any sales revenue from our DM199 product candidate or any future product candidates. We do not expect to generate any revenue from sales of product candidates 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 addition, we expect our operating expenses to increase in 2019 compared to 2018 as a result of our recently obtained Nasdaq-listed U.S. public reporting company status. In the long-term, subject to obtaining regulatory approval of our DM199 product candidate or any other future product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution.

Accordingly, despite our recent initial public offering, 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. While 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, which includes the net proceeds of our recent initial public offering, to be sufficient to allow us to complete our current ongoing Phase II Remedy trial in patients with AIS and our current Phase Ib trial in patients with CKD and a Phase II study in patients with CKD and to otherwise fund our planned operations through 2020. 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. 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 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, 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.

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, 2018, we had outstanding commitments, including R&D contracts and other commitments, that are known and committed of approximately \$1.9 million over the next 12 months and approximately \$600,000 in the following 12 months. These contracts relate to preclinical, clinical, and development activities, including the clinical research organization conducting the Phase II 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, 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, 2018, we had future operating lease commitments totaling approximately \$240,000 over the remainder of the lease, of which \$62,000 is due over the next 12 months.

We have 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, 2018, two milestones remain which include \$185,000 due upon the initiation of dosing in our first Phase III 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 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 2018 and 2017, 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.

Internal Control Over Financial Reporting

Pursuant to Section 404(a) of the Sarbanes-Oxley Act, commencing with our annual report on Form 10-K next year, our management will be required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a U.S. public reporting company under the Exchange Act, we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

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

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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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, shareholders’ equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Baker Tilly Virchow Krause, LLP

We have served as the Company’s auditors since 2016.
Minneapolis, MN
March 19, 2019

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash	\$ 16,823	\$ 1,353
Amounts receivable	780	80
Prepaid expenses	369	61
Total current assets	17,972	1,494
Deposit	271	271
Property and equipment, net	96	37
Total non-current assets	367	308
Total assets	\$ 18,339	\$ 1,802
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,291	\$ 919
Capital lease obligation	5	—
Warrant liability	—	84
Total current liabilities	1,296	1,003
Long term liabilities:		
Capital lease obligation, non-current	18	—
Total long term liabilities	18	—
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 11,956,874 and 6,370,661 shares issued and outstanding, as of December 31, 2018 and 2017, respectively	—	—
Additional paid-in capital	62,993	41,033
Accumulated deficit	(45,968)	(40,234)
Total shareholders' equity	17,025	799
Total liabilities and shareholders' equity	\$ 18,339	\$ 1,802

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,	
	2018	2017
Operating revenues:		
License revenues	\$ 500	\$ —
Operating expenses:		
Research and development	4,522	3,206
General and administrative	2,739	1,313
Total operating expenses	7,261	4,519
Operating loss	(6,761)	(4,519)
Other (income) expense:		
Governmental assistance – research incentives	(1,214)	(244)
Other (income) expense	68	(6)
Change in fair value of warrant liability	39	(9)
Total other income	(1,107)	(259)
Loss before income tax expense	(5,654)	(4,260)
Income tax expense	80	—
Net loss and comprehensive loss	\$ (5,734)	\$ (4,260)
Basic and diluted net loss per share	\$ (0.74)	\$ (0.72)
Weighted average shares outstanding – basic and diluted	7,743,520	5,935,790

See accompanying notes to consolidated financial statements.

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

	Common Shares	Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2016	5,526,046	\$ 37,085	\$ (35,974)	\$ 1,111
Issuance of common shares and warrants, net of offering costs of \$292	707,536	2,917	—	2,917
Exercise of common share purchase warrants	134,079	615	—	615
Exercise of common stock option	3,000	7	—	7
Share-based compensation expense	—	409	—	409
Net loss	—	—	(4,260)	(4,260)
Balances at December 31, 2017	6,370,661	\$ 41,033	\$ (40,234)	\$ 799
Issuance of common shares and warrants, net of offering costs of \$529	1,322,965	5,840	—	5,840
Issuance of common shares, net of offering costs of \$1,674	4,100,000	14,726	—	14,726
Exercise of common share purchase warrants	146,294	731	—	731
Exercise of common stock option	16,954	43	—	43
Share-based compensation expense	—	620	—	620
Net loss	—	—	(5,734)	(5,734)
Balances at December 31, 2018	11,956,874	\$ 62,993	\$ (45,968)	\$ 17,025

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

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (5,734)	\$ (4,260)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	620	409
Change in fair value of warrant liability	39	(9)
Depreciation	15	4
Changes in operating assets and liabilities:		
Amounts receivable	(700)	(27)
Prepaid expenses	(308)	6
Deposits	—	(271)
Accounts payable and accrued liabilities	372	248
Net cash used in operating activities	(5,696)	(3,900)
Cash flows from investing activities:		
Purchase of property and equipment	(50)	(22)
Net cash used in investing activities	(50)	(22)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	14,726	2,917
Proceeds from issuance of common shares and warrants, net offering costs	5,840	—
Proceeds from the exercise of common share purchase warrants	607	615
Proceeds from exercise of stock options	43	7
Net cash provided by financing activities	21,216	3,539
Net increase (decrease) in cash	15,470	(383)
Cash at beginning of year	1,353	1,736
Cash at end of year	\$ 16,823	\$ 1,353
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 11	\$ 57
Supplemental disclosure of non-cash transactions:		
Reclassification of warrant liability upon warrant exercise	\$ 123	\$ —
Assets acquired under capital lease	\$ 24	\$ —

See accompanying notes to consolidated financial statements.

DiaMedica Therapeutics Inc.
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 kidney and neurological diseases with our primary focus on chronic kidney disease and acute ischemic stroke. Our parent company is governed under the Canada Business Corporations Act and, commencing on December 4, 2018, our common shares are publicly traded on The Nasdaq Capital Market under the symbol “DMAC.” The Company’s shares were previously traded on the TSX Venture Exchange in Canada and on the OTCQB in the United States.

Effective November 15, 2018, we implemented a 1-for-20 consolidation of our common shares. No fractional shares were issued in connection with the share consolidation. Instead, the Company rounded to the nearest whole number the number of shares shareholders would be entitled to receive in connection with the consolidation. The share consolidation was approved by our shareholders as of November 6, 2018 and was implemented to increase the market price per common share to a level that qualified for listing on The Nasdaq Capital Market. Proportional adjustments were also made to common shares reserved for issuance under the Company’s equity-based compensation plans and outstanding stock options, deferred share units and warrants. All references to share and per share amounts included in these consolidated financial statements have been retroactively restated to reflect the share consolidation.

2. Risks and Uncertainties

DiaMedica is subject to many risks and uncertainties. We are in the clinical stage of development of our initial product candidate, DM199, for the treatment of chronic kidney disease and acute ischemic stroke. 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 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 several years, if at all. The Company’s future success is dependent upon the success of its development efforts, its ability to demonstrate clinical progress for its DM199 product candidate in the United States or other markets, its ability to obtain required governmental approvals of its product candidate and ultimately 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, 2018, we have incurred losses of \$46.0 million since our inception in 2000. For the year ended December 31, 2018, we incurred a net loss of \$5.7 million and negative cash flows from operating activities of \$5.7 million. We expect to continue to incur operating losses until such time as any future product sales, royalty payments, licensing fees, and/or milestone payments are sufficient to generate revenue to fund our continuing operations. Further, we expect our operating losses to increase in the near term as we continue the research, development and clinical trials of, and to seek regulatory approval for, our product candidate. In addition, we expect our operating expenses to increase in 2019 compared to 2018 as a result of our recently obtained Nasdaq-listed U.S. public reporting company status. As of December 31, 2018, DiaMedica had cash of \$16.8 million, working capital of \$16.7 million and shareholders’ equity of \$17.0 million. Our principal sources of cash have included net proceeds from the issuance of equity securities, including most recently an initial public offering of our common shares in the United States in December 2018. See Note 8 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.

Despite our recent initial public offering in the United States, 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 product candidate, DM199, or any future product candidates, to a point where they may be commercially sold. We expect our current cash, which includes the net proceeds of our recent initial public offering, to be sufficient to allow us to complete our currently ongoing Phase II Remedy trial in patients with AIS, our Phase Ib trial in patients with CKD and a planned Phase II study in patients with CKD caused by rare diseases and to otherwise fund our planned operations through 2020. 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.

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 statement of loss 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.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. Cash is deposited in demand and savings accounts at commercial banks. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash.

Fair value of financial instruments

Carrying amounts of certain of the Company's financial instruments, including amounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. Certain of the Company's common share purchase warrants are required to be reported at fair value. The fair value of common share purchase warrants is disclosed in Note 10 titled "Warrant Liability."

Fair value measurements

Fair value is defined as the exit price, or 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—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or model-derived valuations for which all significant inputs are observable, either directly or indirectly.
- Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable.

Our cash is comprised of bank deposits in demand and savings accounts. As of December 31, 2018, 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.

Common share warrant liability

The common share warrants that were issued in connection with the February 2016 private placements of common shares were classified as a liability in the consolidated balance sheets, as the common share warrants had an exercise price stated in Canadian dollars, which is different than our functional currency, and thus these warrants qualified as derivative instruments. The fair value of these common share warrants was re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in our consolidated statements of operations. These warrants were exercised in February 2018, see Note 8 titled "Warrant Liability."

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.

Revenue recognition

We followed ASC 606, "Revenue from Contracts with Customers" in accounting for our License and Collaboration agreement with Ahon Pharmaceutical Co Ltd. Accordingly, the Company recognizes revenue upon transfer of control of the product to our customer in an amount that reflects the consideration we expect to receive in exchange.

We intend to enter into arrangements for the research and development (R&D) and/or manufacture of products and product candidates. Such arrangements may require us to deliver various rights, services and/or goods, including (i) intellectual property rights or licenses, (ii) R&D services or (iii) manufacturing services. The underlying terms of these arrangements generally would provide for consideration to DiaMedica in the form of nonrefundable, up-front license fees, development and commercial-performance milestone payments, cost sharing, royalty payments and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. We intend to utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

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 testing and accumulating data related to non-clinical studies; sponsored research agreements; developing the manufacturing process necessary to produce sufficient amounts of the DM199 compound for use in our non-clinical studies and human clinical trials; 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 (“CROs”). 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 and CROs, 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.

Patent costs

Costs associated with prosecuting and maintaining patents are expensed as incurred given the uncertainty of patent approval and, if approved, resulting in 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 \$156,000 and \$160,000 for the years ended December 31, 2018 and 2017, 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 Canadian Government bond rates appropriate for the expected term of each award. Expected volatility rates are based on the on 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.

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, 2018 and 2017. See Note 13, “Income Taxes” for additional information. The Company’s policy is to classify interest and penalties related to income taxes as income tax expense in the Consolidated Statements of Operations and Comprehensive Loss.

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 was initially recognized when reasonable assurance existed that the Company complied with the conditions attached to the incentive program and that the incentive payments would be received. In subsequent periods, the government assistance was recognized when the related expenditures were incurred. During 2018, we recognized \$621,000 and \$593,000 for research activities performed in 2018 and 2017, respectively. During 2017, we recognized \$244,000 for research activities performed in 2016.

Net loss per share

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

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

	Year Ended December 31	
	2018	2017
Net loss	\$ (5,734)	\$ (4,260)
Weighted average shares outstanding—basic and diluted	7,743,520	5,935,790
Basic and diluted net loss per share	\$ (0.74)	\$ (0.72)

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	
	2018	2017
Employee and non-employee stock options	639,359	480,035
Common shares issuable under common share purchase warrants	807,563	216,213
Common shares issuable under deferred unit plan	21,183	21,183
	<u>1,468,105</u>	<u>717,431</u>

Recently adopted accounting pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The new revenue recognition standard and clarifying standards require an entity to recognize revenue when control of promised goods or services is transferred to the customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018, but the adoption as of this date had no impact on our financial statements, as we had no revenue until the third quarter of 2018. We followed ASC 606, “Revenue from Contracts with Customers” in accounting for our License and Collaboration agreement with Ahon Pharmaceutical Co Ltd. (Note 11).

Recently issued accounting pronouncements

In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases*. The guidance in ASU 2016-02 supersedes the lease recognition requirements in the Accounting Standards Codification Topic 840, *Leases*. ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. The new standard requires the immediate recognition of all excess tax benefits and deficiencies in the income statement and requires classification of excess tax benefits as an operating activity as opposed to a financing activity in the statements of cash flows. This standard became effective for us on January 1, 2019.

The FASB has subsequently issued the following amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2019, and which we collectively refer to as the new leasing standards:

- ASU No. 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*, which permits an entity to elect an optional transition practical expedient to not evaluate under Topic 842 land easements that existed or expired prior to adoption of Topic 842 and that were not previously accounted for as leases under the prior standard, ASC 840, *Leases*.
- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02.
- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.
- ASU No. 2018-20, *Narrow-Scope Improvements for Lessors*, which contains certain narrow scope improvements to the guidance issued in ASU 2016-02.

We adopted the new leasing standards on January 1, 2019, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019; and, consequently, financial information will not be updated and the disclosures required under Topic 842 will not be provided for dates and periods prior to January 1, 2019. We have reviewed our existing lease contracts and the impact of the new leasing standards on our consolidated results of operations, financial position and disclosures. Upon adoption of the new leasing standards, we expect to recognize a lease liability and related right-of-use asset on our consolidated balance sheet of approximately \$200,000. The impact of adoption of the new leasing standards will not have a material impact on our consolidated statements of operations.

In June 2018, the FASB issued ASU No. 2018-07, “*Improvements to Nonemployee Share-Based Payment Accounting*,” to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. This ASU is effective for public entities for fiscal years beginning after December 15, 2018, with early adoption permitted. Prior to the adoption of this ASU, stock-based compensation awarded to non-employees was subject to revaluation over its vesting terms. Subsequent to the adoption of this ASU, non-employee share-based payment awards are measured on the date of grant, similar to share-based payment awards granted to employees. We do not expect that the adoption of this ASU will impact our financial position or our consolidated statements of operations.

4. Amounts Receivable

Amounts receivable consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Research and development incentives	\$ 622	\$ —
Sales-based taxes receivable	134	—
Other	24	80
Total amounts receivable	<u>\$ 780</u>	<u>\$ 80</u>

5. Deposit

Deposit consisted of the following (in thousands):

	December 31, 2018	December 31, 2017
Advances to vendor	\$ 271	\$ 271
Total deposit	<u>\$ 271</u>	<u>\$ 271</u>

We have advanced funds to a vendor engaged to support the performance of the REMEDY Phase 2 clinical trial. The funds advanced will be held, interest free, by this vendor until the completion of the trial and applied to final trial invoices or refunded. This deposit is classified as non-current as the trial is not expected to be completed during 2019.

6. Property and Equipment

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

	December 31, 2018	December 31, 2017
Furniture and equipment	\$ 49	\$ 40
Computer equipment	71	23
	120	63
Less accumulated depreciation	(24)	(26)
Property and equipment, net	<u>\$ 96</u>	<u>\$ 37</u>

Depreciation expense for the years ended December 31, 2018 and 2017 was \$15,000 and \$4,000, respectively. During 2018, we disposed of \$17,000 of equipment, which was fully depreciated.

7. Accounts Payable and Accrued Liabilities

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

	December 31, 2018	December 31, 2017
Trade and other payables	\$ 483	\$ 513
Accrued compensation	417	355
Accrued clinical study costs	292	—
Accrued research and other professional fees	65	45
Accrued taxes and other liabilities	34	6
Total accrued liabilities	<u>\$ 1,291</u>	<u>\$ 919</u>

8. Warrant Liability

In February 2016, the Company completed, in two tranches, a non-brokered private placement of 234,375 units with each unit consisting of one common share and one half of one common share purchase warrant. The Company issued 117,188 warrants. Each warrant entitled the holder to purchase one common share at a price of \$5.00 Canadian dollars at any time prior to expiry on February 18 or 25, 2018 for Tranche 1 and Tranche 2, respectively.

As the warrant exercise price was stated in Canadian dollars and the Company's functional currency is the U.S. dollar, the warrants were deemed to be derivative instruments, with their estimated fair value classified as a liability on the Company's consolidated balance sheet. The initial estimated fair value of the warrants was recorded as a warrant liability with subsequent changes in the estimated fair value recognized in the consolidated statements of operations and comprehensive loss. The Company allocated \$281,000 of the net proceeds to the warrant liability and the balance of the proceeds to the common shares. The initial fair value of the warrants was determined using a Black-Scholes pricing model with the following assumptions: expected volatilities of 191.8 – 225.0%, risk-free interest rates of 0.43 – 0.49%, and expected life of 2 years.

In connection with the offering, the Company issued an aggregate of 10,915 compensation warrants. Each compensation warrant entitled the holder to purchase one common share at \$5.00 Canadian dollars for a period of 2 years from the date of issuance. The Company estimated the value of these warrants at \$24,000, which was included in the issuance costs. The initial fair value of the warrants was determined using a Black-Scholes valuation model with the following assumptions: expected volatilities of 191.8 – 225.0%, risk-free interest rates of 0.43 – 0.49%, and expected life of 2 years.

During February 2018, 121,256 common shares were issued on the exercise of warrants for gross proceeds of approximately \$483,000 and the remaining 4,346 warrants expired.

The fair value of the Company's common share purchase warrant liability was calculated using a Black-Scholes valuation model and is classified as Level 3 in the fair value hierarchy. The fair values at the time of exercise of the warrants were estimated using the following valuation assumptions: expected volatilities of 16.7%, risk-free interest rates of 1.8%, and expected life of 0.01-0.03 years.

The following is a rollforward of the fair value of the warrants (in thousands):

	Warrant Liability
Ending balance December 31, 2017	\$ 84
Change in fair value	39
Exercises	(123)
Ending balance December 31, 2018	<u>\$ —</u>

9. 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 relate to preclinical, clinical and development activities, including the clinical research organization conducting our Phase II clinical trial for acute ischemic stroke. 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, amount of time to complete study enrollments and the time required to finalize the analysis and reporting of study results. Clinical research agreements are generally cancelable upon 30 days' notice, with the Company's obligation then limited to costs incurred up to that date. Cancellation terms for product development contracts vary and are generally dependent upon timelines for sourcing research materials and reserving laboratory time. As of December 31, 2018, the Company estimates that its outstanding commitments including research and development contracts are approximately \$1.9 million over the next 12 months and approximately \$600,000 in the following 12 months.

On September 11, 2017, the Company announced the initiation of REMEDY, a 60-patient Phase II clinical trial evaluating DM199 in patients with acute ischemic stroke. The study drug (DM199 or placebo) will be administered as an intravenous infusion within 24 hours of stroke symptom onset, followed by subcutaneous (under the skin) injections later that day and once every 3 days for 21 days. The study is designed to measure safety and tolerability along with multiple tests designed to investigate DM199's therapeutic potential including plasma-based biomarkers and standard functional stroke measures assessed at 90 days post-stroke (Modified Rankin Scale, National Institutes of Health Stroke Scale, Barthel Index, and C-reactive protein, a measure of inflammation).

On February 14, 2019, the Company announced the first enrollment in its Phase Ib dose ranging study in patients with moderate or severe CKD caused by Type I or Type II diabetes. The results from this Phase Ib study will assist us in the design of upcoming Phase II studies in patients suffering from rare diseases and CKD. The DM199 drug levels from this Phase Ib study will be used to determine the optimal dose levels for testing in the Phase II studies.

Additional clinical trials will be subsequently required if the results of the Phase II are positive. However, 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. Clinical trial costs are expensed as incurred.

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, 2018, two milestones remain which include \$185,000 due upon the initiation of dosing in our first Phase III 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 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 2018 and 2017.

Indemnification of directors and officers

The Company, as permitted under laws of the Canada and in accordance with the Company's by-laws 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, 2018, 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 (the "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 (the "SEC"), 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, 2018 or 2017.

Future minimum lease payments

The Company leases certain office space under a non-cancelable operating lease. On May 3, 2017, the Company amended the lease agreement to extend its lease term by 42 months, for an expiration date of August 31, 2022, and increase its leased space. Rent is expensed on a straight-line basis.

Future minimum lease payments under this operating lease are as follows (in thousands):

2019	\$	64
2020		66
2021		68
2022		46
Total	\$	<u>244</u>

10. Shareholders' Equity

Authorized capital stock

The Company 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.

Shareholders rights plan

The Company adopted a shareholder rights plan agreement (the “Rights Plan”). The Rights Plan is designed to provide adequate time for the Board of Directors and the shareholders to assess an unsolicited takeover bid for the Company, to provide the Board of Directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, and to provide shareholders with an equal opportunity to participate in a takeover bid and receive full and fair value for their common shares. The Rights Plan was renewed at the Company’s annual meeting of shareholders in December 2017 and is set to expire at the close of the Company’s annual meeting of shareholders in 2020.

The rights issued under the Rights Plan will initially attach to and trade with the common shares and no separate certificates will be issued unless an event triggering these rights occurs. The rights will become exercisable only when a person, including any related person or entity, acquires or attempts to acquire 20% or more of the outstanding common shares without complying with the “Permitted Bid” provisions of the Rights Plan or without approval of the Board of Directors. Should such an acquisition occur or be announced, each right would, upon exercise, entitle a rights holder, other than the acquiring person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Plan, a Permitted Bid is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties have been tendered, the offeror may take up and pay for the common shares but must extend the bid for a further 10 days to allow other shareholders to tender.

The issuance of common shares upon the exercise of the rights is subject to receipt of certain regulatory approvals.

Public offering during 2018

On December 11, 2018, the Company issued and sold an aggregate of 4,100,000 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 \$16.4 million, which resulted in net proceeds to the Company of approximately \$14.7 million, after deducting underwriting discounts and commissions and offering expenses. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. On December 11, 2018, as additional underwriting compensation and in exchange for cash consideration of \$50, the Company granted the underwriter a warrant to purchase 205,000 common shares (equal to 5.0% of the common shares sold in the initial public offering) at an exercise price of \$4.80 per share (equal to 120% of the initial public offering price per common share in the initial public offering), subject to customary anti-dilution provisions. The warrant is exercisable for a term of five years. The warrant includes a cashless exercise provision entitling the underwriter to surrender a portion of the underlying common shares that has a value equal to the aggregate exercise price in lieu of paying cash upon exercise.

Private placements during 2018

On March 29, 2018, the Company completed, in two tranches, a brokered and non-brokered private placement of 1,322,965 units at a price of \$4.90 per unit for aggregate gross proceeds of approximately \$6.3 million. Each unit consisted of one common share and one half of one common share purchase warrant. The Company issued 661,482 warrants. Each warrant entitles the holder to purchase one common share at a price of \$7.00 at any time prior to expiry on March 19, 2020 and March 29, 2020 for Tranche 1 and Tranche 2, respectively. The warrants are subject to early expiry under certain conditions. The warrant expiry date can be accelerated at the option of the Company, in the event that the volume-weighted average trading price of the Company’s common shares exceeds \$12.00 per common share for any 21 consecutive trading days. In connection with this offering, the Company paid aggregate finder’s fees of approximately \$384,000 and issued an aggregate of 80,510 compensation warrants. Each compensation warrant entitles the holder to purchase one common share at \$4.90 for a period of 2 years from the closing of this offering, subject to acceleration on the same terms as the common share purchase warrants.

During the year ended December 31, 2018, 128,594 common shares were issued on the exercise of warrants for gross proceeds of \$607,000 and 16,954 common shares were issued on the exercise of options for gross proceeds of \$43,000.

Private placements during 2017

On December 18, 2017, the Company completed a non-brokered private placement of 181,220 units at a price of \$5.20 per unit for aggregate gross proceeds of approximately \$944,000, or \$934,000 net of issuance costs. Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$7.00 at any time prior to expiry on December 19, 2019. Warrants are subject to early expiry, at the option of the Company, if on any date the volume-weighted average closing trading price of the common shares on any recognized stock exchange equals or exceeds \$12.00 for a period of 21 consecutive trading days.

On April 17, 2017, the Company completed a non-brokered private placement of 526,316 units at a price of \$3.80 per unit for aggregate gross proceeds of approximately \$2,000,000, or \$1,983,000 net of issuance costs. Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$4.60 at any time prior to expiry on April 17, 2019. The warrants were subject to early expiry, at the option of the Company, if on any date the volume-weighted average closing trading price of the common shares on any recognized Canadian stock exchange equaled or exceeded \$6.00 for a period of 10 consecutive trading days, which occurred in October 2017. The Company exercised its call option and 131,578 shares were issued for the warrants exercised and the remaining warrants were cancelled.

During the year ended December 31, 2017, 134,079 common shares were issued on the exercise of warrants for gross proceeds of \$615,000 and 3,000 common shares were issued on the exercise of options for gross proceeds of \$7,000.

Shares reserved

	December 31, 2018
Stock options outstanding	639,359
Deferred share units outstanding	21,183
Shares available for grant under the Option Plan	123,376
Common shares issuable under common share purchase warrants	807,563
Total	1,591,479

11. License and Collaboration Agreement with Related Party

On September 27, 2018, the Company entered into a license and collaboration agreement (the “License Agreement”) with Ahon Pharmaceutical Co Ltd. (“Ahon Pharma”), which grants Ahon Pharma exclusive rights to develop and commercialize DM199 for acute ischemic stroke in mainland China, Taiwan, Hong Kong S.A.R. and Macau S.A.R. Under the terms of the agreement, the Company is entitled to receive a non-refundable upfront payment of \$500,000 due upon signing the License Agreement and an additional non-refundable payment of \$4.5 million upon regulatory clearance to initiate a clinical trial in China. The Company also has the potential to receive up to an additional \$27.5 million in development and sales related milestones and up to approximately 10% royalties on net sales of DM199 in the licensed territories. All development, regulatory, sales, marketing, and commercial activities and associated costs in the licensed territories will be the sole responsibility of Ahon Pharma. The License Agreement may be terminated at any time by Ahon Pharma by providing 120 days written notice.

The Company received the \$500,000 upfront license fee and recorded it as revenue during the year ended December 31, 2018. The \$4.5 million payment and the up to \$27.5 million in additional development and sales related milestones were determined to be at-risk substantive performance milestones and were not recordable as revenue as they were determined to be fully constrained using the most likely amount method. Revenue will be recognized for these milestones when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Under the terms of the License Agreement, the Company is obligated to pay, and Ahon Pharma may withhold, approximately 10% of any license fee as income tax due in China. The Company will record this withholding as income tax at the time it records the related license fee revenue. Accordingly, with respect to the \$500,000 license fee, the Company recorded this withholding as income tax at the time it recorded this license fee revenue.

Ahon Pharma is a subsidiary of Shanghai Fosun Pharmaceutical (Group) co. Ltd. (“Fosun Pharma”) which, through its partnership with SK Group, a South Korea based company, is an investor in DiaMedica, holding approximately 8.4% of our common shares as of December 31, 2018. This investment was made in 2016.

12. Share-Based Compensation

Deferred share unit plan

The DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan (“DSU Plan”) promotes greater alignment of long-term interests between non-executive directors and executive officers of the Company and its shareholders through the issuance of deferred share units (“DSUs”). Since the value of DSUs increases or decreases with the market price of the common shares, DSUs reflect a philosophy of aligning the interests of directors and executive officers by tying compensation to share price performance. For the year ended December 31, 2018 and 2017, there were no DSUs or common shares underlying DSUs issued. The Company has reserved for issuance up to 100,000 common shares under the DSU Plan and 21,183 DSUs were outstanding at December 31, 2018 and 2017.

Stock option plan

The DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018 (the “Option Plan”) allows the Board of Directors from time to time, in its sole discretion, and in accordance with the requirements of the Nasdaq Stock Market, to grant the Company’s directors, officers, employees and certain consultants (as such terms are used in the Option Plan) non-transferable options to purchase common shares. The shareholders approved the adoption of the Option Plan on September 22, 2011, which was then amended and restated on October 23, 2015, December 21, 2017 and November 6, 2018. The number of common shares reserved for issuance under the Option Plan at any time is equal to the lesser of: 783,918 (subject to adjustment) and 10% of the issued common shares at the relevant time and the aggregate number of common shares reserved for issuance under any other compensation or incentive mechanism or plan (including deferred share unit plans or employee stock option plans, if any), shall not exceed 10% of our issued shares at the relevant time. In addition, the maximum number of common shares that may be issued under the Option Plan upon the exercise of incentive stock options within the meaning of Section 422 of the United States Internal Revenue Code of 1986, as amended (the “Code”) is 283,918 shares (subject to adjustment).

As of December 31, 2018, options to purchase 639,359 common shares were outstanding. Options granted vest at various rates and have terms of up to 10 years. As the TSX Venture Exchange was the principal trading market for the Company's common shares, all options previously granted under the Option Plan have been priced in Canadian dollars.

The aggregate number of common shares reserved for issuance under the Option Plan and the DSU Plan as of December 31, 2018 was 783,918.

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

	December 31, 2018	December 31, 2017
Research and development	\$ 170	\$ 60
General and administrative	450	349
Total share-based compensation	\$ 620	\$ 409

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 (CAD\$)	Aggregate Intrinsic Value (CAD\$)
Balances at December 31, 2016	427,850	\$ 7.68	\$ 187
Granted	127,635	6.11	
Exercised	(3,000)	3.00	
Expired/cancelled	(72,450)	13.29	
Forfeited	—	—	
Balances at December 31, 2017	480,035	\$ 6.45	\$ 674
Granted	196,800	11.08	
Exercised	(16,954)	3.29	
Expired/cancelled	—	—	
Forfeited	(20,522)	8.99	
Balances at December 31, 2018	639,359	\$ 7.87	\$ —

A summary of the status of our unvested shares during the year ended and as of December 31, 2018 is as follows:

	Shares Under Option	Weighted Average Grant Date Fair Value Per Share (CAD\$)
Unvested at December 31, 2017	216,793	\$ 3.69
Granted	196,800	9.30
Vested	(150,739)	4.48
Forfeitures	(20,522)	7.27
Unvested at December 31, 2018	<u>\$ 242,332</u>	<u>\$ 7.45</u>

Information about stock options outstanding, vested and expected to vest as of December 31, 2018, is as follows:

Per Share Exercise Price	Outstanding, Vested and Expected to Vest			Options Vested and Exercisable	
	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price (CAD\$)	Options Exercisable	Weighted Average Remaining Contractual Life (Years)
\$2.00 - \$2.60	50,000	6.8	\$ 2.00	50,000	6.8
\$2.80 - \$3.20	125,400	6.9	3.00	125,400	6.9
\$3.40 - \$5.20	130,405	8.0	5.12	91,239	8.0
\$5.40 - \$10.20	98,063	8.5	6.39	50,563	8.5
\$10.40 - \$34.00	235,491	8.2	13.86	79,825	5.9
	<u>639,359</u>	<u>7.8</u>	<u>\$ 7.87</u>	<u>397,027</u>	<u>7.1</u>

The cumulative grant date fair value of employee options vested during the years ended December 31, 2018 and 2017 was \$508,000 and \$213,000, respectively. Total proceeds received for options exercised during the years ended December 31, 2018 and 2017 were \$43,000 and \$7,000, respectively.

As of December 31, 2018 and 2017, total compensation expense related to unvested employee stock options not yet recognized was \$1.4 million and \$551,000, respectively, which is expected to be allocated to expenses over a weighted-average period of 2.01 and 1.97 years, respectively.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 was \$104,000 and 12,000, 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, 2018 and 2017:

	2018	2017
Common share fair value	\$8.84 - \$9.33	\$5.20 - \$8.40
Risk-free interest rate	2.1 - 2.2%	1.1%
Expected dividend yield	0%	0%
Expected option life	4.8 - 5.0	4.5
Expected stock price volatility	123.5 - 135.7%	84.7 - 156.8%

Nonemployee share-based compensation

We account for stock options granted to nonemployees in accordance with FASB ASC 505. In connection with stock options granted to nonemployees, we recorded \$205,000 and \$308,000 for nonemployee share-based compensation during the years ended December 31, 2018 and 2017, respectively.

These amounts were based upon the fair values of the vested portion of the grants. Amounts expensed during the remaining vesting period will be determined based on the fair value at the time of vesting.

13. Employee Benefit Plan

We maintain an employee 401(k) retirement savings plan (the “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 equal 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 \$45,000 and \$33,000 for the years ended December 31, 2018 and 2017, respectively.

14. 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 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,	
	2018	2017
Deferred tax assets (liabilities):		
Non-capital losses carried forward	\$ 9,280	\$ 7,233
Research and development expenditures	887	887
Share issue costs	529	117
Patents and other	293	319
Accruals	(97)	—
Property and equipment	(6)	(4)
Total deferred tax asset, net	10,886	8,552
Valuation allowance	(10,886)	(8,552)
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:

	Year Ended December 31,	
	2018	2017
Statutory income tax rate	27.0%	27.0%
Income tax recovery based on statutory rate	(1,119)	(1,160)
Share-based compensation	243	110
Gain on revaluation of warrant liability	(450)	(2)
Australian research and development incentive	103	314
Other	172	204
Change in unrecognized temporary differences	1,131	534
Income tax expense	<u>(80)</u>	<u>—</u>

Net operating losses and tax credit carryforwards as of December 31, 2018, are as follows:

	Amount	Expiration Years
	(In thousands)	
Non-capital income tax losses, net	\$ 32,002	Beginning 2026
Research and development expense carry forwards	3,284	Indefinitely
Tax credits	525	Beginning 2020

The Company is subject to taxation in the 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

This annual report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our registered independent public accounting firm due to a transition period established by rules of the SEC for newly public 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, 2018 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

DiaMedica Therapeutics Inc. 2018 Short-Term Incentive Payouts

On March 14, 2019, the Compensation Committee (the “Compensation Committee”) of the Board of Directors of DiaMedica Therapeutics Inc. approved payouts under DiaMedica’s 2018 Short-Term Incentive (“STI”) program for our executive officers.

In addition to base compensation, we provide our named executive officers the opportunity to earn short-term incentive (STI) compensation based on the achievement of certain annual corporate and individual related performance goals. Our STI program directly aligns the interests of our executive officers and shareholders by providing an incentive for the achievement of key corporate and individual performance objectives that are critical to the success of our company and linking a significant portion of each executive’s annual compensation to the achievement of such objectives.

Under the 2018 STI program, each executive officer named in our most recent Summary Compensation Table (“named executive officer”) had a target incentive percentage that was a percentage of his base salary:

Name	Percentage of Salary Base
Rick Pauls	50%
Scott Kellen	30%
Todd Verdoorn	30%

2018 STI payouts were based on the achievement of two pre-established corporate performance objectives that related to regulatory and clinical milestones and three to five pre-established individual performance objectives. Mr. Paul’s individual performance objectives for fiscal 2018 related to raising additional financing, building the executive team and obtaining a U.S. Nasdaq listing. Mr. Kellen’s individual performance objectives for fiscal 2018 related to raising additional financing, financial accounting objectives and obtaining a U.S. Nasdaq listing. Mr. Verdoorn’s individual performance objectives for fiscal 2018 related to research and development objectives.

The table below sets forth the overall achievement percentage by each named executive officer of their performance objectives and their respective 2018 STI payout:

Name	Achievement Percentage	2018 STI Payout
Rick Pauls	95.0%	\$ 163,875
Scott Kellen	97.5%	70,200
Todd Verdoorn	50.0%	36,000

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 “Executive Officers.”

Section 16(a) Beneficial Ownership Reporting Compliance

The information in the “Stock Ownership—Section 16(a) Beneficial Ownership Reporting Compliance” 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.

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., 2 Carlson Parkway, Suite 260, Minneapolis, Minnesota 55447.

Changes to Nomination Procedures

During the fourth quarter of fiscal 2018, we made no material changes to the procedures by which shareholders may recommend nominees to the Company’s 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 Certain 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, 2018. Our equity compensation plans as of December 31, 2018 were the DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018 and the DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan.

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	660,542 ⁽¹⁾	\$ 7.87 ⁽²⁾	123,376 ⁽³⁾
Equity compensation plans not approved by security holders	—	\$ —	—
Total	660,542⁽¹⁾	\$ 7.87	123,376⁽³⁾

(1) Amount includes 639,359 common shares issuable upon the exercise of stock options outstanding as of December 31, 2018 under the DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018 and 21,183 common shares issuable under the DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan.

(2) Not included in the weighted-average exercise price calculation are 21,183 DSU awards.

(3) Amount includes 123,376 shares remaining available at December 31, 2018 for future issuance under DiaMedica Therapeutics Inc. Stock Option Plan Amended and Restated November 6, 2018 and the DiaMedica Therapeutics Inc. Amended and Restated Deferred Share Unit Plan. Of these shares, a maximum of 78,817 common shares are available at December 31, 2018 for future issuance under the Deferred Share Unit 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 Four—Appointment of Baker Tilly Virchow Krause, LLP as our Independent Registered Public Accounting Firm and Authorization of the Board of Directors to Fix the Auditors’ Remuneration—Audit, Audit-Related, Tax and Other Fees” and “Voting Proposal Four—Appointment of Baker Tilly Virchow Krause, LLP as our Independent Registered Public Accounting Firm and Authorization of the Board of Directors to Fix the Auditors’ Remuneration—Audit Committee Pre-Approval Policies and Procedures” 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.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statements

Our consolidated financial statements are included in “Part III, 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 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., 2 Carlson Parkway, Suite 260, Minneapolis, Minnesota 55447, Attn: Shareholder Information.

<u>Item No.</u>	<u>Item</u>	<u>Method of Filing</u>
1.1	<u>Underwriting Agreement dated December 6, 2018 between Craig-Hallum Capital Group LLC and DiaMedica Therapeutics Inc.</u>	Incorporated by reference to Exhibit 1.1 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)
3.1	<u>Certificate of Continuance of DiaMedica Therapeutics Inc. dated April 11, 2016</u>	Incorporated by reference to Exhibit 3.1 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)
3.2	<u>Certificate of Amendment of DiaMedica Therapeutics Inc. dated December 28, 2016</u>	Incorporated by reference to Exhibit 3.2 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)
3.3	<u>Certificate of Amendment of DiaMedica Therapeutics Inc. dated September 24, 2018</u>	Incorporated by reference to Exhibit 3.3 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
3.4	<u>Certificate of Amendment of DiaMedica Therapeutics Inc. dated November 15, 2018</u>	Incorporated by reference to Exhibit 3.4 to DiaMedica's Registration Statement on Form S-1/A as filed with the Securities and Exchange Commission on November 19, 2018 (File No. 333-228313)
3.5	<u>By-Law No. 1 and 2 of DiaMedica Therapeutics Inc. as amended and restated on September 30, 2018</u>	Incorporated by reference to Exhibit 3.5 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)
4.1	<u>Investment Agreement between Hermeda Industrial Co., Ltd. and DiaMedica Inc. dated July 16, 2016</u>	Incorporated by reference to Exhibit 4.1 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)
4.2	<u>Shareholder Rights Plan Agreement dated December 21, 2017 by and between DiaMedica Therapeutics Inc. and Computershare Investor Services Inc.</u>	Incorporated by reference to Exhibit 4.2 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)
4.9	<u>Form of Investor Warrant issued in connection with the March 2018 private placement</u>	Incorporated by reference to Exhibit 4.9 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)
4.10	<u>Form of Broker Warrant issued in connection with the March 2018 private placement</u>	Incorporated by reference to Exhibit 4.10 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)
4.11	<u>Form of Investor Warrant issued in connection with the December 2017 private placement</u>	Incorporated by reference to Exhibit 4.11 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)

Item No.	Item	Method of Filing
4.12	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)
4.13	Specimen Certificate representing common shares of DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 4.13 to DiaMedica's Registration Statement on Form S-1/A as filed with the Securities and Exchange Commission on November 19, 2018 (File No. 333-228313)
10.1#	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)
10.2#	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)
10.3#	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)
10.4#	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)
10.5#	Form of Indemnification Agreement	Incorporated by reference to Exhibit 10.5 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
10.6#	Employment Agreement by and between DiaMedica Therapeutics 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)
10.7#	Employment Agreement by and between DiaMedica Therapeutics Inc. and Scott Kellen	Filed herewith
10.8#	Employment Agreement by and between DiaMedica Therapeutics Inc. and Todd Verdoorn, Ph.D.	Incorporated by reference to Exhibit 10.7 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#	Employment Agreement by and between DiaMedica Therapeutics Inc. and Harry Alcorn, Ph.D.	Filed herewith
10.10	Two Carlson Parkway Office Lease between One Two Holdings LLC and DiaMedica USA Inc. dated September 18, 2015	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)
10.11	Supplemental to Lease Agreement between One Two Holdings LLC and DiaMedica USA Inc. dated December 16, 2015	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)
10.12	First Amendment to Lease between One Two Holdings LLC and DiaMedica USA Inc. dated May 3, 2017	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)
10.13	Second Amendment to Lease between One Two Holdings LLC and DiaMedica USA Inc. dated September 5, 2017	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)

Item No.	Item	Method of Filing
10.14 ⁽¹⁾	<u>GPEX[®]- Derived Cell Line Sale Agreement between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC dated February 2, 2012-</u>	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)
10.15	<u>First Amendment to GPEX[®]-Development and Manufacturing Agreement between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC dated April 10, 2017</u>	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)
10.16 ⁽¹⁾	<u>License and Collaboration Agreement between DiaMedica Therapeutics Inc. and Ahon Pharmaceutical Co., Ltd. dated September 27, 2018</u>	Incorporated by reference to Exhibit 10.14 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 ⁽¹⁾	<u>Supply Agreement between DiaMedica Therapeutics Inc. and Ahon Pharmaceutical Co., Ltd. dated September 27, 2018</u>	Incorporated by reference to Exhibit 10.15 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)
21.1	<u>Subsidiaries of DiaMedica Therapeutics Inc.</u>	Filed herewith
23.1	<u>Consent of Baker Tilly Virchow Krause, LLP</u>	Filed herewith
31.1	<u>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</u>	Filed herewith
31.2	<u>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</u>	Filed herewith
32.1	<u>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</u>	Furnished herewith
32.2	<u>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</u>	Furnished herewith

Item No.	Item	Method of Filing
101	The following materials from DiaMedica Therapeutics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, 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 19, 2019

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Rick Pauls</u> Rick Pauls	President, Chief Executive Officer and Director (principal executive officer)	March 19, 2019
<u>/s/ Scott Kellen</u> Scott Kellen	Chief Financial Officer and Secretary (principal financial and accounting officer)	March 19, 2019
<u>/s/ Richard Pilnik</u> Richard Pilnik	Chairman of the Board	March 19, 2019
<u>/s/ Michael Giuffre, M.D.</u> Michael Giuffre, M.D.	Director	March 19, 2019
<u>/s/ James Parsons</u> James Parsons	Director	March 19, 2019
<u>/s/ Zhenyu Xiao, Ph.D.</u> Zhenyu Xiao, Ph.D.	Director	March 19, 2019

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is effective as of September 12, 2018 ("Effective Date"), by and between DiaMedica USA, Inc. a Delaware corporation (the "Company"), and Scott Kellen, an individual ("Executive"). The Company and Executive are sometimes referred to as the "Parties" or "Party" in this Agreement, and the Company may designate the parent company of the Company or a subsidiary to be the employer of the Executive.

In consideration of the mutual promises, covenants and agreements contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. EMPLOYMENT AND DUTIES.

A. Job Title and Responsibilities. The Company hereby employs Executive, and Executive hereby agrees to be employed, as Chief Financial Officer (together with such other position or positions consistent with Executive's title as the Company's Chief Executive Officer may specify from time to time), reporting to the Company's Chief Executive Officer and will have such duties and responsibilities commensurate with such title. The Parties understand, acknowledge and agree that Executive may also serve in similar positions with the parent company of the Company or any subsidiary.

B. Full-Time Best Efforts. Executive agrees to devote Executive's full professional time and attention to the business of the Company (and its subsidiaries, affiliates, or related entities) and the performance of Executive's obligations under this Agreement, and will at all times faithfully, industriously and to the best of Executive's ability, experience and talent, perform all of Executive's obligations hereunder. Executive shall not, at any time during Executive's employment by the Company, directly or indirectly, act as a partner, officer, director, consultant or Executive, or provide services in any other capacity to any other business enterprise that conflicts with the Company's business or Executive's duty of loyalty to the Company. Executive shall seek the written consent of the Company prior to accepting any outside board positions.

C. Duty of Loyalty. Executive acknowledges that during Executive's employment with the Company, Executive has participated in and will participate in relationships with existing and prospective clients, customers, partners, suppliers, service providers and vendors of the Company that are essential elements of the Company's goodwill. The parties acknowledge that Executive owes the Company a fiduciary duty to conduct all affairs of the Company in accordance with all applicable laws and the highest standards of good faith, trust, confidence and candor, and to endeavor, to the best of Executive's ability, to promote the best interests of the Company.

D. Conflict of Interest. Executive agrees that while employed by the Company, and except with the advance written consent of the Board, Executive will not enter into, on behalf of the Company, or cause the Company or any of its affiliates to enter into, directly or indirectly, any transactions with any business organization in which Executive or any member of Executive's immediate family may be interested as a shareholder, partner, member, trustee, director, officer, employee, consultant, lender or guarantor or otherwise; provided, however, that nothing in this Agreement shall restrict transactions between the Company and any company whose stock is listed on a national securities exchange or actively traded in the over-the-counter market and over which Executive does not have the ability to control or significantly influence policy decisions.

2. COMPENSATION.

A. Base Pay. The Company agrees to pay Executive gross annual compensation of \$240,000 ("Base Salary"), less usual and customary withholdings, which shall be payable in arrears in accordance with the Company's customary payroll practices. The Base Salary will be subject to normal periodic review, and such review will consider Executive's contributions to the Company and the Company's overall performance.

B. Bonus and Incentive Compensation. Executive shall be eligible for discretionary bonus and incentive based compensation approved by the Board of Directors of the Company (or a committee thereof) (the "Board") from time to time at its sole discretion as to eligibility and timing of payments.

C. Equity Award. Subject to approval by the Board (or a committee thereof), Executive shall be eligible to receive equity-based compensation awards from time to time as determined by the Board pursuant to the DiaMedica Therapeutics Inc. Stock Option Plan, or any successor plan thereto (such plan, the "Plan"). The type of equity award(s), grant timing and vesting terms will be in the sole discretion of the Board (or a committee thereof).

D. Benefits. During Executive's employment, Executive will be eligible to participate in the Company's benefit programs, as governed by the terms of the official plan documents. Executive acknowledges that the Company may amend or terminate any of its benefit plans or programs at any time and for any reason. Executive will be eligible for paid time off or PTO per year, in accordance with the Company's policies in effect from time to time.

E. Clawback. Executive agrees that any incentive or other compensation or benefits provided by the Company under this Agreement or otherwise will be subject to recoupment or clawback by the Company under any applicable clawback or recoupment policy of the Company as may be in effect from time to time or as required by applicable law, regulation or stock exchange listing requirement.

3. CONFIDENTIAL INFORMATION.

A. Non-Disclosure, Non-Use and Definition of Confidential Information. Executive understands that during Executive's employment relationship with the Company, the Company intends to provide Executive with information, including Confidential Information (as defined herein), without which Executive would not be able to perform Executive's duties to the Company. Executive agrees, at all times during the term of Executive's employment relationship and thereafter, to hold in strictest confidence, and not to use or disclose, except for the benefit of the Company to the extent necessary to perform Executive's obligations to the Company, any Confidential Information that Executive obtains, accesses or creates during the term of the relationship, whether or not during working hours, until such Confidential Information becomes publicly and widely known and made generally available through no wrongful act of Executive or of others under confidentiality obligations as to the information involved. Executive understands that "Confidential Information" means information and physical material not generally known or available outside the Company and information and physical material entrusted to the Company by third parties under an obligation of non-disclosure or non-use or both. "Confidential Information" includes, without limitation, inventions, technical data, trade secrets, know-how, clinical data, regulatory information and strategies, marketing ideas or plans, research, product or service ideas or plans, business strategies, investments, investment opportunities, potential investments, market studies, industry studies, historical financial data, financial information and results, budgets, identity of customers, forecasts (financial or otherwise), possible or pending transactions, customer lists and domain names, price lists, and pricing methodologies. Any information that Executive knows or should reasonably know is Confidential Information, or that Employer treats as Confidential Information, will be presumed to be Confidential Information.

B. Exceptions. At all times, both during Executive's employment and after its termination, Executive will keep and hold all such Confidential Information in strict confidence and trust. Executive will not use or disclose any Confidential Information without the prior written consent of the Company, except as may be necessary to perform Executive's duties as an Executive of the Company for the benefit of the Company. Executive may disclose information that Executive is required to disclose by valid order of a government agency or court of competent jurisdiction, provided that Executive will:

1. Notify the Company in writing immediately upon learning that such an order may be sought or issued,
2. Cooperate with the Company as reasonably requested if the Company seeks to contest such order or to place protective restrictions on the disclosure pursuant to such order, and
3. Comply with any protective restrictions in such order and disclose only the information specified in the order.

C . Return of Confidential Information. Upon termination of employment with the Company, Executive will promptly deliver to the Company all documents and materials of any nature pertaining to Executive's work with the Company.

D . Copyright Information. Executive agrees not to infringe the copyrights of the Company, its customers or third parties (including, without limitation, Executive's previous employers, customers, etc.) by unauthorized or unlawful copying, modifying or distributing of copyrighted material, including plans, drawings, reports, financial analyses, market studies, computer software and the like.

4. COVENANT NOT TO COMPETE.

A. Non-Competition Covenant. Executive agrees that during the Restricted Period (as defined below), without the prior written consent of the Company, Executive shall not, directly or indirectly within the Territory (as defined below): (i) personally, by agency, as an Executive, independent contractor, consultant, officer, director, manager, agent, associate, investor (other than as a passive investor holding less than five percent (5%) of the outstanding equity of an entity), or by any other artifice or device, engage in any Competitive Business (as defined below), (ii) assist others, including but not limited to Executives of the Company, to engage in any Competitive Business, or (iii) own, purchase, finance or organize a Competitive Business.

B. Definitions.

1. "Competitive Business" means (i) any person, entity or organization which is engaged in, consulting regarding or engaged in the development, production, marketing or selling of any pharmaceutical-based product, process, technology, invention or service which resembles, competes with or is intended to resemble or compete with a product, process, technology, device, invention or service under or being considered for research or development or being promoted, marketed, sold or serviced by the Company or any subsidiary; or (ii) any other line of business that the Company or any subsidiary, is actively preparing to pursue at any time during the term of Executive's employment with the Company and in which Executive is involved.

2. "Territory" means the United States of America or locations where the Company is directly or indirectly developing or selling products or services.

3. "Restricted Period" means the period of Executive's employment with the Company and for a period of twelve (12) months following the termination of Executive's employment.

5. NON-SOLICITATION AND NON-INTERFERENCE COVENANTS.

A. Non-Solicitation of Employees and Others. During the Restricted Period, (i) Executive shall not, directly or indirectly, solicit, recruit, or induce, or attempt to solicit, recruit or induce any employee, consultant, independent contractor, vendor, supplier, or agent to terminate or otherwise adversely affect his or her employment or other business relationship (or prospective employment or business relationship) with the Company, and (ii) Executive shall not, directly or indirectly, solicit, recruit, or induce, or attempt to solicit, recruit or induce any employee to work for Executive or any other person or entity, other than the Company or its affiliates or related entities.

B. Non-Solicitation of Customers. During the Restricted Period, Executive shall not, directly or indirectly, solicit, recruit, or induce any Customer (as defined below) for the purpose of (i) providing any goods or services related to a Competitive Business, or (ii) interfering with or otherwise adversely affecting the contracts or relationships, or prospective contracts or relationships, between the Company (including any related or affiliated entities) and such Customers. "Customer" means a person or entity with which Executive had contact or about whom Executive gained information while an employee of the Company, and to which the Company was selling or providing products or services, was in active negotiations for the sale of its products or services, or was otherwise doing business as of the date of the cessation of Executive's employment with the Company or for whom the Company had otherwise done business within the twelve (12) month period immediately preceding the cessation of Executive's employment with the Company.

6. ACKNOWLEDGEMENTS. EXECUTIVE ACKNOWLEDGES AND AGREES THAT:

A. The geographic and duration restrictions contained in Sections 4 and 5 of this Agreement are fair, reasonable, and necessary to protect the Company's legitimate business interests and trade secrets, given the geographic scope of the Company's business operations, the competitive nature of the Company's business, and the nature of Executive's position with the Company;

B. Executive's employment creates a relationship of confidence and trust between Executive and the Company with respect to the Confidential Information, and Executive will have access to Confidential Information (including but not limited to trade secrets) that would be valuable or useful to the Company's competitors;

C. The Company's Confidential Information is a valuable asset of the Company, and any violation of the restrictions set forth in this Agreement would cause substantial injury to the Company;

D. The restrictions contained in this Agreement will not unreasonably impair or infringe upon Executive's right to work or earn a living after Executive's employment with the Company ends; and

E. This Agreement is a contract for the protection of trade secrets under applicable law and is intended to protect the Confidential Information (including trade secrets) identified above.

7. "BLUE PENCIL" AND SEVERABILITY PROVISION.

If a court of competent jurisdiction declares any provision of this Agreement invalid, void, voidable, or unenforceable, the court shall reform such provision(s) to render the provision(s) enforceable, but only to the extent absolutely necessary to render the provision(s) enforceable and only in view of the parties' express desire that the Company be protected to the greatest possible extent under applicable law from improper competition and the misuse or disclosure of trade secrets and Confidential Information. To the extent such a provision (or portion thereof) may not be reformed so as to make it enforceable, it may be severed and the remaining provisions shall remain fully enforceable.

8. INVENTIONS.

A. Inventions Retained and Licensed. Executive acknowledges and agrees that Executive has no rights in any Inventions (as that term is defined below) other than inventions and information created, discovered or developed by Executive, whether or not patentable or registrable under patent, copyright or similar statutes, made or conceived or reduced to practice or learned by Executive, either alone or with others before Executive's employment with the Company, which list of inventions Executive has provided the Company in writing on or prior to the Effective Date ("Prior Inventions"). Executive shall not incorporate, or permit to be incorporated, any Prior Invention owned by Executive or in which he has an interest in a Company product, process or machine without the Company's prior written consent. Notwithstanding the foregoing, if, in the course of Executive's employment with the Company, Executive directly or indirectly incorporates into a Company product, process or machine a Prior Invention owned by Executive or in which Executive has an interest, the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, world-wide license to make, have made, modify, use, create derivative works from and sell such Prior Invention as part of or in connection with such product, process or machine.

B. Assignment of Inventions. Executive shall promptly make full, written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and hereby irrevocably transfers and assigns, and agrees to transfer and assign, to the Company, or its designee, all Executive's right, title and interest in and to any and all inventions, original works of authorship, developments, concepts, improvements, designs, discoveries, ideas, trademarks (and all associated goodwill), mask works, or trade secrets, whether or not they may be patented or registered under copyright or similar laws, which Executive may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, during Executive's employment by the Company (the "Inventions"). Executive further acknowledges that all original works of authorship which are made by Executive (solely or jointly with others) within the scope of and during the period of Executive's employment with the Company and which may be protected by copyright are "Works Made For Hire" as that term is defined by the United States Copyright Act. Executive understands and agrees that the decision whether to commercialize or market any Invention developed by Executive solely or jointly with others is within the Company's sole discretion and the Company's sole benefit and that no royalty will be due to Executive as a result of the Company's efforts to commercialize or market any such invention.

Executive recognizes that Inventions relating to Executive's activities while working for the Company and conceived or made by Executive, whether alone or with others, within one (1) year after cessation of Executive's employment, may have been conceived in significant part while employed by the Company. Accordingly, Executive acknowledges and agrees that such Inventions shall be presumed to have been conceived during Executive's employment with the Company and are to be, and hereby are, assigned to the Company unless and until Executive has established the contrary.

The requirements of this Section 8B do not apply to any intellectual property for which no equipment, supplies, facility or trade secret information of the Company was used, and which was developed entirely on the Executive's own time, and (i) which does not relate (x) directly to the Company's business or (y) to the Company's actual or demonstrably anticipated research and development or (ii) which does not result from any work the Executive performed for the Company.

C . Maintenance of Records. Executive agrees to keep and maintain adequate and current written records of all Inventions made by Executive (solely or jointly with others) during Executive's employment with the Company. The records will be in the form of notes, sketches, drawings and any other format that may be specified by the Company. The records will be available to and remain the sole property of the Company at all times.

D . Patent, Trademark and Copyright Registrations. Executive agrees to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in the Inventions and any copyrights, patents, trademarks, service marks, mask works, or any other intellectual property rights in any and all countries relating thereto, including, but not limited to, the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments the Company reasonably deems necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title, and interest in and to such inventions, and any copyrights, patents, trademarks, service marks, mask works, or any other intellectual property rights relating thereto. Executive further agrees that Executive's obligation to execute or cause to be executed, when it is in Executive's power to do so, any such instrument or paper shall continue after termination or expiration of this Agreement or the cessation of Executive's employment with the Company. If the Company is unable because of Executive's mental or physical incapacity or for any other reason, after reasonably diligent efforts, to secure Executive's signature to apply for or to pursue any application for any United States or foreign patents, trademarks or copyright registrations covering inventions or original works of authorship assigned to the Company as above, then Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agent and attorney-in-fact to act for and in Executive's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent, trademarks or copyright registrations thereon with the same legal force and effect as if executed by Executive; this power of attorney shall be a durable power of attorney which shall come into existence upon Executive's mental or physical incapacity.

9. SURVIVAL AND REMEDIES.

Executive's obligations of nondisclosure, non-solicitation, non-interference, and non-competition under this Agreement shall survive the cessation of Executive's employment with the Company and shall remain enforceable. In addition, Executive acknowledges that upon a breach or threatened breach of any obligation of nondisclosure, non-solicitation, non-interference, or non-competition of this Agreement, the Company may suffer irreparable harm and damage for which money alone cannot fully compensate the Company. Executive therefore agrees that upon such breach or threat of imminent breach of any such obligation, the Company shall be entitled to seek a temporary restraining order, preliminary injunction, permanent injunction or other injunctive relief, without posting any bond or other security, barring Executive from violating any such provision. This Section 9 shall not be construed as an election of any remedy, or as a waiver of any right available to the Company under this Agreement or the law, including the right to seek damages from Executive for a breach of any provision of this Agreement and the right to require Executive to account for and pay over to the Company all profits or other benefits derived or received by Executive as the result of such a breach, nor shall this Section 9 be construed to limit the rights or remedies available under state law for any violation of any provision of this Agreement.

10. TERMINATION.

A. Termination By Either Party. Either Party may terminate the Executive's at-will employment at any time with or without notice, and with or without cause. Except as provided in this Section 10, upon termination of employment, Executive shall only be entitled to Executive's accrued but unpaid Base Salary, any earned but unpaid bonus for the year prior to the date of termination, and other benefits earned under any Company-provided plans, policies and arrangements for the period preceding the effective date of the termination of employment. With respect to any earned but unpaid bonus for the year prior to the date of termination, the terms of which bonus plan require Executive to be an employee of the Company as of the date of payment, no payment will be made to Executive (or if applicable, the Executive's beneficiary) if Executive's employment with the Company terminates voluntarily by Executive, other than for Good Reason pursuant to Section 10C, or if Executive's employment with the Company is terminated by the Company for Cause, but will be paid if Executive's employment with the Company terminates due to Executive's death or disability.

B . Termination Without Cause. If the Company terminates Executive's employment without Cause (defined below), Executive shall be entitled to receive, in addition to the amounts due under Section 10A, as continuing severance pay at a rate equal to Executive's Base Salary, as then in effect, for nine (9) months from the date of termination of employment, plus a lump-sum payment equal to a pro rata portion of Executive's target annual bonus for the year in which the date of termination occurs (based on the date of termination), in each case, less all required tax withholdings and other applicable deductions, payable in accordance with the Company's standard payroll procedures, commencing on the effective date of a Separation Agreement and Release of claims against the Company and after the end of any applicable rescission or revocation period, and provided that Executive has not revoked or rescinded (or attempted to revoke or rescind) any claims under such Release, in substantially the form of Exhibit A attached hereto, the timely execution and performance by Executive of which is specifically a condition to Executive's receipt of any of the payments and benefits provided under this Section 10B; provided that (1) such Separation Agreement and Release shall be executed and be fully effective within sixty (60) days of the Executive's termination of employment; (2) the first payment shall include any amounts that would have been paid to Executive if payment had commenced on the date of termination of employment; and (3) Executive shall not be required to execute a release of any claims arising from the Company's failure to comply with its obligations under Section 10A. Subject to Executive's execution and non-revocation of the Separation Agreement and Release, if Executive timely and effectively elects continuation coverage under the Company's group health plan pursuant to COBRA or similar state law, the Company will pay or reimburse the premiums for such coverage of Executive (and Executive's dependents, as applicable) at the same rate it pays for active employees for a period for nine (9) months from the date of termination of employment; provided that the Company's obligation to make such payments shall immediately expire if Executive ceases to be eligible for continuation coverage under COBRA or similar state law or otherwise terminates such coverage. Notwithstanding the foregoing, any of the foregoing payments due under this Section 10B shall commence within seventy (70) days of Executive's termination of employment, provided that if such seventy (70)-day period spans two (2) calendar years, payments shall commence in the latter calendar year. In addition to the foregoing and subject to Executive's timely execution of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, Executive shall be entitled to the immediate vesting of all outstanding equity awards then held by Executive.

C . Termination Upon a Change in Control. If the Company or any successor in interest to the Company terminates Executive's employment without Cause in connection with or within twelve (12) months after a Change in Control (defined below) or if Executive terminates Executive's employment for Good Reason (defined below) within twelve (12) months after a Change in Control, Executive shall be entitled to receive, in addition to the amounts due under Section 10A, a lump-sum payment equal to twelve (12) months of Executive's Base Salary, as then in effect or as in effect immediately prior to a material reduction of Executive's Base Salary which was the reason Executive resigned for Good Reason, plus a lump-sum payment equal to a pro rata portion of Executive's target annual bonus for the year in which the date of termination occurs (based on the date of termination), in each case, less all tax withholdings and other applicable deductions the Company reasonably determines are required to be made, payable on the first regular payroll date after the effective date of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, in substantially the form of Exhibit A attached hereto, the execution and performance by Executive of which is specifically a condition to Executive's receipt of any of the payments and benefits provided under this Section 10C; provided that Executive shall not be required to execute a release of any claims arising from the Company's failure to comply with its obligations under Section 10A. Subject to Executive's execution and non-revocation of the Separation Agreement and Release, if Executive timely and effectively elects continuation coverage under the Company's group health plan pursuant to COBRA or similar state law, the Company will pay or reimburse the premiums for such coverage of Executive (and Executive's dependents, as applicable) at the same rate it pays for active employees for a period for twelve (12) months from the date of termination of employment; provided that the Company's obligation to make such payments shall immediately expire if Executive ceases to be eligible for continuation coverage under COBRA or similar state law or otherwise terminates such coverage. Notwithstanding the previous provisions of this Section 10C, any payments due under this Section 10C shall commence within seventy (70) days of Executive's termination of employment, provided that if such seventy (70)-day period spans two calendar years, payments shall commence in the latter calendar year. In addition to the foregoing and subject to Executive's timely execution of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, Executive shall be entitled to the immediate vesting of all outstanding equity awards then held by Executive. The payments and benefits described in this Section 10C are in lieu of, and not in addition to, the payments and benefits described in Section 10B, it being understood by Executive that he shall be paid and receive only one set of severance payments and benefits.

Notwithstanding any other provisions of this Agreement, if any “payments” (including, without limitation, any benefits or transfers of property or the acceleration of the vesting of any benefits) in the nature of compensation under any arrangement that is considered contingent on a “change in control” for purposes of Section 280G of the Internal Revenue Code of 1986, as amended (the “Code”), together with any other payments that Executive has the right to receive from the Company or any corporation that is a member of an “affiliated group” (as defined in Section 1504(a) of the Code without regard to Section 1504(b) of the Code) of which the Company is a member, would constitute a “parachute payment” (as defined in Section 280G(b)(2) of the Code), such “payments” may, at Executive’s sole election, be reduced to the largest amount as will result in no portion of such “payments” being subject to the excise tax imposed by Section 4999 of the Code. Any reduction of the payments shall be made in the following order: (1) options with an exercise price above the fair market value of the stock, provided the options give rise to a payment; (2) pro rata among amounts that constitute deferred compensation under Code Section 409A; and (3) reduction of any remaining payments in the manner determined at the discretion of Executive.

The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the change in control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within sixty (60) calendar days after the date on which Executive’s right to a payment is triggered and the payment will be paid to Executive within seventy-four (74) calendar days of the date on which Executive’s right to a payment is triggered. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

D . Termination for Cause, Death or Disability, or Resignation. If Executive’s employment with the Company terminates voluntarily by Executive, other than for Good Reason pursuant to Section 10C above, or if Executive’s employment with the Company is terminated by the Company for Cause or due to Executive’s death or disability, then payments of compensation by the Company to Executive hereunder will terminate immediately, except that Executive (or the Executive’s beneficiary if Executive’s termination is on account of death) will be entitled to the amounts due under Section 10A.

E. Definitions.

1. “Cause.” For all purposes under this Agreement, “Cause” is defined as (a) gross negligence or willful failure to perform Executive’s duties and responsibilities to the Company; (b) commission of any act of fraud, theft, embezzlement, financial dishonesty or any other willful misconduct that has caused or is reasonably expected to result in injury to the Company; (c) conviction of, or pleading guilty or *nolo contendere* to, any felony or a lesser crime involving dishonesty or moral turpitude; (d) material breach by Executive of any of Executive’s obligations under this Agreement or any written agreement or covenant with the Company, including the policies adopted from time to time by the Company applicable to all Executives, that has not been cured within thirty (30) days of notice of such breach or (e) the Company terminates the employment of Executive in connection with a liquidation, dissolution or winding down of the Company.

2. “Good Reason.” For all purposes under this Agreement, “Good Reason” is defined as Executive’s resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive’s express written consent: (a) a material reduction of Executive’s duties, authority, reporting level, or responsibilities, relative to Executive’s duties, authority, reporting level, or responsibilities in effect immediately prior to such Change in Control; (b) a material reduction in Executive’s base compensation; or (c) the Company’s requiring of Executive to change the principal location at which Executive is to perform Executive’s services by more than fifty (50) miles. Executive will not resign for Good Reason without first providing the Company with written notice within thirty (30) days of the initial occurrence of the event that Executive believes constitutes “Good Reason” specifically identifying the acts or omissions constituting the grounds for Good Reason and providing Company a reasonable cure period of not less than thirty (30) days following the date of such notice and during which such condition has not been cured.

3. “Change in Control.” For all purposes under this Agreement, a “Change in Control” will mean the occurrence of any of the following:

a. the acquisition, other than from the Company or Parent (as defined below), by any individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (“Exchange Act”)) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding common shares, no par value (“Common Shares”), of DiaMedica Therapeutics Inc., a company organized under the laws of Canada (“Parent”), or the combined voting power of the then outstanding voting securities of Parent entitled to vote generally in the election of directors, but excluding, for this purpose, any such acquisition by Parent or any of its subsidiaries, or any employee benefit plan (or related trust) of Parent or its subsidiaries, or any entity with respect to which, following such acquisition, more than fifty percent (50%) of, respectively, the then outstanding equity of such entity and the combined voting power of the then outstanding voting equity of such entity entitled to vote generally in the election of all or substantially all of the members of such entity’s governing body is then beneficially owned, directly or indirectly, by the individuals and entities who were the beneficial owners, respectively, of the Common Shares and voting securities of Parent immediately prior to such acquisition in substantially the same proportion as their ownership, immediately prior to such acquisition, of the then outstanding Common Shares or the combined voting power of the then outstanding voting securities of Parent entitled to vote generally in the election of directors, as the case may be; or

b. the consummation of a reorganization, merger or consolidation of Parent, in each case, with respect to which all or substantially all of the individuals and entities who were the respective beneficial owners of the Common Shares and voting securities of Parent immediately prior to such reorganization, merger or consolidation do not, following such reorganization, merger or consolidation, beneficially own, directly or indirectly, more than fifty percent (50%) of, respectively, the then outstanding Common Shares and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the corporation resulting from such reorganization, merger or consolidation; or

c. the sale or other disposition of all or substantially all of the assets of Parent; provided the occurrence under (a), (b) or (c), constitutes a “change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portions of the assets of a corporation” under Section 409A of the Code.

F. No Other Benefits. In the event of a termination of Executive’s employment with the Company, the provisions of this Section 10 are Executive’s exclusive right to severance benefits and are in lieu of participation in any other severance policy or plan to which Executive might otherwise be entitled.

G. Termination from any Offices Held. Upon Executive’s termination of employment with the Company, Executive agrees that any and all offices held with Parent or any subsidiary, including the Company, if applicable, shall be automatically terminated. Executive agrees to cooperate with the Company and execute any documents reasonably required by the Company or competent authorities to effect this provision.

H. Return of Company Property. All devices, records, reports, data, notes, compilations, lists, proposals, correspondence, specifications, equipment, drawings, blueprints, manuals, planners, calendars, schedules, discs, financial plans and information, or other recorded matter, whether in hard copy, electronic media or otherwise (including all copies or reproductions made or maintained, whether on the Company’s premises or otherwise), pertaining to Executive’s work for the Company, or relating to the Company or the Company’s Confidential Information, whether created or developed by Executive alone or jointly during Executive’s employment with the Company, are the exclusive property of the Company. Executive shall surrender the same (as well as any other property of the Company) to the Company upon its request or promptly upon the cessation of employment.

11. NO CONFLICTING AGREEMENTS OR IMPROPER USE OF THIRD-PARTY INFORMATION.

During Executive's employment with the Company, Executive shall not improperly use or disclose any Confidential information or trade secrets of any former employer or other person or entity, and Executive shall not bring on to the premises of the Company any unpublished document or Confidential information belonging to any such former employer, person or entity, unless consented to in writing by the former employer, person or entity. Executive represents that he has not improperly used or disclosed any Confidential information or trade secrets of any other person or entity during the application process or while employed or affiliated with the Company. Executive also acknowledges and agrees that he is not subject to any contract, agreement, or understanding that would prevent Executive from performing Executive's duties for the Company or otherwise complying with this Agreement. To the extent Executive violates this provision, or Executive's employment with the Company constitutes a breach or threatened breach of any contract, agreement, or obligation to any third party, Executive shall indemnify and hold the Company harmless from all damages, expenses, costs (including reasonable attorneys' fees) and liabilities incurred in connection with, or resulting from, any such violation or threatened violation.

12. GENERAL PROVISIONS.

A . Governing Law; Consent To Personal Jurisdiction. The laws of the State of Minnesota shall govern the Executive's employment and this Agreement without regard to conflict of laws principles. Executive and the Company each hereby consents to the personal jurisdiction of the state courts located in Hennepin County, State of Minnesota, and the federal district court sitting in Hennepin County, State of Minnesota, if that court otherwise possesses jurisdiction over the matter, for any legal proceeding concerning Executive's employment or termination of employment, or arising from or related to this Agreement or any other agreement executed between Executive and the Company.

B . Entire Agreement. This Agreement, together with the Exhibits hereto, sets forth this entire Agreement between the Company (and any of its related or affiliated entities, officers, agents, owners or representatives) and Executive relating to the subject matter herein, and supersedes any and all prior discussions and agreements, whether written or oral, on the subject matter hereof, including without limitation that certain offer letter agreement dated as of January 2, 2018. To the extent that this Agreement may conflict with the terms of another written agreement between Executive and the Company, the terms of this Agreement will control.

C . Modification. No modification of or amendment to this Agreement will be effective unless in writing and signed by Executive and an authorized representative of the Company.

D . Waiver. The Company's failure to enforce any provision of this Agreement shall not act as a waiver of its ability to enforce that provision or any other provision. The Company's failure to enforce any breach of this Agreement shall not act as a waiver of that breach or any future breach. No waiver of any of the Company's rights under this Agreement will be effective unless in writing. Any such written waiver shall not be deemed a continuing waiver unless specifically stated, and shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

E. Successors and Assigns. This Agreement shall be assignable to, and shall inure to the benefit of and bind, the Company's, affiliates, subsidiaries, successors and assigns. Executive shall not have the right to assign Executive's rights or obligations under this Agreement.

F. Construction. The language used in this Agreement will be deemed to be language chosen by Executive and the Company to express their mutual intent, and no rules of strict construction will be applied against either Party.

G. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable, and all of which together shall constitute one agreement. Signatures of the parties that are transmitted in person or by facsimile or e-mail shall be accepted as originals.

H. Further Assurances. Executive agrees to execute any proper oath or verify any document required to carry out the terms of this Agreement.

I. Title and Headings. The titles, captions and headings of this Agreement are included for ease of reference only and will be disregarded in interpreting or construing this Agreement.

J. Notices. All notices and communications that are required or permitted to be given under this Agreement shall be in writing and shall be sufficient in all respects if given and delivered in person, by electronic mail, by facsimile, by overnight courier, or by certified mail, postage prepaid, return receipt requested, to the receiving Party at such Party's address shown in the signature blocks below or to such other address as such Party may have given to the other by notice pursuant to this Section. Notice shall be deemed given (i) on the date of delivery in the case of personal delivery, electronic mail or facsimile, or (ii) on the delivery or refusal date as specified on the return receipt in the case of certified mail or on the tracking report in the case of overnight courier.

K. Code Section 409A. The amounts payable under this Agreement are intended to be exempt from the requirements of Section 409A of the Code ("Section 409A"). For purposes of Section 409A, any right to a series of installment payments is to be treated as a right to a series of separate payments. Any payments due under this Agreement on account of a termination of employment shall only be payable if the termination constitutes a "separation from service" within the meaning of Section 409A. To the extent that any such payments are determined to be deferred compensation subject to Section 409A, (i) the terms of this Agreement shall be interpreted to avoid incurring any penalties under Section 409A, and (ii) any payments due to a "specified Executive" of a publicly-traded company upon a separation from service shall be delayed until the first day of the seventh month following such separation from service. Notwithstanding the foregoing, in no event shall the Company be responsible for any taxes or penalties due under Section 409A.

13. EXECUTIVE'S ACKNOWLEDGMENTS.

Executive acknowledges that he is executing this Agreement voluntarily and without duress or undue influence by the Company or anyone else and that Executive has carefully read this Agreement and fully understands the terms, consequences, and binding effect of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, and intending to be legally bound, the Parties have executed this Employment Agreement as of the date first written above.

EXECUTIVE

DIAMEDICA USA, INC.

/s/ Scott Kellen
Scott Kellen

Date: 9/14/2018
Address: 2 Carlson Parkway, Suite 260
Minneapolis, MN 55447

Print Name: Rick Pauls

Signature: /s/ Rick Pauls
Title: President & CEO
Date: 9/14/2018

EXHIBIT A

FORM OF SEPARATION AGREEMENT AND RELEASE

This Separation Agreement ("Agreement") and the Release, which is attached and incorporated by reference as Exhibit A ("Release"), are made by and between Scott Kellen ("Executive"), and DiaMedica USA, Inc., its affiliates, related or predecessor corporations, parent, subsidiaries, successors and assigns ("Employer").

Employer and Executive (collectively, "Parties") wish to end their employment relationship in an honorable, dignified and orderly fashion. Toward that end, the Parties have agreed to separate according to the following terms.

IN CONSIDERATION OF THIS AGREEMENT, THE PARTIES AGREE AS FOLLOWS:

1. Termination. Executive's employment shall end on a date and time Employer shall determine ("Termination Date").
2. Consideration. Employer shall, (1) after receipt of a fully executed Agreement and Release; (2) after expiration of all applicable rescission periods; and (3) provided Executive complies with Executive's obligations under this Agreement, provide Executive with separation benefits ("Consideration") in compliance with Executive's Employment Agreement attached as Exhibit B:
3. Termination of Benefits. Except as otherwise provided by this Agreement, Executive's participation in Employer's employee benefits, bonus, and all other compensation or commission plans, will terminate on the Termination Date, unless otherwise provided by law, or benefit plan. Executive shall receive no compensation or benefits under such plans, except as specifically provided in Section 2 of this Agreement.
4. Execution of Agreement and Release of all Claims. Executive agrees to fully execute this Agreement, and the Release attached as Exhibit A, releasing any and all actual or potential claims which may have arisen at any time during Executive's employment with or termination from employment with Employer. Executive's failure to execute this Agreement and/or Release, or any attempt to rescind this Agreement or that Release, shall terminate this Agreement, and the Parties' respective rights and obligations under this Agreement.
5. Satisfactory Performance and Cooperation During Transition. Executive shall fully cooperate with Employer in responding to questions, providing assistance and information, and defending against claims of any type, and will otherwise assist Employer as Employer may request through Executive's Termination Date ("Transition Period"). More specifically:
 - a. During the Transition Period, Executive shall reasonably cooperate with Employer as it meets and otherwise communicates/works, with Employer's employees, customers, strategic relationships, consultants, and vendors on the transition of Executive's duties to other individuals. Executive shall be available, upon reasonable notice, during business hours to respond to Employer's questions and electronic communications. Employer shall reimburse Executive for Executive's reasonable out-of-pocket expenses (such reimbursement shall not include compensation for any such time or Executive's attorney's fees) incurred in accordance with this Section upon submission of receipts to Employer for such expenses.

b. Executive shall not, absent Employer's specific approval, initiate any form of communication with Employer's employees, customers or strategic partners regarding Employer, Employer's products or employees, and shall communicate with such persons in the above capacity only in conjunction with person(s) who Employer has designated to participate in such communications.

6 . Stipulation of No Charges. Executive affirmatively represents that Executive has not filed nor caused to be filed any charges, claims, complaints, or actions against Employer before any federal, state, or local administrative agency, court, or other forum. Except as expressly provided in this Agreement or required by law, Executive acknowledges and agrees that Executive has been paid all wages, bonuses, compensation, benefits and other amounts that are due, with the exception of any vested right under the terms of a written ERISA-qualified benefit plan. Executive waives any right to any form of recovery or compensation from any legal action, excluding any action claiming this Agreement and Release violate the Age Discrimination in Employment Act ("ADEA") and/or the Older Workers Benefit Protection Act ("OWBPA"), filed or threatened to be filed by Executive or on Executive's behalf based on Executive's employment, terms of employment, or separation from, Employer. Executive understands that any Consideration paid to Executive pursuant to this Agreement may be deducted from any monetary award Executive may receive as a result of a successful ADEA and/or OWBPA claim or challenge to this Agreement and Release. This does not preclude Executive from eligibility for unemployment benefits, and does not preclude or obstruct Executive's right to file a Charge with the Equal Employment Opportunity Commission ("EEOC").

7 . Return of Property. Executive shall return, on or before the Termination Date, all Employer property in Executive's possession or control, including but not limited to any drawings, orders, files, documents, notes, computers, laptop computers, fax machines, cell phones, smart devices, access cards, fobs, keys, reports, manuals, records, product samples, correspondence and/or other documents or materials related to Employer's business that Executive has compiled, generated or received while working for Employer, including all electronically stored information, copies, samples, computer data, disks, or records of such materials. Executive must return to Employer, and Executive shall not retain, any Employer property as previously defined in this section.

8 . Agreement Not to Seek Future Employment. Executive agrees that Executive will never knowingly seek nor accept employment or a consulting/independent contractor relationship with Employer, nor any other entity owned by Employer, either directly or through a consulting firm.

9. Withholding for Amounts Owed to Employer. Execution of this Agreement shall constitute Executive's authorization for Employer to make deductions from Executive's Consideration, for Executive's indebtedness to Employer, or to repay Employer for unaccrued vacation or other Paid Time Off already taken, Executive purchases, wage or benefit overpayment, or other Employer claims against Executive, to the extent permitted by applicable law.

10. Non-Disparagement. Executive agrees that, unless it is in the context of an EEOC or other civil rights or other government enforcement agency investigation or proceeding, Executive will make no critical, disparaging or defamatory comments regarding Employer or any Released Party, as defined in the Release, in any respect or make any comments concerning the conduct or events which precipitated Executive's separation. Furthermore, Executive agrees not to assist or encourage in any way any individual or group of individuals to bring or pursue a lawsuit, charge, complaint, or grievance, or make any other demands against Employer or any Released Party. This provision does not prohibit Executive from participating in an EEOC or other civil rights or other government enforcement agency charge, investigation or proceeding, or from providing testimony or documents pursuant to a lawful subpoena or as otherwise required by law.

11. Compliance with Employment Agreement and Protection of Confidential Information. Executive agrees to comply with the provisions of and the restrictions set forth in Executive's Employment Agreement (Exhibit B), including without limitation the obligation not to use or disclose Confidential Information (as defined in the Employment Agreement).

12. Confidentiality. It is the intent of Employer and Executive that the terms of this Agreement be treated as Confidential Information (as defined in the Employment Agreement), except to the extent this Agreement is required to be disclosed under applicable federal securities laws, as determined by Employer. Executive warrants that Executive has not and agrees that Executive will not in the future disclose the terms of this Agreement, or the terms of the Consideration to be paid by Employer to Executive as part of this Agreement, to any person other than Executive's attorney, tax advisor, spouse, or representatives of any state or federal regulatory agency, who shall be bound by the same prohibitions against disclosure as bind Executive, and Executive shall be responsible for advising those individuals or agencies of this confidentiality provision. Executive shall not provide or allow to be provided to any person this Agreement, or any copies thereof, nor shall Executive now or in the future disclose the terms of this Agreement to any person, with the sole exception of communications with Executive's spouse, attorney and tax advisor, unless otherwise ordered to do so by a court or agency of competent jurisdiction.

13. Invalidity. In case any one or more of the provisions of this Agreement or Release shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Agreement and Release will not in any way be affected or impaired thereby.

14. Non-Admissions. The Parties expressly deny any and all liability or wrongdoing and agree that nothing in this Agreement or the Release shall be deemed to represent any concession or admission of such liability or wrongdoing or any waiver of any defense.

15. Governing Law. The laws of the State of Minnesota shall govern this Agreement without regard to conflict of laws principles. The Parties each hereby consent to the personal jurisdiction of the state courts located in Hennepin County, State of Minnesota, and the federal district court sitting in Hennepin County, State of Minnesota, if that court otherwise possesses jurisdiction over the matter, for any legal proceeding concerning or related to this Agreement.

16. Voluntary and Knowing Action. Executive acknowledges that Executive has had sufficient opportunity to review the terms of this Agreement and attached Release, and that Executive has voluntarily and knowingly entered into this Agreement. Employer shall not be obligated to provide any Consideration to Executive pursuant to this Agreement in the event Executive elects to rescind/revoke the Release. The Release becomes final and binding on the Parties upon expiration of the rescission/revocation period, provided Executive has not exercised Executive's option to rescind/revoke the Release. Any attempt by Executive to rescind any part of the Release obligates Executive to immediately return all Consideration under this Agreement to counsel for Employer.

17. Legal Counsel and Fees. Except as otherwise provided in this Agreement and the Release, the Parties agree to bear their own costs and attorneys' fees, if any. Executive acknowledges that Employer, by this Agreement, has advised him that Executive may consult with an attorney of Executive's choice prior to executing this Agreement and the Release. Executive acknowledges that Executive has had the opportunity to be represented by legal counsel during the negotiation and execution of this Agreement and the Release, and that Executive understands Executive will be fully bound by this Agreement and the Release.

18. Modification. This Agreement may be modified or amended only by a writing signed by both Employer and Executive.

19. Successors and Assigns. This Agreement is binding on and inures to the benefit of the Parties' respective successors and assigns.

20. Notices. All notices and communications that are required or permitted to be given under this Agreement shall be in writing and shall be sufficient in all respects if given and delivered in person, by electronic mail, by facsimile, by overnight courier, or by certified mail, postage prepaid, return receipt requested, to the receiving Party at such Party's address below or to such other address as such Party may have given to the other by notice pursuant to this Section. Notice shall be deemed given (i) on the date of delivery in the case of personal delivery, electronic mail or facsimile, or (ii) on the delivery or refusal date as specified on the return receipt in the case of certified mail or on the tracking report in the case of overnight courier.

If to Employer: DIAMEDICA USA, INC.
Attention: Chief Executive Officer
Two Carlson Parkway, Suite 260
Minneapolis, MN 55447

With a copy to: Amy E. Culbert
Fox Rothschild LLP
Campbell Mithun Tower - Suite 2000
222 South Ninth Street
Minneapolis, MN 55402-3338

If to Executive: Scott Kellen

21. Waivers. No failure or delay by either Party in exercising any right or remedy under this Agreement will waive any provision of this Agreement.

22. Miscellaneous. This Agreement may be executed simultaneously in counterparts, each of which shall be an original, but all of which shall constitute but one and the same agreement.

23. Entire Agreement. Except for any continuing, post-employment, obligations under Exhibit B, or employment related Employer policy, or as otherwise provided in this Agreement, this Agreement, the attached Release, and Exhibit B are the entire Agreement between Employer and Executive relating to Executive's employment and separation. Executive understands that this Agreement and the Release cannot be changed unless it is done in writing and signed by both Employer and Executive.

[Remainder of page intentionally left blank]

EXECUTIVE

Scott Kellen

Dated: _____, 20____

DIAMEDICA USA, INC.

By: _____

Its: _____

Dated: _____, 20____

RELEASE

- I. Definitions. I, Scott Kellen, intend all words used in this release ("Release") to have their plain meanings in ordinary English. Technical legal words are not needed to describe what I mean. Specific terms I use in this Release have the following meanings:
- A. "I" "Me," and "My" individually and collectively mean Scott Kellen and anyone who has or obtains or asserts any legal rights or claims through Me or on My behalf.
- B. "Employer" as used in this Release, shall at all times mean DiaMedica USA, Inc. and any affiliates, related or predecessor corporations, parent corporations or subsidiaries, successors and assigns.
- C. "Released Party" or "Released Parties" as used in this Release, shall at all times mean DiaMedica USA, Inc. and its affiliates, related or predecessor corporations, parent corporations, subsidiaries, successors and assigns, present or former officers, directors, shareholders, agents, employees, representatives and attorneys, whether in their individual or official capacities, and its affiliates, related or predecessor corporations, parent corporations or subsidiaries, successors and assigns, present or former officers, directors, shareholders, agents, employees, representatives and attorneys, whether in their individual or official capacities, benefit plans and plan administrators, and insurers, insurers' counsel, whether in their individual or official capacities, and the current and former trustees or administrators of any pension, 401(k), or other benefit plan applicable to the employees or former employees of Employer, in their official and individual capacities.
- D. "My Claims" mean any and all of the actual or potential claims of any kind whatsoever I may have had, or currently may have against Employer or any Released Party, whether known or unknown, that are in any way related to My employment with or separation from employment with Employer, including, but not limited to any claims for: invasion of privacy; breach of written or oral, express or implied, contract; fraud; misrepresentation; violation of the Age Discrimination in Employment Act of 1967 ("ADEA"), 29 U.S.C. § 626, as amended; the Genetic Information Nondiscrimination Act of 2008 ("GINA"), 42 U.S.C. § 2000, et seq., the Older Workers Benefit Protection Act of 1990 ("OWBPA"), 29 U.S.C. § 626(f), Title VII of the Civil Rights Act of 1964 ("Title VII"), 42 U.S.C. § 2000e, et seq., the Americans with Disabilities Act ("ADA"), 29 U.S.C. § 2101, et seq., and as amended ("ADAAA"), the Executive Retirement Income Security Act of 1974 ("ERISA"), as amended, 29 U.S.C. § 1001, et seq., Equal Pay Act ("EPA"), 29 U.S.C. § 206(d), the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101, et seq., the Family and Medical Leave Act ("FMLA"), 29 U.S.C. § 2601, et seq.; National Labor Relations Act, 29 U.S.C. § 141, et seq., the False Claims Act, 31 U.S.C. § 3729, et seq., Anti-Kickback Statute, 42 U.S.C. § 1320a, et seq., the Minnesota Human Rights Act, Minn. Stat. § 363A.01, et seq., Minn. Stat. § 181, et seq., the Minnesota Whistleblower Act, Minn. Stat. § 181.931, et seq., or any and all other Minnesota, and other state human rights or fair employment practices statutes, administrative regulations, or local ordinances, and any other Minnesota or other federal, state, local or foreign statute, law, rule, regulation, ordinance or order, all as amended. This includes, but is not limited to, claims for violation of any civil rights laws based on protected class status; claims for assault, battery, defamation, intentional or negligent infliction of emotional distress, breach of the covenant of good faith and fair dealing; promissory estoppel; negligence; negligent hiring; retention or supervision; retaliation; constructive discharge; violation of whistleblower protection laws; unjust enrichment; violation of public policy; and, all other claims for unlawful employment practices, and all other common law or statutory claims.

 EXECUTIVE INITIALS

- II. Agreement to Release My Claims. Except as stated in Section V of this Release, I agree to release all My Claims and waive any rights to My Claims. I also agree to withdraw any and all of My charges and lawsuits against Employer; *except that* I may, but am not required to, withdraw or dismiss, or attempt to withdraw or dismiss, any charges that I may have pending against Employer with the Employment Opportunity Commission (“EEOC”) or other civil rights enforcement agency. In exchange for My agreement to release My Claims, I am receiving satisfactory Consideration from Employer to which I am not otherwise entitled by law, contract, or under any Employer policy. The Consideration I am receiving is a full and fair consideration for the release of all My Claims. Employer does not owe Me anything in addition to what I will be receiving according to the Separation Agreement which I have signed.
- III. Unknown Claims. In waiving and releasing any and all actual, potential, or threatened claims against Employer, whether or not now known to me, I understand that this means that if I later discover facts different from or in addition to those facts currently known by me, or believed by me to be true, the waivers and releases of this Release will remain effective in all respects – despite such different or additional facts and my later discovery of such facts, even if I would not have agreed to the Separation Agreement and this Release if I had prior knowledge of such facts.
- IV. Confirmation of No Claims, Etc. I am not aware of any other facts, evidence, allegations, claims, liabilities, or demands relating to alleged or potential violations of law that may give rise to any claim or liability on the part of any Released Party under the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the False Claims Act, the Anti-kickback Statute. I understand that nothing in this Release interferes with My right to file a complaint, charge or report with any law enforcement agency, with the Securities and Exchange Commission (“SEC”) or other regulatory body, or to participate in any manner in an SEC or other governmental investigation or proceeding under any such law, statute or regulation, or to require notification or prior approval by Employer of any such a complaint, charge or report. I understand and agree, however, that I waive My right to recover any whistleblower award under the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or other individual relief in any administrative or legal action whether brought by the SEC or other governmental or law enforcement agency, Me, or any other party, unless and to the extent that such waiver is contrary to law. I agree that the Released Parties reserve any and all defenses which they might have against any such allegations or claims brought by Me or on My behalf. I understand that Employer is relying on My representations in this Release and related Separation Agreement.

EXECUTIVE INITIALS

V. Exclusions from Release.

- A. The term “Claims” does not include My rights, if any, to claim the following: unemployment insurance benefits; workers compensation benefits; claims for My vested post-termination benefits under any 401(k) or similar retirement benefit plan; My rights to group medical or group dental insurance coverage pursuant to section 4980B of the Internal Revenue Code of 1986, as amended (“COBRA”); My rights to enforce the terms of this Release; or My rights to assert claims that are based on events occurring after this Release becomes effective.
- B. Nothing in this Release interferes with My right to file or maintain a charge with the Equal Employment Opportunity Commission or other local civil rights enforcement agency or participate in any manner in an EEOC or other such agency investigation or proceeding. I, however, understand that I am waiving My right to recover individual relief including, but not limited to, back pay, front pay, reinstatement, attorneys’ fees, and/or punitive damages, in any administrative or legal action whether brought by the EEOC or other civil rights enforcement agency, Me, or any other party.
- C. Nothing in this Release interferes with My right to challenge the knowing and voluntary nature of this Release under the ADEA and/or OWBPA.
- D. I agree that Employer reserves any and all defenses, which it has or might have against any claims brought by Me. This includes, but is not limited to, Employer’s right to seek available costs and attorneys’ fees as allowed by law, and to have any monetary award granted to Me, if any, reduced by the amount of money that I received in consideration for this Release.

EXECUTIVE INITIALS

VI. Older Workers Benefit Protection Act. The Older Workers Benefit Protection Act applies to individuals age 40 and older and sets forth certain criteria for such individuals to waive their rights under the Age Discrimination in Employment Act in connection with an exit incentive program or other employment termination program. I understand and have been advised that, if applicable, the above release of My Claims is subject to the terms of the OWBPA. The OWBPA provides that a covered individual cannot waive a right or claim under the ADEA unless the waiver is knowing and voluntary. If I am a covered individual, I acknowledge that I have been advised of this law, and I agree that I am signing this Release voluntarily, and with full knowledge of its consequences. I understand that Employer is giving Me twenty-one (21) days from the date I received a copy of this Release to decide whether I want to sign it. I acknowledge that I have been advised to use this time to consult with an attorney about the effect of this Release. If I sign this Release before the end of the twenty-one (21) day period it will be My personal, voluntary decision to do so, and will be done with full knowledge of My legal rights. I agree that material and/or immaterial changes to the Separation Agreement or this Release will not restart the running of this consideration period. I also acknowledge that the Separation Agreement, this Release and any other attachments or exhibits have each been written in a way that I understand.

VII. Right to Rescind and/or Revoke. I understand that insofar as this Release relates to my rights under the Age Discrimination in Employment Act, it shall not become effective or enforceable until seven (7) days after I sign it. I also have the right to rescind (or revoke) this Release insofar as it extends to potential claims under the ADEA by written notice to Employer within seven (7) calendar days following my signing this Release, and within fifteen (15) calendar days as to waiver of claims under the Minnesota Human Rights Act (the "Rescission Period"). Any such rescission (or revocation) must be in writing and hand-delivered to Employer or, if sent by mail, postmarked within the applicable time period, sent by certified mail, return receipt requested, and addressed as follows:

- A. post-marked within the seven (7) day Rescission Period or, if applicable, fifteen (15) day Rescission Period;
- B. properly addressed to DiaMedica USA, Inc., Attention: Chief Executive Officer, Two Carlson Parkway, Suite 260, Minneapolis, MN 55447; and
- C. sent by certified mail, return receipt requested.

I understand that the Consideration I am receiving for settling and releasing my Claims is contingent upon my agreement to be bound by the terms of this Release. Accordingly, if I decide to revoke this Release as provided herein, I understand that I am not entitled to the Consideration offered in the Separation Agreement. I further understand that if I attempt to revoke my release of ADEA, MHRA or any other claims, I must immediately return to the Employer any Consideration that I may have received under my Separation Agreement.

VIII. I Understand the Terms of this Release. I have had the opportunity to read this Release carefully and understand all its terms. I have had the opportunity to review this Release with My own attorney. In agreeing to sign this Release, I have not relied on any oral statements or explanations made by Employer, including its employees or attorneys. I understand and agree that this Release and the attached Agreement contain all the agreements between Employer and Me. We have no other written or oral agreements.

Scott Kellen

Dated: _____, 20____

EXECUTIVE INITIALS

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is effective as of September 12, 2018 ("Effective Date"), by and between DiaMedica USA, Inc. a Delaware corporation (the "Company"), and Harry Alcorn, an individual ("Executive"). The Company and Executive are sometimes referred to as the "Parties" or "Party" in this Agreement, and the Company may designate the parent company of the Company or a subsidiary to be the employer of the Executive.

In consideration of the mutual promises, covenants and agreements contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. EMPLOYMENT AND DUTIES.

A. Job Title and Responsibilities. The Company hereby employs Executive, and Executive hereby agrees to be employed, as Chief Medical Officer (together with such other position or positions consistent with Executive's title as the Company's Chief Executive Officer may specify from time to time), reporting to the Company's Chief Executive Officer and will have such duties and responsibilities commensurate with such title. The Parties understand, acknowledge and agree that Executive may also serve in similar positions with the parent company of the Company or any subsidiary.

B. Full-Time Best Efforts. Executive agrees to devote Executive's full professional time and attention to the business of the Company (and its subsidiaries, affiliates, or related entities) and the performance of Executive's obligations under this Agreement, and will at all times faithfully, industriously and to the best of Executive's ability, experience and talent, perform all of Executive's obligations hereunder. Executive shall not, at any time during Executive's employment by the Company, directly or indirectly, act as a partner, officer, director, consultant or Executive, or provide services in any other capacity to any other business enterprise that conflicts with the Company's business or Executive's duty of loyalty to the Company. Executive shall seek the written consent of the Company prior to accepting any outside board positions.

C. Duty of Loyalty. Executive acknowledges that during Executive's employment with the Company, Executive has participated in and will participate in relationships with existing and prospective clients, customers, partners, suppliers, service providers and vendors of the Company that are essential elements of the Company's goodwill. The parties acknowledge that Executive owes the Company a fiduciary duty to conduct all affairs of the Company in accordance with all applicable laws and the highest standards of good faith, trust, confidence and candor, and to endeavor, to the best of Executive's ability, to promote the best interests of the Company.

D. Conflict of Interest. Executive agrees that while employed by the Company, and except with the advance written consent of the Board, Executive will not enter into, on behalf of the Company, or cause the Company or any of its affiliates to enter into, directly or indirectly, any transactions with any business organization in which Executive or any member of Executive's immediate family may be interested as a shareholder, partner, member, trustee, director, officer, employee, consultant, lender or guarantor or otherwise; provided, however, that nothing in this Agreement shall restrict transactions between the Company and any company whose stock is listed on a national securities exchange or actively traded in the over-the-counter market and over which Executive does not have the ability to control or significantly influence policy decisions.

2. COMPENSATION.

A. Base Pay. The Company agrees to pay Executive gross annual compensation of \$240,000 ("Base Salary"), less usual and customary withholdings, which shall be payable in arrears in accordance with the Company's customary payroll practices. The Base Salary will be subject to normal periodic review, and such review will consider Executive's contributions to the Company and the Company's overall performance.

B. Bonus and Incentive Compensation. Executive shall be eligible for discretionary bonus and incentive based compensation approved by the Board of Directors of the Company (or a committee thereof) (the "Board") from time to time at its sole discretion as to eligibility and timing of payments.

C. Equity Award. Subject to approval by the Board (or a committee thereof), Executive shall be eligible to receive equity-based compensation awards from time to time as determined by the Board pursuant to the DiaMedica Therapeutics Inc. Stock Option Plan, or any successor plan thereto (such plan, the "Plan"). The type of equity award(s), grant timing and vesting terms will be in the sole discretion of the Board (or a committee thereof).

D. Benefits. During Executive's employment, Executive will be eligible to participate in the Company's benefit programs, as governed by the terms of the official plan documents. Executive acknowledges that the Company may amend or terminate any of its benefit plans or programs at any time and for any reason. Executive will be eligible for paid time off or PTO per year, in accordance with the Company's policies in effect from time to time.

E. Clawback. Executive agrees that any incentive or other compensation or benefits provided by the Company under this Agreement or otherwise will be subject to recoupment or clawback by the Company under any applicable clawback or recoupment policy of the Company as may be in effect from time to time or as required by applicable law, regulation or stock exchange listing requirement.

3. CONFIDENTIAL INFORMATION.

A. Non-Disclosure, Non-Use and Definition of Confidential Information. Executive understands that during Executive's employment relationship with the Company, the Company intends to provide Executive with information, including Confidential Information (as defined herein), without which Executive would not be able to perform Executive's duties to the Company. Executive agrees, at all times during the term of Executive's employment relationship and thereafter, to hold in strictest confidence, and not to use or disclose, except for the benefit of the Company to the extent necessary to perform Executive's obligations to the Company, any Confidential Information that Executive obtains, accesses or creates during the term of the relationship, whether or not during working hours, until such Confidential Information becomes publicly and widely known and made generally available through no wrongful act of Executive or of others under confidentiality obligations as to the information involved. Executive understands that "Confidential Information" means information and physical material not generally known or available outside the Company and information and physical material entrusted to the Company by third parties under an obligation of non-disclosure or non-use or both. "Confidential Information" includes, without limitation, inventions, technical data, trade secrets, know-how, clinical data, regulatory information and strategies, marketing ideas or plans, research, product or service ideas or plans, business strategies, investments, investment opportunities, potential investments, market studies, industry studies, historical financial data, financial information and results, budgets, identity of customers, forecasts (financial or otherwise), possible or pending transactions, customer lists and domain names, price lists, and pricing methodologies. Any information that Executive knows or should reasonably know is Confidential Information, or that Employer treats as Confidential Information, will be presumed to be Confidential Information.

B. Exceptions. At all times, both during Executive's employment and after its termination, Executive will keep and hold all such Confidential Information in strict confidence and trust. Executive will not use or disclose any Confidential Information without the prior written consent of the Company, except as may be necessary to perform Executive's duties as an Executive of the Company for the benefit of the Company. Executive may disclose information that Executive is required to disclose by valid order of a government agency or court of competent jurisdiction, provided that Executive will:

1. Notify the Company in writing immediately upon learning that such an order may be sought or issued,
2. Cooperate with the Company as reasonably requested if the Company seeks to contest such order or to place protective restrictions on the disclosure pursuant to such order, and
3. Comply with any protective restrictions in such order and disclose only the information specified in the order.

C. Return of Confidential Information. Upon termination of employment with the Company, Executive will promptly deliver to the Company all documents and materials of any nature pertaining to Executive's work with the Company.

D. Copyright Information. Executive agrees not to infringe the copyrights of the Company, its customers or third parties (including, without limitation, Executive's previous employers, customers, etc.) by unauthorized or unlawful copying, modifying or distributing of copyrighted material, including plans, drawings, reports, financial analyses, market studies, computer software and the like.

4. COVENANT NOT TO COMPETE.

A. Non-Competition Covenant. Executive agrees that during the Restricted Period (as defined below), without the prior written consent of the Company, Executive shall not, directly or indirectly within the Territory (as defined below): (i) personally, by agency, as an Executive, independent contractor, consultant, officer, director, manager, agent, associate, investor (other than as a passive investor holding less than five percent (5%) of the outstanding equity of an entity), or by any other artifice or device, engage in any Competitive Business (as defined below), (ii) assist others, including but not limited to Executives of the Company, to engage in any Competitive Business, or (iii) own, purchase, finance or organize a Competitive Business.

B. Definitions.

1. "Competitive Business" means (i) any person, entity or organization which is engaged in, consulting regarding or engaged in the development, production, marketing or selling of any pharmaceutical-based product, process, technology, invention or service which resembles, competes with or is intended to resemble or compete with a product, process, technology, device, invention or service under or being considered for research or development or being promoted, marketed, sold or serviced by the Company or any subsidiary; or (ii) any other line of business that the Company or any subsidiary, is actively preparing to pursue at any time during the term of Executive's employment with the Company and in which Executive is involved.

2. "Territory" means the United States of America or locations where the Company is directly or indirectly developing or selling products or services.

3. "Restricted Period" means the period of Executive's employment with the Company and for a period of twelve (12) months following the termination of Executive's employment.

5. NON-SOLICITATION AND NON-INTERFERENCE COVENANTS.

A. Non-Solicitation of Employees and Others. During the Restricted Period, (i) Executive shall not, directly or indirectly, solicit, recruit, or induce, or attempt to solicit, recruit or induce any employee, consultant, independent contractor, vendor, supplier, or agent to terminate or otherwise adversely affect his or her employment or other business relationship (or prospective employment or business relationship) with the Company, and (ii) Executive shall not, directly or indirectly, solicit, recruit, or induce, or attempt to solicit, recruit or induce any employee to work for Executive or any other person or entity, other than the Company or its affiliates or related entities.

B. Non-Solicitation of Customers. During the Restricted Period, Executive shall not, directly or indirectly, solicit, recruit, or induce any Customer (as defined below) for the purpose of (i) providing any goods or services related to a Competitive Business, or (ii) interfering with or otherwise adversely affecting the contracts or relationships, or prospective contracts or relationships, between the Company (including any related or affiliated entities) and such Customers. "Customer" means a person or entity with which Executive had contact or about whom Executive gained information while an employee of the Company, and to which the Company was selling or providing products or services, was in active negotiations for the sale of its products or services, or was otherwise doing business as of the date of the cessation of Executive's employment with the Company or for whom the Company had otherwise done business within the twelve (12) month period immediately preceding the cessation of Executive's employment with the Company.

6. ACKNOWLEDGEMENTS. EXECUTIVE ACKNOWLEDGES AND AGREES THAT:

A. The geographic and duration restrictions contained in Sections 4 and 5 of this Agreement are fair, reasonable, and necessary to protect the Company's legitimate business interests and trade secrets, given the geographic scope of the Company's business operations, the competitive nature of the Company's business, and the nature of Executive's position with the Company;

B. Executive's employment creates a relationship of confidence and trust between Executive and the Company with respect to the Confidential Information, and Executive will have access to Confidential Information (including but not limited to trade secrets) that would be valuable or useful to the Company's competitors;

C. The Company's Confidential Information is a valuable asset of the Company, and any violation of the restrictions set forth in this Agreement would cause substantial injury to the Company;

D. The restrictions contained in this Agreement will not unreasonably impair or infringe upon Executive's right to work or earn a living after Executive's employment with the Company ends; and

E. This Agreement is a contract for the protection of trade secrets under applicable law and is intended to protect the Confidential Information (including trade secrets) identified above.

7. "BLUE PENCIL" AND SEVERABILITY PROVISION.

If a court of competent jurisdiction declares any provision of this Agreement invalid, void, voidable, or unenforceable, the court shall reform such provision(s) to render the provision(s) enforceable, but only to the extent absolutely necessary to render the provision(s) enforceable and only in view of the parties' express desire that the Company be protected to the greatest possible extent under applicable law from improper competition and the misuse or disclosure of trade secrets and Confidential Information. To the extent such a provision (or portion thereof) may not be reformed so as to make it enforceable, it may be severed and the remaining provisions shall remain fully enforceable.

8. INVENTIONS.

A. Inventions Retained and Licensed. Executive acknowledges and agrees that Executive has no rights in any Inventions (as that term is defined below) other than inventions and information created, discovered or developed by Executive, whether or not patentable or registrable under patent, copyright or similar statutes, made or conceived or reduced to practice or learned by Executive, either alone or with others before Executive's employment with the Company, which list of inventions Executive has provided the Company in writing on or prior to the Effective Date ("Prior Inventions"). Executive shall not incorporate, or permit to be incorporated, any Prior Invention owned by Executive or in which he has an interest in a Company product, process or machine without the Company's prior written consent. Notwithstanding the foregoing, if, in the course of Executive's employment with the Company, Executive directly or indirectly incorporates into a Company product, process or machine a Prior Invention owned by Executive or in which Executive has an interest, the Company is hereby granted and shall have a non-exclusive, royalty-free, irrevocable, perpetual, world-wide license to make, have made, modify, use, create derivative works from and sell such Prior Invention as part of or in connection with such product, process or machine.

B. Assignment of Inventions. Executive shall promptly make full, written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and hereby irrevocably transfers and assigns, and agrees to transfer and assign, to the Company, or its designee, all Executive's right, title and interest in and to any and all inventions, original works of authorship, developments, concepts, improvements, designs, discoveries, ideas, trademarks (and all associated goodwill), mask works, or trade secrets, whether or not they may be patented or registered under copyright or similar laws, which Executive may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice, during Executive's employment by the Company (the "Inventions"). Executive further acknowledges that all original works of authorship which are made by Executive (solely or jointly with others) within the scope of and during the period of Executive's employment with the Company and which may be protected by copyright are "Works Made For Hire" as that term is defined by the United States Copyright Act. Executive understands and agrees that the decision whether to commercialize or market any Invention developed by Executive solely or jointly with others is within the Company's sole discretion and the Company's sole benefit and that no royalty will be due to Executive as a result of the Company's efforts to commercialize or market any such invention.

Executive recognizes that Inventions relating to Executive's activities while working for the Company and conceived or made by Executive, whether alone or with others, within one (1) year after cessation of Executive's employment, may have been conceived in significant part while employed by the Company. Accordingly, Executive acknowledges and agrees that such Inventions shall be presumed to have been conceived during Executive's employment with the Company and are to be, and hereby are, assigned to the Company unless and until Executive has established the contrary.

The requirements of this Section 8B do not apply to any intellectual property for which no equipment, supplies, facility or trade secret information of the Company was used, and which was developed entirely on the Executive's own time, and (i) which does not relate (x) directly to the Company's business or (y) to the Company's actual or demonstrably anticipated research and development or (ii) which does not result from any work the Executive performed for the Company.

C . Maintenance of Records. Executive agrees to keep and maintain adequate and current written records of all Inventions made by Executive (solely or jointly with others) during Executive's employment with the Company. The records will be in the form of notes, sketches, drawings and any other format that may be specified by the Company. The records will be available to and remain the sole property of the Company at all times.

D . Patent, Trademark and Copyright Registrations. Executive agrees to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's rights in the Inventions and any copyrights, patents, trademarks, service marks, mask works, or any other intellectual property rights in any and all countries relating thereto, including, but not limited to, the disclosure to the Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments the Company reasonably deems necessary in order to apply for and obtain such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title, and interest in and to such inventions, and any copyrights, patents, trademarks, service marks, mask works, or any other intellectual property rights relating thereto. Executive further agrees that Executive's obligation to execute or cause to be executed, when it is in Executive's power to do so, any such instrument or paper shall continue after termination or expiration of this Agreement or the cessation of Executive's employment with the Company. If the Company is unable because of Executive's mental or physical incapacity or for any other reason, after reasonably diligent efforts, to secure Executive's signature to apply for or to pursue any application for any United States or foreign patents, trademarks or copyright registrations covering inventions or original works of authorship assigned to the Company as above, then Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agent and attorney-in-fact to act for and in Executive's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent, trademarks or copyright registrations thereon with the same legal force and effect as if executed by Executive; this power of attorney shall be a durable power of attorney which shall come into existence upon Executive's mental or physical incapacity.

9. SURVIVAL AND REMEDIES.

Executive's obligations of nondisclosure, non-solicitation, non-interference, and non-competition under this Agreement shall survive the cessation of Executive's employment with the Company and shall remain enforceable. In addition, Executive acknowledges that upon a breach or threatened breach of any obligation of nondisclosure, non-solicitation, non-interference, or non-competition of this Agreement, the Company may suffer irreparable harm and damage for which money alone cannot fully compensate the Company. Executive therefore agrees that upon such breach or threat of imminent breach of any such obligation, the Company shall be entitled to seek a temporary restraining order, preliminary injunction, permanent injunction or other injunctive relief, without posting any bond or other security, barring Executive from violating any such provision. This Section 9 shall not be construed as an election of any remedy, or as a waiver of any right available to the Company under this Agreement or the law, including the right to seek damages from Executive for a breach of any provision of this Agreement and the right to require Executive to account for and pay over to the Company all profits or other benefits derived or received by Executive as the result of such a breach, nor shall this Section 9 be construed to limit the rights or remedies available under state law for any violation of any provision of this Agreement.

10. TERMINATION.

A. Termination By Either Party. Either Party may terminate the Executive's at-will employment at any time with or without notice, and with or without cause. Except as provided in this Section 10, upon termination of employment, Executive shall only be entitled to Executive's accrued but unpaid Base Salary, any earned but unpaid bonus for the year prior to the date of termination, and other benefits earned under any Company-provided plans, policies and arrangements for the period preceding the effective date of the termination of employment. With respect to any earned but unpaid bonus for the year prior to the date of termination, the terms of which bonus plan require Executive to be an employee of the Company as of the date of payment, no payment will be made to Executive (or if applicable, the Executive's beneficiary) if Executive's employment with the Company terminates voluntarily by Executive, other than for Good Reason pursuant to Section 10C, or if Executive's employment with the Company is terminated by the Company for Cause, but will be paid if Executive's employment with the Company terminates due to Executive's death or disability.

B . Termination Without Cause. If the Company terminates Executive's employment without Cause (defined below), Executive shall be entitled to receive, in addition to the amounts due under Section 10A, as continuing severance pay at a rate equal to Executive's Base Salary, as then in effect, for nine (9) months from the date of termination of employment, plus a lump-sum payment equal to a pro rata portion of Executive's target annual bonus for the year in which the date of termination occurs (based on the date of termination), in each case, less all required tax withholdings and other applicable deductions, payable in accordance with the Company's standard payroll procedures, commencing on the effective date of a Separation Agreement and Release of claims against the Company and after the end of any applicable rescission or revocation period, and provided that Executive has not revoked or rescinded (or attempted to revoke or rescind) any claims under such Release, in substantially the form of Exhibit A attached hereto, the timely execution and performance by Executive of which is specifically a condition to Executive's receipt of any of the payments and benefits provided under this Section 10B; provided that (1) such Separation Agreement and Release shall be executed and be fully effective within sixty (60) days of the Executive's termination of employment; (2) the first payment shall include any amounts that would have been paid to Executive if payment had commenced on the date of termination of employment; and (3) Executive shall not be required to execute a release of any claims arising from the Company's failure to comply with its obligations under Section 10A. Subject to Executive's execution and non-revocation of the Separation Agreement and Release, if Executive timely and effectively elects continuation coverage under the Company's group health plan pursuant to COBRA or similar state law, the Company will pay or reimburse the premiums for such coverage of Executive (and Executive's dependents, as applicable) at the same rate it pays for active employees for a period for nine (9) months from the date of termination of employment; provided that the Company's obligation to make such payments shall immediately expire if Executive ceases to be eligible for continuation coverage under COBRA or similar state law or otherwise terminates such coverage. Notwithstanding the foregoing, any of the foregoing payments due under this Section 10B shall commence within seventy (70) days of Executive's termination of employment, provided that if such seventy (70)-day period spans two (2) calendar years, payments shall commence in the latter calendar year. In addition to the foregoing and subject to Executive's timely execution of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, Executive shall be entitled to the immediate vesting of all outstanding equity awards then held by Executive.

C . Termination Upon a Change in Control. If the Company or any successor in interest to the Company terminates Executive's employment without Cause in connection with or within twelve (12) months after a Change in Control (defined below) or if Executive terminates Executive's employment for Good Reason (defined below) within twelve (12) months after a Change in Control, Executive shall be entitled to receive, in addition to the amounts due under Section 10A, a lump-sum payment equal to twelve (12) months of Executive's Base Salary, as then in effect or as in effect immediately prior to a material reduction of Executive's Base Salary which was the reason Executive resigned for Good Reason, plus a lump-sum payment equal to a pro rata portion of Executive's target annual bonus for the year in which the date of termination occurs (based on the date of termination), in each case, less all tax withholdings and other applicable deductions the Company reasonably determines are required to be made, payable on the first regular payroll date after the effective date of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, in substantially the form of Exhibit A attached hereto, the execution and performance by Executive of which is specifically a condition to Executive's receipt of any of the payments and benefits provided under this Section 10C; provided that Executive shall not be required to execute a release of any claims arising from the Company's failure to comply with its obligations under Section 10A. Subject to Executive's execution and non-revocation of the Separation Agreement and Release, if Executive timely and effectively elects continuation coverage under the Company's group health plan pursuant to COBRA or similar state law, the Company will pay or reimburse the premiums for such coverage of Executive (and Executive's dependents, as applicable) at the same rate it pays for active employees for a period for twelve (12) months from the date of termination of employment; provided that the Company's obligation to make such payments shall immediately expire if Executive ceases to be eligible for continuation coverage under COBRA or similar state law or otherwise terminates such coverage. Notwithstanding the previous provisions of this Section 10C, any payments due under this Section 10C shall commence within seventy (70) days of Executive's termination of employment, provided that if such seventy (70)-day period spans two calendar years, payments shall commence in the latter calendar year. In addition to the foregoing and subject to Executive's timely execution of a Separation Agreement and Release that has been executed and not revoked within any applicable rescission period that has expired within sixty (60) days of the Executive's termination of employment, Executive shall be entitled to the immediate vesting of all outstanding equity awards then held by Executive. The payments and benefits described in this Section 10C are in lieu of, and not in addition to, the payments and benefits described in Section 10B, it being understood by Executive that he shall be paid and receive only one set of severance payments and benefits.

Notwithstanding any other provisions of this Agreement, if any “payments” (including, without limitation, any benefits or transfers of property or the acceleration of the vesting of any benefits) in the nature of compensation under any arrangement that is considered contingent on a “change in control” for purposes of Section 280G of the Internal Revenue Code of 1986, as amended (the “Code”), together with any other payments that Executive has the right to receive from the Company or any corporation that is a member of an “affiliated group” (as defined in Section 1504(a) of the Code without regard to Section 1504(b) of the Code) of which the Company is a member, would constitute a “parachute payment” (as defined in Section 280G(b)(2) of the Code), such “payments” may, at Executive’s sole election, be reduced to the largest amount as will result in no portion of such “payments” being subject to the excise tax imposed by Section 4999 of the Code. Any reduction of the payments shall be made in the following order: (1) options with an exercise price above the fair market value of the stock, provided the options give rise to a payment; (2) pro rata among amounts that constitute deferred compensation under Code Section 409A; and (3) reduction of any remaining payments in the manner determined at the discretion of Executive.

The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the change in control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within sixty (60) calendar days after the date on which Executive’s right to a payment is triggered and the payment will be paid to Executive within seventy-four (74) calendar days of the date on which Executive’s right to a payment is triggered. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive.

D . Termination for Cause, Death or Disability, or Resignation. If Executive’s employment with the Company terminates voluntarily by Executive, other than for Good Reason pursuant to Section 10C above, or if Executive’s employment with the Company is terminated by the Company for Cause or due to Executive’s death or disability, then payments of compensation by the Company to Executive hereunder will terminate immediately, except that Executive (or the Executive’s beneficiary if Executive’s termination is on account of death) will be entitled to the amounts due under Section 10A.

E. Definitions.

1. “Cause.” For all purposes under this Agreement, “Cause” is defined as (a) gross negligence or willful failure to perform Executive’s duties and responsibilities to the Company; (b) commission of any act of fraud, theft, embezzlement, financial dishonesty or any other willful misconduct that has caused or is reasonably expected to result in injury to the Company; (c) conviction of, or pleading guilty or *nolo contendere* to, any felony or a lesser crime involving dishonesty or moral turpitude; (d) material breach by Executive of any of Executive’s obligations under this Agreement or any written agreement or covenant with the Company, including the policies adopted from time to time by the Company applicable to all Executives, that has not been cured within thirty (30) days of notice of such breach or (e) the Company terminates the employment of Executive in connection with a liquidation, dissolution or winding down of the Company.

2. “Good Reason.” For all purposes under this Agreement, “Good Reason” is defined as Executive’s resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive’s express written consent: (a) a material reduction of Executive’s duties, authority, reporting level, or responsibilities, relative to Executive’s duties, authority, reporting level, or responsibilities in effect immediately prior to such Change in Control; (b) a material reduction in Executive’s base compensation; or (c) the Company’s requiring of Executive to change the principal location at which Executive is to perform Executive’s services by more than fifty (50) miles. Executive will not resign for Good Reason without first providing the Company with written notice within thirty (30) days of the initial occurrence of the event that Executive believes constitutes “Good Reason” specifically identifying the acts or omissions constituting the grounds for Good Reason and providing Company a reasonable cure period of not less than thirty (30) days following the date of such notice and during which such condition has not been cured.

3. “Change in Control.” For all purposes under this Agreement, a “Change in Control” will mean the occurrence of any of the following:

a. the acquisition, other than from the Company or Parent (as defined below), by any individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (“Exchange Act”)) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of fifty percent (50%) or more of either the then outstanding common shares, no par value (“Common Shares”), of DiaMedica Therapeutics Inc., a company organized under the laws of Canada (“Parent”), or the combined voting power of the then outstanding voting securities of Parent entitled to vote generally in the election of directors, but excluding, for this purpose, any such acquisition by Parent or any of its subsidiaries, or any employee benefit plan (or related trust) of Parent or its subsidiaries, or any entity with respect to which, following such acquisition, more than fifty percent (50%) of, respectively, the then outstanding equity of such entity and the combined voting power of the then outstanding voting equity of such entity entitled to vote generally in the election of all or substantially all of the members of such entity’s governing body is then beneficially owned, directly or indirectly, by the individuals and entities who were the beneficial owners, respectively, of the Common Shares and voting securities of Parent immediately prior to such acquisition in substantially the same proportion as their ownership, immediately prior to such acquisition, of the then outstanding Common Shares or the combined voting power of the then outstanding voting securities of Parent entitled to vote generally in the election of directors, as the case may be; or

b. the consummation of a reorganization, merger or consolidation of Parent, in each case, with respect to which all or substantially all of the individuals and entities who were the respective beneficial owners of the Common Shares and voting securities of Parent immediately prior to such reorganization, merger or consolidation do not, following such reorganization, merger or consolidation, beneficially own, directly or indirectly, more than fifty percent (50%) of, respectively, the then outstanding Common Shares and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the corporation resulting from such reorganization, merger or consolidation; or

c. the sale or other disposition of all or substantially all of the assets of Parent; provided the occurrence under (a), (b) or (c), constitutes a “change in the ownership or effective control of a corporation, or a change in the ownership of a substantial portions of the assets of a corporation” under Section 409A of the Code.

F. No Other Benefits. In the event of a termination of Executive’s employment with the Company, the provisions of this Section 10 are Executive’s exclusive right to severance benefits and are in lieu of participation in any other severance policy or plan to which Executive might otherwise be entitled.

G. Termination from any Offices Held. Upon Executive’s termination of employment with the Company, Executive agrees that any and all offices held with Parent or any subsidiary, including the Company, if applicable, shall be automatically terminated. Executive agrees to cooperate with the Company and execute any documents reasonably required by the Company or competent authorities to effect this provision.

H. Return of Company Property. All devices, records, reports, data, notes, compilations, lists, proposals, correspondence, specifications, equipment, drawings, blueprints, manuals, planners, calendars, schedules, discs, financial plans and information, or other recorded matter, whether in hard copy, electronic media or otherwise (including all copies or reproductions made or maintained, whether on the Company’s premises or otherwise), pertaining to Executive’s work for the Company, or relating to the Company or the Company’s Confidential Information, whether created or developed by Executive alone or jointly during Executive’s employment with the Company, are the exclusive property of the Company. Executive shall surrender the same (as well as any other property of the Company) to the Company upon its request or promptly upon the cessation of employment.

11. NO CONFLICTING AGREEMENTS OR IMPROPER USE OF THIRD-PARTY INFORMATION.

During Executive's employment with the Company, Executive shall not improperly use or disclose any Confidential information or trade secrets of any former employer or other person or entity, and Executive shall not bring on to the premises of the Company any unpublished document or Confidential information belonging to any such former employer, person or entity, unless consented to in writing by the former employer, person or entity. Executive represents that he has not improperly used or disclosed any Confidential information or trade secrets of any other person or entity during the application process or while employed or affiliated with the Company. Executive also acknowledges and agrees that he is not subject to any contract, agreement, or understanding that would prevent Executive from performing Executive's duties for the Company or otherwise complying with this Agreement. To the extent Executive violates this provision, or Executive's employment with the Company constitutes a breach or threatened breach of any contract, agreement, or obligation to any third party, Executive shall indemnify and hold the Company harmless from all damages, expenses, costs (including reasonable attorneys' fees) and liabilities incurred in connection with, or resulting from, any such violation or threatened violation.

12. GENERAL PROVISIONS.

A . Governing Law; Consent To Personal Jurisdiction. The laws of the State of Minnesota shall govern the Executive's employment and this Agreement without regard to conflict of laws principles. Executive and the Company each hereby consents to the personal jurisdiction of the state courts located in Hennepin County, State of Minnesota, and the federal district court sitting in Hennepin County, State of Minnesota, if that court otherwise possesses jurisdiction over the matter, for any legal proceeding concerning Executive's employment or termination of employment, or arising from or related to this Agreement or any other agreement executed between Executive and the Company.

B . Entire Agreement. This Agreement, together with the Exhibits hereto, sets forth this entire Agreement between the Company (and any of its related or affiliated entities, officers, agents, owners or representatives) and Executive relating to the subject matter herein, and supersedes any and all prior discussions and agreements, whether written or oral, on the subject matter hereof, including without limitation that certain offer letter agreement dated as of January 2, 2018. To the extent that this Agreement may conflict with the terms of another written agreement between Executive and the Company, the terms of this Agreement will control.

C . Modification. No modification of or amendment to this Agreement will be effective unless in writing and signed by Executive and an authorized representative of the Company.

D . Waiver. The Company's failure to enforce any provision of this Agreement shall not act as a waiver of its ability to enforce that provision or any other provision. The Company's failure to enforce any breach of this Agreement shall not act as a waiver of that breach or any future breach. No waiver of any of the Company's rights under this Agreement will be effective unless in writing. Any such written waiver shall not be deemed a continuing waiver unless specifically stated, and shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

E. Successors and Assigns. This Agreement shall be assignable to, and shall inure to the benefit of and bind, the Company's, affiliates, subsidiaries, successors and assigns. Executive shall not have the right to assign Executive's rights or obligations under this Agreement.

F. Construction. The language used in this Agreement will be deemed to be language chosen by Executive and the Company to express their mutual intent, and no rules of strict construction will be applied against either Party.

G. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable, and all of which together shall constitute one agreement. Signatures of the parties that are transmitted in person or by facsimile or e-mail shall be accepted as originals.

H. Further Assurances. Executive agrees to execute any proper oath or verify any document required to carry out the terms of this Agreement.

I. Title and Headings. The titles, captions and headings of this Agreement are included for ease of reference only and will be disregarded in interpreting or construing this Agreement.

J. Notices. All notices and communications that are required or permitted to be given under this Agreement shall be in writing and shall be sufficient in all respects if given and delivered in person, by electronic mail, by facsimile, by overnight courier, or by certified mail, postage prepaid, return receipt requested, to the receiving Party at such Party's address shown in the signature blocks below or to such other address as such Party may have given to the other by notice pursuant to this Section. Notice shall be deemed given (i) on the date of delivery in the case of personal delivery, electronic mail or facsimile, or (ii) on the delivery or refusal date as specified on the return receipt in the case of certified mail or on the tracking report in the case of overnight courier.

K. Code Section 409A. The amounts payable under this Agreement are intended to be exempt from the requirements of Section 409A of the Code ("Section 409A"). For purposes of Section 409A, any right to a series of installment payments is to be treated as a right to a series of separate payments. Any payments due under this Agreement on account of a termination of employment shall only be payable if the termination constitutes a "separation from service" within the meaning of Section 409A. To the extent that any such payments are determined to be deferred compensation subject to Section 409A, (i) the terms of this Agreement shall be interpreted to avoid incurring any penalties under Section 409A, and (ii) any payments due to a "specified Executive" of a publicly-traded company upon a separation from service shall be delayed until the first day of the seventh month following such separation from service. Notwithstanding the foregoing, in no event shall the Company be responsible for any taxes or penalties due under Section 409A.

13. EXECUTIVE'S ACKNOWLEDGMENTS.

Executive acknowledges that he is executing this Agreement voluntarily and without duress or undue influence by the Company or anyone else and that Executive has carefully read this Agreement and fully understands the terms, consequences, and binding effect of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, and intending to be legally bound, the Parties have executed this Employment Agreement as of the date first written above.

EXECUTIVE

DIAMEDICA USA, INC.

/s/ Harry Alcorn Jr.

Harry Alcorn Jr.

Date: 9/14/2018

Address: 2 Carlson Parkway, Suite 260

Minneapolis, MN 55447

Print Name: Rick Pauls

Name:

Signature: /s/ Rick Pauls

Title: President & CEO

Date: 9/14/2018

EXHIBIT A

FORM OF SEPARATION AGREEMENT AND RELEASE

This Separation Agreement ("Agreement") and the Release, which is attached and incorporated by reference as Exhibit A ("Release"), are made by and between Harry Alcorn ("Executive"), and DiaMedica USA, Inc., its affiliates, related or predecessor corporations, parent, subsidiaries, successors and assigns ("Employer").

Employer and Executive (collectively, "Parties") wish to end their employment relationship in an honorable, dignified and orderly fashion. Toward that end, the Parties have agreed to separate according to the following terms.

IN CONSIDERATION OF THIS AGREEMENT, THE PARTIES AGREE AS FOLLOWS:

1. Termination. Executive's employment shall end on a date and time Employer shall determine ("Termination Date").
2. Consideration. Employer shall, (1) after receipt of a fully executed Agreement and Release; (2) after expiration of all applicable rescission periods; and (3) provided Executive complies with Executive's obligations under this Agreement, provide Executive with separation benefits ("Consideration") in compliance with Executive's Employment Agreement attached as Exhibit B:
3. Termination of Benefits. Except as otherwise provided by this Agreement, Executive's participation in Employer's employee benefits, bonus, and all other compensation or commission plans, will terminate on the Termination Date, unless otherwise provided by law, or benefit plan. Executive shall receive no compensation or benefits under such plans, except as specifically provided in Section 2 of this Agreement.
4. Execution of Agreement and Release of all Claims. Executive agrees to fully execute this Agreement, and the Release attached as Exhibit A, releasing any and all actual or potential claims which may have arisen at any time during Executive's employment with or termination from employment with Employer. Executive's failure to execute this Agreement and/or Release, or any attempt to rescind this Agreement or that Release, shall terminate this Agreement, and the Parties' respective rights and obligations under this Agreement.
5. Satisfactory Performance and Cooperation During Transition. Executive shall fully cooperate with Employer in responding to questions, providing assistance and information, and defending against claims of any type, and will otherwise assist Employer as Employer may request through Executive's Termination Date ("Transition Period"). More specifically:
 - a. During the Transition Period, Executive shall reasonably cooperate with Employer as it meets and otherwise communicates/works, with Employer's employees, customers, strategic relationships, consultants, and vendors on the transition of Executive's duties to other individuals. Executive shall be available, upon reasonable notice, during business hours to respond to Employer's questions and electronic communications. Employer shall reimburse Executive for Executive's reasonable out-of-pocket expenses (such reimbursement shall not include compensation for any such time or Executive's attorney's fees) incurred in accordance with this Section upon submission of receipts to Employer for such expenses.

b. Executive shall not, absent Employer's specific approval, initiate any form of communication with Employer's employees, customers or strategic partners regarding Employer, Employer's products or employees, and shall communicate with such persons in the above capacity only in conjunction with person(s) who Employer has designated to participate in such communications.

6 . Stipulation of No Charges. Executive affirmatively represents that Executive has not filed nor caused to be filed any charges, claims, complaints, or actions against Employer before any federal, state, or local administrative agency, court, or other forum. Except as expressly provided in this Agreement or required by law, Executive acknowledges and agrees that Executive has been paid all wages, bonuses, compensation, benefits and other amounts that are due, with the exception of any vested right under the terms of a written ERISA-qualified benefit plan. Executive waives any right to any form of recovery or compensation from any legal action, excluding any action claiming this Agreement and Release violate the Age Discrimination in Employment Act ("ADEA") and/or the Older Workers Benefit Protection Act ("OWBPA"), filed or threatened to be filed by Executive or on Executive's behalf based on Executive's employment, terms of employment, or separation from, Employer. Executive understands that any Consideration paid to Executive pursuant to this Agreement may be deducted from any monetary award Executive may receive as a result of a successful ADEA and/or OWBPA claim or challenge to this Agreement and Release. This does not preclude Executive from eligibility for unemployment benefits, and does not preclude or obstruct Executive's right to file a Charge with the Equal Employment Opportunity Commission ("EEOC").

7 . Return of Property. Executive shall return, on or before the Termination Date, all Employer property in Executive's possession or control, including but not limited to any drawings, orders, files, documents, notes, computers, laptop computers, fax machines, cell phones, smart devices, access cards, fobs, keys, reports, manuals, records, product samples, correspondence and/or other documents or materials related to Employer's business that Executive has compiled, generated or received while working for Employer, including all electronically stored information, copies, samples, computer data, disks, or records of such materials. Executive must return to Employer, and Executive shall not retain, any Employer property as previously defined in this section.

8 . Agreement Not to Seek Future Employment. Executive agrees that Executive will never knowingly seek nor accept employment or a consulting/independent contractor relationship with Employer, nor any other entity owned by Employer, either directly or through a consulting firm.

9. Withholding for Amounts Owed to Employer. Execution of this Agreement shall constitute Executive's authorization for Employer to make deductions from Executive's Consideration, for Executive's indebtedness to Employer, or to repay Employer for unaccrued vacation or other Paid Time Off already taken, Executive purchases, wage or benefit overpayment, or other Employer claims against Executive, to the extent permitted by applicable law.

10. Non-Disparagement. Executive agrees that, unless it is in the context of an EEOC or other civil rights or other government enforcement agency investigation or proceeding, Executive will make no critical, disparaging or defamatory comments regarding Employer or any Released Party, as defined in the Release, in any respect or make any comments concerning the conduct or events which precipitated Executive's separation. Furthermore, Executive agrees not to assist or encourage in any way any individual or group of individuals to bring or pursue a lawsuit, charge, complaint, or grievance, or make any other demands against Employer or any Released Party. This provision does not prohibit Executive from participating in an EEOC or other civil rights or other government enforcement agency charge, investigation or proceeding, or from providing testimony or documents pursuant to a lawful subpoena or as otherwise required by law.

11. Compliance with Employment Agreement and Protection of Confidential Information. Executive agrees to comply with the provisions of and the restrictions set forth in Executive's Employment Agreement (Exhibit B), including without limitation the obligation not to use or disclose Confidential Information (as defined in the Employment Agreement).

12. Confidentiality. It is the intent of Employer and Executive that the terms of this Agreement be treated as Confidential Information (as defined in the Employment Agreement), except to the extent this Agreement is required to be disclosed under applicable federal securities laws, as determined by Employer. Executive warrants that Executive has not and agrees that Executive will not in the future disclose the terms of this Agreement, or the terms of the Consideration to be paid by Employer to Executive as part of this Agreement, to any person other than Executive's attorney, tax advisor, spouse, or representatives of any state or federal regulatory agency, who shall be bound by the same prohibitions against disclosure as bind Executive, and Executive shall be responsible for advising those individuals or agencies of this confidentiality provision. Executive shall not provide or allow to be provided to any person this Agreement, or any copies thereof, nor shall Executive now or in the future disclose the terms of this Agreement to any person, with the sole exception of communications with Executive's spouse, attorney and tax advisor, unless otherwise ordered to do so by a court or agency of competent jurisdiction.

13. Invalidity. In case any one or more of the provisions of this Agreement or Release shall be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Agreement and Release will not in any way be affected or impaired thereby.

14. Non-Admissions. The Parties expressly deny any and all liability or wrongdoing and agree that nothing in this Agreement or the Release shall be deemed to represent any concession or admission of such liability or wrongdoing or any waiver of any defense.

15. Governing Law. The laws of the State of Minnesota shall govern this Agreement without regard to conflict of laws principles. The Parties each hereby consent to the personal jurisdiction of the state courts located in Hennepin County, State of Minnesota, and the federal district court sitting in Hennepin County, State of Minnesota, if that court otherwise possesses jurisdiction over the matter, for any legal proceeding concerning or related to this Agreement.

16. Voluntary and Knowing Action. Executive acknowledges that Executive has had sufficient opportunity to review the terms of this Agreement and attached Release, and that Executive has voluntarily and knowingly entered into this Agreement. Employer shall not be obligated to provide any Consideration to Executive pursuant to this Agreement in the event Executive elects to rescind/revoke the Release. The Release becomes final and binding on the Parties upon expiration of the rescission/revocation period, provided Executive has not exercised Executive's option to rescind/revoke the Release. Any attempt by Executive to rescind any part of the Release obligates Executive to immediately return all Consideration under this Agreement to counsel for Employer.

17. Legal Counsel and Fees. Except as otherwise provided in this Agreement and the Release, the Parties agree to bear their own costs and attorneys' fees, if any. Executive acknowledges that Employer, by this Agreement, has advised him that Executive may consult with an attorney of Executive's choice prior to executing this Agreement and the Release. Executive acknowledges that Executive has had the opportunity to be represented by legal counsel during the negotiation and execution of this Agreement and the Release, and that Executive understands Executive will be fully bound by this Agreement and the Release.

18. Modification. This Agreement may be modified or amended only by a writing signed by both Employer and Executive.

19. Successors and Assigns. This Agreement is binding on and inures to the benefit of the Parties' respective successors and assigns.

20. Notices. All notices and communications that are required or permitted to be given under this Agreement shall be in writing and shall be sufficient in all respects if given and delivered in person, by electronic mail, by facsimile, by overnight courier, or by certified mail, postage prepaid, return receipt requested, to the receiving Party at such Party's address below or to such other address as such Party may have given to the other by notice pursuant to this Section. Notice shall be deemed given (i) on the date of delivery in the case of personal delivery, electronic mail or facsimile, or (ii) on the delivery or refusal date as specified on the return receipt in the case of certified mail or on the tracking report in the case of overnight courier.

If to Employer: DIAMEDICA USA, INC.
Attention: Chief Executive Officer
Two Carlson Parkway, Suite 260
Minneapolis, MN 55447

With a copy to: Amy E. Culbert
Fox Rothschild LLP
Campbell Mithun Tower - Suite 2000
222 South Ninth Street
Minneapolis, MN 55402-3338

If to Executive: Harry Alcorn

21. Waivers. No failure or delay by either Party in exercising any right or remedy under this Agreement will waive any provision of this Agreement.

22. Miscellaneous. This Agreement may be executed simultaneously in counterparts, each of which shall be an original, but all of which shall constitute but one and the same agreement.

23. Entire Agreement. Except for any continuing, post-employment, obligations under Exhibit B, or employment related Employer policy, or as otherwise provided in this Agreement, this Agreement, the attached Release, and Exhibit B are the entire Agreement between Employer and Executive relating to Executive's employment and separation. Executive understands that this Agreement and the Release cannot be changed unless it is done in writing and signed by both Employer and Executive.

[Remainder of page intentionally left blank]

EXECUTIVE

Harry Alcorn

Dated: _____, 20____

DIAMEDICA USA, INC.

By: _____

Its: _____

Dated: _____, 20____

RELEASE

- I. Definitions. I, Harry Alcorn, intend all words used in this release ("Release") to have their plain meanings in ordinary English. Technical legal words are not needed to describe what I mean. Specific terms I use in this Release have the following meanings:
- A. "I" "Me," and "My" individually and collectively mean Harry Alcorn and anyone who has or obtains or asserts any legal rights or claims through Me or on My behalf.
 - B. "Employer" as used in this Release, shall at all times mean DiaMedica USA, Inc. and any affiliates, related or predecessor corporations, parent corporations or subsidiaries, successors and assigns.
 - C. "Released Party" or "Released Parties" as used in this Release, shall at all times mean DiaMedica USA, Inc. and its affiliates, related or predecessor corporations, parent corporations, subsidiaries, successors and assigns, present or former officers, directors, shareholders, agents, employees, representatives and attorneys, whether in their individual or official capacities, and its affiliates, related or predecessor corporations, parent corporations or subsidiaries, successors and assigns, present or former officers, directors, shareholders, agents, employees, representatives and attorneys, whether in their individual or official capacities, benefit plans and plan administrators, and insurers, insurers' counsel, whether in their individual or official capacities, and the current and former trustees or administrators of any pension, 401(k), or other benefit plan applicable to the employees or former employees of Employer, in their official and individual capacities.
 - D. "My Claims" mean any and all of the actual or potential claims of any kind whatsoever I may have had, or currently may have against Employer or any Released Party, whether known or unknown, that are in any way related to My employment with or separation from employment with Employer, including, but not limited to any claims for: invasion of privacy; breach of written or oral, express or implied, contract; fraud; misrepresentation; violation of the Age Discrimination in Employment Act of 1967 ("ADEA"), 29 U.S.C. § 626, as amended; the Genetic Information Nondiscrimination Act of 2008 ("GINA"), 42 U.S.C. § 2000, et seq., the Older Workers Benefit Protection Act of 1990 ("OWBPA"), 29 U.S.C. § 626(f), Title VII of the Civil Rights Act of 1964 ("Title VII"), 42 U.S.C. § 2000e, et seq., the Americans with Disabilities Act ("ADA"), 29 U.S.C. § 2101, et seq., and as amended ("ADAAA"), the Executive Retirement Income Security Act of 1974 ("ERISA"), as amended, 29 U.S.C. § 1001, et seq., Equal Pay Act ("EPA"), 29 U.S.C. § 206(d), the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101, et seq., the Family and Medical Leave Act ("FMLA"), 29 U.S.C. § 2601, et seq.; National Labor Relations Act, 29 U.S.C. § 141, et seq., the False Claims Act, 31 U.S.C. § 3729, et seq., Anti-Kickback Statute, 42 U.S.C. § 1320a, et seq., the Minnesota Human Rights Act, Minn. Stat. § 363A.01, et seq., Minn. Stat. § 181, et seq., the Minnesota Whistleblower Act, Minn. Stat. § 181.931, et seq., or any and all other Minnesota, and other state human rights or fair employment practices statutes, administrative regulations, or local ordinances, and any other Minnesota or other federal, state, local or foreign statute, law, rule, regulation, ordinance or order, all as amended. This includes, but is not limited to, claims for violation of any civil rights laws based on protected class status; claims for assault, battery, defamation, intentional or negligent infliction of emotional distress, breach of the covenant of good faith and fair dealing; promissory estoppel; negligence; negligent hiring; retention or supervision; retaliation; constructive discharge; violation of whistleblower protection laws; unjust enrichment; violation of public policy; and, all other claims for unlawful employment practices, and all other common law or statutory claims.

EXECUTIVE INITIALS

- II. Agreement to Release My Claims. Except as stated in Section V of this Release, I agree to release all My Claims and waive any rights to My Claims. I also agree to withdraw any and all of My charges and lawsuits against Employer; *except that* I may, but am not required to, withdraw or dismiss, or attempt to withdraw or dismiss, any charges that I may have pending against Employer with the Employment Opportunity Commission (“EEOC”) or other civil rights enforcement agency. In exchange for My agreement to release My Claims, I am receiving satisfactory Consideration from Employer to which I am not otherwise entitled by law, contract, or under any Employer policy. The Consideration I am receiving is a full and fair consideration for the release of all My Claims. Employer does not owe Me anything in addition to what I will be receiving according to the Separation Agreement which I have signed.
- III. Unknown Claims. In waiving and releasing any and all actual, potential, or threatened claims against Employer, whether or not now known to me, I understand that this means that if I later discover facts different from or in addition to those facts currently known by me, or believed by me to be true, the waivers and releases of this Release will remain effective in all respects – despite such different or additional facts and my later discovery of such facts, even if I would not have agreed to the Separation Agreement and this Release if I had prior knowledge of such facts.
- IV. Confirmation of No Claims, Etc. I am not aware of any other facts, evidence, allegations, claims, liabilities, or demands relating to alleged or potential violations of law that may give rise to any claim or liability on the part of any Released Party under the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the False Claims Act, the Anti-kickback Statute. I understand that nothing in this Release interferes with My right to file a complaint, charge or report with any law enforcement agency, with the Securities and Exchange Commission (“SEC”) or other regulatory body, or to participate in any manner in an SEC or other governmental investigation or proceeding under any such law, statute or regulation, or to require notification or prior approval by Employer of any such a complaint, charge or report. I understand and agree, however, that I waive My right to recover any whistleblower award under the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or other individual relief in any administrative or legal action whether brought by the SEC or other governmental or law enforcement agency, Me, or any other party, unless and to the extent that such waiver is contrary to law. I agree that the Released Parties reserve any and all defenses which they might have against any such allegations or claims brought by Me or on My behalf. I understand that Employer is relying on My representations in this Release and related Separation Agreement.

EXECUTIVE INITIALS

V. Exclusions from Release.

- A. The term “Claims” does not include My rights, if any, to claim the following: unemployment insurance benefits; workers compensation benefits; claims for My vested post-termination benefits under any 401(k) or similar retirement benefit plan; My rights to group medical or group dental insurance coverage pursuant to section 4980B of the Internal Revenue Code of 1986, as amended (“COBRA”); My rights to enforce the terms of this Release; or My rights to assert claims that are based on events occurring after this Release becomes effective.
- B. Nothing in this Release interferes with My right to file or maintain a charge with the Equal Employment Opportunity Commission or other local civil rights enforcement agency or participate in any manner in an EEOC or other such agency investigation or proceeding. I, however, understand that I am waiving My right to recover individual relief including, but not limited to, back pay, front pay, reinstatement, attorneys’ fees, and/or punitive damages, in any administrative or legal action whether brought by the EEOC or other civil rights enforcement agency, Me, or any other party.
- C. Nothing in this Release interferes with My right to challenge the knowing and voluntary nature of this Release under the ADEA and/or OWBPA.
- D. I agree that Employer reserves any and all defenses, which it has or might have against any claims brought by Me. This includes, but is not limited to, Employer’s right to seek available costs and attorneys’ fees as allowed by law, and to have any monetary award granted to Me, if any, reduced by the amount of money that I received in consideration for this Release.

EXECUTIVE INITIALS

VI. Older Workers Benefit Protection Act. The Older Workers Benefit Protection Act applies to individuals age 40 and older and sets forth certain criteria for such individuals to waive their rights under the Age Discrimination in Employment Act in connection with an exit incentive program or other employment termination program. I understand and have been advised that, if applicable, the above release of My Claims is subject to the terms of the OWBPA. The OWBPA provides that a covered individual cannot waive a right or claim under the ADEA unless the waiver is knowing and voluntary. If I am a covered individual, I acknowledge that I have been advised of this law, and I agree that I am signing this Release voluntarily, and with full knowledge of its consequences. I understand that Employer is giving Me twenty-one (21) days from the date I received a copy of this Release to decide whether I want to sign it. I acknowledge that I have been advised to use this time to consult with an attorney about the effect of this Release. If I sign this Release before the end of the twenty-one (21) day period it will be My personal, voluntary decision to do so, and will be done with full knowledge of My legal rights. I agree that material and/or immaterial changes to the Separation Agreement or this Release will not restart the running of this consideration period. I also acknowledge that the Separation Agreement, this Release and any other attachments or exhibits have each been written in a way that I understand.

VII. Right to Rescind and/or Revoke. I understand that insofar as this Release relates to my rights under the Age Discrimination in Employment Act, it shall not become effective or enforceable until seven (7) days after I sign it. I also have the right to rescind (or revoke) this Release insofar as it extends to potential claims under the ADEA by written notice to Employer within seven (7) calendar days following my signing this Release, and within fifteen (15) calendar days as to waiver of claims under the Minnesota Human Rights Act (the "Rescission Period"). Any such rescission (or revocation) must be in writing and hand-delivered to Employer or, if sent by mail, postmarked within the applicable time period, sent by certified mail, return receipt requested, and addressed as follows:

- A. post-marked within the seven (7) day Rescission Period or, if applicable, fifteen (15) day Rescission Period;
- B. properly addressed to DiaMedica USA, Inc., Attention: Chief Executive Officer, Two Carlson Parkway, Suite 260, Minneapolis, MN 55447; and
- C. sent by certified mail, return receipt requested.

I understand that the Consideration I am receiving for settling and releasing my Claims is contingent upon my agreement to be bound by the terms of this Release. Accordingly, if I decide to revoke this Release as provided herein, I understand that I am not entitled to the Consideration offered in the Separation Agreement. I further understand that if I attempt to revoke my release of ADEA, MHRA or any other claims, I must immediately return to the Employer any Consideration that I may have received under my Separation Agreement.

VIII. I Understand the Terms of this Release. I have had the opportunity to read this Release carefully and understand all its terms. I have had the opportunity to review this Release with My own attorney. In agreeing to sign this Release, I have not relied on any oral statements or explanations made by Employer, including its employees or attorneys. I understand and agree that this Release and the attached Agreement contain all the agreements between Employer and Me. We have no other written or oral agreements.

Harry Alcorn

Dated: _____, 20____

EXECUTIVE INITIALS

SUBSIDIARIES OF THE REGISTRANT

	Entity Name	Country of Incorporation
1.	DiaMedica USA Inc.	Delaware, USA
2.	DiaMedica Australia Pty Ltd.	Australian

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File Nos. 333-228821) of DiaMedica Therapeutics Inc. and Subsidiaries of our report dated March 19, 2019, relating to the consolidated financial statements of DiaMedica Therapeutics Inc. and Subsidiaries, which appears on page 74 of this annual report on Form 10-K for the fiscal year ended December 31, 2018.

/s/ Baker Tilly Virchow Krause, LLP

Minneapolis, Minnesota

March 19, 2019

**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)) 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (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 19, 2019

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

**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)) 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (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 19, 2019

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

**CERTIFICATION PURSUANT TO SECTION 302(A) 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, 2018 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 19, 2019

**CERTIFICATION PURSUANT TO SECTION 302(A) 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, 2018 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 19, 2019