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, 2025
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____.

Commission file number: 001-36291

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
301 Carlson Parkway, Suite 210	**55305**
Minneapolis, Minnesota	(Zip Code)
(Address of principal executive offices)	

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Shares, no par value per share	**DMAC**	**The Nasdaq 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's voting common shares held by non-affiliates, computed by reference to the closing sales price at which the voting common shares were last sold as of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), as reported by The Nasdaq Capital Market on that date, was $95.8 million.

As of March 27, 2026, there were 53,882,506 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 2026 Annual General Meeting of Shareholders which we intend to file with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

DIAMEDICA THERAPEUTICS INC.

ANNUAL REPORT ON FORM 10-K
FISCAL YEAR ENDED DECEMBER 31, 2025

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This annual report on Form 10-K contains certain forward-looking statements that are within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. For more information, see "Cautionary Note Regarding Forward-Looking Statements."

As used in this report, references to "DiaMedica," the "Company," "we," "our" or "us," unless the context otherwise requires, refer to DiaMedica Therapeutics Inc. and its subsidiaries, all of which are consolidated in DiaMedica's consolidated financial statements. References in this report to "common shares" mean our voting common shares, no par value per share.

We own various unregistered trademarks and service marks, including our corporate logo. Solely for convenience, the trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the owner of such trademarks and trade names will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this annual report on Form 10-K that are not descriptions of historical facts are forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 that are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition, prospects 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 but are not limited to, statements concerning the following:

- our plans to develop, obtain regulatory approval for the clinical study of DM199 for preeclampsia (PE), fetal growth restriction (FGR) and ultimately to obtain regulatory approval for and commercialize our DM199 product candidate for the treatment of PE, FGR and acute ischemic stroke (AIS);

- our ability to conduct successful clinical testing of our DM199 product candidate for PE, FGR and AIS and meet certain anticipated or target milestones and dates thereof with respect to our clinical studies;

- the ability of our physician collaborators to successfully complete the current Phase 2, proof-of-concept investigator-sponsored clinical trial of DM199 for the treatment of PE and FGR, our reliance on these physician collaborators to conduct the study, and our expectations related to the timing of Part 1b and Parts 2 and 3 of this study;

- our ability to meet anticipated site activations, enrollment and interim analysis timing with respect to our Phase 2/3 ReMEDy2 clinical trial of DM199 for the treatment of AIS, especially in the light of slower than expected site activations and enrollment which we believe are due, in part, to hospital and medical facility staffing shortages; inclusion/exclusion criteria in the study protocol; concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns regarding the prior clinically significant hypotension events and circumstances surrounding the clinical hold which was lifted in June 2023; use of artificial intelligence and telemedicine which have enabled smaller hospitals to retain AIS patients not eligible for mechanical thrombectomy instead of sending these patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological clinical trials;

- the success of the actions we are taking to mitigate the impact of the factors adversely affecting our ReMEDy2 trial site activations and enrollment rate, including significantly expanding our internal clinical team and bringing in-house certain trial activities, such as study site identification, qualification and activation, clinical site monitoring, supporting vendor management and overall program management; globally expanding the trial; and making certain changes to the study protocol; and risks associated with these mitigation actions;

- uncertainties relating to regulatory applications and related filing and approval timelines, especially in light of recent changes in funding and staffing levels for the U.S. Food and Drug Administration (FDA) and other government agencies;

- pending and future government agency requests for additional studies and uncertainty and potential delays in obtaining results from the same;

- the possible occurrence of future adverse events associated with or unfavorable results from the Phase 2 investigator-sponsored PE trial or our ReMEDy2 trial and their potential to adversely effect current or future trials;

- the adaptive design of our ReMEDy2 trial, which is intended to enroll approximately 300 patients at up to 100 sites globally, and the possibility that the final sample size, which will be determined based upon the results of an interim analysis of 200 participants, may be up to 728 patients, according to a pre-determined statistical plan, other possible changes in the trial, including as a result of input from the FDA, and the results of the interim analysis as determined by our independent data safety monitoring board;

- our expectations regarding the perceived benefits of our DM199 product candidate over existing treatment options for PE, FGR and AIS;

- our ability to partner with and generate revenue from biopharmaceutical or pharmaceutical partners to develop, obtain regulatory approval for, and commercialize our DM199 product candidate for PE, FGR and AIS;

- the potential size of the markets for our DM199 product candidate for PE, FGR and AIS and our or any future partner's ability to serve those markets, the rate and degree of market acceptance of and ability to obtain coverage and adequate reimbursement for, our DM199 product candidate for PE, FGR and AIS both in the United States and internationally;

- the success, cost and timing of our clinical trials, as well as our reliance on our key executives, clinical personnel, advisors and third parties in connection with our trials;

- our or any future partner's ability to commercialize, market and manufacture DM199;

- expectations regarding U.S. federal, state and foreign regulatory requirements and developments affecting our pending and future clinical trials and regulatory approvals of our DM199 product candidate for PE, FGR and AIS and future commercialization and manufacturing of such products if required regulatory approvals are obtained;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our DM199 product candidate;

- expectations regarding competition and our ability to obtain data exclusivity for our DM199 product candidate for PE, FGR and AIS; and

- our estimates regarding expenses, market opportunity for our product candidates, future revenue, and capital requirements; our anticipated use of the net proceeds from our prior private placements; how long our current cash resources will last; and our need for and ability to obtain additional financing to fund our operations, including funding necessary to complete our current clinical trials and obtain regulatory approvals for our DM199 product candidate for PE, FGR and/or AIS.

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 highly competitive and rapidly-changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements should not be relied upon as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, including the securities laws of the United States, we do not intend to update any forward-looking statements to conform these statements to actual results or to changes in our expectations.

INDUSTRY AND MARKET DATA

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

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

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company committed to improving the lives of people suffering from severe ischemic disease with two main clinical programs focused on preeclampsia (PE) / fetal growth restriction (FGR) and acute ischemic stroke (AIS). Our lead candidate DM199 (rinvecalinase alfa), is the first pharmaceutically active recombinant (synthetic) form of the human tissue kallikrein-1 (rhKLK1) protein to be clinically studied in patients and has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of AIS. Kallikrein-1 (KLK1), extracted from human urine, is an established therapeutic modality in Asia for the treatment of AIS, and KLK1 produced from pig pancreas, is an established therapeutic modality for the treatment of cardio renal disease, including hypertension, in Asia. We plan to advance DM199 through required clinical trials to create shareholder value by establishing its clinical and commercial potential as a therapy for PE, FGR and AIS. Longer term, we plan to develop DM300, our patented recombinant human ulinastatin, a broad-spectrum serine protease inhibitor, as a potential therapy for severe acute pancreatitis.

KLK1 is a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism believed to enhance endothelial health, microcirculatory blood flow and tissue perfusion by increasing production of nitric oxide (NO), prostacyclin (PGI_2) and endothelium-derived hyperpolarizing factor (EDHF). In PE and FGR, DM199 is intended to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta, potentially disease modifying results that improve both maternal and perinatal outcomes. In the case of AIS, DM199 is intended to enhance blood flow and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the vascular occlusion and inhibition of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis.

Our clinical development program in PE currently centers around an investigator-sponsored safety, tolerability and pharmacodynamic, proof-of-concept Phase 2 study in PE patients being conducted at the Tygerberg Hospital in Cape Town, South Africa. This Phase 2 study consists of three studies in PE (Part 1a, dose-escalation; Part 1b, dose-expansion; and Part 2, expectant management) and a fourth study in fetal growth restriction (FGR, Part 3, expectant management). Part 1a topline study results are intended to identify a suitable dose for Parts 1b, 2, and 3. Up to approximately 100 women with PE and potentially an additional 30 subjects with fetal growth restriction may be evaluated. The first subject in Part 1a was enrolled in the fourth quarter of 2024 and interim results from Part 1a of the study were released in July 2025. The interim results (N=28 subjects) demonstrate that DM199 appears safe and well-tolerated with clinically-relevant pharmacodynamic activity with no evidence of placental transfer. Additionally, subjects exhibited rapid, statistically significant reductions in blood pressure with duration of effect that was sustained up to 24 hours post-infusion compared to pre-treatment baseline. An extension cohort of approximately 10 subjects is currently being enrolled at the expected therapeutic dose levels. Preparations are underway to initiate Part 1b where up to 30 subjects with PE and expected delivery within 72 hours will be treated with a dose regimen identified from Part 1a. Based in part upon these interim results, we believe DM199 has the potential to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta.

We are preparing for an open-label, dose-ranging Phase 2 study of DM199 in participants with early onset preeclampsia to be conducted in North America (United States & Canada) and the United Kingdom (UK). In March 2026, we received approval from Health Canada to initiate this Phase 2 study and we are currently finalizing plans to commence site activation in the second half of this year. In the second quarter of 2026, we anticipate filing a clinical trial application to expand this Phase 2 study to include sites in the UK. Regarding the status of this clinical program in the United States, in the fourth quarter of 2025, we participated in a productive, in-person pre-investigational new drug (IND) meeting with the FDA to discuss the planned Phase 2 study, at which the FDA requested an additional non-clinical, 10-day modified embryo-fetal development and pre- and postnatal development (ePPND) study in a rabbit model, a non-rodent species. Preliminary results of the rabbit study suggest that the animals developed an antibody response to DM199, a humanized recombinant protein, preventing us from completing the requested ePPND study in the rabbit model. In earlier pregnant rabbit studies, there was no evidence of teratogenicity (i.e., no external, visceral or skeletal malformations in developing rabbit fetuses) attributable to DM199 in the approximately 200 rabbit offspring produced. The fetal effects with pregnant rabbits that were observed, embryo/fetal lethality and decreased fetal body weights, were considered secondary to frank maternal toxicity that was observed at all doses. We are currently evaluating alternate animal models to address the FDA's ePPND study request. Depending on the alternative species, and its gestational period, results from the ePPND study may be substantially delayed.

Our clinical program in AIS centers on our ReMEDy2 clinical trial (NCT05065216) of DM199 for the treatment of AIS. Our ReMEDy2 clinical trial is a Phase 2/3, adaptive design, randomized, double-blind, placebo-controlled trial intended to enroll approximately 300 participants at up to 100 sites globally. The adaptive design component includes an interim analysis by our independent data safety monitoring board after the first 200 participants have completed the trial. Based on the results of the interim analysis, the study may be stopped for futility, or the final sample size will be determined, ranging between 300 and 728 patients, according to a pre-determined statistical plan.

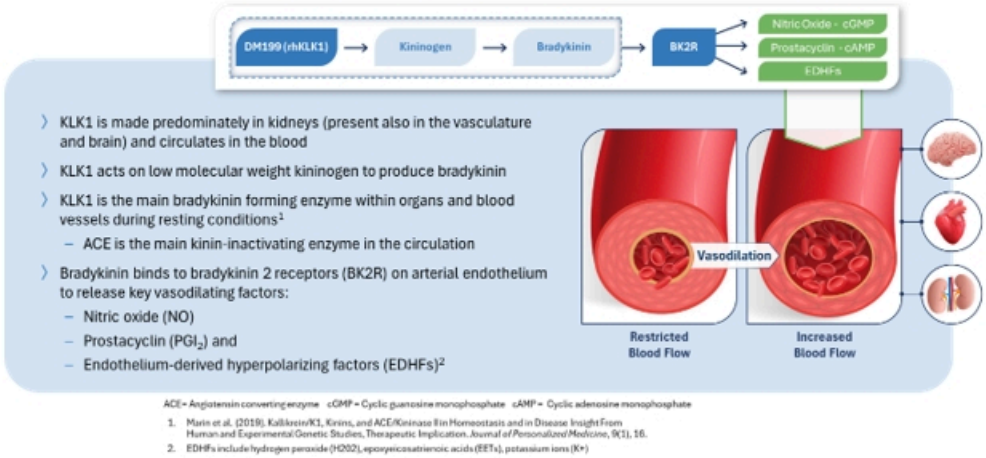
We believe DM199 has the potential to treat a variety of diseases where restoring healthy function requires sufficient activity of KLK1 and the kallikrein-kinin system (KKS). Today, forms of KLK1 derived from human urine and the pancreas of pigs are approved and sold in Japan, China and South Korea to treat AIS, hypertension and other related vascular diseases. We believe millions of patients have been treated with these KLK1 therapies, including up to one million AIS patients now being treated annually with human urinary-derived KLK1 in China. Over 200 clinical studies in China have found urinary-derived KLK1 effective for increasing blood flow, decreasing ischemia in the penumbra, and reducing infarct size. Importantly, human urinary-derived KLK1 has been shown to be generally safe and well tolerated and does not increase the risk of severe intracranial hemorrhage. Similarly, in the use of KLK1 to treat PE, preliminary evidence from several Asia-based studies using KLK1 derived from pig pancreas has shown reductions in maternal blood pressure and improvements in placental perfusion. However, given the small sample size of these studies, we remain cautious in our interpretation of the reported results and believe further study is necessary. We further note that there are numerous regulatory, commercial and clinical drawbacks associated with KLK1 derived from these sources which we believe can be overcome by developing a recombinant version of KLK1 (rhKLK1) such as DM199. We believe higher regulatory standards and the potential for impurities, endotoxins and chemical byproducts due to the inherent variability in the isolation and purification process are the primary reasons why urinary- or animal-derived KLK1s are not currently available and or approved in the United States or Europe. We are not aware of any recombinant version of KLK1 with regulatory approval for clinical use in any country, nor are we aware of any recombinant version in development, other than our drug candidate, DM199.

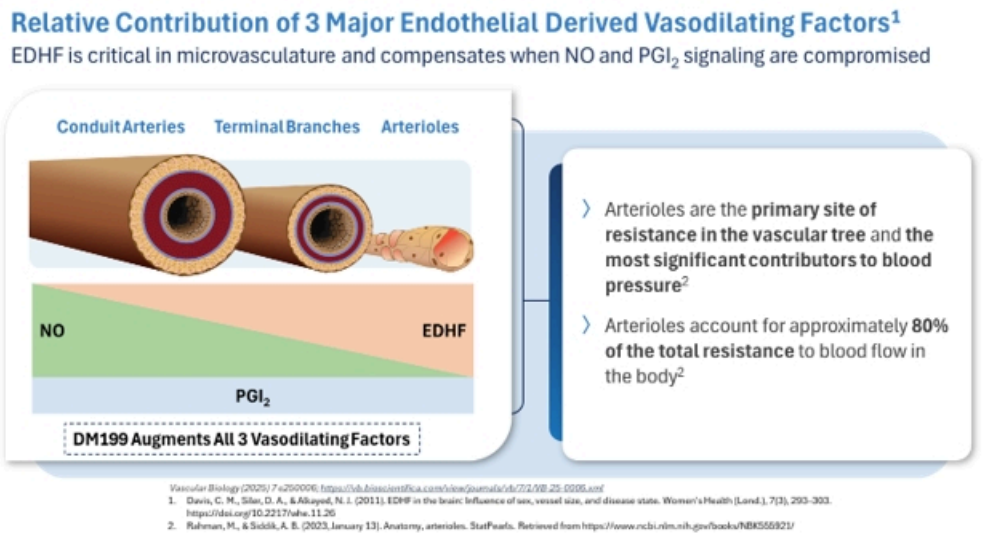
DM199 Background

Kallikrein-Kinin System

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

KLK1 is involved in multiple biochemical processes. The most well-characterized activity of KLK1 is the enzymatic cleavage of low molecular weight kininogen (LMWK) to produce bradykinin (BK) which activates BK receptors (primarily BK2R since the BK1R is typically only activated in pathological situations). As illustrated below, activation of BK receptors by kinins sets in motion metabolic pathways which locally produce NO, prostaglandins (primarily PGI_2in endothelial cells) and EDHF. Increased nitric oxide and prostacyclin work through the cyclic guanosine monophosphate (cGMP) and cyclic adenosine monophosphate (cAMP) pathways, to preferentially relax smooth muscle cells and improve blood flow (through vasodilation), potentially protecting 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 stroke, renal diseases and hypertension. Although individual pharmacologic activators of each pathway—such as NO donors, PGI_2 analogues, and EDHF stimulators—show preclinical promise; however, none have achieved regulatory approval, and no current therapy targets all three pathways simultaneously. DM199, as a protein augmentation therapy, is intended to increase KLK1 levels to more fully activate the KKS driving the local generation of all three endothelial pathways, NO, PGI_2 and EDHF, to promote endothelial health and protect the brain and kidney from damage. By providing additional supply of the KLK1 protein, DM199 treatment could potentially improve blood flow to the placenta and brain while reducing inflammation in damaged end-organs, such as the brain and the kidneys, supporting their structural integrity and normal functioning.





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

Supporting Data for Use of DM199 (KLK1)

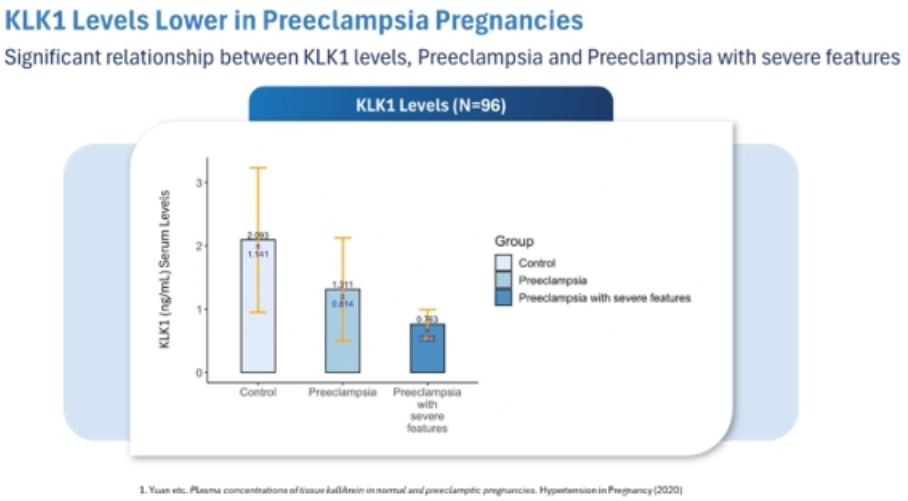
Preeclampsia and Fetal Growth Restriction:

Studies have shown that KLK1 levels are reduced in women suffering from preeclampsia. Further, the lowest levels are observed in women with preeclampsia with severe features. KLK1 plays a central physiological role in regulating vascular tone and perfusion through the generation of active kinins, including bradykinin. Bradykinin is a potent, locally acting vasodilator that promotes relaxation of blood vessels, improves endothelial function, and lowers blood pressure. By activating existing vascular signaling pathways, KLK1 enhances blood flow without introducing foreign or non-physiological mechanisms into the maternal circulation. DM199, a recombinant form of human KLK1, leverages these existing pathways to promote vasodilation and improve tissue perfusion, effects that have already been demonstrated across multiple clinical studies in non-pregnant populations with hypertension and vascular disease. These characteristics make KLK1 a strong therapeutic candidate for conditions driven by impaired blood flow and endothelial dysfunction.

Preeclampsia is widely understood to originate from inadequate maternal blood flow to the placenta, resulting in placental ischemia and the subsequent release of anti-angiogenic and pro-inflammatory factors such as sFlt-1 and soluble endoglin (sEng). These circulating factors drive systemic endothelial dysfunction and the clinical manifestations of the disease, including hypertension and organ injury. By improving maternal vascular function and placental perfusion, KLK1 therapy has the potential to address this upstream pathology. Enhancing blood flow to the placenta may reduce ischemic stress and limit the release of harmful mediators, offering a disease-modifying approach rather than symptomatic management alone.

Use of Porcine-derived KLK1 for the Treatment of PE in China

A porcine-derived form of KLK1 has been used for decades in Asia to treat vascular conditions such as hypertension and chronic kidney disease. In preeclampsia, Chinese investigators have shown that maternal plasma concentrations of KLK1 were significantly lower in preeclampsia compared with patients with mild PE or normal pregnancies and that low levels of tissue KLK1 may be a marker of severe PE as summarized in the figure below (Yuan, et al, 2020). Thus, several small, single center, open-label case studies have been conducted in China exploring the empiric administration of porcine-derived KLK1, in combination with magnesium sulfate, to determine if augmentation of maternal plasma levels of KLK1 could have potential therapeutic benefit in severe PE. Improvements in uterine and umbilical blood flow, reduced blood pressure, improved renal function, extended gestation and increased birthweight have been observed without reported safety issues. These collective findings give support for further development of a recombinant KLK1 (DM199) in patients with PE.

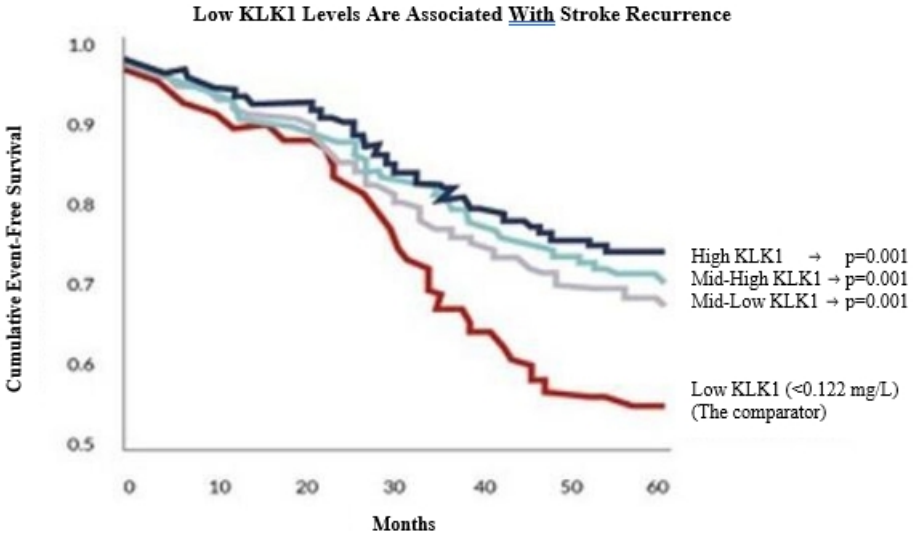


1. Yuan etc. *Plasma concentrations of tissue kallikrein in normal and preeclamptic pregnancies.* Hypertension in Pregnancy (2020)

Acute Ischemic Stroke:

KLK1, derived from human urine, was first approved as a treatment for AIS in China in 2005. KLK1 derived from the pancreas of pigs has been approved for the treatment of hypertension, certain chronic kidney and other vascular diseases in Japan, China and South Korea for several decades. There is one company selling human urine-derived KLK1 in China (Kailikang®, Tech-pool BioPharma/Shanghai Pharmaceuticals), and we believe human urine-derived KLK1 is currently being used to treat up to one million AIS patients per year. We believe that approximately 20 companies are marketing porcine-derived KLK1 in Japan, China and South Korea. We have identified several hundred papers supporting the clinical use of urinary- and porcine-derived KLK1 from China, Japan and South Korea in the treatment of AIS.

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



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

The observations of low plasma levels of KLK1 in both stroke recurrence and PE further support the approach of KLK1 augmentation as a means to provide a therapeutic benefit.

Near-Term Goals

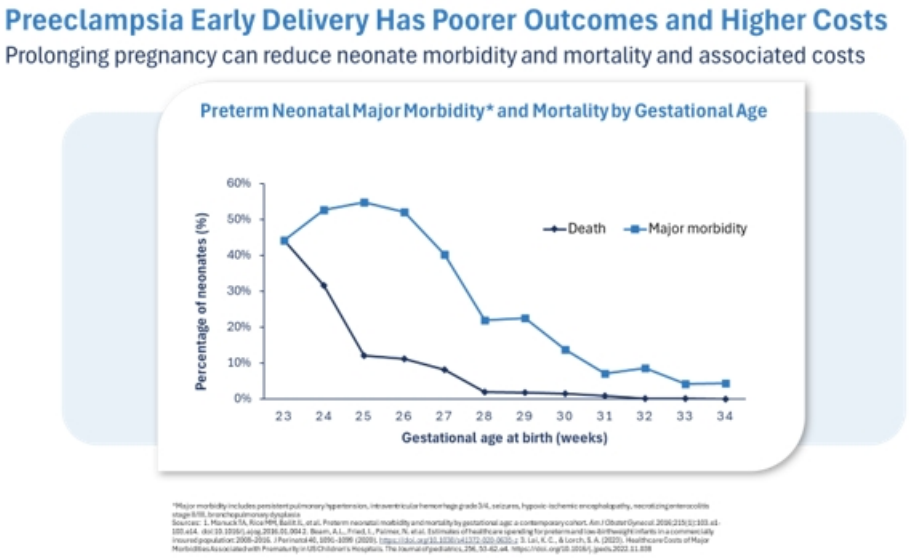
Our mission is to improve the lives of people suffering from serious ischemic diseases. Our near-term goals are to principally focus on supporting the Phase 2 investigator-sponsored trial (IST) of DM199 in PE, initiating a global Phase 2 trial in early-onset PE and executing our ReMEDy2 Phase 2/3 trial of DM199 in AIS. Key elements of our strategy include:

- DM199 for PE – complete Part 1a (dose-ranging in PE patients with expected delivery within 72-hours) and then Part 1b (PE patients with expected delivery within 72-hours at does selected from Part 1a) of the Phase 2 IST;
- File applications for a global Phase 2 trial (North America and United Kingdom) in early-onset preeclampsia and engage regulatory agencies in multiple countries regarding our PE development program and submit applications for Fast Track and/or Breakthrough designations, where available;
- DM199 for AIS – continue to execute our ReMEDy2 Phase 2/3 (NCT05065216) trial with the activation of up to 100 global clinical sites and continue participant enrollment;
- Continue manufacturing process development to support anticipated applications for commercial approval of DM199; and
- Identify a strategic partner(s) to assist with future clinical development and commercialization of DM199.

Preeclampsia Background and Disease Pathology

Preeclampsia Background

PE is a complex disorder affecting multiple body systems, with approximately 10 million cases occurring globally each year. It typically presents after 20 weeks of gestation with new onset hypertension and organ dysfunction, such as renal or liver impairment. It is a major cause of maternal and infant morbidity and mortality, especially in cases of early onset preeclampsia occurring before 34 weeks of gestation. Globally, this condition leads to the deaths of approximately 76,000 women and 500,000 newborns each year. Both pre-eclampsia and fetal growth restriction arise from poor placental function due to reduced placental perfusion, histopathologically evident as maternal vascular malperfusion injuries. Preeclampsia is further characterized by endothelial dysfunction and maternal vascular injury. This leads to vasoconstriction of vessels and hypertension, which damages many end organs supplied by these vessels. Preeclampsia is associated with placental and systemic inflammation, oxidative stress and an anti-angiogenic state. Hence, a drug that vasodilates blood vessels to improve organ and placenta perfusion and promotes vascular health (via pro-angiogenesis and reductions in inflammation and oxidative stress) may be a treatment for both conditions.



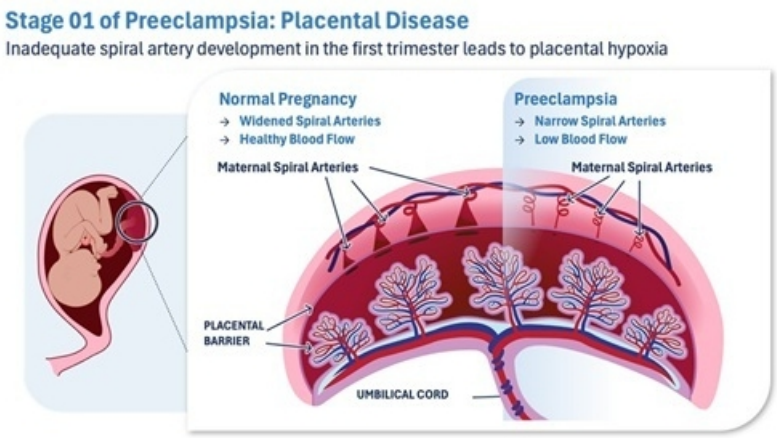
There are currently no FDA-approved therapeutics for PE and the only cure is delivery of the fetus, often prematurely. Control of blood pressure is the mainstay treatment for preeclampsia, but it does not modify progression of the disease and first-line hypertension medications angiotensin converting enzyme inhibitors (ACEi) and angiotensin receptor blockers (ARBs) are contraindicated due to causing fetal harm. Magnesium sulfate is used to prevent seizures in women and steroids are given to enhance fetal lung maturation.

Fetal growth restriction is a condition of fetal undergrowth due to a poorly functioning placenta – the life support system of the unborn child. Fetal growth restriction is the leading cause of stillbirth. For those that survive the pregnancy, unhealthy fetal development in utero leaves a legacy of poor health echoing across the child's lifespan. Currently, no approved treatment exists for this condition.

The pathogenesis of preeclampsia has been described in a two-stage model as illustrated below (Bisson et al, 2023).

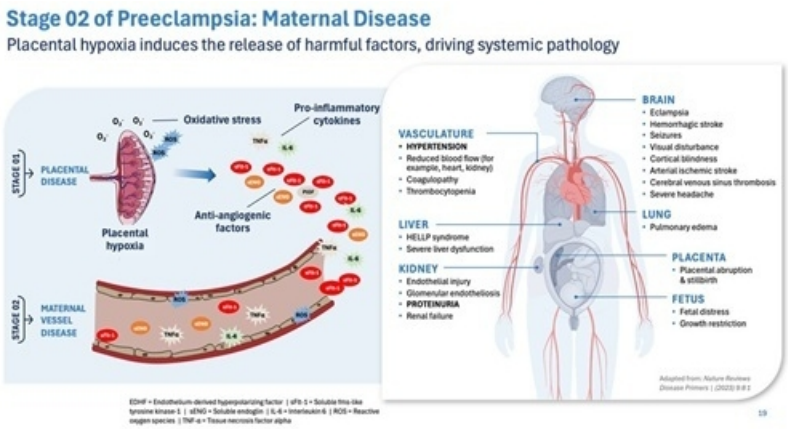
Stage 1: Placental Disease

The maternal spiral arteries supply blood to the intervillous space of the placenta, undergoing significant structural, cellular, molecular, and functional changes from approximately week 10 to week 22 of gestation to support the growing fetus's increasing metabolic demands. During the first trimester, placental trophoblasts invade these arteries, replacing the endothelial cells and smooth muscle cells with extravillous trophoblast cells, resulting in the loss of vasomotor control and a transformation into rigid, fixed-diameter vessels. This process enlarges the vessel diameter by at least 10-fold, creating a low-resistance, high-capacity uteroplacental interface that allows for maximal and constant blood flow to the villous. The remodeled spiral artery network is essential for efficient nutrient and waste exchange, as the uteroplacental blood flow increases from 45 mL/min to 750 mL/min at term to support the high metabolic demands of the fetus. In PE, trophoblast invasion is impaired leading to incomplete remodeling of the spiral arteries and shallow placentation. This defective placentation in preeclampsia results in high resistance uterine circulation, causing impaired placental perfusion.



Stage 2: Maternal Vascular Disease and Subsequent Endothelial Dysfunction

When deprived of adequate blood flow, the hypoxic placenta experiences oxidative stress and releases antiangiogenic factors (sFlt-1, sEng), proinflammatory cytokines (TNF-α, IL-6), and other harmful substances into the maternal blood stream. These factors damage the maternal endothelium, elevate blood pressure, and contribute to organ damage. Moreover, this damage also depresses intrauterine blood flow causing reduced placental perfusion leading to a negative feedback loop. This cycle accelerates further with the increasing metabolic demands of a growing fetus, creating the perfect ischemic storm.



Unmet Medical Need in Preeclampsia

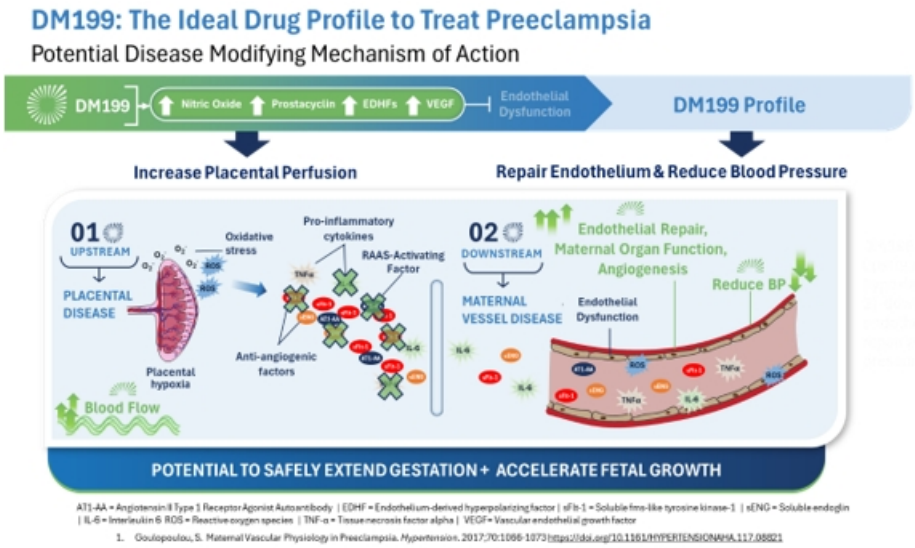
According to the Preeclampsia Foundation, one in every 12 pregnancies is affected by preeclampsia, with an annual incidence of approximately 200,000 pregnancies in the United States. Early-onset preeclampsia, which occurs before 34 weeks of gestation, affects up to 30,000 pregnancies annually and is more severe than late-onset preeclampsia (occurring after 34 weeks). Early-onset preeclampsia poses a higher risk of fetal morbidity and mortality, with infants being born significantly earlier, increasing their risk of future developmental challenges. Women with preeclampsia are twice as likely to develop heart disease or suffer a stroke and four times as likely to develop high blood pressure. Additionally, preeclampsia disproportionately affects African American women, who are 60% more likely to develop the condition than white women and are also more likely to experience severe forms of preeclampsia.

DM199 – Our Novel Solution for the Treatment of Preeclampsia and Fetal Growth Restriction

We are developing DM199 as a potentially disease-modifying treatment to safely extend gestation and improve maternal and fetal outcomes in preeclampsia. In the maternal vasculature, DM199 may lower blood pressure, improve endothelial health, and enhance blood flow to key organs. It also has the potential to increase placental perfusion by dilating intrauterine arteries, which could promote fetal growth and reduce harmful placental factors such as sFlt-1 and sEng. This effect is believed to result from the inadequate remodeling of spiral arteries supplying the placenta, leaving endothelial and smooth muscle cells intact and vasoactive, making them a suitable pharmaceutical target for DM199.

A key potential safety advantage of DM199 in preeclampsia is that it is a large protein that, in testing to-date, has been shown to not cross the placental barrier. In contrast, small molecules, including most oral medications, passively cross the placental barrier, while monoclonal antibodies are transported through active transport mechanisms. By avoiding transfer to the fetus, DM199 potentially offers a significant safety advantage over small molecules such as ACEi, angiotensin receptor blockers (ARBs) and phosphodiesterase 5 (PDE5) inhibitors (e.g., sildenafil), which are known to cross the placental barrier and cause harm to the fetus.

The mechanism of action of DM199 is believed to involve the increased production of endothelial nitric oxide, prostacyclin, and endothelium-derived hyperpolarizing factor, pathways that are typically suppressed or impaired in preeclampsia. Additionally, DM199 may enhance vascular endothelial growth factor (VEGF) signaling, which is disrupted in preeclampsia due to elevated levels of circulating sFlt-1. This mechanism is thought to involve activation of the bradykinin 2 receptor, leading to either direct transactivation of the VEGF2 receptor or crosstalk between the nitric oxide and VEGF intracellular signaling pathways.



DM199 has demonstrated blood pressure reductions in multiple prior studies. Post hoc analysis of all participants with elevated blood pressure (baseline systolic blood pressure ≥ 130 mmHg) from the DM199 Phase 2 REDUX clinical trial (NCT04123613), in three types of chronic kidney disease (CKD), demonstrated significant reductions in systolic blood pressure (SBP) at day 95:

REDUX Phase 2 CKD Trial Results: Baseline SBP*

	SBP ≥130 mmHg	**SBP ≥140 mmHg**	**SBP ≥150 mmHg**
Day 95 Change from Baseline	-7.7 mmHg	-12.6 mmHg	-22.1 mmHg
P-value (Student's T-Test)	0.011	0.004	0.003
Number of Participants	47	31	15

*Includes participants from all cohorts

AIS Background and Disease Pathology

Acute Ischemic Stroke Background

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

More specifically, with respect to an ischemic stroke, at the site of a blood flow blockage in the brain, there exist two major ischemic zones – the core ischemic zone with nearly complete loss of blood flow (blood flow reduction of 75% to 90%, or more), and the surrounding ischemic penumbra, a rim of mild to moderately ischemic tissue surrounding the core ischemic zone. Within minutes, the significant lack of blood flow in the core ischemic zone deprives these cells of glucose and oxygen which rapidly depletes energy stores and triggers the loss of ion gradients, ultimately leading to neuronal cell death, or apoptosis. The ischemic penumbra zone, however, may remain viable for several hours via collateral arteries that branch from the main occluded artery in the core ischemic zone. Unfortunately, the penumbra is at great risk of delayed tissue damage due to inflammation which may also lead to neuronal cell death. As time goes on, a lack of blood flow in the core ischemic zone (infarct) may lead to fluid buildup (edema) and swelling which creates intracranial pressure. This pressure on the brain leads to tissue compression resulting in additional ischemia. Additional events in AIS include vascular damage to the blood vessel lining or endothelium, loss of structural integrity of brain tissue and blood vessels, and inflammation. A stroke can lead to permanent damage with memory loss, speech problems, reading and comprehension difficulties, physical disabilities and emotional/behavioral problems. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation, and/or long-term institutional or family care. However, provided the extended window of viability in the penumbra, next generation stroke therapies are being developed to protect valuable brain tissue during the hours to a week after a stroke.

Unmet Medical Need in AIS

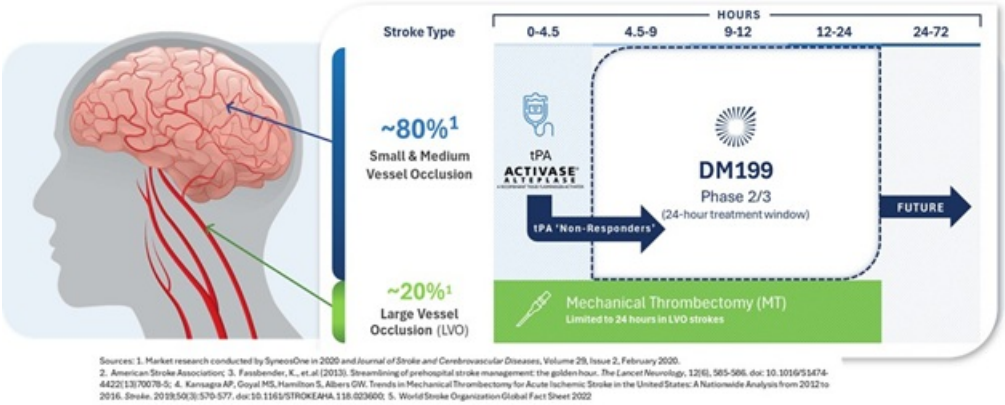
According to the World Stroke Organization, each year approximately 12.0 million people worldwide suffer a stroke, of which 7.8 million are acute ischemic strokes. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately 800,000 people in the U.S. suffer a stroke each year, of which 87% are acute ischemic strokes. We believe that stroke represents an area of significant unmet medical need and a KLK1 therapy (such as DM199) could provide a significant patient benefit, in particular, given its proposed treatment window of up to 24 hours after the first sign of symptoms.

Limitations of Current Treatments for Acute Ischemic Stroke

Tissue plasminogen activators (clot-busting enzymes or thrombolytics) are the only FDA-approved treatment of acute ischemic stroke. Alteplase (tPA, Activase®, Genentech) was approved in 1996 as a 60-minute intravenous (IV) infusion and tenecteplase (TNK, TNKase®, Genentech), a second-generation recombinant tissue plasminogen activator with higher fibrin affinity/specificity was recently approved in March 2025 as a single, 5-second IV bolus administration. Unfortunately, these clot busting enzymes have several drawbacks that limit their clinical usage. These include its narrow therapeutic window of 3 to 4.5 hours, potential complications with IV administration, and risk of bleeding into the brain (intracranial hemorrhage), which, due to a lack of reversibility, is the most severe complication of treatment, limiting its usefulness for the majority of stroke patients.

A newer treatment option for patients with acute ischemic stroke is mechanical thrombectomy (MT), a minimally invasive surgical procedure that uses a mechanical device to remove an intra-arterial blood clot in patients who present with large vessel occlusion (LVO) stroke. Large vessels are the main arteries supplying blood to the brain, including the internal carotid artery, middle cerebral artery, anterior cerebral artery, or basilar artery. During an MT procedure, a computed tomography (CT) angiogram scan confirms the location and size of the clot, which is then removed mechanically using a catheter threaded through the arteries. Clinical studies show the method can significantly increase a stroke patient's return to independent life and drastically reduce mortality. While MT represents a significant advancement in AIS care, LVO stroke as described above represents only approximately 30% of all AIS, thereby leaving the majority of patients without acute treatment. Moreover, the medical infrastructure required to identify and treat a patient with an LVO is such that this therapy is limited to nations with comprehensive healthcare systems.

The limitations of both tPA/TNK and endovascular thrombectomy treatments leave up to 80% of patients without acute intervention. Therefore, there is a significant unmet need for a widely accessible, off-the-shelf drug with a broad therapeutic window that is safe, effective, and reversible in the event of unwanted bleeding.



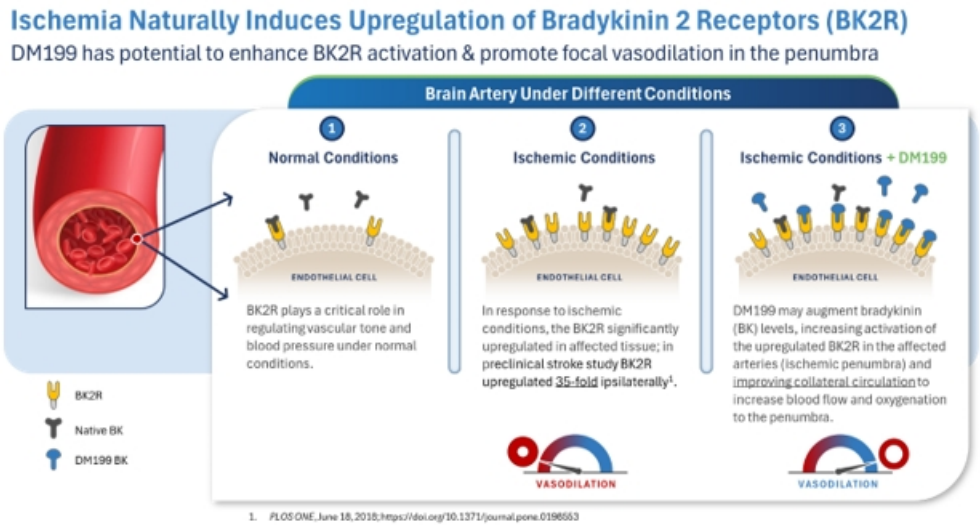
Sources: 1. Market research conducted by SyneosOne in 2020 and *Journal of Stroke and Cerebrovascular Diseases*, Volume 29, Issue 2, February 2020. 2. American Stroke Association; 3. Fassbender, K., et.al (2013). Streamlining of prehospital stroke management: the golden hour. *The Lancet Neurology*, 12(6), 585-586. doi: 10.1016/S1474-4422(13)70078-5; 4. Kansagra AP, Goyal MS, Hamilton S, Albers GW. Trends in Mechanical Thrombectomy for Acute Ischemic Stroke in the United States: A Nationwide Analysis from 2012 to 2016. *Stroke*. 2019;50(3):570-577. doi:10.1161/STROKEAHA.118.023600; 5. World Stroke Organization Global Fact Sheet 2022

According to the CDC, stroke incidence in the United States and its related effects include:

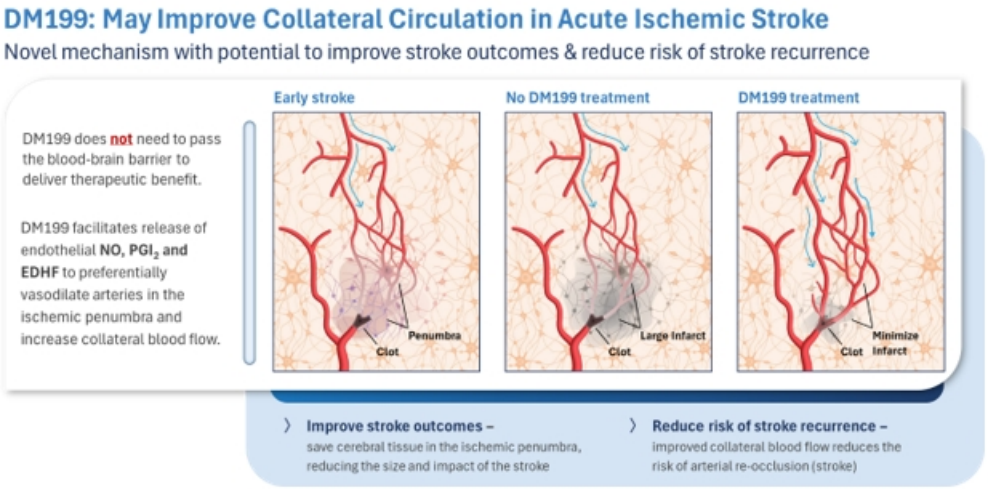
- Every year in the United States, approximately 800,000 people experience a stroke (ischemic or hemorrhagic). Approximately 600,000 of these are first events and nearly 1 in 4, or 185,000, are recurrent stroke events.
- Approximately one of every 20 deaths in the United States is caused by stroke, which is the fifth leading cause of death. On average, someone in the United States has a stroke every 40 seconds and someone dies from a stroke every 3.2 minutes.
- Stroke is a leading cause of serious long-term disability and reduces mobility in more than half of stroke survivors aged 65 and over.
- Risk of having a first stroke is nearly twice as high for non-Hispanic black adults as for white adults, and non-Hispanic black adults and Pacific Islander adults have the highest rate of death due to stroke.
- Six in 10 people who die from stroke are women.
- Stroke-related costs in the United States came to nearly $56.2 billion between 2019 and 2020, including the cost of health care services, medications and missed days of work.

DM199 – Our Novel Solution for the Treatment of AIS

In response to an ischemic stroke, bradykinin 2 receptors (BK2) are significantly upregulated (increased) in the arteries affected by the stroke, the ischemic penumbra. This phenomenon has been observed in animal stroke models, showing a 36-fold increase on the ipsilateral side and a 10-fold increase on the contralateral side (*PLOS ONE (2018), 13(6), e0198553.* https://doi.org/10.1371/ *journal.pone.0198553*). In these oxygen depleted arteries, the increased BK2 receptors signal the need for BK to bind and restore blood flow to these at-risk arteries in the ischemic penumbra. The treatment with DM199 is intended to increase the availability of BK to bind with the BK2 receptors to improve collateral circulation and increase oxygenation to the ischemic penumbra. In binding with the BK2 receptors expressed on endothelial cells (exposed to internal lumen of the artery), DM199, via production of bradykinin, activates the body's natural physiologic processes and therefore does not need to pass through the blood brain barrier, which is a specialized structure that is difficult for many therapeutic agents to cross.



As depicted in the graphic below, we believe the mechanism of action for DM199 (rhKLK1) has the potential to preserve "at risk" penumbral brain tissue by facilitating the release of endothelial nitric oxide, prostacyclin and endothelium-derived hyper polarizing factor which may acutely increase cerebral blood flow by selectively vasodilating these penumbral arteries increasing collateral blood flow and restoring oxygen levels preserving/rescuing these cerebral tissues.



In January 2019, we published a paper titled "Human Tissue Kallikrein in the Treatment of Acute Ischemic Stroke" in a peer reviewed journal (*Therapeutic Advances in Neurological Disorders (2019), 12:1-15,.https://doi.org/10.1177/1756286418821918*). 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-stroke treatment of AIS in China and data has been published from clinical trials involving over 4,000 patients. The paper offers a series of testable therapeutic hypotheses for demonstrating the long-term beneficial effect of KLK1 treatment in AIS patients and the reasons for this action.

We are developing DM199 to treat AIS patients with a therapeutic window of up to 24 hours after the first sign of symptoms, well beyond the current window of 3 hours for tPA/TNK (on-label) and up to 4.5 hours as recommended by the American Heart Association (AHA)/American Stroke Association (ASA) practice guidelines, thereby filling a large unmet need for those patients who cannot receive tPA/TNK under the currently available treatment window. This important attribute of an extended therapeutic window could potentially make DM199 therapy available to the millions of patients worldwide who currently have limited treatment options.

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

In China, Kailikang is approved and marketed by Techpool Bio-Pharma Inc., a company controlled by Shanghai Pharmaceuticals Holding Co. Ltd. Kailikang has been approved for the treatment of AIS in China. We believe the initial treatment window is up to 48 hours after stroke symptom onset. Based on data from IQVIA real world and health data, other publications and our own internal analysis, we estimate that over 600,000 stroke patients in China were treated in 2022 with Kailikang. More than 50 published clinical studies, covering over 4,000 stroke patients, have demonstrated a beneficial effect of Kailikang treatment in AIS, including improvements in standard stroke scores, increased blood flow, and reduced infarct size/ischemia in the brain. In a double-blinded, placebo-controlled trial of 446 participants treated with either Kailikang or a placebo with initial treatment administered up to 48 hours after symptom onset showed significantly better scores on the European Stroke Scale and Activities of Daily Living at three weeks post-treatment and after three months using the Barthel Index, (*China Journal of Neurology (2007), 40:306–310*).

Additionally, a comprehensive meta-analysis covering 24 clinical studies involving 2,433 patients 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 (*Journal of Evidence-Based Medicine (2012) 5:31-39,* https://doi.org/10.1111/j.1756-5391.2012.01167.x*)*

Furthermore, in a retrospective study covering 300 consecutive AIS subjects treated with human urinary KLK1, there was an observed 6.5% absolute reduction (p=0.009) in recurrent strokes (39% relative reduction) within one year (*Brain and Behavior (2018), https://onlinelibrary.wiley.com/doi/pdf/10.1002/brb3.1033).*

Our Competition and Current Treatments for Preeclampsia 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 DM199 product candidate, development capabilities, experience and scientific knowledge provide us with certain competitive advantages. However, we face significant potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other research institutions. Any product candidates that we successfully develop and commercialize will compete with any then-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 greater experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for competitive products and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize, thus limiting our market share and resulting in a longer period before we can recover the expenses of developing and commercializing our DM199 product candidate.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, 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 adversely impact our ability to: recruit or retain qualified clinical, scientific and management personnel; engage specific advisors or clinical research organizations due to conflicts of interest or their capacity constraints; and may also delay recruitment of clinical study sites and study volunteers, any of which may impede 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.

Preeclampsia

There are currently no FDA-approved treatments for preeclampsia and only a limited number of therapeutics in development. Metformin, an established treatment for type 2 diabetes that improves insulin sensitivity and lowers glucose levels, is being studied in late-stage clinical trials in South Africa and Sweden but not in the United States. CBP-4888, a short interfering RNA (siRNA) targeting sFlt-1, is being developed by Comanche Biopharma. It has completed healthy volunteer studies and is expected to be studied in the treatment of pregnant patients with preeclampsia in the future.

Acute Ischemic Stroke

Currently, there are two approved pharmaceutical treatments for AIS in the United States. Both treatments are thrombolytic (clot-busting) agents: tissue plasminogen activator (tPA, alteplase, Activase), and tenecteplase (TNK, TNKase), and their labeled therapeutic window is limited to 3-hours after onset of AIS (up to 4.5 hours per AHA/ASA guidelines). 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:

- BB-031 (Basking Biosciences)
- TS23 (Translational Sciences)
- Solvateltide (Pharmazz)
- Edaravone/dexborneol (Sanbexin®, Simcere Pharmaceutical Group)
- LT3001 (Lumosa Therapeutics)
- Asundexian (Bayer)
- Milvexian (Janssen/BMS)

There is a large unmet therapeutic need for AIS treatments that can be administered beyond the 4.5-hour time window of tPA/TNK. With this large unmet therapeutic need, there is significant competition to develop new therapeutic options. Currently, the most advanced treatment for AIS uses a medical device for the mechanical removal of blood clots in the large arteries supplying blood to the brain through sophisticated catheter-based approaches, referred to as mechanical thrombectomy. According to published research, use of mechanical thrombectomy is growing and the window of time after a stroke where the procedure can be used is widening. New therapeutic options in development include tissue protection focused therapies (deliverable from hours to days after the stroke) that are intended to preserve and protect brain cells beyond the tPA/TNK therapeutic window. 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/TNK therapy. We believe there is a very significant market opportunity for a drug that has a therapeutic window beyond that of tPA/TNK and is able to obtain regulatory approval.

DM199 Clinical Trials

Preeclampsia Phase 2 Investigator-Sponsored Trial

Our clinical development program in PE currently centers around an investigator-sponsored safety, tolerability and pharmacodynamic, proof-of-concept Phase 2 study in PE patients. This Phase 2 study consists of three studies in PE (Part 1a, dose-escalation; Part 1b, dose-expansion; and Part 2, expectant management) and a fourth study in fetal growth restriction (FGR, Part 3, expectant management). Part 1a topline study results are intended to identify a suitable dose for Parts 1b, 2, and 3. Up to approximately 100 women with PE and potentially an additional 30 subjects with fetal growth restriction may be evaluated. The first subject in Part 1a was enrolled in the fourth quarter of 2024 and interim results from Part 1a of the study were released in July 2025. An extension cohort of approximately 10 subjects is currently being enrolled at the expected therapeutic dose levels.

The interim results (N=28 subjects) announced in July 2025 demonstrate that DM199 appears safe and well-tolerated with clinically-relevant pharmacodynamic activity with no evidence of placental transfer. Additionally, subjects exhibited rapid, statistically significant reductions in blood pressure with duration of effect that was sustained up to 24 hours post-infusion compared to pre-treatment baseline specifically:

Blood Pressure Reduction

The study revealed a dose-dependent reduction in both systolic blood pressure (SBP) and diastolic blood pressure (DBP):

- Cohort 9 (n=3; highest dose) achieved the most substantial mean reductions at 5 minutes post-infusion:
  - SBP reductions: -35 mmHg (p<0.05)
  - DBP reductions: -15 mmHg (p<0.05)

- Pooled cohorts 6–9 (n=12), the potentially therapeutic dose range, exhibited statistically significant mean blood pressure reductions at 5 minutes, 30 minutes, and 24 hours post-infusion, showing a durable response over time:
  - SBP reductions: -25mmHg (p=0.0003), -15mmHg (p=0.0018) and -20 mmHg (p=0.0031)
  - DBP reductions: -13mmHg (p=0.0007), -13mmHg (p=0.0002) and -10 mmHg (p=0.0294)

Safety

DM199 demonstrated no placental transfer and no serious treatment emergent adverse events (TEAEs) were reported across all cohorts. TEAEs events were mild and limited to nausea (n=4, 14%), headache (n=3, 11%) and flushing (n=1, 4%). Additionally, there were no discontinuations of treatment and no inductions of early labor.

Dilation of Uterine Arteries

DM199 also produced a statistically significant reduction in pulsatility index (PI) measures, with a 13.2% (p=0.0003) mean reduction in blood flow resistance at the 2-hour mark, indicating a reduction in uterine artery resistance which suggests an improvement in uterine artery blood flow and placental perfusion. Improved perfusion may reduce placental hypoxia, supporting fetal growth and potential disease modification. The uterine artery pulsatility index is a doppler ultrasound measurement that reflects blood flow resistance in the uterine arteries.

Patient Demographics and Dosing:

- Participants were an average of 32.5 years old, had a mean gestation of 37 weeks at enrollment, and had a mean SBP of 165 mmHg and mean DBP of 102 mmHg at baseline.

- Following enrollment and baseline measurements, participants received DM199 IV infusion, followed by SBP and DBP measurements at 5 and 30 minutes post-IV. For cohorts 2 through 9, at 1 hour post-IV, participants received subcutaneous injection of DM199. SBP and DBP were measured again at/through 24 hours post-IV.

- Approximately 80% of deliveries occurred within 24 hours following enrollment, with a total of 9 vaginal deliveries and 16 cesarean sections.

Based in part upon these interim results, we believe DM199 has the potential to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta.

AIS Phase 2/3 ReMEDy2 Trial

We are currently conducting our ReMEDy2 clinical trial (NCT05065216) of DM199 for the treatment of AIS. Our ReMEDy2 clinical trial is a Phase 2/3, adaptive design, randomized, double-blind, placebo-controlled trial intended to enroll approximately 300 participants at up to 100 sites globally. The adaptive design component includes an interim analysis by our independent data safety monitoring board after the first 200 participants have completed the trial. Based on the results of the interim analysis, the study may be stopped for futility, or the final sample size will be determined, ranging between 300 and 728 patients, according to a pre-determined statistical plan. Patients enrolled in the trial will be treated with either DM199 or placebo within 24 hours of the onset of AIS symptoms. The trial excludes patients who received mechanical thrombectomy or participants with large vessel occlusions in the intracranial carotid artery or the M1 segment for the middle cerebral, vertebral or basilary arteries or those that are otherwise eligible for MT. In 2024, the protocol was amended to allow patients treated with tPA or TNK (thrombolytic agents), intended to dissolve blood clots, to be eligible for participation if they continue to experience a persistent neurological deficit after receiving thrombolytic treatment and meet all other trial criteria, including repeat brain imaging to assess any hemorrhagic (bleeding) transformation. The study population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA/TNK and/or MT. We believe that the ReMEDy2 trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

The primary endpoint of the ReMEDy2 trial is physical recovery from stroke as measured by the well-established modified Rankin Scale at day 90. The mRS is a commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke. Secondary endpoints for the trial will evaluate, among other things, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity), participant deaths, the National Institute of Health Stroke Score (NIHSS), Barthel Index (BI) stroke scales, and stroke recurrence. Recurrent strokes represent 25% of all ischemic strokes, often occurring in the first few weeks after an initial stroke and are typically more disabling, costly and fatal than initial strokes.

As previously disclosed, we have experienced and continue to experience slower than expected site activations and enrollment in our ReMEDy2 trial. We believe these conditions may be due to hospital and medical facility staffing shortages; inclusion/exclusion criteria in the study protocol; concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns regarding the prior clinically significant hypotension events and circumstances surrounding the previous clinical hold; use of artificial intelligence and telemedicine which have enabled smaller hospitals to retain AIS patients not eligible for mechanical thrombectomy instead of sending these patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological trials. We continue to reach out to current and potential study sites to understand the specific issues at each study site. In an effort to mitigate the impact of these factors, we significantly expanded our internal clinical team and have brought in-house certain trial activities, including site identification, qualification and activation, clinical site monitoring, supporting vendor management and overall program management. We are currently conducting the trial in the United States and in the countries of Canada, Georgia and the United Kingdom. We recently received regulatory approval from the European Medicines Agency and are initiating study sites in six European countries. We continue to work closely with our contract research organizations and other supporting vendors to develop procedures to support both U.S. and global study sites and potential participants as needed. We intend to continue to monitor the results of these efforts and, if necessary, implement additional actions to enhance site activations and enrollment in our ReMEDy2 trial; however, no assurances can be provided as to the success of these actions and if or when these issues will resolve. Failure to resolve these issues may result in further delays in our ReMEDy2 trial and increase the difficulty in forecasting enrollment.

In September 2021, the FDA granted Fast Track designation to DM199 for the treatment of AIS. The FDA may grant Fast Track designation to a drug that is intended to treat a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need. The FDA provides opportunities for frequent interactions with the review team for a Fast Track product, including end-of-Phase 2 meetings with the FDA to discuss study design, extent of safety data required to support approval, dose-response concerns, and use of biomarkers. A Fast Track product may also be eligible for rolling review, where the FDA reviews portions of a marketing application before the sponsor submits the complete application.

Phase 1C Open Label Safety Trial

Concurrently with performing the requested in-use study to lift the prior clinical hold, we also conducted a Phase 1C open label, single ascending dose (SAD) study of DM199 administered with the PVC IV bags used in the ReMEDy2 trial. The purpose of the study was to confirm, with human data, the DM199 blood concentration levels achieved with the IV dose and further evaluate safety and tolerability. This study was conducted in Australia. The third cohort, which received the 0.50 µg/kg dose level used in the ReMEDy2 trial, was dosed in April 2023 with no significant adverse events related to DM199. The pharmacokinetic data, including the DM199 blood concentration levels, for all cohorts was included as supplemental information in our clinical hold response to the FDA. In investigating the cause of the unexpected instances of hypotension, we noted that all three participants were receiving ACEi therapy at the time of their enrollment. Given this, we also completed an additional, fourth cohort of hypertensive patients (Part B) being treated with ACEi prior to enrolling. All ACEi patients received the full IV dose at the 0.5 µg/kg level with no instances of hypotension. We believe that these results provide further assurance to investigators in our ReMEDy2 trial that ACEi patients may be safely included in the ReMEDy2 trial.

AIS Phase 2 ReMEDy1 Trial

In May 2020, we announced top-line data from our Phase 2 ReMEDy1 trial assessing the safety, tolerability and markers of therapeutic efficacy of DM199 in patients suffering from AIS. We initiated treatment in this trial in February 2018 and completed enrollment in October 2019 with 92 participants. The study drug (DM199 or placebo) was administered as an IV infusion within 24 hours of stroke symptom onset, followed by subcutaneous injections later that day and once every 3 days for 21 days. The trial was 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 and the Barthel Index. The trial met primary safety and tolerability endpoints and was generally safe and well tolerated. In addition, there was a demonstrated therapeutic effect on the rate of severe stroke recurrence inclusive of all participants and there was also a demonstrated therapeutic effect on the physical recoveries of participants that received tPA prior to enrollment but not in participants receiving mechanical thrombectomy prior to enrollment.

Prior to enrollment, 46 of the 91 evaluable participants received mechanical thrombectomy intervention, a catheter-based treatment intended to physically remove clots and potentially available for patients who have a large vessel occlusion and can be treated within 6 to 24 hours of the onset of stroke symptoms. While approximately 20% of AIS patients are believed to be eligible for a mechanical thrombectomy, currently only about 5% to 10% receive the treatment due to elapsed time post-stroke or unavailability of the therapy at the hospital where the patient presents. DM199 is intended to treat the approximately 80% of AIS patients who are not eligible for either mechanical thrombectomy or tPA. Treatment for these patients is limited to supportive care. Due to the large volume of participants receiving mechanical thrombectomy prior to enrollment in the ReMEDy1 trial, and a disproportionate distribution of these participants between the active treatment and placebo groups, DM199 did not produce a therapeutic effect on physical recoveries in the overall trial analysis.

When participants treated with mechanical thrombectomy are excluded from the ReMEDy1 trial data set, which represents the group of participants most closely aligned with the target treatment population for DM199 in the ReMEDy2 trial, a positive therapeutic effect on participant physical recoveries was observed. As shown in the table below, when evaluating the participants treated with DM199 (n=25) vs. supportive care and/or tPA (n=21), the results showed that 36% of participants receiving DM199 progressed to a full or nearly full recovery at 90 days (NIHSS: 0-1), compared to 14% of participants in the placebo group. This represents a 22% absolute increase in the proportion of participants achieving a full or nearly full recovery. Additionally, subject deaths decreased from 24% in the placebo group to 12% in the active therapy group, a 50% relative reduction. Note that the number of subjects in these subsets were insufficient for statistical significance.

DM199 vs. Supportive Care and/or tPA

	NIHSS Outcomes at 90 Days			
	0-1	**2-8**	**≥9**	**Death**
Placebo (n=21)	14%	57%	5%	24%
DM199 (n=25)	36%	36%	16%	12%

In addition, in the evaluable participants (n=91), a significant reduction in the number of participants with recurrent ischemic stroke was noted in the active treatment group: 0 (0%) participants treated with DM199 vs. 6 (13%) on placebo (p=0.012), with 4 of the 6 resulting in participant death.

We believe these findings from our Phase 2 ReMEDy1 trial, which are consistent with the use of Kailikang in China, provide a signal that recombinant human KLK1 appears safe and may have promise as a new treatment for physicians who have limited options for the treatment of patients following an AIS.

CKD Phase 2 REDUX Trial

Our REDUX trial (NCT04123613) was a multi-center, open-label investigation of participants with mild or moderate chronic kidney disease (Stage II or III) and albuminuria. The trial was conducted in the United States and included three cohorts: non-diabetic, hypertensive African Americans (AA) (n=24); IgA Nephropathy (IgAN) (n=25); and Type 2 diabetics with CKD, hypertension and albuminuria (n=35). The trial evaluated two dose levels of DM199 within each cohort. Study participants received DM199 by subcutaneous (SC) injection twice weekly for 95 days. The primary study endpoints, evaluated after three months of treatment, included safety, tolerability, blood pressure, albuminuria and kidney function, which are evaluated by changes from baseline in estimated glomerular filtration rate, albuminuria, as measured by the urinary albumin to creatinine ratio, and blood pressure in hypertensive participants.

DM199 was generally safe and well tolerated across all cohorts. Adverse events (AEs) were generally mild to moderate in severity, with the most common being local injection site irritation, and all resolved without medical intervention.

DM199 Safety Summary

Intravenously/subcutaneously administered DM199, in doses ranging from 0.025 μg/kg to 50.0 μg/kg, has been administered to over 250 subjects across 5 completed clinical studies and has been shown to be generally safe and well tolerated. The most frequently reported treatment-emergent adverse events in our Phase 2 ReMEDy1 AIS trial were constipation, oral candidiasis and nausea. These events were predominately mild to moderate in severity. A less common but important adverse event has been clinically significant, transient, hypotension (low blood pressure) during IV infusion of DM199 that was observed in a number of subjects. These hypotensive episodes were rapidly reversed upon cessation of the IV infusion with complete recovery; hypotensive episodes have not been observed with subcutaneous administration of DM199.

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 the pancreas of pigs are approved and sold in Japan, China and South Korea to treat AIS, retinopathy, hypertension and related diseases. We are not aware of any recombinant version of KLK1 with regulatory approval for human use in any country, nor any recombinant version in development other than our drug candidate DM199. We believe at least five companies have attempted, unsuccessfully, to create a recombinant version of KLK1.

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

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

- **KLK1 treatment has had limited side effects and has been well tolerated in studies to date**. KLK1 is naturally produced by the human body; and, therefore, the body's own control mechanisms act to limit potential side effects. The side effect observed to limit participant tolerability in our clinical trials was orthostatic hypotension, or a sudden drop in blood pressure, which has been primarily seen at doses 10 to 20 times higher than our anticipated therapeutic dose levels. Most recently, clinically significant, transient hypotension (low blood pressure) occurring shortly after initiation of the IV dose of DM199 was experienced by three participants in our ReMEDy2 trial which were the cause of us pausing participant enrollment and the FDA placing a clinical hold on the IND for our ReMEDy2 trial. The blood pressure levels of the three participants recovered back to their baseline blood pressure within minutes after the IV infusion was stopped and the participants suffered no injuries. We believe that these events were caused by our switching away from the type of IV bag used in the prior ReMEDy1 trial, where no hypotensive episodes were reported, which resulted in an unintended, elevated dose of DM199 being delivered in the ReMEDy2 trial. We believe that by reducing the dose rate for the IV infusion to a level that matches the effective dose rate in the ReMEDy1 trial, we can manage and/or eliminate the clinically significant hypotensive events.

Moreover, we understand that routine clinical use of KLK1 treatment in Asia has been well-tolerated by patients for several decades. In 2017, we completed a clinical trial comparing the pharmacokinetic profile of DM199 to the human urinary form of KLK1 (Kailikang), which showed DM199, when administered in IV form, had a similar pharmacokinetic profile. Further, when DM199 was administered subcutaneously, DM199 demonstrated a longer acting pharmacokinetic profile, superior to the IV administered Kailikang and DM199.

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

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

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

- **Regulatory.** We are not aware of any attempts by manufacturers of the urine or porcine based KLK1 products to pursue regulatory approvals in the United States. We believe that this is related to challenges presented by using inconsistent and potentially hazardous biomaterials, such as human urine and the pancreas of pigs, 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 in the United States under the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

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

Regulatory Approval

Securing regulatory approval for the manufacture and sale of human therapeutic products in the United States, Europe, Canada and other commercial territories is a long and costly process that is controlled by each territory's national regulatory agency. The national regulatory agency in the United States is the FDA, in Europe it is the European Medicines Agency (EMA), and in Canada it is Health Canada. Other national regulatory agencies have similar regulatory approval requirements, 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 therapeutic 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, as well as approval of manufacturing facilities, including adherence to good manufacturing practices (GMP) during production and storage, and control of marketing activities, including labeling and advertising.

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 current or future 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 proceedings, penalties or sanctions, including refusal by the applicable regulatory authority to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

U.S. Approval Process

In the United States, the FDA is responsible for the review and approval of therapeutic products. The FDA's mission is to ensure that all therapeutic products on the market are safe and effective. The FDA's approval process examines and thoroughly reviews potential new therapeutic products and only those that meet the applicable standard for approval or licensure, are approved.

DM199 is subject to regulatory approval by FDA in the United States because it is a therapeutic product intended for use in humans. The regulatory approval process for DM199 is likely a Biological License Application (BLA) under the Public Health Service Act because DM199 is a recombinant form of the human tissue KLK1 protein. Biological products, like drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to drugs, which are generally chemically-synthesized, biological products are generally derived from living material and include most protein products intended for therapeutic use. Biological products are considered a subset of drugs and, therefore, also regulated under the Food, Drug & Cosmetic Act (FDCA), like drugs. However, the regulatory approval process for a drug is based on a new drug application (NDA) per the drug approval provisions of the FDCA; whereas, the regulatory approval process for a biologic is based on the biological license application (BLA) under the Public Health Service Act.

In addition to regulatory approval, the FDCA and corresponding regulations require licensing of manufacturing facilities, carefully controlled research and testing of products, governmental review and approval of test results prior to marketing of therapeutic products, and adherence to GMP, as defined by each licensing jurisdiction, during production.

A generic description of the different stages in the biologic license application and drug approval process in the United States follows.

Stage 1: Preclinical Research. After an experimental product 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 product and to help understand how the product works. Information from these experiments is submitted to the FDA as part of an IND. The FDA reviews the information in the IND and decides if the product is safe to study in humans.

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

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

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

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

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

Stage 3: FDA Review for Approval. Following the completion of Phase 3 clinical studies, the company prepares an electronic common technical document reporting all clinical, nonclinical and chemistry, manufacturing and control studies conducted on the product that is transmitted to the FDA as a Biologics License Application. The FDA reviews the information in the BLA to determine if the product is safe and effective for its intended use. For novel products or those raising significant questions, the FDA may convene an advisory panel meeting regarding the product to allow the FDA to gain feedback from experts. If the FDA determines that the product is safe and effective, the product may be approved and/or subject to additional labeling revisions or post-marketing requirements as a condition of approval.

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

All FDA approved therapeutic products are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA guidance documents, and promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, promoting 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 or social media. Failure to comply with FDA requirements is likely to have negative consequences, including adverse publicity, warning or enforcement letters from the FDA, mandated corrective advertising or communications with doctors, product seizures or recalls and state or federal civil or criminal prosecution, injunctions and penalties.

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

DM199 may qualify for 4 years of data exclusivity and 12 years of market exclusivity under the BPCIA. This means that FDA cannot accept any biosimilar applications based on data from a reference product for a period of four years from the date the reference product was first licensed. Additionally, under the BPCIA, a BLA may provide for 12 years of market exclusivity for a newly approved biologic product. This means FDA cannot approve any biosimilar applications for a period of 12 years from the date the reference product was first licensed. However, 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 reference product. The new law is complex and is only beginning to be interpreted and implemented by the FDA.

European Approval Process

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

Other Healthcare Laws and Compliance Requirements

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

Research and Development

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

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

R&D expenses include:

- expenses incurred with third-party service providers, such as contract research organizations, clinical data management services and other study support services;
- expenses incurred under agreements with clinical trial sites that conduct research activities on our behalf;
- 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;
- employee and consultant-related expenses, which include salaries, benefits, consulting fees, travel and share-based compensation; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supply costs.

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

We expect that it will be at least three to four 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 DM199, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We rely on Catalent Pharma Solutions, LLC (Catalent), a contract development and manufacturing organization (CDMO) with proven GMP experience in the manufacturing of recombinant proteins for clinical trials, for procuring all of our required raw materials and producing active pharmaceutical ingredient for our clinical trials. We have licensed certain gene expression technology from and we contract with Catalent for the manufacture of DM199 drug substance. We currently employ internal resources and third-party consultants to manage our manufacturing relationship with Catalent.

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for our initial product candidate, DM199, or any future product candidates. 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 intellectual property protecting our proprietary technology from infringement by competitors. To that end, patents are reviewed frequently and continue to be sought in relation to those components or concepts of our preclinical and clinical products to provide protection. Our strategy, where possible, is to file patent applications to protect our product candidates, as well as methods of manufacturing, administering and using a product candidate. Prior art searches of both patent and scientific databases are performed to evaluate novelty, inventiveness and freedom-to-operate. We require all employees, consultants and parties to a collaborative research agreement to execute confidentiality agreements upon the commencement of employment, consulting relationships or a collaboration with us. These agreements require that all confidential information developed or made known during the course of the engagement with us is to be kept confidential. We also maintain agreements with our scientific staff and all parties contracted in a scientific capacity affirming that all inventions resulting from work performed for us, using our property or relating to our business and conceived or completed during the period covered by the agreement are the exclusive property of DiaMedica.

Our DM199 patent portfolio includes five granted U.S. patents, a granted European patent, a granted Canadian patent, a granted Australian patent and pending applications in Australia, Canada, China, Europe, India, Japan, South Korea, Hong Kong and the United States. Granted or pending claims offer various forms of protection for DM199, including claims to compositions of matter, pharmaceutical compositions, specific formulations and dosing levels and methods for treating a variety of diseases, including 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. These patents are due to expire in 2033. A second patent family includes an issued U.S. patent with claims directed to methods of treating subjects by administering a SC formulation of DM199 or related recombinant kallikrein-1 (KLK1) polypeptides and is predicted to expire in 2033. An additional patent application family 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, among others, pulmonary arterial hypertension, cardiac ischemia, chronic kidney disease, diabetes, stroke and vascular dementia, which if granted, are predicted to expire in 2038. This family has an issued U.S. patent directed to a range of dose levels for treating ischemic conditions and is predicted to expire in 2039 because of patent term adjustment. This patent family has another issued U.S. patent directed to a range of dose levels for treating vascular dementia and is predicted to expire in 2038. An additional patent family is pending in the US only and is directed to treating chronic kidney disease based on a selection of biomarkers. This application is predicted to expire in 2043. A further patent family includes pending PCT and US applications directed to treating pregnancy disorders such as preeclampsia and is predicted to expire in 2045. Another patent family includes pending PCT and US applications directed to KLK1 formulations suitable for use with polyolefin-containing intravenous bags and is predicted to expire in 2045.

Our DM300 (recombinant human ulinastatin) patent portfolio includes one issued patent in each of the United States, Taiwan and Japan and pending applications in Brazil, Canada, China, Europe, Hong Kong, India, Japan, South Korea, Taiwan and the United States. Granted or pending claims held by us offer various forms of protection for DM300. For instance, granted or pending claims in a first patent family cover the DM300 composition of matter based on mutants and optimized glycosylation patterns of human ulinastatin and methods of using the same for treating various conditions such as acute pancreatitis. This family is predicted to expire in 2041. Pending claims in a second patent family relate to methods of using DM300 and other ulinastatin polypeptides for treating diseases associated with neutrophil elastase (NE) including inflammatory lung diseases such as A1AT-deficiency. This family is predicted to expire in 2042.

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

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

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

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

Patent/Application Number	Title	Geography	Predicted Expiration
	DM199 Patent Family		
Issued patents			
US 9,364,521	Human Tissue Kallikrein 1 Glycosylation Isoforms	U.S.	2033
US 9,839,678	Human Tissue Kallikrein 1 Glycosylation Isoforms	U.S.	2033
CA 2880085	Human Tissue Kallikrein 1 Glycosylation Isoforms	Canada	2033
EP 2 854 841	Human Tissue Kallikrein 1 Glycosylation Isoforms	Europe	2033
US 9,616,015	Formulations for Human Tissue Kallikrein-1 for Parenteral Delivery and Related Methods	U.S.	2033
US 11,857,608	Dosage Forms of Tissue Kallikrein 1	U.S.	2039
US 12,329,805	Dosage Forms of Tissue Kallikrein 1	U.S.	2038
AU 2018230478	Dosage Forms of Tissue Kallikrein 1	Australia	2038
Pending applications			
AU 2025202779	Dosage Forms of Tissue Kallikrein 1	Australia	2038
CA 3054962	Dosage Forms of Tissue Kallikrein 1	Canada	2038
CN 201880016380.4	Dosage Forms of Tissue Kallikrein 1	China	2038
EP 18763243.5	Dosage Forms of Tissue Kallikrein 1	Europe	2038
IN 201917037712	Dosage Forms of Tissue Kallikrein 1	India	2038
JP 2019-548655	Dosage Forms of Tissue Kallikrein 1	Japan	2038
JP 2024-225007	Dosage Forms of Tissue Kallikrein 1	Japan	2038
KR 10-2024-7038300	Dosage Forms of Tissue Kallikrein 1	SK	2038
HK 62020009783.5	Dosage Forms of Tissue Kallikrein 1	Hong Kong	2038
HK 62020007146.7	Dosage Forms of Tissue Kallikrein 1	Hong Kong	2038
US 19/211,792	Dosage Forms of Tissue Kallikrein 1	U.S.	2038
US 19/577,830	Dosage Forms of Tissue Kallikrein 1	U.S.	2038
US 18/295,991	Tissue Kallikrein 1 for Treating Chronic Kidney Disease	U.S.	2043
US 19/041,742	Tissue Kallikrein-1 for Treating Pregnancy Disorders	U.S.	2045
PCT/US2025/013869	Tissue Kallikrein-1 for Treating Pregnancy Disorders	PCT	2045
US 19/178,631	Intravenous Compositions of Tissue Kallikrein-1 and Related Methods	U.S.	2045
PCT/US2025/024594	Intravenous Compositions of Tissue Kallikrein-1 and Related Methods	PCT	2045
US 69/980,517	Tissue Kallikrein-1 for Treating Resistant Hypertension	U.S.	2046

DM300 Patent Family			
Issued patents			
US 11,725,043	Ulinastatin Polypeptides	U.S.	2041
TW I888497	Ulinastatin Polypeptides	Taiwan	2041
JP 7778077	Ulinastatin Polypeptides	Japan	2041
Pending applications			
US 18/338,970	Ulinastatin Polypeptides	U.S.	2041
BR 1120220177186	Ulinastatin Polypeptides	Brazil	2041
CA 3174478	Ulinastatin Polypeptides	Canada	2041
CN 202180032829.8	Ulinastatin Polypeptides	China	2041
EP 21764369.1	Ulinastatin Polypeptides	Europe	2041
HK 62023075807.5	Ulinastatin Polypeptides	Hong Kong	2041
IN 202217056697	Ulinastatin Polypeptides	India	2041
JP 2022-553090	Ulinastatin Polypeptides	Japan	2041
JP 2025-197322	Ulinastatin Polypeptides	Japan	2041
US 17/586,238	Ulinastatin Polypeptides for Treating Diseases	U.S.	2042
CA 3206854	Ulinastatin Polypeptides for Treating Diseases	Canada	2042
CN 202280021674.2	Ulinastatin Polypeptides for Treating Diseases	China	2042
EP22746605.9	Ulinastatin Polypeptides for Treating Diseases	Europe	2042
HK 62024091076.5	Ulinastatin Polypeptides for Treating Diseases	Hong Kong	2042
JP 2023-546004	Ulinastatin Polypeptides for Treating Diseases	Japan	2042

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the U.S. Patent and Trademark Office. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may also be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of an FDA-approved drug, an FDA-approved method of treatment using the drug, and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug. Some foreign jurisdictions, including Europe and Japan, also have patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when our pharmaceutical products receive FDA approval, we expect to apply for patent term extension on patents covering those products, their methods of use, and/or methods of manufacture.

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Companies typically rely on trade secrets to protect aspects of their business that are not amenable to, or that they do not consider appropriate for, patent protection. We protect trade secrets, if any, and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. These agreements provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all relevant inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Employees

As of December 31, 2025, we had 35 employees, all of whom were full-time employees. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements. We believe our employee relations are good.

Information About Our Executive Officers

The following table sets forth information as of the date of this filing regarding each of our current executive officers:

Name	Age	Positions
Rick Pauls	54	President and Chief Executive Officer, Director
Julie Krop, M.D.	60	Chief Medical Officer
Scott Kellen	60	Chief Financial Officer and Secretary

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 2010. Mr. Pauls has served as a member of our Board of Directors since 2005 and served as Chairman of the Board from 2008 to 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 2002 until 2010. Mr. Pauls was an analyst for Centara Corporation, another early stage venture capital fund, from 2000 until 2002. From 1997 until 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. from 2006 to 2017. 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.

Julie Krop, M.D. joined DiaMedica as our Chief Medical Officer in August 2025. Prior to joining DiaMedica, Dr. Krop provided independent consulting services as President of JSK Consulting, a clinical development consulting firm, from April 2024 until August 2025. From August 2021 to August 2025, Dr. Krop served as the Chief Medical Officer and Head of Development of PureTech Health, a clinical-stage pharmaceutical company focused on the development of drugs for the treatment of multiple rare diseases. Prior to PureTech Health, Dr. Krop served as Chief Medical Officer at Freeline Therapeutics, a clinical-stage pharmaceutical company focused on gene therapy programs from 2020 to 2021. From 2020 to 2021, Dr. Krop also served as Chief Medical Officer and Executive Vice President at AMAG Pharmaceuticals. Previously, she held various roles of increasing responsibility at Vertex Pharmaceuticals, Stryker Regenerative Medicine, Peptimmune, Millennium Pharmaceuticals, and Pfizer. Dr. Krop received her medical degree from Brown University School of Medicine and completed her internal medicine residency at Georgetown University Hospital. She completed fellowships in epidemiology, clinical trial design and endocrinology at Johns Hopkins School of Medicine. Dr. Krop is board-certified in Endocrinology.

Scott Kellen joined DiaMedica as our Vice President of Finance in January 2018 and was appointed our Chief Financial Officer and Secretary in April 2018. Prior to joining DiaMedica, Mr. Kellen served as Vice President and Chief Financial Officer of Panbela Therapeutics, Inc., formerly known as Sun BioPharma, Inc., a publicly traded clinical stage drug development company, from 2015 until 2018. From 2010 to 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 2012. From 2007 to 2009, Mr. Kellen served as Finance Director of Transoma Medical, Inc. From 2005 to 2007, Mr. Kellen served as Corporate Controller of ev3 Inc. From 2003 to 2005, Mr. Kellen served as Senior Manager, Audit and Advisory Services of Deloitte & Touche, LLP. Altogether, Mr. Kellen has spent more than 30 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).

Available Information

We are a corporation governed by British Columbia's Business Corporations Act (BCBCA). Our company was initially incorporated pursuant to The Corporations Act (Manitoba) by articles of incorporation dated January 21, 2000. Our articles were subsequently amended several times, including on April 11, 2016 to continue the Company from The Corporations Act (Manitoba) to the Canada Business Corporations Act (CBCA) and on May 31, 2019, to continue our existence from a corporation incorporated under the CBCA into British Columbia under the BCBCA. Our registered office is located at 301-1665 Ellis Street, Kelowna, British Columbia, Canada V1Y 2B3 and our principal executive office is hosted by our wholly owned subsidiary, DiaMedica USA Inc., and located at 301 Carlson Parkway, Suite 210, Minneapolis, Minnesota, USA 55305. 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 United States Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the United States Securities and Exchange Commission (SEC). Reports filed with the SEC may be viewed at www.sec.gov.

Item 1A. Risk Factors

Below are material factors known to us that could materially adversely affect our business, operating results, financial condition, prospects or share price. The summary of risk factors is not complete and should be read in conjunction with the more complete and detailed descriptions of risk factors that follow. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, operating results, financial condition, prospects or share price.

Risk Factors Summary

Risks Related to Our Business Model

- Our business model assumes we will generate revenue by, among other activities, marketing or out-licensing the product candidates we develop. Since our product candidates are in various stages of development and we have no products approved for commercialization, there is a limited amount of information about us upon which you can base an evaluation of our business and prospects.
- We may need to establish relationships with strategic partners to fully develop, and if approved, market any product candidate.

Risks Related to Our Current and Future Clinical Trials and DM199 Product Candidate

- We have had and may continue to have difficulty enrolling patients in our ReMEDy2 trial or we may experience other clinical testing delays or setbacks.
- The adaptive design of our ReMEDy2 trial could result in a requirement to enroll more patients than anticipated in the trial and an increase in time and costs to complete the trial.
- The expansion of our DM199 clinical development program into PE and our investigator-sponsored PE trial involves risks.
- DM199 and any other product candidates we choose to develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if granted.
- We face the risk of product liability claims and may be unable to maintain product liability insurance sufficient to cover such claims or as required under our contractual agreements.
- The initial investigator-sponsored PE trial is being conducted in South Africa, we are commencing a PE trial in Canada and the global expansion of our ReMEDy2 trial involves risks.
- Data from the PE trials could adversely affect our ReMEDy2 trial and any interim, “top-line” or preliminary trial results could differ from the full final results of the trial.
- If our ReMEDy2 trial fails to adequately demonstrate the safety and efficacy of DM199 to treat AIS, we will not be able to obtain the regulatory approvals required to market and commercialize DM199 to treat AIS.
- We may be required to suspend, repeat or terminate our ReMEDy2 trial or future clinical trials if they are deemed not to have been conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trial is not well designed.
- Our prospects depend on the clinical and commercial success of our DM199 product candidate, which in turn depends upon many factors outside of our control.

Risks Related to Our Financial Position and Need for Additional Capital

- Since we have no revenue from product sales and do not expect any revenue from product sales for at least two to three, we will likely need additional funding to continue our clinical development activities and other operations, which may not be available to us on acceptable terms, or at all.
- We have incurred substantial losses since our inception and expect to continue to incur substantial losses for at least two to three years and may never become profitable, or if achieved, be able to sustain profitability.

Risks Related to Governmental and Regulatory Compliance and Approvals

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

Risks Related to Our Reliance on Third Parties

- We rely on third parties to support the planning, execution and/or monitoring of our preclinical and clinical trials, and their failure to perform as required could cause delays in completing our product development and substantially harm to our business.
- We rely extensively on contract development and manufacturing organizations (CDMOs) for the manufacture and testing of DM199 under current good manufacturing procedures (cGMP).
- Future development collaborations are expected to be important to us.

Risks Related to Intellectual Property

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

Risks Related to Human Capital Management

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

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

- The successful commercialization of DM199 or any future product candidate, if approved, will depend on achieving market acceptance and we may not be able to gain sufficient acceptance to generate significant revenue.
- If we fail to obtain coverage and adequate reimbursement for DM199 or any future product candidate, its revenue-generating ability will be diminished and there is no assurance that the anticipated market for the product will develop or be sustained.
- We or any future partner will likely face competition from other biotechnology and pharmaceutical companies, many of which have substantially greater resources than us.
- Our DM199 product candidate may face competition sooner than expected.
- Our estimates of the market opportunity for our DM199 product candidate are based on a number of assumptions and may prove to be inaccurate.

Risks Related to Our Common Shares

- Our common share price has been volatile and may continue to be volatile.
- We do not have a history of a very active trading market for our common shares.
- We may issue additional common shares resulting in share ownership dilution, and if there are substantial sales of our shares or the perception that such sales may occur, the market price of our shares could decline.
- A limited number of shareholders possess substantial voting power.

Risks Related to Our Jurisdiction of Organization

- We are governed by the corporate laws of British Columbia, which in some cases have a different effect on shareholders than the corporate laws in effect in the United States.
- We were classified as a “passive foreign investment company” (PFIC) for our taxable years 2025, 2024 and 2023 and certain other prior years and may continue to be so classified in the current and/or future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders and adversely affect the level of interest in our common shares by U.S. investors. Any common shareholder who held our shares in years when we were classified as a PFIC will be subject to special reporting rules in order to avoid adverse PFIC tax consequences. Even if we subsequently no longer qualify as a PFIC in a future taxable year, shareholders will still be subject to the PFIC rules for shares acquired in years when we were a PFIC unless a so-called “purging election” is made, as described below.

Risks Related to Our Business Model

Our business model assumes we will generate revenue by, among other activities, marketing or out-licensing the product candidates we develop. Since our product candidates are in various stages of development and we have no products approved for commercialization, there is a limited amount of information about us upon which you can base an evaluation of our business and prospects.

None of our product candidates have completed clinical development, and therefore, we have no product candidates approved for commercialization and thus have not begun to market or generate revenues from the commercialization of any product candidates. Because no product candidate has completed clinical development and been approved for commercialization, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. For example, to execute our business plan, we will need to successfully:

- Demonstrate safety and efficacy of our product candidates in human clinical studies;
- Complete manufacturing development activities relating to our DM199 product candidate for the treatment of AIS or PE or any other indications we decide to pursue and any other product candidates we choose to develop;
- Receive FDA approval and/or approval from similar foreign regulatory bodies;
- Gain market acceptance for the commercialization of any products we develop and have not out-licensed such rights;
- Obtain reimbursement by commercial and/or government payors at a rate that permits commercial viability;
- Develop and maintain successful strategic relationships with suppliers, distributors and commercial licensing partners;
- Build, maintain, and protect an adequate intellectual property portfolio; and
- Manage our spending and cash requirements as our expenses are anticipated to increase in the near term as we ramp up enrollment in our clinical trials and if we add new indications for DM199 and other product candidates and conduct additional preclinical and clinical trials.

If we are unsuccessful in accomplishing these objectives or in making sufficient progress toward these objectives, we may not be able to develop and maintain successful strategic relationships, raise capital, and continue our operations.

We may need to establish relationships with strategic partners to fully develop our product candidates and, if approved, market any product candidates that are approved.

Our business strategy includes securing license agreements and collaborations with other pharmaceutical and biotech companies to support the development of DM199 for various indications. We do not possess all of the financial resources necessary to complete the development and commercialization of our product candidates, if and when they are approved. Unless we expand our own internal sales and marketing capability, we will likely need to make arrangements with other strategic partners to commercialize any product candidates that may be approved. We may not be able to attract such partners, and even if we are able to enter into such partnerships, the terms may be less favorable than anticipated. Further, entering into partnership agreements may limit our commercialization options and would require us to share revenues and profits with our partners. If we do not find appropriate partners, or if such future agreements are not successful, our ability to commercialize products could be adversely affected. Even if we are able to find collaborative partners, the overall success of the commercialization of product candidates in those programs will depend largely on the efforts of those other parties and may be beyond our control and our licensees may elect to assume greater control over these programs. In addition, in the event we pursue our commercialization strategy through collaboration or licenses to third parties, there are a variety of technical, business and legal risks, including, among others:

- We may be unable to control the amount and timing of resources that our collaborators may be willing or able to devote to the commercialization of our product candidates including to their marketing and distribution efforts; and
- Disputes may arise between us and our collaborators that result in the delay or termination of the commercialization of our product candidates or that result in costly litigation or arbitration that diverts our management’s resources.

The occurrence of any of the above events or other related events could impair our ability to generate revenues and harm our business, prospects, operating results and financial condition.

Risks Related to Our Current and Future Clinical Trials and DM199 Product Candidate

We have had and may continue to have difficulty enrolling patients in our ReMEDy2 trial or we may experience other clinical testing delays or setbacks, which would delay our ability or the ability of a future partner to obtain regulatory approval for DM199 to treat AIS and commercialize it, which would substantially harm our business and prospects.

Our ReMEDy2 trial is a Phase 2/3, adaptive design, randomized, double-blind, placebo-controlled trial that is intended to enroll approximately 300 patients at up to 100 sites globally. We have had and may continue to have difficulty enrolling patients in our ReMEDy2 trial, which could delay further completion of the trial or even jeopardize the viability of the trial. We believe these enrollment difficulties may be due, in part, to hospital and medical facility staffing shortages; inclusion/exclusion criteria in the study protocol; concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns regarding the prior clinically significant hypotension events and circumstances surrounding the clinical hold which was lifted in June 2023; use of artificial intelligence and telemedicine which have enabled smaller hospitals to retain AIS patients not eligible for mechanical thrombectomy instead of sending these patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological trials.

In addition, it is possible that we may experience other clinical testing delays or setbacks, which would further delay completion of the ReMEDy2 trial. Product development costs typically increase with delays in clinical testing. Significant clinical trial delays could not only extend the time period for obtaining regulatory approval of DM199 to treat AIS and increase our costs, but also shorten any periods during which we or a future partner may have the exclusive right to commercialize DM199 to treat AIS or allow our competitors to bring competitive products to market before us, which would adversely affect the ability to successfully commercialize DM199 and may harm our business, prospects, operating results and financial condition. The ReMEDy2 trial may be delayed for a number of reasons, including without limitation those described above as well as the following:

- sites waiting for internal approvals of the most recently revised protocol for the trial;
- patients choosing to participate in competing clinical trials or not at all;
- scheduling conflicts with participating clinicians and clinical sites;
- complexities in setting up and coordinating with sites that are located outside the United States and additional risks involved in a trial that is being conducted, in part, outside the United States;
- suspension or termination of the ReMEDy2 trial by regulators for any reason, including concerns about patient safety or failure of our contract manufacturers to comply with current Good Manufacturing Practices (cGMP) requirements;
- any changes to our manufacturing process that may be necessary or desired which affect our ability to produce adequate or timely clinical drug supply;
- delays or failure to obtain clinical drug supply of DM199 from contract manufacturers necessary to conduct clinical trials;
- our DM199 product candidate demonstrating a lack of safety or efficacy at the planned interim analysis of the ReMEDy2 trial;
- patients failing to enroll or complete the ReMEDy2 trial at the rates and within the timelines we expect due to dissatisfaction with the treatment, side effects or other reasons;
- clinical investigators not performing the ReMEDy2 trial on their anticipated schedule, dropping out of a trial or employing methods not consistent with the clinical trial protocol and regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of our 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 another clinical hold on the IND for our ReMEDy2 trial; or
- public health crises, epidemics or pandemics, such as COVID-19, which may adversely impact our ability to continue to engage and activate clinical trial sites, recruit or enroll subjects for our ReMEDy2 trial or any future trial and obtain the requisite staffing for our ReMEDy2 trial or any future trial.

Our product development costs may increase if we need to perform a larger or more clinical trials than planned. Additionally, changes in regulatory requirements and policies may occur, and we may need to amend trial protocols or alter our manufacturing processes to reflect these changes. Amendments typically require us to resubmit our trial protocols to the FDA and other regulatory authorities and IRBs or ethics committees, for re-examination, which may impact the cost, timing or successful completion of our ReMEDy2 trial. Delays or increased product development costs or any of these events would likely have a material adverse effect on our business, prospects, operating results and financial condition.

The adaptive design of our ReMEDy2 trial could result in the trial being required to enroll more patients than anticipated, which would increase the time and costs to complete the trial.

Our ReMEDy2 trial is an adaptive design trial intended to enroll approximately 300 patients. The adaptive design component includes an interim analysis by our independent data safety monitoring board after the first 200 participants have completed the trial. Based on the results of the interim analysis, the study may be stopped for futility or a new total sample size may be determined, ranging between 300 and 728 participants, according to a pre-determined statistical analysis plan. Because of the ReMEDy2 trial's adaptive design, it is possible that the number of participants required to complete the trial may increase significantly from the 300 patients we are currently targeting. If we are required to enroll more participants than currently anticipated, it will increase the time and costs to complete the trial, which may result in a need for additional funding that may not be available to us on acceptable terms, or at all.

The expansion of our DM199 clinical development program into PE involves certain risks related to timing, regulatory approvals, costs and enrollment, and the fact that the initial PE trial is investigator-sponsored, raises additional risks.

We are currently financially supporting the conduct of a Phase 2 open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored trial of DM199 for the treatment of PE at the Tygerberg Hospital, Cape Town, South Africa. This study may enroll up to approximately 100 women with PE and potentially an additional 30 women with fetal growth restriction may be evaluated. Part 1a top line study results were released in July 2025 which we believe demonstrated the potential for DM199 to lower maternal blood pressure and improve uterine artery dilation. We have received approval to commence an additional Phase 2 study of PE in early-onset preeclampsia in Canada which we anticipate initiating in the second half of 2026.

The expansion of our DM199 clinical development program into PE and the progress of that program may not occur on the anticipated timeline or at all. In addition, these Phase 2 PE trials may cost us more than we anticipate. Additionally, the first trial is investigator-sponsored and the conduct of the second trial is expected to rely on a contract research organization (CRO), we have less control over the timing and costs of these studies and the ability to recruit trial participants than if we conducted the study with our own personnel. There is no guarantee that our physician collaborators or CRO will devote adequate time and resources to perform these studies and/or maintain adequate clinical trial information regarding our product candidate. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to the study protocol, or fail to act in accordance with regulatory requirements or our agreement with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then the current PE trial or future clinical trials may be extended or delayed with additional costs incurred, or our data may be rejected by applicable regulatory agencies.

Data collected from the current on-going investigator-sponsored PE program in South Africa will serve as the basis for the design of Phase 2 clinical studies to be conducted in North America and other parts of the world. There is risk that the safety and pharmacodynamic results, differing standards of care, dose and dosing regimens used in a South African population may not translate or generalize to a typical PE population in North America or other parts of the world and could affect the safety/efficacy profile of DM199, the need for additional clinical studies, leading to additional development delays and expenses.

Any of these risks could adversely impact our business, prospects, operating results and financial position, including our ability to raise additional financing, if and when needed.

DM199 and any other product candidates we choose to develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if granted.

As with most pharmaceutical products, DM199 and any future product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Although the most common DM199 related adverse events that have occurred to date in our clinical trials have been constipation, injection site reaction, nausea, headache and flushing. A less common but important adverse event has been clinically significant, transient, hypotension (low blood pressure) during IV infusion of DM199 that was observed in a number of subjects. These hypotensive episodes were rapidly reversed upon cessation of the IV infusion with complete recovery; hypotensive episodes have not been observed with subcutaneous administration of DM199. Side effects or adverse events associated with the use of DM199, or any future product candidates, may be observed at any time during clinical development. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the Institutional Review Boards, or independent ethics committees at the institutions in which our studies are conducted, or the data safety monitoring board, could suspend or terminate our clinical trials, similar to when the FDA imposed a clinical hold on our current ReMEDY2 trial in 2022, 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.

Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may be required to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. The safety profile of DM199 observed in one disease indication could affect the labeling, dosing, route of administration, and/or commercial value of DM199 in another disease indication. Any of these occurrences may prevent us, or any future partner from achieving or maintaining market acceptance of the affected product candidate and may harm our business, prospects, operating results and financial condition.

Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, toxicity or other safety issues, and could require us to perform additional studies, including preclinical studies, or halt development of DM199 or any future product candidates, or expose us to product liability lawsuits that would likely harm our business. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory authority in a timely manner, if ever, which could harm our business, prospects, operating results and financial condition.

We are required by the FDA and other comparable foreign regulatory authorities to report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA other comparable foreign regulatory authorities could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products, halting our clinical trials or delay in approval or clearance of future product candidates.

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

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

Insurance covering product liability claims is expensive. To protect against potential product liability risks, we carry product liability insurance coverage at a level we deem appropriate based upon the current safety profile of DM199 and our stage of development. We may choose or find it necessary to increase our insurance coverage in the future; 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. Any liability for damages resulting from a product liability claim could exceed the amount of our coverage, require us to pay a substantial monetary award from our own cash resources and otherwise have a material adverse effect on our business, operating results and financial condition.

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

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

The initial investigator-sponsored PE trial is being conducted in South Africa, we are commencing a PE trial in Canada and we are in the process of globally expanding our ReMEDy2 trial to countries outside the United States, raising additional international risks, which could materially adversely affect our business.

The initial investigator-sponsored PE trial is currently being conducted in South Africa, we are commencing a PE trial in Canada and we are currently expanding our ReMEDy2 trial to certain non-U.S. countries, including Canada, Australia, Georgia, United Kingdom and certain countries in the European Union. In addition, we plan to seek regulatory approval of DM199, or any future product candidates, outside of the United States. Accordingly, we are subject to risks related to operating in foreign countries including, among others:

- different standards of care or ethnic composition of patient populations in various countries that could complicate the design of our clinical trials and/or the evaluation of our product candidates;
- compliance with differing regulatory requirements for drug approvals;
- availability of different competitive drugs or therapies indicated to treat the indications for which our product candidates are or will be developed;

- compliance with different United States and foreign drug import and export rules;
- the imposition of U.S. or international sanctions against a country, company, person or entity where or with whom we are conducting clinical studies that would restrict or prohibit continued development in that country or with that company, person or entity;
- compliance with the Foreign Corrupt Practices Act and other anti-corruption and anti-bribery laws;
- foreign taxes, including withholding of payroll taxes;
- foreign currency exchange rate fluctuations, which could result in increased operating expenses and other obligations incident to performing clinical trials in another country;
- difficulties in managing and staffing international operations and increases in infrastructure costs, including legal, tax, accounting, and information technology;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability resulting from development work conducted by foreign partners or collaborators;
- delays and interruptions in delivering study drug and related supplies to clinical trial sites;
- interruptions in our development resulting from natural disasters or geopolitical actions, including war, such as the current war between Russia and Ukraine and the conflict between Israel and Hamas and in the Middle East, 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.

It is possible that the FDA and comparable foreign regulatory authorities may not accept trial data from countries located outside the United States.

The initial investigator-sponsored PE trial is being conducted in South Africa, we are commencing a PE trial in Canada and we are currently globally expanding our ReMEDy2 trial to countries outside the United States. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice (GCP) regulations; and (iii) the FDA, or comparable foreign regulatory authority, is able to validate the data through an on-site inspection or other appropriate means. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional participants or trials, which would be costly and time-consuming and delay regulatory approval and commercialization of our DM199 product candidate.

Data from the investigator-sponsored PE trial, which we expect earlier than data from our ReMEDy2 trial, may adversely affect our ReMEDy2 trial, which could adversely impact our business, prospects, operating results and financial position and harm our ability to raise additional financing, if and when needed.

Our drug candidate, DM199, is currently in clinical development in two areas, PE/FGR and AIS. We announced interim data from Part 1a of the investigator-sponsored Phase 2 PE clinical trial in July of 2025. Part 1a topline study results demonstrated improvements in blood pressure and the pulsatility index. However, future data from the Phase 2 PE trial may materially change from the reported Part 1a topline study results. Should this occur, we may be required to repeat clinical or non-clinical studies, our clinical development plans may be significantly delayed, and we may incur additional costs, which could adversely impact our business, prospects, operating results and financial position. Adverse results from any future Phase 2 PE trial could adversely affect our ability to raise additional financing, if and when needed.

Interim, "***topline***" ***and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim, topline or preliminary results from our clinical trials. We announced Part 1a topline study results for the Phase 2 PE clinical trial in July 2025. Interim results from clinical trials are subject to the risk that one or more of the reported clinical outcomes may materially change as participant enrollment continues and more participant data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, topline or interim data and final data could significantly harm our business and prospects and may cause the trading price of our common shares to fluctuate significantly. We also make estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory authorities, may not accept or agree with our estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business and prospects.

If our ReMEDy2 trial fails to adequately demonstrate the safety and efficacy of DM199 to treat AIS or if the PE trials fail to adequately demonstrate the safety and initial signs of efficacy of DM199 to treat PE, we will not be able to obtain required regulatory approvals, which would substantially harm our business, prospects and financial condition.

Before obtaining marketing approval from the FDA and other comparable foreign regulatory authorities for the sale of DM199 to treat AIS or the approval to continue testing DM199 as a treatment for PE, we must demonstrate the safety and efficacy of DM199 to treat AIS or PE to a level acceptable to the FDA or similar regulatory bodies in other jurisdictions. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and has uncertain outcomes. The outcome of early clinical trials may not predict the success of later clinical trials, and the interim results of ReMEDy2 and the interim topline results from Part 1a of the investigator-sponsored PE trial may 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, including the emergence of undesirable side effects, notwithstanding promising results in earlier trials. We do not know whether our ReMEDy2 trial by itself will demonstrate adequate efficacy and safety to support regulatory approvals to market DM199 to treat AIS in the United States, or in any other jurisdiction, or that a second confirmatory trial will be required. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. In addition, the patient population in our ReMEDy2 trial often have co-morbidities that may cause severe illness or death, which may be attributed to DM199 in a manner that negatively affects the safety profile of our DM199 product candidate. If the results of our ReMEDy2 trial are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance or if there are unanticipated safety concerns or adverse events that emerge during the ReMEDy2 trial, the PE trial or other clinical trials, such as the events that caused the FDA to place the prior clinical hold on the IND for our ReMEDy2 trial, we may be prevented from or delayed in obtaining marketing approval, and even if we obtain marketing approval, any sales of DM199 for the treatment of AIS may be limited.

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

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

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

The design and implementation of clinical trials is a complex process. As a Company, we have limited experience designing and implementing clinical trials. We may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints. A clinical trial that is not well designed or that yields unforeseen adverse side effects or undue risks to trial subjects may delay or even prevent initiation of the trial, can lead to increased difficulty in site activations and enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the trial 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 or that yields unforeseen adverse side effects or undue risks to trial subjects could be delayed and more expensive than it otherwise would have been, or we may incorrectly estimate the costs to complete the clinical trial, which could lead to a shortfall in funding. We can provide no assurance that our ReMEDy2 trial, the PE trials or any other clinical trial conducted or sponsored by us has been or will be designed and implemented successfully or achieve its desired clinical endpoints.

Our prospects depend on the clinical and commercial success of our DM199 product candidate.

We are highly dependent on the success of DM199 and we, or a future partner, may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate. To date, we have expended significant time, resources, and effort on the development of DM199, including conducting preclinical and clinical trials, for the treatment of AIS and cardio renal disease. DM199 requires significant additional clinical testing and investment prior to seeking marketing approval. A commitment of substantial resources by us and any potential partner or collaborator to continue to conduct the clinical trials for DM199 will be required to obtain required regulatory approvals and successfully commercialize this product candidate. Although we intend to study the use of DM199 to treat multiple diseases, we have no other product candidates in our current clinical development pipeline, with the exception of our new second candidate, DM300, which is in the early, preclinical stage of development and is intended to treat other inflammatory diseases, such as acute pancreatitis. The ability of us or a future partner to generate revenue from product sales and to achieve commercial success with DM199 will depend almost entirely on our ability to demonstrate sufficient safety and efficacy to obtain regulatory approval for DM199. We may fail to complete required clinical trials successfully and not be able to obtain regulatory approvals or commercialize DM199. Competitors may develop alternative products and methodologies to treat the diseases or indications that we are pursuing, thus reducing or eliminating the anticipated competitive advantages of DM199. We do not know whether any of our product development efforts will prove to be effective, meet applicable regulatory standards required to obtain marketing approval, be capable of being manufactured at a reasonable cost, or be successfully marketed. DM199 is not expected to be commercially viable for at least two to three years. In addition, although the most common DM199 related adverse events that have occurred to date in our clinical trials have been constipation, injection site reaction, nausea and headache, it is possible that DM199 may be observed to cause undesirable side effects. If regulatory authorities do not approve DM199 for the treatment of AIS, PE or any other indications, or if we fail to maintain regulatory compliance, we, or a future partner, would be unable to commercialize DM199 and our business, prospects, operating results and financial condition would be harmed. If we do succeed in developing viable products from DM199, we will face many potential future obstacles, such as the need to develop or obtain manufacturing, sales and marketing, and distribution capabilities, if we do not partner with a third party to provide these functions.

Risks Related to Our Financial Position and Need for Additional Capital

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

We expect we will need substantial additional capital to further our R&D activities, planned clinical trials and regulatory activities and to otherwise develop our DM199 product candidate to a point where it may be commercially sold. We expect our current cash resources of $59.9 million in cash, cash equivalents and marketable securities as of December 31, 2025 to be sufficient to allow us to continue our Phase 2/3 trial in patients with AIS, the PE trial and to otherwise fund our planned operations for at least the next 12 months from the date of issuance of the consolidated financial statements included in this report. However, the amount and timing of our future funding requirements will depend on many factors, including, among others:

- the rate of progress in the development of and the conduct of clinical trials with respect to DM199 or any future product candidates;
- the timing and results of our ongoing development efforts, including in particular our Phase 2/3 ReMEDy2 trial and the PE trial;

- the costs of our development efforts, including the conduct of clinical trials with respect to DM199 or any future product candidates;
- the costs associated with identifying additional product candidates and the potential expansion of our current development programs or potential new development programs;
- the costs necessary to obtain regulatory approvals for DM199 or any future product candidates;
- the costs of developing and validating manufacturing processes for DM199 or any future product candidates;
- the costs associated with being a U.S. public reporting company with shares listed on The Nasdaq Capital Market;
- the costs we incur in the filing, prosecution, maintenance and defense of our intellectual property; and
- the costs related to general and administrative support.

We may require significant additional funds earlier than we currently expect, and there is no assurance that we will not need or seek additional funding prior to such time. We may elect to raise additional funds even before we need them if circumstances or market conditions for raising additional capital are favorable.

Since our inception, we have financed our operations primarily from public and private sales of equity securities, the exercise of warrants and stock options, interest income on funds available for investment and government grants and tax incentives. 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 we experience additional adverse events, if our clinical data is not positive, or economic and market conditions deteriorate.

Although we previously have 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 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 could be affected by many factors, including, among others:

- the results of our clinical trials and other scientific and clinical research;
- our ability to obtain regulatory approvals;
- market acceptance of DM199 or any future product candidates;
- the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies;
- various events outside our control, including without limitation geopolitical events and current wars;
- the status of strategic alliance agreements; and
- other relevant commercial considerations.

If adequate funding is not available, we may be required to implement cost reduction strategies; delay, reduce or eliminate one or more of our product development programs; relinquish significant rights to DM199 or future product candidates; 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 have incurred substantial losses since our inception and expect to continue to incur substantial losses for at least two to three years and may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company focused on the development of our DM199 product candidate. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront financial expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and do not expect to generate any revenue from the sale of products for at least two to three years. We have incurred significant R&D and G&A expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have incurred significant operating losses in every reporting period since our inception and we may never achieve or sustain profitability. For the years ended December 31, 2025 and 2024, we incurred a net loss of $32.8 million and $24.4 million, respectively. As of December 31, 2025, we had an accumulated deficit of $172.8 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital. We expect to continue to incur substantial operating losses as we continue our R&D activities, planned clinical trials, including our Phase 2/3 ReMEDy2 trial and the PE trial, regulatory activities and other administrative expenses and to support the development of DM199 or any future product candidate to a point where it can be out-licensed or receives required regulatory approvals and may be commercially sold and we begin to recognize future product sales, or receive royalty payments, licensing fees and/or milestone payments sufficient to generate revenues to fund our continuing operations. We expect our operating losses to increase in the near term as we continue development of DM199 and the clinical trials required to seek regulatory approval for DM199, or any future product candidate. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Our failure to achieve and sustain profitability may depress the market price of our common shares and could impair our ability to raise capital, continue to develop DM199, or any future product candidate, expand our business and product offerings or continue our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

Risks Related to Governmental and Regulatory Compliance and Approvals

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future partner or collaborator from obtaining approvals for the commercialization of DM199 or any future product candidate.

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

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

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. The FDA and DOJ impose restrictions on manufacturers' communications regarding off-label use, sales and marketing activities, transparency laws, and reimbursement obligations, which restrictions can change substantially based on new and/or amended government interpretations of regulatory priorities, new and/or amended federal regulations, and other external forces. If we do not market our products for approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the federal False Claims Act, the federal Anti-Kickback Statute, the Sunshine Act and other federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

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

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

We may be unable to obtain regulatory acceptances necessary to conduct clinical trials in the jurisdictions or on the timelines we expect.

We must obtain appropriate regulatory clearances before commencing new clinical trials for DM199 or any future product candidate. Delays in obtaining the requisite clearances may occur for a variety of reasons beyond our control, including supplemental data requests from regulators, clinical holds, government shutdowns, and agency funding or staffing reductions.

For example, prior to commencing additional clinical trials in the United States for DM199 or any future product candidate, we must have an accepted IND for each product candidate and for each targeted indication. In April 2021, we filed, and in May 2021, the FDA accepted, an IND for the Phase 2/3 ReMEDy2 trial in patients with AIS. However, in July 2022, the FDA imposed a clinical hold on the IND under which we are conducting our Phase 2/3 ReMEDy2 trial, which clinical hold was subsequently lifted in June 2023. We plan to file an IND to enable us to commence additional clinical trials studying DM199 for the treatment of PE in the United States, and comparable filings to conduct additional clinical trials studying PE in Canada and the United Kingdom. In the fourth quarter of 2025, we participated in a productive, in-person pre-IND meeting with the FDA to discuss the planned Phase 2 study, at which the FDA requested an additional non-clinical, 10-day modified embryo-fetal development and pre- and postnatal development (ePPND) study in a rabbit model, a non-rodent species. Preliminary results of the rabbit study suggest that the rabbits developed an antibody response to DM199, a humanized recombinant protein, preventing us from completing the requested ePPND study in the rabbit model. We are currently evaluating alternate animal models to address the FDA's ePPND study request. Depending on the alternative species, and its gestational period, results from the ePPND study may be substantially delayed.

In March 2026, we received a "No Objection Letter" from Health Canada allowing us to perform the trial in Canada. However, there is no assurance that the U.S. IND will be filed on a timely basis or accepted by the FDA on a timely basis or at all. A submission of an IND may not necessarily result in the FDA allowing further clinical trials to begin and, once begun, issues, such as clinical holds, 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 obtain required regulatory acceptances may cause the development of DM199 or any future product candidate to be delayed or terminated, which could materially and adversely affect our business and prospects.

We have received Fast Track designation for DM199 for the treatment of AIS, and we may seek such designation for other uses of DM199 or future product candidates. Fast Track designation may not lead to faster development or a faster FDA review or approval process, and it does not increase the likelihood that DM199 will receive marketing approval in the United States. Further, there is no guarantee we will be able to maintain such designation.

In September 2021, we received Fast Track designation from the FDA for DM199 for the treatment of AIS where tPA/TNK and/or mechanical thrombectomy are not indicated or medically appropriate. The FDA may grant Fast Track designation to a drug that is intended to treat a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need. The FDA provides opportunities for more frequent interactions with the review team for a Fast Track product, including pre-IND meetings, end-of-phase 1 meetings and end-of-phase 2 meetings with the FDA to discuss study design, extent of safety data required to support approval, dose-response concerns and use of biomarkers. A Fast Track product may also be eligible for rolling review, where the FDA reviews portions of a marketing application before the sponsor submits the complete application.

However, Fast Track designation for DM199 may not result in a faster development process or a faster review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. Any delay in the review process or in the approval of DM199 will delay revenue from potential sales and will increase the capital necessary to fund our development programs and operations. In addition, the FDA may rescind the Fast Track designation for DM199 if the FDA later determines that DM199 no longer meets the qualifying criteria for Fast Track designation.

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

In the United States and many foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and data privacy that could prevent or delay marketing approval of DM199 or any future product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell DM199 or any future product candidate for which we obtain marketing approval. Further, changes in government administrations may result in changed administrative or legislative priorities and could also prevent or delay marketing approval of DM199 or any future product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell DM199 or any future product candidate for which we obtain marketing approval.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the Affordable Care Act (ACA) enacted in the United States in 2010, and principally taking effect in 2014, included measures to change health care delivery, decrease the number of individuals without insurance, ensure access to certain basic health care services and contain the rising cost of care. This healthcare reform movement, including the enactment of the ACA, has significantly changed health care financing by both governmental and private insurers in the United States. With respect to pharmaceutical manufacturers, the ACA increased the number of individuals with access to health care coverage, including prescription drug coverage, but it simultaneously imposed, among other things, increased liability for rebates and discounts owed to certain entities and government health care programs, fees for the manufacture or importation of certain branded drugs and transparency reporting requirements under the Physician Payments Sunshine Act. In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we may receive for any product, if approved. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

The U.S. federal government has recently prioritized and may continue to prioritize policies targeting reducing drug prices and healthcare spending and may remain committed to lowering spending in federal government programs. The Inflation Reduction Act of 2022, which was signed into law on August 16, 2022, includes provisions aimed at lowering prescription drug costs for Medicare patients and reducing the federal government's spending on prescription drugs by requiring certain prescription drug prices to be negotiated directly with the government, certain rebates to be paid by prescription drug companies, and certain spending caps to be implemented, among other measures. The implementation of cost containment measures or other healthcare reforms may prevent us or a future partner or collaborator from being able to generate sufficient revenue, attain profitability or even commercialize at all DM199 or any future product candidate. Policies implemented by the U.S. federal government may also introduce new, unexpected challenges such as supply chain disruptions based on international tariffs or taxation, other inflation-related measures and other measures that may affect the revenue, profitability and/or commercialization of DM199.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, authorized or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could adversely impact our business.

The ability of the FDA to review and provide marketing authorization for new products or changes to existing products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, federal government shutdowns, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. Decreases in government funding of research and development, including any reductions in funding to the U.S. National Institutes of Health may impact our business, as could changes in government programs that provide funding to research institutions and companies, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of time of the funding process. Disruptions at the FDA and such other agencies may also slow the time necessary for new products, or modifications to authorized products, to be reviewed and/or authorized by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of COVID-19 or emergence of new variants may lead to further inspectional delays. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could adversely affect our business.

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

The FDA and the EMA have each established regulations to govern the therapeutic 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. Additionally, the EMA issued Annex 1: the Manufacture of Sterile Medicinal Products which was effective August 15, 2023, intended to update standards to reflect change in regulatory and manufacturing environments and to remove ambiguity and inconsistencies in regulations governing the manufacture of sterile medicinal products. We cannot predict what if any effect the Cures Act, Annex 1 or any existing or future guidance from the FDA, EMA or other regulatory authorities will have on the development of DM199 or any future product candidate.

Risks Related to Our Reliance on Third Parties

We rely and will continue to rely on third parties to support the planning, execution and/or monitoring of our preclinical and clinical trials, and their failure to perform as required could cause delays in completing our product development and substantial harm to our business.

We rely and will continue to rely on third parties to conduct a significant portion of our preclinical and clinical development activities. Preclinical activities include in vitro and in vivo studies in specific disease models, pharmacology and toxicology studies and assay development. Clinical development activities include trial design, regulatory submissions, clinical site and 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, including as a result of staffing disruptions, our development programs may face delays. Further, if any of these third parties fail to perform as we expect or if their work fails to meet regulatory requirements, our clinical testing could be delayed, cancelled or rendered ineffective. For example, our prior contract research organization that we engaged to assist with our ReMEDy2 trial did not perform as we anticipated, thereby adversely affecting the conduct of the trial and resulting in delays in site activation and enrollment. No assurance can be provided that will not have similar issues with CROs that we have engaged to assist with the trial in non-U.S. jurisdictions. In addition, in connection with a prior clinical trial, we commenced litigation against Pharmaceutical Research Associates Group B.V., which was acquired by ICON plc (PRA Netherlands), as a result of its handling of a double-blinded, placebo-controlled, single-dose and multiple-dose study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and proof of concept of DM199 in healthy subjects and in patients with Type 2 diabetes mellitus, as described later in this report.

We rely extensively on contract development and manufacturing organizations (CDMOs) for the manufacture and testing of DM199 under current good manufacturing procedures (cGMP), and we are subject to many manufacturing risks, any of which could substantially increase our costs and/or limit supply of DM199.

We require the services of third-party CDMOs to provide process development, analytical method development, formulation development, and manufacturing. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture and test bulk drug substance or filled drug product for use in clinical trials or commercialization. As a result, we rely completely on CDMOs, which entails risks to which we would not be subject if we manufactured DM199 or any potential future product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture DM199 and any potential future product candidates) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us.

DM199 is a biologic, and the manufacture and testing of biologic products is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls, and advanced analytical testing capability. As a result, the manufacture and testing of our product candidate is subject to many risks, including the following, some of which we may experience:

- product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions;
- difficulties with product yields, quality control release testing, including challenges related to analytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- challenges with long-term stability of our product candidate and products at reasonable and expected storage conditions;
- challenges with comparability of product made following changes in the manufacturing process such as a change in the manufacturing facility, scale-up, changes in the storage container used for drug product, or other changes; control release testing, including challenges related to analytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- challenges with comparability of product made following changes in the manufacturing process such as a change in the manufacturing facility, scale-up, changes in the storage container used for drug product, or other changes;
- the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations;
- major deviations from normal manufacturing processes, which may result in reduced production yields, product defects and other supply disruptions;
- the presence of microbial, viral or other contaminants discovered in our product candidate or in the manufacturing facilities in which it is made, which can necessitate closure of facilities for an extended period of time to investigate and eliminate the contamination;
- the negative consequences of our CDMOs' failure to be approved for commercial production following an audit by regulatory authorities, by us or by our partners;

- our CDMOs' changing strategies and/or competing business priorities, which can affect the availability of facilities where we intend to manufacture our product candidate;

- the possible termination or nonrenewal of agreements by our CDMOs at a time that is costly or inconvenient for us; and

- our CDMOs' manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of natural disasters, cyber attacks, power failures, local political unrest or other factors.

We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur now or in the future. If we or our CDMOs experience any such issues there could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business.

In addition, to date, DM199 has been manufactured and tested by our drug substance and drug product CDMOs solely for clinical trials. We intend to continue to use CDMOs for these purposes, and also for the supply of larger quantities that may be required to conduct larger, later clinical trials and for commercialization if we advance our product candidates through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CDMO manufacturing slots and other capabilities generally, which may have a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials or commercialization.

The scale up and validation of the manufacturing processes in the CDMOs' facilities to manufacture larger quantities or different formats, such as a pre-filled syringe, involve complex activities and coordination. Scale up and process validation activities entail risks such as process reproducibility and robustness, stability of in-process intermediates, product quality consistency and other technical challenges. We may be unable to scale up or validate our manufacturing processes, which can be expensive and time-consuming and could delay the initiation or completion of our clinical trials.

Similarly, we or our CDMOs may make changes to our manufacturing processes at various points in product development for many reasons, including changing manufacturing facilities, scaling up, facility fit, raw material or component availability, improving process robustness and reproducibility, decreasing processing times, changing the storage container, or others. In some circumstances, we may fail to demonstrate that the product from the new process is comparable to product from the prior process and we may be required to perform additional bridging studies, animal or human studies to demonstrate that the product used in earlier clinical trials are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and, if required, there is no assurance that they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all, and could require the conduct of additional clinical trials.

We currently have a single source of supply for our drug substance and for our drug product. Single sourcing minimizes our leverage with our CDMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their strategies and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and/or other difficulties in timely supplying us with materials. We do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for DM199 or any of our future product candidates, including a second-source supplier to mitigate the risks of single-source supply, it would take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign health, there could be a shortage of drug substance or drug product which could impact our ability to continue or initiate clinical trials in a timely manner.

If our CDMOs are unable to source certain raw materials and components from their supplier and if they must obtain such materials from a different supplier, additional testing, and regulatory approvals, may be required, which may negatively impact manufacturing timelines. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify alternative materials or components, could considerably delay the manufacture of our current or future product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, for our product candidates.

In addition, our CDMOs' facilities and operations may be adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CDMOs may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates.

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

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

Future collaborations we may enter into may involve significant risks, including, among others:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to the collaboration;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may insist upon our relinquishment of certain rights with respect to our product candidates;
- collaborators may delay nonclinical or clinical development, provide insufficient funding for product development of targets selected by us, stop or abandon nonclinical or clinical development for a product candidate, or repeat or conduct new nonclinical and clinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our future collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the preclinical or clinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

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

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

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

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

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

Risks Related to Intellectual Property

We could lose important intellectual property rights that we currently license from a third party if we fail to comply with our obligations under the license agreements under which we license intellectual property rights from this third party or otherwise experience disruptions to our business relationships with our licensor.

We are a party to a license agreement relating to an expression system and cell line for use in the production of DM199 and DM300. 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 current or future in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain access to technologies that are material to our business, and we may be required to cease our development and commercialization of DM199 or other product candidates that we may identify or to seek alternative manufacturing methods. However, suitable alternatives may not be available or the development of suitable alternatives may result in a significant delay in our commercialization of DM199. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which, our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from a third party 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 in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We believe that patents and other proprietary rights are key to our business. Our policy is to file patent applications to protect technology, inventions and improvements that may be important to the development of DM199 or any future product candidate. We also rely upon trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position. We plan to enforce our issued patents and our rights to proprietary information and technology. We review third-party patents and patent applications, both to refine our own patent strategy and to monitor the landscape related to our technology.

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

To the extent that development, manufacturing and testing of our product candidates is performed by third-party contractors, such work is performed pursuant to fee for service contracts. Under the contracts, all intellectual property, technology know-how and trade secrets related to our product candidate 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 will be enforceable or would be upheld by a court.

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

We or a future partner may require additional third-party licenses to effectively develop, manufacture and commercialize DM199, or any future product candidate, and such licenses might not be available on commercially acceptable terms, or at all.

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 any future collaborator, would be required to seek licenses from the holders of these patents in order to manufacture, use or sell our product candidates, and payments under them would reduce profits from our 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 and have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or any 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, the U.S. Patent and Trademark Office (USPTO) and the European Patent Office (EPO), the laws and regulations governing patents could change in unpredictable ways that would weaken our or any licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we or any 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 (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 is 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 any licensor 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 any licensor's patents or patent applications.

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

Intellectual property litigation may be expensive, time consuming and may cause delays in the development, manufacturing and commercialization of DM199 or any future product candidate.

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

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

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

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

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

Because we rely on third parties to develop and manufacture our DM199 product candidate, we may share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, employment or consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of our collaborators, advisors, employees, and consultants to publish data potentially relating to our trade secrets. In the future, we may also conduct joint R&D programs which may require us to share trade secrets under the terms of R&D collaboration or similar agreements. We cannot be certain that our current or any future agreements have been or will be 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, financial condition, results of operations, and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Certain 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. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers 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. 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. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

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

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Risks Related to Human Capital Management

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

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

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

As we advance our DM199 product candidate through clinical trials and develop future product candidates, we have expanded our product development, scientific, clinical, regulatory and compliance, and administrative headcount. As of December 31, 2025, we had 35 full time employees, compared to 28 full time employees, as of December 31, 2024. In addition, to continue to meet our obligations as a U.S. public reporting company, we will likely need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

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

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

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

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

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

- demonstration of sufficient clinical efficacy and safety;

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

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

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

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

We or any future partner will likely face competition from other biotechnology and pharmaceutical companies, many of which have substantially greater resources, and our DM199 product candidate may face competition sooner than expected and our financial condition and operations will suffer if we fail to compete effectively.

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

Our DM199 product candidate may face competition sooner than expected.

We believe that DM199 could qualify for 12 years of data exclusivity in the United States under the Biologics Price Competition and Innovation Act of 2009. Under the BPCIA, an application for a biosimilar product, or abbreviated BLA, cannot be submitted to the FDA until four years, or if approved by the FDA, until 12 years, after the original 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 reference product. Any such approvals could have a material adverse effect on the future commercial prospects for DM199 or any future product candidate that is a biologic. There is also a risk that the U.S. Congress could repeal or amend the BPCIA to shorten this exclusivity period, potentially creating the opportunity for biosimilar competition sooner than anticipated after the expiration of our patent protection.

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

Our estimates of the market opportunity for our DM199 product candidate for the treatment of AIS, PE and any other indications we choose to pursue or any other product candidates we develop are based on a number of assumptions and may prove to be inaccurate. The actual market may be smaller than we believe, which would adversely affect our business, prospects, operating results and financial condition.

Our ReMEDy2 trial excludes patients who are eligible to receive mechanical thrombectomy, specifically participants with large vessel occlusions in the intracranial carotid artery or the M1 segment of the middle cerebral, vertebral or basilary arteries or those that are otherwise eligible for MT. As a result of our recent protocol amendment for the ReMEDy2 trial, participants treated with tPA or TNK, (thrombolytic agents) intended to dissolve blood clots, are now eligible for participation if they continue to experience a persistent neurological deficit after receiving thrombolytic treatment and meet all other trial criteria, including repeat brain imaging to assess any hemorrhagic (bleeding) transformation. We believe the ReMEDy2 trial population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA/TNK and/or MT.

We estimate total addressable markets for our DM199 product candidate for the treatment of AIS, PE and any other indications we choose to pursue or any other product candidates we develop. Our estimates and forecasts are based on a number of complex assumptions, internal and third-party estimates in published literature, and other business data, including assumptions and estimates relating to our ability to manage operating expenses of, invest in, and develop and generate revenue from DM199 or any other product candidates we develop in the future. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and metrics. Consequently, our estimates of the total addressable markets and our forecasts of market growth may prove to be incorrect. For example, if the annual total addressable markets or the potential market growth is smaller than we have estimated or if the key business metrics we utilize to forecast commercial opportunities are inaccurate, it may have an adverse effect on our business, prospects, operating results and financial condition.

Risks Related to Our Common Shares

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

Our common shares trade on The Nasdaq Capital Market under the trading symbol "DMAC." During 2025, the sale price of our common shares ranged from $3.19 to $10.42 per share. A number of factors could influence the volatility in the trading price of our common shares, including changes in the economy and in the financial markets, industry related developments in the overall biotech and pharmaceutical sectors, and the impact of material events and changes in our operations, such as our progress in our clinical trials, results thereof, operating results and financial condition. Each of these factors could lead to increased volatility in the market price of our common shares. In addition, the market prices of the securities of our competitors may also lead to fluctuations in the trading price of our common shares.

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

During 2025, the daily trading volume of our common shares ranged from approximately 24,100 shares to 3,185,200 shares. Although we anticipate a more active trading market for our common shares in the future, we can give no assurance that a more active trading market will develop or be sustained. If we do not have an active trading market for our common shares, it may be difficult for you to sell our common shares at a favorable price or at all.

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

Future dilution will likely occur due to anticipated future equity issuances by us. To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted. As of December 31, 2025, we had the ability to sell $86.2 million of our common shares under our At-the-Market sales agreement with TD Cowen. In addition we had outstanding options to purchase 6,502,444 common shares, deferred stock units representing 164,770 common shares and 1,601,791 common shares reserved for future issuance in connection with future grants under the DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan and the DiaMedica Therapeutics Inc. 2021 Employment Inducement Incentive Plan and options to purchase 362,410 common shares and deferred stock units representing 9,745 common shares under our prior equity compensation plans. If these or any future outstanding options or deferred stock units are exercised or otherwise converted into our common shares, our shareholders will experience additional dilution.

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

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

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

We are currently a "smaller reporting company" under the U.S. federal securities laws and, as such, are subject to scaled disclosure requirements afforded to such companies. For example, as a smaller reporting company, we are subject to reduced executive compensation disclosure requirements. Our shareholders and investors may find our common shares less attractive as a result of our status as a "smaller reporting company" and our reliance on the reduced disclosure requirements afforded to these companies. If some of our shareholders or investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the market price of our common shares may be more volatile.

A limited number of shareholders possess substantial voting power and could limit other shareholders' ability to influence the outcome of key transactions, including changes of control.

As of December 31, 2025, four holders of greater than five percent of our common stock collectively beneficially owned shares constituting approximately 47.6% and individually or collectively could be able to influence significantly all matters requiring approval by our shareholders, including elections of directors and the approval of mergers or other significant corporate transactions. These shareholders may have interests that differ from those of other shareholders, and they may vote in ways with which other shareholders disagree, potentially adverse to their interests. The concentration of ownership of our common stock may have the effect of delaying, preventing, or deterring a change of control of our company, could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our Company, and may affect the market price of our common stock. This concentration of ownership of our common stock may also influence the completion of a change in control that may not be in the best interests of all of our shareholders.

Risks Related to Our Jurisdiction of Organization

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

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

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

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

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

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

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

We were classified as a "passive foreign investment company" in 2025, 2024 and 2023 and certain other prior years and may be so classified in the current and/or future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders and adversely affect the level of interest in our common shares by U.S. investors.

General Rule. For any taxable year in which 75% or more of our gross income, including our pro rata share of the gross income of any corporation in which we are considered to own at least 25% of the shares by value, is passive income, or at least 50% of the value of our assets, including our pro rata share of the assets of any corporation in which we are considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income, we would be characterized as a "passive foreign investment company" (PFIC) for U.S. federal income tax purposes.

The tests for determining PFIC status for any taxable year are dependent upon a number of factors, some of which are beyond our control, including the value of our assets, the market price of our common shares, and the amount and type of our gross income. Based on these tests, we believe that we were a PFIC for the taxable year ended December 31, 2016 and again for each of the taxable years ended December 31, 2022, 2023, 2024[, and December 31, 2025]. Our status as a PFIC is a fact-intensive determination made for each taxable year, and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, 2026 or for future taxable years.

If we are or were classified as a PFIC for any taxable year during which a U.S. Holder (as defined in "— *Certain U.S. Federal Income Tax Considerations -– U.S. Holders*") holds our common shares, such U.S. Holder could be subject to adverse U.S. federal income tax consequences (regardless of whether we continue to be a PFIC), including increased tax liability on disposition gains and certain "excess distributions" and additional reporting requirements. Please see the section entitled "— *Certain U.S. Federal Income Tax Considerations — U.S. Holders – Passive Foreign Investment Company Considerations*" for a more detailed discussion with respect to our potential PFIC status. U.S. Holders are urged to consult their tax advisors regarding our PFIC status for any taxable year and the possible application of the PFIC rules to an investment in our common shares, including the availability and the advisability of making certain elections under the PFIC rules.

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

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

General Risk Factors

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

From time to time, we may announce the timing of certain events we expect to occur, such as the anticipated number of clinical sites and pace of enrollment and the timing of the interim analysis for our ReMEDy2 trial and the timing of completion of the PE trial. 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 projected timing of events such as the anticipated number of clinical sites and pace of enrollment for our ReMEDy2 trial or the 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 or events that we anticipate may occur as a result of different factors, including regulatory actions, the nature of the results obtained during a clinical trial or during a research phase, problems with a CDMO or CRO, health crises, epidemics or pandemics, full or partial clinical holds that may be imposed by the FDA or any other event having the effect of delaying the publicly announced timeline or leading to results that are different from what we expect. 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 or changes in other events of which we anticipate could have a material adverse effect on our business plan, financial condition or operating results, and the trading price of our common shares.

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

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

We, or our third-party contract research organizations or consultants, may be subject to information technology (IT) systems failures, network disruptions, breaches in data security and computer crime and cyber-attacks, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are dependent upon IT systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party consultants who have access to our confidential information.

IT system failures, network disruptions, breaches of data security and sophisticated and targeted computer crime and cyber-attacks could disrupt our operations by impeding our development programs, including delays in our clinical trials, the manufacture or shipment of our drug product candidate or other clinical supplies, the processing of transactions or reporting of financial results, or by causing an unintentional disclosure of confidential information. Despite our security measures, our IT and infrastructure may be attacked by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. In the ordinary course of our business, we collect and store sensitive data on our network, including intellectual property, proprietary business information, and personal information of our business partners and employees. Despite our efforts to protect sensitive, confidential or personal data or information, our facilities and systems and those of our third-party service providers may experience security breaches, theft, misplaced or lost data, programming and/or human errors that could potentially lead to the compromising of sensitive, confidential or personal data or information, improper use of our systems, software solutions or networks, unauthorized access, use, disclosure, modification or destruction of information, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, clinical trials and results of operations. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate for these events on a timely basis, we may suffer interruptions in our ability to manage our clinical trials and other operations. In addition, we and the third parties on which we rely may be more susceptible to security breaches and other security incidents due to many of our and their employees working remotely for some portion of time. While management has taken steps to address these concerns by conducting employee training, implementing certain data and system redundancy, hardening and fail-over along with other network security, comprehensive monitoring of our networks and systems, maintenance of backup and protective systems and other internal control measures, there can be no assurance that the measures we have implemented to date would be sufficient in the event of a system failure, loss of data or security breach. Because the techniques used to obtain unauthorized access change frequently and can be difficult to detect, anticipating, identifying or preventing these intrusions or mitigating them if and when they occur may be challenging. Although we have been the target of cyber attacks and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication, the aggregate impact of these attacks on our operations and financial condition has not been material. However, in light of the fact that cybersecurity threats have been rapidly evolving in sophistication and prevalence, no assurance can be provided that we will not become subject to future attacks, especially when our cybersecurity protection is dependent at least to some extent on the lack of human error. SEC rules related to cybersecurity risk management may further increase our regulatory burden and the cost of compliance in such events. As a result, in the event of such a failure, loss of data or security breach, our financial condition and operating results could be adversely affected.

We currently use limited traditional and generative artificial intelligence (AI) solutions for certain administrative and other functions. We may incorporate additional AI solutions into our information systems in the future and these solutions may become important in our operations over time. The ever-increasing use and evolution of technology, including cloud-based computing and AI, creates opportunities for the potential loss or misuse of personal data that we use to run our business, and unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices, which may result in significantly increased business and security costs, a damaged reputation, administrative penalties, or costs related to defending legal claims.

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

Our insurance policies are expensive and protect us only from certain business risks, which could leave us exposed to significant uninsured liabilities. Additionally, future fluctuations in insurance cost and availability could adversely affect our operating results or risk management profile.

We hold a number of insurance policies, including, but not limited to, product and general liability insurance, directors' and officers' liability insurance, property insurance, and workers' compensation insurance. The costs of maintaining adequate insurance coverage, most notably directors' and officers' liability insurance, have increased significantly in the past and could do so again in the future, thereby adversely affecting our operating results. If such costs increase, we may be forced to accept lower coverage levels and higher deductibles, which, in the event of a claim, could require significant, unplanned expenditures of cash, which could adversely affect our business. Future potential directors and officers could view our directors' and officers' liability insurance coverage as limited or even inadequate. Limited directors' and officers' liability insurance coverage, or the perception that our directors' and officers' liability insurance coverage is inadequate, may make it difficult to attract and retain directors and officers, and we may lose potential independent board members and management candidates to other companies that have more extensive directors' and officers' liability insurance coverage. In addition, if any of our current insurance coverages should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers.

The widespread outbreak of communicable diseases could delay our clinical trials and otherwise materially and adversely affect our business, operating results and financial condition.

We face risks related to health epidemics or outbreaks of communicable diseases, for example, the outbreak around the world of the highly transmissible and pathogenic coronavirus COVID-19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries. Many countries around the world may impose quarantines and restrictions on travel and mass gatherings to slow the spread of communicable diseases and close non-essential businesses. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could delay our clinical trials and materially affect our business, operating results and financial condition.

A pandemic or outbreak could result in difficulty securing additional clinical trial site locations, and adversely affect the ability of investigators and other study staff enrolling participants and may also adversely impact the ability of activities of CROs, trial monitors, laboratories and other critical vendors and consultants supporting our clinical trials. The potential negative impacts also include the inability to have study visits at trial sites, incomplete collection of safety and efficacy data, and higher rates of drop-out of subjects from ongoing trials, delays in site entry of study data into the data base, delays in monitoring of trial data because of restricted physical access to sites, delays in site responses to queries, delays in data-base lock, delays in data analyses, delays in time to top-line data, and delays in completing study reports. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the willingness of participants to enroll in our current or future clinical trials. These situations could cause delays in our clinical trial plans and increase expected costs, all of which could have a material adverse effect on our business, prospects, operating results and financial condition. Additionally, the manufacturing of DM199 and other product candidates, as well as other clinical supplies required to conduct our studies may be delayed by related supply chain issues, specifically supply of raw materials, compounded by international shipping delays.

Further, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital and negatively affect our liquidity. In addition, it could materially affect the value of our common shares.

Our business or the value of our common shares could be negatively affected as a result of actions by activist shareholders.

We value constructive input from our shareholders, and our Board of Directors and management team are committed to acting in the best interests of our shareholders. However, shareholders may from time to time engage in proxy solicitations, advance shareholder proposals or otherwise attempt to effect changes or acquire control over the Company. Responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting our operations and diverting the attention of our Board of Directors and senior management from the pursuit of business strategies. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist shareholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, employees, and joint venture partners, and cause our share price to experience periods of volatility or stagnation.

Item 1B. Unresolved Staff Comments

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

Item 1C. Cybersecurity

We recognize the importance of identifying, assessing, and managing material risks associated with cybersecurity threats, which risks include, among other things, operational risks, intellectual property theft, fraud, extortion, harm to employees or participants in our clinical trials, and violation of data privacy or security laws. In the ordinary course of our business, we collect and store certain confidential information such as information about our employees, contractors, vendors, suppliers, and clinical data. We augment the capabilities of our people, processes, and technologies in order to address our cybersecurity risks. Our cybersecurity risks, and the controls designed to mitigate those risks, are integrated into our overall risk management governance and are reviewed regularly by our Audit Committee.

Risk Management and Strategy

Identifying, assessing, and managing cybersecurity risk is integrated into our overall enterprise risk management systems and processes. Our cybersecurity risk management program has been developed based upon prevailing security standards and the National Institute of Standards and Technology (NIST) framework for evaluating and responding to potential cybersecurity risks, and addressing cybersecurity threats and incidents to the extent they arise. We have designed our business applications to minimize the impact that cybersecurity incidents could have on our business and have identified back-up systems where appropriate. Security events and data incidents are evaluated, ranked by severity, and prioritized for response and remediation when or if they occur. Incidents are evaluated to determine materiality, as well as operational, business and privacy impact. An important component of this program is employee awareness of and vigilance regarding cybersecurity risks. Our employees receive ongoing cybersecurity awareness trainings, including specific topics related to social engineering, phishing and email fraud.

Recognizing the complexity and evolving nature of cybersecurity threats, incidents and risks, we engage third-party experts, including managed information technology (IT) service providers and cybersecurity consultants, to evaluate and support our risk management systems, monitor potential vulnerabilities, periodically test our cybersecurity controls and procedures, and respond to cybersecurity incidents affecting us, including prompt escalation and communication of major security incidents to legal counsel, senior management and the Audit Committee of our Board of Directors. We utilize advanced technologies for continuous cybersecurity monitoring across our IT environment which are designed to prevent, detect and minimize cybersecurity attacks, as well as alert management of such attacks.

Governance

The Audit Committee of our Board of Directors is responsible for overseeing our cyber security risk management and strategy, including overseeing management's responsibility to assess, manage and mitigate risks associated with our business and operational activities, to administer our various compliance programs, in each case including cybersecurity concerns, and to oversee our IT systems, processes and data. Our Chief Financial Officer and cybersecurity consultants regularly meet with and provides periodic briefings to our Audit Committee regarding our cybersecurity risks and activities, including any recent cybersecurity incidents, if any, and related responses, and cybersecurity systems testing.

Management has implemented risk management policies and procedures, and management is responsible for the day-to-day cybersecurity risk management. Our Chief Financial Officer is responsible for the day-to-day assessment and management of our cybersecurity risks.

Cybersecurity Threat Disclosure

As of the date of this annual report on Form 10-K, risks from cybersecurity threats including as a result of any previous cybersecurity incidents, have not materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations, or financial condition. However, cybersecurity threats are constantly evolving, becoming more frequent and more sophisticated and are being made by groups of individuals with a wide range of expertise and motives, which increases the difficulty of detecting and successfully defending against them. While we have implemented measures to safeguard our operational and technology systems, the evolving nature of cybersecurity attacks and vulnerabilities means that these protections may not always be effective.

For further discussion of cybersecurity risks, please see Item 1A, "Risk Factors".

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 301 Carlson Parkway, Suite 210, Minneapolis, Minnesota, USA 55305. We lease these premises, which consist of approximately 6,000 square feet, pursuant to a lease that expires in January 2028. We believe that our facilities are adequate for our current needs and that suitable additional space will be available if and when needed on acceptable terms.

Item 3. Legal Proceedings

Resolution of Litigation with Pharmaceutical Research Associates Group B.V.

Beginning in 2018, we initiated legal proceedings against Pharmaceutical Research Associates Group B.V., acquired by ICON plc as of July 1, 2021, (ICON/PRA Netherlands). As previously disclosed, in October 2025, we entered into a Settlement Agreement, pursuant to which the parties agreed to settle any and all disputes, claims, and liabilities that had arisen, or will arise, out of their relationship, past and present, including, but not limited to, the pending legal proceedings.

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. 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 Stock Market LLC under the trading symbol "DMAC".

Number of Record Holders

As of March 16, 2026, we had 43 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.

Dividends

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

Purchases of Equity Securities by the Company

We did not purchase any common shares or other equity securities of our Company during the fourth quarter ended December 31, 2025.

Recent Sales of Unregistered Equity Securities

We did not sell any unregistered equity securities of our Company during the fourth quarter ended December 31, 2025.

Exchange Controls

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

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

The following is, as of March 1, 2026, a summary of the principal Canadian federal income tax considerations under the *Income Tax Act* (Canada) (Tax Act) generally applicable to a holder of our common shares who, for purposes of the Tax Act and at all relevant times, is neither resident in Canada nor deemed to be resident in Canada for purposes of the Tax Act and any applicable income tax treaty or convention, and who does not use or hold (and is not deemed to use or hold) common shares in the course of carrying on a business in Canada, deals at arm's length with us, is not affiliated with us, is not a "specified shareholder" of us (within the meaning of subsection 18(5) of the Tax Act) and holds our common shares as capital property (Holder). A "specified shareholder" for these purposes generally includes a person who (either alone or together with persons with whom that person is not dealing at arm's length for the purposes of the Tax Act) owns or has the right to acquire or control 25% or more of the common shares determined on a votes or fair market value basis. Generally, common shares will be considered to be capital property to a Holder thereof provided that the Holder does not hold common shares in the course of carrying on a business and such Holder has not acquired them in one or more transactions considered to be an adventure or concern in the nature of trade.

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

This summary is based upon the provisions of the Tax Act (including the regulations (Regulations) thereunder) in force as of March 1, 2026 and our understanding of the current administrative policies and assessing practices of the Canada Revenue Agency (CRA) published in writing by the CRA prior to March 1, 2026. This summary takes into account all specific proposals to amend the Tax Act (and the Regulations) publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof (Tax Proposals) and assumes that the Tax Proposals will be enacted in the form proposed, although no assurance can be given that the Tax Proposals will be enacted in their current form or at all. This summary does not otherwise take into account any changes in law or in the administrative policies or assessing practices of the CRA, whether by legislative, governmental or judicial decision or action. This summary is not exhaustive of all possible Canadian federal income tax considerations and does not take into account other federal or any provincial, territorial or foreign income tax legislation or considerations, which may differ materially from those described in this summary.

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

Dividends

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

Disposition of Common Shares

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

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

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

Certain U.S. Federal Income Tax Considerations

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

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (Code), U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the United States and Canada (Convention), all as in effect on the date hereof and all of which are subject to change and differing interpretation, possibly with retroactive effect. This summary is applicable to U.S. Holders who are residents of the United States for purposes of the Convention and who qualify for the full benefits of the Convention. This summary does not discuss the potential effects, whether adverse or beneficial, of any proposed legislation. Each prospective investor is responsible for monitoring developments with their own tax advisors, and we do not undertake to update any of the information in this summary based on any change in law after the effective date hereof, including any change that may have retroactive effect.

No legal opinion from U.S. legal counsel or ruling from the Internal Revenue Service (IRS) has been requested, or will be obtained, regarding the U.S. federal income tax consequences of the acquisition, ownership, and disposition of common shares. This summary is not binding on the IRS or the courts, and none of the IRS or the courts are precluded from taking a position that is different from, or contrary to, the positions presented in this summary. In addition, because the guidance on which this summary is based is subject to various interpretations, the IRS and the U.S. courts could disagree with one or more of the positions described in this summary.

This discussion is limited to U.S. Holders and Non-U.S. Holders that hold our common shares as "capital assets" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax considerations that may be relevant to any particular U.S. Holder or Non-U.S. Holder, or to U.S. Holders or Non-U.S. Holders subject to special treatment under U.S. federal income tax law (including, without limitation, banks, certain financial institutions, insurance companies, brokers or dealers in securities, traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities, governmental organizations, retirement plans, regulated investment companies, real estate investment trusts, U.S. expatriates and former citizens or long-term residents of the United States, persons who hold common shares as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment, persons that have a "functional currency" other than the U.S. dollar, persons that own (or are deemed to own) 10% or more (by voting power or value) of our common shares, "controlled foreign corporations," "passive foreign investment companies," persons that acquire their common shares as part of a compensation arrangement, persons deemed to sell our common shares under the constructive sale provisions of the Code, persons subject to special tax accounting rules as a result of any item of gross income with respect to our common shares being taken into account in an applicable financial statement, corporations that accumulate earnings to avoid U.S. federal income tax, persons subject to the anti-inversion, base erosion or anti-abuse rules, and S corporations, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address all U.S. federal income tax consequences relevant to a U.S. Holder's or Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income or the alternative minimum tax, and does not address any U.S. state or local or non-U.S. tax considerations or any other U.S. federal tax considerations, such as under the estate and gift tax laws. In addition, except as specifically set forth below, this summary does not discuss applicable tax reporting requirements.

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

This discussion is for informational purposes only and is not tax advice. Investors should consult their own tax advisors as to the particular tax considerations applicable to them relating to the purchase, ownership and disposition of common shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws, and of any applicable income tax treaty.

U.S. Holders

As used in this discussion, the term "U.S. Holder" means a beneficial owner of common shares that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source, or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more persons that is a "United States person" (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all of its substantial decisions, or (y) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

Distributions

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

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

Distributions on the common shares that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute "passive category income." Because we are not a U.S. corporation, such dividends will not be eligible for the "dividends received" deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations. Dividends paid by a "qualified foreign corporation" to a U.S. Holder who is an individual, trust or estate will generally be treated as "qualified dividend income" and eligible for taxation at the lower applicable long-term capital gain rate, provided that a holding period requirement and certain other requirements are met, subject to certain exceptions. However, if we are treated as a "passive foreign investment company" (a PFIC) for the taxable year in which the dividend is paid or the preceding taxable year (see discussion below under "*Passive Foreign Investment Company Considerations*"), we will not be treated as a qualified foreign corporation, and therefore the reduced capital gains tax rate described above will not apply. Each U.S. Holder is advised to consult its own tax advisors regarding the availability of the reduced tax rate on dividends.

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

Sale, Exchange or Other Taxable Disposition of Common Shares

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

If common shares are sold, exchanged or otherwise disposed of in a taxable transaction for Canadian dollars or other non-U.S. currency, the amount realized with respect to such Canadian dollars or other non-U.S. currency generally will be the U.S. dollar value of the Canadian dollars or other non-U.S. currency received based on the spot rate in effect on the date of sale, exchange or other taxable disposition. If a U.S. Holder is a cash method taxpayer and the common shares are traded on an established securities market, Canadian dollars or other non-U.S. currency paid or received by such U.S. Holder will be translated into U.S. dollars at the spot rate on the settlement date of the sale. An accrual method taxpayer may elect the same treatment with respect to the sale of common shares traded on an established securities market, provided that the election is applied consistently from year to year. Such election cannot be changed without the consent of the IRS. Canadian dollars or other non-U.S. currency received on the sale, exchange or other taxable disposition of common shares generally will have a tax basis equal to its U.S. dollar value as determined pursuant to the rules above. Any gain or loss recognized by a U.S. Holder on a sale, exchange or other taxable disposition of the Canadian dollars or other non-U.S. currency will be ordinary income or loss and generally will be U.S.-source gain or loss.

Passive Foreign Investment Company Considerations

General Rule. The U.S. federal income tax considerations relating to the purchase, ownership and disposition of our common shares by U.S. Holders will differ depending on whether or not we are considered a PFIC during such U.S. Holder's holding period. In general, for any taxable year in which 75% or more of our gross income, including our pro rata share of the gross income of any corporation in which we are considered to own at least 25% of the shares by value, is passive income, or at least 50% of the value of our assets, including our pro rata share of the assets of any corporation in which we are considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income, we would be characterized as a PFIC for U.S. federal income tax purposes.

The percentage of a corporation's assets that produce or are held for the production of passive income generally is determined based upon the average ratio of passive assets to total assets calculated at the end of each measuring period. Calculation of the value of assets is generally made at the end of each of the four quarters that make up the company's taxable year, unless an election is made to use an alternative measuring period (such as a week or month). The "weighted average" of those periodic values is then used to determine the value of assets for the passive asset test for the taxable year.

Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. However, proposed regulations section 1.1297-1(d)(2) provides a limited exception to the passive asset test valuation rules for working capital required to meet the short-term cash needs of operating companies. This proposed regulation provides that an amount of cash held in a non-interest bearing account that is held for the present needs of an active trade or business and is no greater than the amount reasonably expected to cover 90 days of operating expenses incurred in the ordinary course of the trade or business of the foreign corporation (for example, accounts payable for ordinary operating expenses or employee compensation) is not treated as a passive asset. Taxpayers are permitted to rely on the proposed rule provided they consistently follow the rule for each subsequent taxable year beginning before the date of filing of the Treasury decision adopting the rule as a final regulation. The Treasury Department and the IRS indicated that they continue to study the appropriate treatment of working capital for purposes of the passive asset test.

PFIC Status Determination. The tests for determining PFIC status for any taxable year are dependent upon a number of factors, some of which are beyond our control, including the value of our assets, the market price of our common shares, and the amount and type of our gross income. Based on these tests (i) we believe that we *were* a PFIC for the taxable year ended December 31, 2016, (ii) we do *not* believe that we were a PFIC for any of the taxable years ended December 31, 2017, 2018, 2019, 2020, or 2021, and (iii) we believe that we *were* a PFIC for each of the taxable years ended December 31, 2022, 2023, 2024 [and 2025]. Our status as a PFIC is a fact-intensive determination made for each taxable year, and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, 2026 or for future taxable years. U.S. Holders who own our common shares for any period during which we are a PFIC will be required to file IRS Form 8621 for each tax year during which they hold our common shares, unless, after we are no longer a PFIC, any such U.S. Holder makes the "purging election" discussed below.

Certain PFIC Consequences. If we are a PFIC for any year during a U.S. Holder's holding period of our common shares, and such U.S. Holder does not make a "qualified electing fund" election (QEF Election) or a "mark-to-market" election, both as described below, then such U.S. Holder generally will be required to treat any gain recognized upon a disposition of our common shares, or any so-called "excess distribution" received on our common shares (generally, any distributions on our common shares in a taxable year that are greater than 125% of the average annual distributions received by such U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period), as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would not be available. This income generally would be allocated over a U.S. Holder's holding period with respect to our common shares and the amount allocated to prior years will be subject to tax at the highest tax rate in effect for that year for individuals or corporations, as applicable, without regard to the U.S. Holder's other items of income and loss for such year, and an interest charge would be imposed on the amount of deferred tax on any such income allocated to prior taxable years. Any such interest charge will be non-deductible interest expense for individual U.S. Holders. Pursuant to the specific provisions of the PFIC rules, a taxpayer may realize gain on the disposition of common shares if the securities are disposed of by a holder whose securities are attributed to the U.S. Holder, if the securities are pledged as security for a loan, transferred by gift or death, or are subject to certain corporate distributions.

QEF Election. In general, if we are determined to be a PFIC, a U.S. Holder may be able to avoid certain of the adverse tax consequences described above by making a timely and effective QEF election. A U.S. Holder who makes a QEF election generally must report, on a current basis, its share of our ordinary earnings and net capital gains, whether or not we distribute any amounts to our shareholders, and would be required to comply with specified information reporting requirements. A U.S. Holder generally may make a separate election to defer the payment of taxes on undistributed income inclusions under the QEF rules, but if deferred, any such taxes will be subject to an interest charge. Any gain subsequently recognized upon the sale by that U.S. Holder of the common shares generally would be taxed as capital gain. The QEF election is available only if we provide certain information regarding our earnings and capital gains, as required under applicable U.S. Treasury regulations. We intend to reasonably endeavor to, upon a U.S. Holder's request, provide all information and documentation that such U.S. Holder making a QEF election is required to obtain for U.S. federal income tax purposes (e.g., the U.S. Holder's pro rata share of ordinary income and net capital gain, and a "PFIC Annual Information Statement" as described in applicable U.S. Treasury regulations). However, there can be no assurance that we will have timely knowledge of our status as a PFIC in the future or that we will be able to provide such required information to a U.S. Holder on a timely basis or at all.

Mark-to-Market Election. As an alternative to a QEF Election, a U.S. Holder that owns shares in a PFIC that are treated as marketable stock may also make a timely "mark-to-market" election. A U.S. Holder who makes the mark-to-market election for the first taxable year of such U.S. Holder in which it holds (or is deemed to hold) our common shares and for which we are determined to be a PFIC generally must include as ordinary income each year the increase in the fair market value of the common shares and deduct from gross income the decrease in the value of such shares during each of its taxable years. Losses would be allowed only to the extent of the net mark-to-market gain previously included in income under the election. The U.S. Holder's adjusted tax basis in the common shares with respect to which the mark-to-market election applies would be adjusted to reflect amounts included in gross income or allowed as a deduction as a result of such election. If a U.S. Holder makes an effective mark-to-market election, any gain recognized upon the sale or other disposition of our common shares in a year that we are a PFIC will be treated as ordinary income and any loss will be treated first as ordinary loss (to the extent of any net mark-to-market gains for prior years) and thereafter as capital loss. A mark-to-market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including The Nasdaq Capital Market. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U.S. Holder might not be eligible to make a mark-to-market election if we are characterized as a PFIC.

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

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

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

U.S. Information Reporting with Respect to Foreign Financial Assets and Transfers to Foreign Corporations

Certain U.S. Holders may be required to file an IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) to report a transfer of property (including cash) to us. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement and the period of limitations on assessment and collection of U.S. federal income taxes will be extended in the event of a failure to comply. Furthermore, certain U.S. Holders who are individuals and certain entities will be required to report information with respect to such U.S. Holder's investment in "specified foreign financial assets" on IRS Form 8938 (Statement of Specified Foreign Financial Assets), subject to certain exceptions. An interest in the Company constitutes a specified foreign financial asset for these purposes. U.S. Holders who are required to report specified foreign financial assets and fail to do so may be subject to substantial penalties and the period of limitations on assessment and collection of U.S. federal income taxes will be extended in the event of a failure to comply. Potential investors are urged to consult with their own tax advisors regarding the foreign financial asset and other reporting obligations and their application to an investment in our common shares.

Non-U.S. Holders

A beneficial owner of our common shares, other than an entity or arrangement treated as a partnership or other pass-through entity for U.S. federal income tax purposes, that is not a U.S. Holder is referred to herein as a "Non-U.S. Holder".

Non-U.S. Holders generally will not be subject to U.S. federal income or withholding tax on dividends received from us with respect to our common shares, unless that income is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such Non-U.S. Holder maintains in the United States).

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

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such Non-U.S. Holder maintains in the United States); or

- the Non-U.S. Holder is an individual who is present in the United States for 183 days or more during the taxable year of disposition and other conditions are met (in which case, such gain from United States sources generally is subject to tax at a 30% rate or a lower applicable tax treaty rate, which may be offset by U.S. source capital losses of such Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses).

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

Information Reporting and Backup Withholding

For U.S. Holders, dividends on and proceeds from the sale or other taxable disposition of common shares may be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if (1) the U.S. Holder fails to provide an accurate taxpayer identification number or otherwise establish a basis for exemption, or (2) the U.S. Holder is notified by the IRS that backup withholding applies. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder's U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

For Non-U.S. Holders, information returns may be filed with the IRS in connection with, and Non-U.S. Holders may be subject to U.S. tax withholding on amounts received in respect of, a Non-U.S. Holder's common shares, unless the Non-U.S. Holder furnishes to the applicable withholding agent the required certification as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, as applicable, or the Non-U.S. Holder otherwise establishes an exemption. Distributions paid with respect to common shares and proceeds from the sale or other disposition of common shares received in the United States by a Non-U.S. Holder through certain U.S.-related financial intermediaries may be subject to information reporting and U.S. tax withholding unless such Non-U.S. Holder provides proof of an applicable exemption or complies with certain certification procedures described above. If a Non-U.S. Holder sells its common shares through a U.S. office of a broker, the payment of the proceeds is subject to both U.S. backup withholding and information reporting unless such Non-U.S. Holder certifies that it is a non-U.S. person, under penalties of perjury, or it otherwise establishes an exemption. If a Non-U.S. Holder sells common shares through a non-U.S. office of a non-U.S. broker and the sales proceeds are paid to such Non-U.S. Holder outside the United States, then information reporting and backup withholding generally will not apply to that payment. However, U.S. information reporting requirements, but not backup withholding, will apply to a payment of sales proceeds, even if that payment is made to a Non-U.S. Holder outside the United States, if such Non-U.S. Holder sells common shares through a non-U.S. office of a broker that is a U.S. person or has certain other contacts with the United States, unless such Non-U.S. Holder certifies that it is a non-U.S. person under penalty of perjury, or otherwise establishes an exemption.

The discussion of reporting requirements set forth above is not intended to constitute a complete description of all reporting requirements that may apply to a U.S. Holder or Non-U.S. Holder. A failure to satisfy certain reporting requirements may result in an extension of the time period during which the IRS can assess a tax and, under certain circumstances, such an extension may apply to assessments of amounts unrelated to any unsatisfied reporting requirement. U.S. Holders and Non-U.S. Holders should consult with their own tax advisors regarding their reporting obligations, if any, as a result of their acquisition, ownership, or disposition of our common shares.

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

Item 6. [Reserved]

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 our subsidiaries for the years ended December 31, 2025 and 2024.

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*" in this report for additional cautionary information.

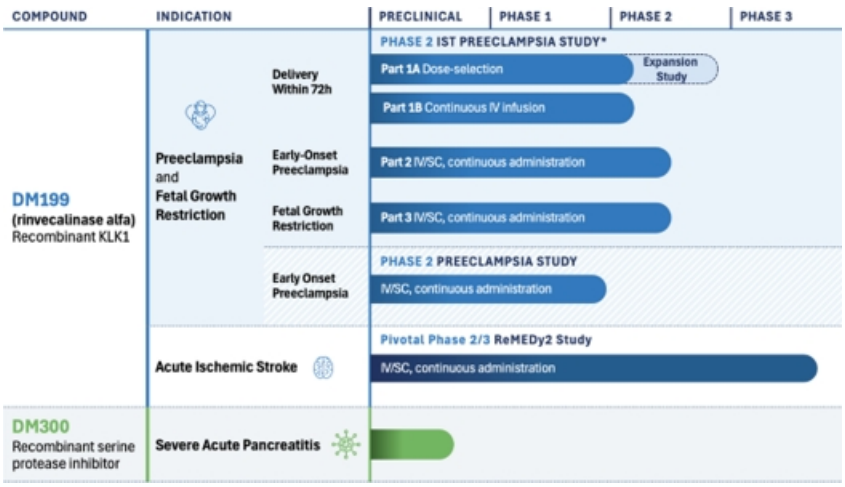
Business Overview

We are a clinical stage biopharmaceutical company committed to improving the lives of people suffering from severe ischemic disease with a focus on PE, FGR and AIS. Our lead candidate DM199 (rinvecalinase alfa; rhKLK1) is the first pharmaceutically active recombinant (synthetic) form of the human tissue kallikrein-1 (KLK1) protein (serine protease enzyme) to be clinically studied in patients. KLK1 is an established therapeutic modality in Asia, with human urinary KLK1 for the treatment of AIS and porcine KLK1 for the treatment of cardio renal disease, including hypertension. We plan to advance DM199 through required clinical trials to create shareholder value by establishing its clinical and commercial potential as a therapy for PE, FGR and AIS. Longer term, we plan to develop DM300, our patented recombinant human ulinastatin, a broad-spectrum serine protease inhibitor, as a potential therapy for severe acute pancreatitis.

DM199 is a recombinant form of the naturally occurring protease enzyme KLK1 (rhKLK1)and the first rhKLK1 undergoing global clinical development studies in PE, FGR and AIS. DM199 has been granted Fast Track designation from the FDA for the treatment of AIS. Naturally occurring KLK1 (extracted from human urine or porcine pancreas) has been an approved therapeutic agent in Asia for decades in the treatment of AIS and hypertension associated with cardiorenal disease. DM199 is produced using recombinant DNA technology without the need for extracted human or animal tissue sources and thereby eliminates risk of pathogen transmission.

KLK1 is a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism believed to enhance endothelial health, microcirculatory blood flow and tissue perfusion by increasing production of NO, PGI_2 and EDHF. In PE and FGR, DM199 is intended to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta, potentially disease modifying results that improve both maternal and perinatal outcomes. In the case of AIS, DM199 is intended to enhance blood flow and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the vascular occlusion and inhibiting apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis.

Our product development pipeline is as follows:



We are developing DM199 to address two major critical unmet needs. In PE and FGR, there are currently no approved agents in any global market to safely lower maternal blood pressure and/or reduce the risk of fetal growth restriction. Historically, the major issue is that traditional vasodilators that are commonly used to reduce essential hypertension (e.g., beta-blockers, angiotensin converting enzyme inhibitors (ACEi)) can readily cross the placental barrier and enter into the fetal circulation and cause harm to the developing fetus. We believe that DM199 is uniquely suited to treat PE since its inherent molecular size, approximately 26 kilodaltons (KD) is typically too large to cross the placental barrier, as was demonstrated in the interim result noted below, and therefore may reduce blood pressure and enhance microcirculatory perfusion to the maternal organs and placenta without entering fetal circulation, a potentially significant safety advantage. Additionally, we believe DM199 has the potential to not only address hypertension of PE, but also to confer disease modifying outcomes for both maternal and perinatal outcomes, including fetal growth restriction. In AIS, up to 80% of AIS patients are not eligible for treatment with currently approved clot-busting (thrombolytic) drugs or catheter-based clot removal procedures (mechanical thrombectomy). DM199 is intended to enhance collateral blood flow and boost neuronal survival in the ischemic penumbra by inhibiting neuronal cell death (apoptosis) and promoting neuronal remodeling and neoangiogenesis, and accordingly, offer a potential treatment option for AIS patients who otherwise have no therapeutic options.

Preeclampsia & Fetal Growth Restriction Program

Our clinical development program in PE currently centers around an investigator-sponsored safety, tolerability and pharmacodynamic, proof-of-concept Phase 2 study in PE patients. This Phase 2 study is being conducted at the Tygerberg Hospital, Cape Town, South Africa and consists of three studies in PE (Part 1a, dose-escalation; Part 1b, dose-expansion; and Part 2, expectant management) and a fourth study in fetal growth restriction (FGR, Part 3, expectant management). Part 1a topline study results are intended to identify a suitable dose for Parts 1b, 2, and 3. Up to 90 women with PE and potentially an additional 30 subjects with fetal growth restriction may be evaluated. The first subject in Part 1a was enrolled in the fourth quarter of 2024 and interim results from Part 1a of the study were released in July 2025. The interim results (N=28 subjects) demonstrate that DM199 appears safe and well-tolerated with clinically-relevant pharmacodynamic activity with no evidence of placental transfer. Additionally, subjects exhibited rapid, statistically significant reductions in blood pressure with duration of effect that was sustained up to 24 hours post-infusion compared to pre-treatment baseline, a durable effect extending up to 24 hours post-infusion. Preparations are underway to initiate Part 1b where up to 30 subjects with PE and expected delivery within 72 hours will be treated with a dose regimen identified from Part 1a.

PE is a serious pregnancy disorder that typically develops after the 20th week of gestation, characterized by high blood pressure and damage to organ systems, often the kidneys and liver. Affecting up to 8% of pregnancies worldwide, preeclampsia can pose significant risks to both the mother and baby, including risk of stroke, placental abruption, progression to eclampsia, premature delivery, and death. Symptoms may include severe headaches, vision changes, upper abdominal pain and swelling in the hands and face. Delivery of the baby, often very prematurely, is the only available option for stopping the progression of preeclampsia. Women who have had preeclampsia have three to four times the risk of high blood pressure and double the risk for heart disease and stroke and there are currently no approved therapeutics for PE in the United States or Europe. Fetal growth restriction is a closely related condition of fetal undergrowth due to a poorly functioning placenta – the life support system of the unborn child. Fetal growth restriction is the leading cause of stillbirth. For those that survive the pregnancy, unhealthy fetal development in utero leaves a legacy of poor health echoing across the child's lifespan. Currently, no approved treatment exists for this condition.

We are preparing for an open-label, dose-ranging Phase 2 study of DM199 in participants with early onset preeclampsia to be conducted in North America (United States & Canada) and the United Kingdom (UK). In March 2026, we received approval from Health Canada to initiate this Phase 2 study and we are currently finalizing plans to commence site activation in the second half of this year. In the second quarter of 2026, we anticipate filing a clinical trial application to expand this Phase 2 study to include sites in the UK. Regarding the status of this clinical program in the United States, in the fourth quarter of 2025, we participated in a productive, in-person pre-investigational new drug (IND) meeting with the US Food and Drug Administration (FDA) to discuss the planned Phase 2 study, at which the FDA requested an additional non-clinical, 10-day modified embryo-fetal development and pre- and postnatal development (ePPND) study in a rabbit model, a non-rodent species. Preliminary results of the rabbit study suggest that the animals developed an antibody response to DM199, a humanized recombinant protein, preventing us from completing the requested ePPND study in the rabbit model. In earlier pregnant rabbit studies, there was no evidence of teratogenicity (i.e., no external, visceral or skeletal malformations in developing rabbit fetuses) attributable to DM199 in the approximately 200 rabbit offspring produced. The fetal effects with pregnant rabbits that were observed, embryo/fetal lethality and decreased fetal body weights were considered secondary to frank maternal toxicity that was observed at all doses. We are currently evaluating alternate animal models to address the FDA's ePPND study request. Depending on the alternative species, and its gestational period, results from the ePPND study may be substantially delayed.

AIS Program and Phase 2/3 ReMEDy2 Trial

Our clinical program in AIS centers on our ReMEDy2 clinical trial (NCT05065216) of DM199 for the treatment of AIS. Our ReMEDy2 clinical trial is a Phase 2/3, adaptive design, randomized, double-blind, placebo-controlled trial intended to enroll approximately 300 participants at up to 100 sites globally. The adaptive design component includes an interim analysis by our independent data safety monitoring board to be conducted after the first 200 participants have completed the trial. Based on the results of the interim analysis, the study may be stopped for futility or the final sample size will be determined, ranging between 300 and 728 patients, according to a pre-determined statistical plan. As previously disclosed, we have experienced and continue to experience slower than expected site activations and enrollment in our ReMEDy2 trial. We believe these conditions may be due to hospital and medical facility staffing shortages; inclusion/exclusion criteria in the study protocol; concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns regarding the prior clinically significant hypotension events and circumstances surrounding the previous clinical hold; use of artificial intelligence and telemedicine which have enabled smaller hospitals to retain AIS patients not eligible for mechanical thrombectomy instead of sending these patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological trials. We continue to reach out to current and potential study sites to understand the specific issues at each study site. In an effort to mitigate the impact of these factors, we have significantly expanded our internal clinical team and have brought in-house certain trial activities, including site identification, qualification and activation, clinical site monitoring, supporting vendor management and overall program management. We are currently conducting the trial in the United States and in the countries of Canada, Georgia and the United Kingdom. We recently received regulatory approval from the European Medicines Agency and are initiating study sites in six European countries. We continue to work closely with our contract research organizations and other supporting vendors to develop procedures to support both U.S. and global study sites and potential participants as needed. We intend to continue to monitor the results of these efforts and, if necessary, implement additional actions to enhance site activations and enrollment in our ReMEDy2 trial; however, no assurances can be provided as to the success of these actions and if or when these issues will resolve. Failure to resolve these issues may result in further delays in our ReMEDy2 trial and increase the difficulty in forecasting enrollment.

Financial Overview

We do not have commercial approval to market any product, nor have we ever had such approval. We have financed our operations principally by the public and private sales of equity securities. We have received additional capital from the exercise of warrants and stock options, interest income on funds available for investment and government grants. During 2025 we received combined gross proceeds of approximately $43.9 million from the sale of common shares under a private placement offering and the sale of common shares under our at-the-market offering. We have incurred a net loss in each year since our inception. Our net losses were $32.8 million and $24.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $59.9 million and an accumulated deficit of $172.8 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development (R&D) activities and general and administrative (G&A) support costs associated with our operations.

We expect to continue to incur significant expenses and operating losses for at least the next few years. We anticipate that our quarterly expenses will increase moderately relative to recent prior periods as we continue to advance our DM199 clinical development program into PE and we continue our ReMEDy2 trial, including the activation of additional study sites in the U.S. and Europe and the enrollment of additional participants in the trial. Our efforts to expand our team to provide support for our clinical programs and administrative operations will also likely contribute to such increases.

While we expect our rate of future negative cash flows per quarter will generally increase moderately relative to recent prior periods as we continue our clinical development programs in PE and AIS, we expect our current cash resources will be sufficient to allow us to fund our planned operations for at least the next 12 months from the date of issuance of the consolidated financial statements included in this report. However, the amount and timing of our future funding requirements will depend on many factors, including timing and results of our ongoing development efforts, including the current Phase 2 PE trial, our current ReMEDy2 trial and in particular the rate of site activation and participant enrollment in the study, the potential further expansion of our current development programs and other factors. We may require or otherwise seek significant additional funds earlier than we currently expect. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable.

Components of Our Results of Operations

Research and Development Expenses

We incurred R&D expenses of $24.6 million and $19.1 million for the years ended December 31, 2025 and 2024, respectively. R&D expenses consist primarily of fees paid to external service providers such as contract research organizations; clinical support services; clinical development including clinical site costs; outside nursing services; and laboratory testing. R&D costs also include non-clinical testing; fees paid to our contract manufacturing and development organizations and outside laboratories for development of DM199 and related manufacturing processes; costs for production runs of DM199; consulting resources with specialized expertise related to the execution of our development plan for DM199; and personnel costs, including salaries, benefits, non-cash share-based compensation expense; and other personnel costs. Our R&D efforts have been primarily focused on developing DM199. At this time, due to the risks inherent in the clinical development process and the clinical stage of our product development programs, we are unable to estimate with any certainty the costs we will incur in completing the development of DM199 through marketing approval. The process of conducting clinical studies necessary to obtain regulatory approval and manufacturing scale-up to support expanded development and potential future commercialization is costly and time consuming. Any failure by us or delay in completing clinical studies, manufacturing scale-up, or in obtaining regulatory approvals could lead to increased R&D expenses and, in turn, have a material adverse effect on our results of operations.

General and Administrative Expenses

We incurred G&A expenses of $9.8 million and $7.6 million for the years ended December 31, 2025 and 2024, respectively. G&A expenses consist primarily of salaries and benefits, including non-cash share-based compensation related to our executive, finance, business development and support functions. G&A expenses also include insurance, including directors' and officers' liability coverage, rent and utilities, travel expenses, patent costs, and professional fees, including for auditing, tax and legal services.

Other Income, Net

Other income, net consists primarily of interest income earned on marketable securities.

Critical Accounting 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 estimates, which are those that are most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Research and Development Costs

We charge R&D costs to expense when incurred. Our human clinical trials are performed at experienced clinical trial sites and are generally administered by us with assistance from contract research organizations (CROs) although, during 2024 and 2025 in an effort to mitigate the impact delays in our ReMEDy2 trial, we have significantly expanded our internal clinical team and have brought in-house certain trial activities, including site identification, qualification and activation, clinical site monitoring, supporting vendor management and overall program management. Trial costs also include outside service providers, such as outside nursing services, testing laboratories and data coordination and collection. Upfront costs of setting up clinical trial sites are accrued upon execution of individual trial agreements. Expenses related to the performance of clinical trials are accrued based on contracted amounts and the achievement of agreed upon milestones, such as participant enrollment, participant follow-up, etc. While we utilize electronic data capture systems to facilitate the transmission and capture of clinical trial activity, such information is often incomplete or delayed. Therefore, we are required to estimate levels of performance under each significant contract, including, among other things, the extent of participant enrollment, the extent of supporting services performed and other activities through communications with the clinical trial sites, CROs and supporting vendors and adjust the estimates, if required, on a quarterly basis so that clinical expenses materially reflect the actual work performed at each clinical trial site and by each CRO or supporting vendor.

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 option awards are estimated using the Black-Scholes option pricing model. The determination of the fair value of share-based awards is affected by our common share price, as well as assumptions regarding a number of complex and subjective variables. Risk-free interest rates are based upon United States Government securities rates appropriate for the expected term of each award. Expected volatility rates are based on the historical volatility experienced over a period equal to the expected term 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 during the years ended December 31, 2025 and 2024:

	2025	2024
Common share fair value	$4.07 - $8.67	$2.40 - $5.38
Risk-free interest rate	3.7% - 4.4%	3.8% - 4.5%
Expected dividend yield	0%	0%
Expected option life (in years)	5.0 – 5.6	5.5 – 5.7
Expected stock price volatility	75.7% - 83.3%	83.0% - 124.1%

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 24,614	$ 19,057
General and administrative expenses	9,783	7,624
Other income, net	(1,659)	(2,267)

Research and Development Expenses

R&D expenses were $24.6 million and $19.1 million for the years ended December 31, 2025 and 2024, respectively. The $5.5 million increase is primarily due to cost increases driven by the continuation of our ReMEDy2 clinical trial, including its global expansion, the expansion of our clinical team in the prior and current year periods, including increased non-cash share-based compensation costs. These increases were partially offset by cost reductions related to manufacturing process development work performed and completed in the prior year period. We expect that our R&D expenses will moderately increase in future periods relative to recent prior periods as we continue our clinical development program in PE and as we continue our ReMEDy2 trial, including our global expansion.

General and Administrative Expenses

G&A expenses were $9.8 million and $7.6 million for the year ended December 31, 2025 and 2024, respectively. G&A expenses increased $2.2 million due to a series of factors including increased non-cash share-based compensation expense, increased personnel costs, increased investor relations expenses and increased patent prosecution costs. We expect G&A expenses to remain steady to slightly increase in future periods as compared to recent prior periods.

Other Income, Net

Other income, net, was $1.7 million for the year ended December 31, 2025 compared to $2.3 million for 2024. The decreases resulted from reduced interest income recognized during the current year related to lower average marketable securities balances as compared to the prior year.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of December 31, 2025 and 2024 and cash flows for each of the years ended December 31, 2025 and 2024, and are intended to supplement the more detailed discussion that follows (in thousands):

Liquidity and Capital Resources	December 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 59,890	$ 44,147
Total assets	61,371	46,345
Total current liabilities	5,132	5,390
Total shareholders' equity	56,111	40,718
Working capital	55,497	39,220

	Year Ended December 31,	
Cash Flow Data	**2025**	**2024**
Cash flow provided by (used in):		
Operating activities	$ (29,062)	$ (22,076)
Investing activities	(2,192)	8,564
Financing activities	43,876	11,994
Net increase (decrease) in cash and cash equivalents	$ 12,622	$ (1,518)

Liquidity and Capital Resources

We had cash, cash equivalents and marketable securities of $59.9 million, current liabilities of $5.1 million, and working capital of $55.5 million as of December 31, 2025, compared to $44.1 million in cash, cash equivalents and marketable securities, $5.4 million in current liabilities, and $39.2 million in working capital as of December 31, 2024. The increases in our combined cash, cash equivalents and marketable securities and in our working capital are due to the net proceeds received from the sale of common shares in our July private placement and under our at-the-market offering program, partially offset by the net cash used in operating activities.

Cash Flows

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $29.1 million compared to $22.1 million for the year ended December 31, 2024. The increase in cash used in operating activities resulted primarily from the increased net loss, partially offset by changes in operating assets and liabilities during the current year period.

Investing Activities

Investing activities consist primarily of purchases and maturities of marketable securities. Net cash used in investing activities was $2.2 million for the year ended December 31, 2025 compared to net cash provided by investing activities of $8.6 million for the year ended December 31, 2024. This change resulted primarily from the investment of proceeds from our July 2025 private placement, partially offset by maturities of our marketable securities during the current year quarter.

Financing Activities

Net cash provided by financing activities was $43.9 million for the year ended December 31, 2025, consisting primarily of net proceeds from the sale of common shares in our July private placement and under our at-the-market offering program. For the year ended December 31, 2024, net cash provided by financing activities was $12.0 million, consisting primarily of net proceeds from the sale of common shares in our June 2024 private placement.

Capital Requirements

Since our inception, we have incurred losses while advancing the development of our DM199 product candidate. We have not generated any revenues from product sales and do not expect to do so for at least two to three years. We do not know when or if we will generate any revenues from product sales or out-licensing of our DM199 product candidate or any future product candidate. We will not generate any revenue from product sales unless and until we obtain required regulatory approvals. We expect to continue to incur substantial operating losses until such time as any future product sales, licensing fees, milestone payments and/or royalty payments are sufficient to generate revenues to fund our continuing operations. We expect our operating losses to moderately increase as compared to recent prior periods as we continue the research, development and clinical studies of, and seek regulatory approval for, our DM199 product candidate, including, in particular, the expansion of our clinical development program into PE and the continuation and global expansion of our ReMEDy2 trial. In the long-term, subject to obtaining regulatory approval of our DM199 product candidate, or any other product candidate, and if we are unable to secure the assistance of, or out-license to, a strategic partner, we expect to incur significant commercialization expenses for product marketing, sales, manufacturing and distribution.

Accordingly, and not withstanding the sale of common shares during 2025, in which we received net proceeds of approximately $43.3 million, we expect we will need substantial additional capital to complete our R&D activities, including current and anticipated future clinical studies, regulatory activities, and otherwise develop our product candidate, DM199, or any future product candidate, to a point where the product candidate may be out-licensed or commercially sold. Although we are striving to achieve these plans, there is no assurance that these and other strategies will be achieved or that additional funding will be obtained on favorable terms or at all. We expect our rate of future negative quarterly cash flows will vary depending on our clinical activities and the timing of expenses incurred and will increase moderately relative to recent prior periods as we expand our PE clinical development program and continue and globally expand our ReMEDy2 trial. We expect our current cash resources to be sufficient to fund our planned operations for at least the next twelve months from the date of issuance of the consolidated financial statements included in this report. The amount and timing of our future funding requirements will depend on many factors, including timing and results of our ongoing development efforts, including our current ReMEDy2 trial and the Phase 2 PE trial, the potential further expansion of our current development programs and other factors on our operating expenses. We may require significant additional funds earlier than we currently expect and there is no assurance that we will not need or seek additional funding prior to such time, especially if market conditions for raising additional capital are favorable.

Historically, we have financed our operations primarily from the public and private sale of equity securities. We have received additional capital from the exercise of warrants and stock options, interest income on funds available for investment and government grants. Our most recent equity financing was our July 2025 private placement in which we issued and sold an aggregate of 8,606,425 common shares pursuant to a securities purchase agreement at a purchase price of $3.50 per share to accredited investors. As a result of the offering, we received net proceeds of $30.0 million, after deducting offering expenses. Additionally we sold 1,724,472 common shares under our at-the-market offering for net proceeds of $13.3 million. We do not have any existing credit facilities under which we could borrow funds. We may seek to raise additional funds through various sources, such as equity or debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if our clinical data is not positive or economic and market conditions deteriorate.

To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted. Debt financing, if available, may involve agreements that include conversion discounts, pledging our intellectual property as collateral or covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, or strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. The availability of financing will be affected by the status of our clinical trials; our clinical data and other results of scientific and clinical research; the ability to obtain regulatory approvals and other regulatory actions; market acceptance of our product candidates; the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies; the status of strategic alliance agreements; and other relevant commercial considerations.

If adequate funding is not available when needed, we may be required to scale back our operations by taking actions that may include, among other things, implementing cost reduction strategies, such as reducing use of outside professional service providers, reducing the number of our employees or employee compensation, modifying or delaying the development of our DM199 product candidate; licensing to third parties the rights to commercialize our DM199 product candidate for PE, FGR, AIS or other indications that we would otherwise seek to pursue, or otherwise relinquishing significant rights to our technologies, future revenue streams, research programs or product candidates or granting licenses on terms that may not be favorable to us; and/or divesting assets or ceasing operations through a merger, sale, or liquidation of our Company.

Commitments and Contingencies

In the normal course of business, we incur obligations to make future payments as we execute our business plan. These obligations may relate to preclinical or clinical studies, manufacturing or manufacturing process development and other related or supporting activities. Currently, these obligations include costs to be incurred with contract research organizations, central laboratory and pharmacy services, clinical study sites, home nursing services, various other vendors supporting the performance of our clinical trials and contract manufacturing and development organizations. The contracts we enter into with these vendors and the commitments within these contracts are subject to significant variability based upon the actual activities/services performed by each vendor. As a result, the ultimate amounts due may be materially different as these obligations are affected by, among other factors, the number and pace of clinical study sites activated, the number of countries in which clinical sites are activated, the number of participants enrolled, the amount of time to complete trial enrollment and the time required to finalize, analyze and report our clinical trial results. Clinical research agreements, including supporting vendors, are generally cancelable upon 60-90 days' notice, with our obligation limited to costs incurred up to that date, including any non-cancelable costs. Cancelation terms for product manufacturing and process development contracts vary and are generally dependent upon timelines for sourcing research materials and reserving laboratory time. As of December 31, 2025, we estimate that our outstanding commitments, including such cancellable contracts, are approximately $24.7 million, of which $19.3 million become due over the next 12 months and approximately $5.4 million become due in the next 12 months thereafter.

As of December 31, 2025, we had future operating lease obligation totaling approximately $225,000 over the remainder of the lease, of which approximately $101,000 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, 2025, one milestone payment obligation remains which is due upon our first regulatory approval of DM199 for commercial sale. Following the launch of our first product, we will also incur a royalty obligation of less than 1% of net sales. The royalty term is indefinite but the license agreement may be canceled by us on 90 days' prior written notice. The license may not be terminated by Catalent unless we fail to make required milestone and royalty payments.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors 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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, shareholders’ equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 30, 2026

We have served as the Company’s auditor since 2018.

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,647	$ 3,025
Marketable securities	44,243	41,122
Prepaid expenses and other assets	481	227
Amounts receivable	258	236
Total current assets	60,629	44,610
Non-current assets:		
Deferred offering costs	400	—
Operating lease right-of-use asset	197	279
Property and equipment, net	145	148
Deposits	—	1,308
Total non-current assets	742	1,735
Total assets	$ 61,371	$ 46,345
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,475	$ 940
Accrued liabilities	3,545	4,347
Operating lease obligation	101	90
Finance lease obligation	11	13
Total current liabilities	5,132	5,390
Non-current liabilities:		
Operating lease obligation, non-current	124	225
Finance lease obligation, non-current	4	12
Total non-current liabilities	128	237
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 53,742,370 and 42,818,660 shares issued and outstanding, as of December 31, 2025 and 2024, respectively	—	—
Paid-in capital	228,829	180,697
Accumulated other comprehensive income	50	23
Accumulated deficit	(172,768)	(140,002)
Total shareholders' equity	56,111	40,718
Total liabilities and shareholders' equity	$ 61,371	$ 46,345

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,	
	2025	**2024**
Operating expenses:		
Research and development	$ 24,614	$ 19,057
General and administrative	9,783	7,624
Total operating expenses	34,397	26,681
Operating loss	(34,397)	(26,681)
Other income:		
Other income, net	1,659	2,267
Total other income, net	1,659	2,267
Loss before income tax expense	(32,738)	(24,414)
Income tax expense	(28)	(30)
Net loss	(32,766)	(24,444)
Other comprehensive income		
Unrealized gain on marketable securities	27	17
Comprehensive loss	$ (32,739)	$ (24,427)
Basic and diluted net loss per share	$ (0.70)	$ (0.60)
Weighted average shares outstanding – basic and diluted	46,980,777	40,404,681

See accompanying notes to consolidated financial statements.

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

	Common Shares	Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
Balances at December 31, 2023	37,958,000	$ 166,609	$ 6	$ (115,558)	$ 51,057
Issuance of common shares under Private Placement, net of offering costs of $0.1 million	4,720,000	11,747	—	—	11,747
Issuance of common shares upon the exercise of stock options	117,000	256	—	—	256
Issuance of common shares upon the vesting and settlement of restricted stock units	23,660	—	—	—	—
Share-based compensation expense	—	2,085	—	—	2,085
Unrealized gain on marketable securities	—	—	17	—	17
Net loss	—	—	—	(24,444)	(24,444)
Balances at December 31, 2024	42,818,660	$ 180,697	$ 23	$ (140,002)	$ 40,718
Issuance of common shares under Private Placement, net of offering costs of $0.2 million	8,606,425	29,967	—	—	29,967
Sale of common shares, net of offering costs of $0.4 million	1,724,472	13,315	—	—	13,315
Issuance of common shares upon the exercise of stock options	415,253	1,004	—	—	1,004
Issuance of common shares in settlement of deferred stock units	142,345	—	—	—	—
Issuance of common shares upon the vesting and settlement of restricted stock units	35,215	—	—	—	—
Share-based compensation expense	—	3,846	—	—	3,846
Unrealized gain on marketable securities	—	—	27	—	27
Net loss	—	—	—	(32,766)	(32,766)
Balances at December 31, 2025	53,742,370	$ 228,829	$ 50	$ (172,768)	$ 56,111

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (32,766)	$ (24,444)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,846	2,085
Amortization of discounts on marketable securities	(942)	(1,343)
Non-cash lease expense	82	75
Depreciation	43	39
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(254)	184
Amounts receivable	(22)	133
Deposits	1,308	(1,308)
Accounts payable	535	14
Accrued liabilities	(892)	2,489
Net cash used in operating activities	(29,062)	(22,076)
Cash flows from investing activities:		
Purchase of marketable securities	(59,278)	(50,411)
Maturities and sales of marketable securities	57,126	59,000
Purchase of property and equipment	(40)	(25)
Net cash provided by (used in) investing activities	(2,192)	8,564
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	43,282	11,747
Proceeds from the exercise of stock options	1,004	256
Principal payments on finance lease obligations	(10)	(9)
Deferred financing costs, net	(400)	—
Net cash provided by financing activities	43,876	11,994
Net increase (decrease) in cash and cash equivalents	12,622	(1,518)
Cash and cash equivalents at beginning of period	3,025	4,543
Cash and cash equivalents at end of period	$ 15,647	$ 3,025
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 28	$ 26
Assets acquired under financing lease	$ —	$ 30

See accompanying notes to consolidated financial statements.

1. Business

DiaMedica Therapeutics Inc. and its wholly owned subsidiaries, DiaMedica USA Inc. and DiaMedica Australia Pty Ltd. (collectively, we, us, our, DiaMedica and the Company), is a clinical stage biopharmaceutical company focused on developing novel treatments for preeclampsia (PE), fetal growth restriction (FGR) and acute ischemic stroke (AIS). DiaMedica's lead product candidate, DM199, is the first pharmaceutically active recombinant (synthetic) form of the human tissue kallikrein-1 (KLK1) protein, an established therapeutic modality in Asia for the treatment of preeclampsia, acute ischemic stroke and other vascular diseases. Our common shares are publicly traded on The Nasdaq Capital Market under the symbol "DMAC."

2. Risks and Uncertainties

DiaMedica operates in a highly regulated and competitive environment. The development, manufacturing and marketing of pharmaceutical products require approval from, and are subject to ongoing oversight by, the United States Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in the European Union, and comparable agencies in other countries. We are in the clinical stage of development of our lead product candidate, DM199, for the treatment of PE and AIS. We have not completed the development of any product candidate and do not generate any revenues from the commercial sale of any product candidate. Our lead product candidate, DM199, requires significant additional clinical testing and investment prior to seeking marketing approval and is not expected to be commercially available for at least three to four years, if at all.

With respect to our PE clinical program, a Phase 2 open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored study of DM199 for the treatment of PE is currently being conducted at the Tygerberg Hospital in Cape Town, South Africa. This Phase 2 study consists of three studies in PE (Part 1a, dose-escalation; Part 1b, dose-expansion; and Part 2, expectant management) and a fourth study in fetal growth restriction (FGR, Part 3, expectant management). Part 1a topline study results are intended to identify a suitable dose for Parts 1b, 2, and 3. Up to 90 women with PE and potentially an additional 30 subjects with fetal growth restriction may be evaluated. The first subject in Part 1a was enrolled in the fourth quarter of 2024 and interim results from Part 1a of the study were released in July 2025. The interim results (N=28 subjects) demonstrated that DM199 appears safe and well-tolerated with clinically-relevant pharmacodynamic activity with no evidence of placental transfer. Additionally, subjects exhibited rapid, statistically significant reductions in blood pressure with duration of effect that was sustained up to 24 hours post-infusion compared to pre-treatment baseline. Preparations are underway to initiate Part 1b where up to 30 subjects with PE and expected delivery within 72 hours will be treated with a dose regimen identified from Part 1a.

With respect to our AIS clinical program, we are currently conducting a Phase 2/3, adaptive design, randomized, double-blind, placebo-controlled trial of DM199 for the treatment of AIS, (the ReMEDy2 trial). Our ReMEDy2 trial is intended to enroll approximately 300 participants at up to 100 sites globally. The adaptive design component includes an interim analysis by our independent data safety monitoring board to be conducted after the first 200 participants have completed the trial. Based on the results of the interim analysis, the study may then be stopped for futility or the final sample size will be determined, ranging between 300 and 728 patients, according to a pre-determined statistical plan. We have experienced and continue to experience slower than expected site activations and enrollment in our ReMEDy2 trial. We believe these conditions may be due to hospital and medical facility staffing shortages; inclusion/exclusion criteria in the study protocol; concerns managing logistics and protocol compliance for participants discharged from the hospital to an intermediate care facility; concerns regarding the prior clinically significant hypotension events and circumstances surrounding the previous clinical hold; use of artificial intelligence and telemedicine which have enabled smaller hospitals to retain AIS patients not eligible for mechanical thrombectomy instead of sending these patients to the larger stroke centers which are more likely to be sites in our trial; and competition for research staff and trial subjects due to other pending stroke and neurological trials. We continue to reach out to current and potential study sites to understand the specific issues at each study site. In an effort to mitigate the impact of these factors, we have significantly expanded our internal clinical team and have brought in-house certain trial activities, including site identification, qualification and activation, clinical site monitoring, supporting vendor management and overall program management. We are currently conducting our ReMEDy2 trial in the United States and in the countries of Canada and Georgia. We are in the process of preparing regulatory filings and identifying and engaging study sites in an additional seven European countries and, on August 28, 2025, received approval for the conduct of this study in the United Kingdom. We continue to work closely with our contract research organizations and other advisors to develop procedures to support both U.S. and global study sites and potential participants as needed. We intend to continue to monitor the results of these efforts and, if necessary, implement additional actions to enhance site activations and enrollment in our ReMEDy2 trial; however, no assurances can be provided as to the success of these actions and if or when these issues will resolve. Failure to resolve these issues may result in further delays in our ReMEDy2 trial and increase the difficulty in forecasting enrollment. We currently estimate that the interim analysis will be completed in the second half of 2026.

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

As of December 31, 2025, we have incurred losses of $172.8 million since our inception in 2000. For the year ended December 31, 2025, we incurred a net loss of $32.8 million and negative cash flows from operating activities of $29.1 million. We expect to continue to incur substantial operating losses until such time as any future product sales, licensing fees, milestone payments and/or royalty payments generate revenue sufficient to fund our continuing operations. For the foreseeable future, we expect to incur significant operating losses as we continue the development and clinical study of, and to seek regulatory approval for, our DM199 product candidate. As of December 31, 2025, we had combined cash, cash equivalents and marketable securities of $59.9 million, working capital of $55.5 million, and shareholders' equity of $56.1 million.

Our principal source of cash has been net proceeds from the issuance of equity securities. Although we have 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 are not positive or if economic and market conditions deteriorate.

We expect that we will need substantial additional capital to further our research and development activities and complete the required clinical studies, regulatory activities and manufacturing development for our product candidate, DM199, or any future product candidates, to a point where they may be licensed or commercially sold. We expect our current cash, cash equivalents and marketable securities to be sufficient to fund our planned operations for at least the next 12 months from the date of issuance of these consolidated financial statements. The amount and timing of our future funding requirements will depend on many factors, including timing and results of our ongoing development efforts, including our current ReMEDy2 trial and the rate of site activation and participant enrollment in the study; the Phase 2 PE trial; the potential expansion of our current development programs; the effects of ongoing site staffing shortages; and other factors on our clinical trials and our operating expenses. We may require significant additional funds earlier than we currently expect and there is no assurance that we will not need or seek additional funding prior to such time, especially if market conditions for raising capital are favorable.

3. Summary of Significant Accounting Policies

Basis of consolidation

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

Functional currency

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

Segments

The Company operates in a single segment focusing on developing potentially transformative treatments for severe ischemic diseases. Consistent with the Company's operational structure, its chief operating decision maker manages and allocates resources for the Company at a consolidated level. Therefore, results of the Company's operations are reported on a consolidated basis for purposes of segment reporting. Substantially all assets of the Company are held in the United States.

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 consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Cash and cash equivalents

The Company considers all bank deposits, including money market funds and other investments, purchased with an original maturity to the Company of three months or less, to be cash and cash equivalents. The carrying amount of the Company's cash equivalents approximates fair value due to the short maturity of the investments.

Marketable securities

The Company's marketable securities may consist of obligations of the United States government and its agencies, bank certificates of deposit and investment grade corporate obligations, which are classified as available-for-sale. Marketable securities which mature within 12 months from their purchase date are included in current assets. Securities are generally valued based on market prices for similar assets using third-party certified pricing sources and are carried at fair value. The amortized cost of marketable securities is adjusted for amortization of premiums or accretion of discounts to maturity. Such amortization or accretion is included in interest income. Realized gains and losses, if any, are calculated on the specific identification method. Interest income is included in other income in the consolidated statements of operations.

We conduct periodic reviews to identify and evaluate each available-for-sale debt security that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Declines in fair value considered to be temporary and caused by noncredit-related factors of the issuer, are recorded in accumulated other comprehensive income or loss, which is a separate component of shareholders' equity. Declines in fair value that are other than temporary or caused by credit-related factors of the issuer, are recorded within earnings as an impairment loss. There were no material other-than-temporary unrealized losses as of December 31, 2025 or 2024.

Concentration of credit risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains its cash balances primarily with two financial institutions. These balances generally exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. The Company believes that the credit risk related to marketable securities is limited due to the adherence to an investment policy focused on the preservation of principal.

Fair value measurements

Under the authoritative guidance for fair value measurements, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The authoritative guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The hierarchy is broken down into three levels defined as follows:

Level 1 Inputs — quoted prices in active markets for identical assets and liabilities

Level 2 Inputs — observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 Inputs — unobservable inputs

As of December 31, 2025, the Company believes that the carrying amounts of its other financial instruments, including amounts receivable, accounts payable and accrued liabilities, approximate their fair value due to the short-term maturities of these instruments. See Note 4, titled "*Marketable Securities*" for additional information.

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 and comprehensive loss. 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.

Leases

We determine if an arrangement is a lease at inception. We have made a policy election to not separate lease and non-lease components for our real estate leases to the extent they are fixed. Non-lease components that are not fixed are expensed as incurred as variable lease expense. Our facility lease includes variable non-lease components, such as common-area maintenance costs. Our operating lease is included in operating lease right-of-use ("ROU") asset and operating lease obligations on our consolidated balance sheets. Our operating lease ROU asset represents our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. The operating lease ROU asset and operating lease obligation are recognized based on the present value of lease payments over the lease term. The lease does not provide an implicit rate and, due to the lack of a commercially salable product, we are generally considered unable to obtain commercial credit. Therefore, considering the quoted rates for the lowest investment-grade debt and the interest rates implicit in recent financing leases, we estimated our incremental borrowing rate. The operating lease ROU asset excludes lease incentives. Our lease includes an option to extend or terminate the lease; lease terms are only adjusted for these options when it is reasonably certain that we will exercise such options to extend or terminate the lease. Lease expense is recognized on a straight-line basis over the lease term.

Assumptions made by us at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Research and development costs

Research and development expenses consist primarily of fees paid to external service providers such as contract research organizations; clinical support services; clinical development including clinical site costs; outside nursing services; and laboratory testing. R&D costs also include non-clinical testing; fees paid to our contract manufacturing and development organizations and outside laboratories for development of DM199 and related manufacturing processes; costs for production runs of DM199; consulting resources with specialized expertise related to the execution of our development plan for DM199; and personnel costs, including salaries, benefits, non-cash share-based compensation expense; and other personnel costs.

We charge research and development costs to expense when incurred. Our human clinical trials are performed at clinical trial sites and are administered jointly by us with assistance from various contract research organizations. Upfront costs of setting up clinical trial sites are accrued upon execution of the study agreement. Expenses related to the performance of clinical trials are recorded or accrued based on actual invoices received and estimates of work completed to date by clinical trial sites, contract research organizations and outside vendors that assist with management and performance of the trials, and those that manufacture the investigational product. While we utilize electronic data capture systems to facilitate the transmission and capture of clinical trial activity, such information is often incomplete or delayed. Therefore, we are required to estimate the levels of performance under each significant contract, including, among other things, the extent of participant enrollment, the extent of supporting services performed and other activities through communications with the clinical trial sites, CROs and supporting vendors and adjust the estimates, if required, on a quarterly basis so that clinical expenses reflect the actual work performed at each clinical trial site and by each CRO or supporting vendor. Additionally, actual costs may be charged to us and are recognized as the tasks are completed by the clinical trial site. Accrued R&D costs may be subject to revisions as clinical trials, non-clinical research and DM199 development programs progress and any revisions are recorded in the period in which the facts that give rise to the revisions become known.

Patent costs

Costs associated with applying for, prosecuting and maintaining patents are expensed as incurred given the uncertainty of patent approval and, if approved, the resulting probable future economic benefit to the Company. Patent-related costs, consisting primarily of legal expenses and filing/maintenance fees, are included in general and administrative costs and were $377,000 and $251,000 for the years ended December 31, 2025 and 2024, 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 option awards is estimated at the date of grant using the Black-Scholes option pricing model. The determination of the fair value of share-based awards is affected by our share price, as well as assumptions regarding a number of complex and subjective variables. Risk free interest rates are based upon United States Government bond rates appropriate for the expected term of each award. Expected volatility rates are based on the historical volatility over a period equal to the expected term 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, and 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, 2025 and 2024. See Note 16, titled "*Income Taxes*" for additional information. The Company's policy is to classify interest and penalties related to income taxes as income tax expense.

Net loss per share

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

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

	Year Ended December 31,	
	2025	**2024**
Net loss	$ (32,766)	$ (24,444)
Weighted average shares outstanding—basic and diluted	46,980,777	40,404,681
Basic and diluted net loss per share	$ (0.70)	$ (0.60)

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,	
	2025	2024
Employee and non-employee stock options	6,864,854	4,692,438
Common shares issuable upon settlement of deferred stock units	174,515	284,886
	7,039,369	4,977,324

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 is intended to improve income tax disclosures primarily through enhanced disclosure of income tax rate reconciliation items, and disaggregation of income (loss) from continuing operations, income tax expense (benefit) and income taxes paid, net disclosures by federal, state and foreign jurisdictions, among others. ASU 2023-09 is effective for annual reporting periods beginning after December 15, 2024, and early adoption is permitted. Adoption of ASU 2023-09 did not have a material effect on the Company's consolidated financial statements and disclosures.

Recently issued accounting pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03), which is intended to improve disclosures about a public business entity's expenses by requiring disaggregated disclosure, in the notes to the consolidated financial statements, of certain categories of expenses included in the financial statements. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. ASU 2024-03 may be applied either on a prospective or retrospective basis, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of ASU 2024-03 on its consolidated financial statement disclosures.

4. Marketable Securities

The available-for-sale marketable securities are primarily comprised of investments in commercial paper, corporate bonds and government securities and consist of the following, measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements as of December 31, 2025 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 4,822	$ —	$ 4,822	$ —
Government securities	39,421	—	39,421	—
Total marketable securities	$ 44,243	$ —	$ 44,243	$ —

		Fair Value Measurements as of December 31, 2024 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Commercial paper and corporate bonds	$ 28,291	$ —	$ 28,291	$ —
Government securities	12,831	—	12,831	—
Total marketable securities	$ 41,122	$ —	$ 41,122	$ —

Accrued interest receivable on available-for-sale securities was $250,000 and $235,000 for the years ended December 31, 2025 and 2024, respectively, and is included in amounts receivable.

There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the year ended December 31, 2025.

Under the terms of the Company's investment policy, purchases of marketable securities are limited to investment grade governmental and corporate obligations and bank certificates of deposit with a primary objective of principal preservation. Maturities of individual securities are less than one year, and the amortized cost of all securities approximated fair value as of December 31, 2025 and 2024.

5. Amounts Receivable

Amounts receivable consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued interest receivable on marketable securities	$ 250	$ 235
Other	8	1
Total amounts receivable	$ 258	$ 236

6. Prepaid Expenses and Other Assets

Prepaid expenses and other assets consist primarily of insurance premiums, yearly subscriptions for services and deposits expected to be recovered during the next twelve months.

7. Deposits

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

8. Property and Equipment

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

	December 31, 2025	December 31, 2024
Computer equipment	$ 151	$ 118
Furniture and equipment	128	128
Leasehold improvements	16	16
	295	262
Less accumulated depreciation	(150)	(114)
Property and equipment, net	$ 145	$ 148

Depreciation expense was $43,000 and $39,000 for the years ended December 31, 2025 and 2024, respectively. During 2025 and 2024, we disposed of $7,000 and $25,000 of equipment, respectively, all of which was fully depreciated.

9. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Compensation	$ 1,380	$ 1,060
Clinical trial costs	1,291	2,277
Research and development services	749	888
Professional services fees	120	112
Other	5	10
Total accrued liabilities	$ 3,545	$ 4,347

10. Operating Lease

In June 2022, we entered into an agreement to lease approximately 6,000 square feet of office space in Minneapolis, Minnesota. The lease commencement date was September 1, 2022, has a term of 65 months expiring on January 31, 2028, and included an incentive of five months of full rent abatement. This incentive is subject to repayment if we default in performance of any material obligations under the lease prior to the 48th month of the lease and the landlord terminates the lease. Upon lease commencement, the Company recognized an operating lease right-of-use asset and a corresponding operating lease obligation of $446,000, respectively.

Our operating lease costs were $104,000 for each of the years ended December 31, 2025 and 2024, respectively. Our variable lease costs were $91,000 and $89,000 for the years ended December 31, 2025 and 2024, respectively. Variable lease costs consist primarily of common area maintenance costs, insurance and taxes which are paid based upon actual costs incurred by the lessor.

Maturities of our operating lease obligation are as follows as of December 31, 2025 (in thousands):

2026	$ 116
2027	119
2028	10
Total lease payments	245
Less interest portion	(20)
Present value of lease obligation	225
Less current portion of operating lease	(101)
Operating lease obligation, non-current	$ 124

11. Commitments and Contingencies

Clinical trials and product development

In the normal course of business, we incur obligations to make future payments as we execute our business plan. These obligations may relate to preclinical or clinical studies, manufacturing or manufacturing process development and other related or supporting activities. Currently, these obligations include costs to be incurred with contract research organizations, central laboratory and pharmacy services, clinical study sites, home nursing services, various other vendors supporting the performance of our clinical trials and contract manufacturing and development organizations. The contracts we enter into with these vendors and the commitments within these contracts are subject to significant variability based upon the actual activities/services performed by each vendor. As a result, the ultimate amounts due may be materially different as these obligations are affected by, among other factors, the number and pace of clinical study sites activated, the number of countries in which clinical sites are activated, the number of participants enrolled, the amount of time to complete trial enrollment and the time required to finalize, analyze and report our clinical trial results. Clinical research agreements, including supporting vendors, are generally cancelable upon 60-90 days' notice, with our obligation limited to costs incurred up to that date, including any non-cancelable costs. Cancelation terms for product manufacturing and process development contracts vary and are generally dependent upon timelines for sourcing research materials and reserving laboratory time. As of December 31, 2025, we estimate that our outstanding commitments, including such cancellable contracts, are approximately $24.7 million of which $19.3 million become due over the next 12 months and approximately $5.4 million become due in the next 12 months thereafter.

Technology license

We have entered into an exclusive 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, 2025, one milestone payment obligation remains which is due upon our first regulatory approval of DM199 for commercial sale. Following the launch of our first product, we will also incur a royalty obligation of less than 1% of net sales. The royalty term is indefinite, but the license agreement may be canceled by us on 90 days' prior written notice. The license may not be terminated by Catalent unless we fail to make required milestone and royalty payments.

Indemnification of directors and officers

The Company, as permitted under laws of the BCBCA and in accordance with the Company's Articles and indemnification agreements, will indemnify and advance expenses to its directors and officers to the fullest extent permitted by law and may choose to indemnify other employees or agents from time to time. The Company has secured insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to the Company. As of December 31, 2025, there was no pending litigation or proceeding involving any director or officer of the Company as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification. Insofar as indemnification for liabilities arising under the United States Securities Act of 1933, as amended (Securities Act) may be permitted to directors, officers and controlling persons of the Company, the Company has been advised that, in the opinion of the United States Securities and Exchange Commission (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, 2025 or 2024.

12. Shareholders' Equity

Authorized capital stock

DiaMedica has authorized share capital of an unlimited number of common voting shares, and the shares do not have a stated par value. Common shareholders are entitled to receive dividends as declared by the Company, if any, and are entitled to one vote per share at the Company's annual general meeting and any extraordinary or special general meeting.

Equity issued during the year ended December 31, 2025

On July 21, 2025, we entered into securities purchase agreements with accredited investors, pursuant to which we agreed to issue and sell an aggregate 8,606,425 common shares at a purchase price of $3.50 per share in a private placement. As a result of the offering, which closed on July 23, 2025, we received gross proceeds of $30.1 million, which resulted in net proceeds to us of approximately $30.0 million, after deducting the offering expenses.

In connection with the July 2025 private placement, we entered into a registration rights agreement (2025 Registration Rights Agreement) with the investors pursuant to which we agreed to file with the SEC a registration statement registering the resale of the shares sold in the July 2025 private placement (2025 Resale Registration Statement). The 2025 Resale Registration Statement was filed with the SEC on August 1, 2025 and declared effective by the SEC on August 8, 2025. Under the terms of the 2025 Registration Rights Agreement, we agreed to keep the 2025 Resale Registration Statement effective at all times until the shares are no longer considered "Registrable Securities" under the 2025 Registration Rights Agreement and if we fail to keep the 2025 Resale Registration Statement effective, subject to certain permitted exceptions, we will be required to pay liquidated damages to the investors in an amount of up to 10% of the invested capital, excluding interest. We also agreed, among other things, to indemnify the selling holders under the 2025 Resale Registration Statement from certain liabilities and to pay all fees and expenses incident to our performance of or compliance with the 2025 Registration Rights Agreement.

On August 12, 2025, we entered into a Sales Agreement (the 2025 Sales Agreement) with TD Securities (USA) LLC (TD Cowen) under which the Company may, from time to time, sell common shares having an aggregate offering price of up to $100 million, through an "at-the-market" offering program (ATM Offering). TD Cowen receives a customary commission from the Company for any common shares sold under the 2025 Sales Agreement. Any shares offered and sold in the ATM Offering are to be issued pursuant to the Company's shelf registration statement on Form S-3 424(b)(2), the prospectus contained therein, and one or more prospectus supplements. As of December 31, 2025, the remaining availability under this ATM was $86.2 million.

During the year ended December 31, 2025, 142,345 common shares were issued upon settlement of deferred share units, 35,215 common shares were issued upon the vesting and settlement of restricted stock units, 415,253 common shares were issued upon the exercise of stock options for gross proceeds of $1.0 million and 1,724,472 common shares were issued and sold under our ATM Offering program for aggregate gross proceeds of $13.8 million.

Equity issued during the year ended December 31, 2024

On June 25, 2024, we entered into securities purchase agreements with accredited investors, pursuant to which we issued and sold an aggregate 4,720,000 common shares at a purchase price of $2.50 per share in a private placement. As a result of the offering, which closed on June 28, 2024, we received gross proceeds of $11.8 million, which resulted in net proceeds to us of approximately $11.7 million, after deducting the offering expenses.

In connection with the June 2024 private placement, we entered into a registration rights agreement (2024 Registration Rights Agreement) with the investors pursuant to which we agreed to file with the SEC a registration statement registering the resale of the shares sold in the June 2024 private placement. This registration statement was filed with the SEC on July 10, 2024 and declared effective by the SEC on July 18, 2024. Under the terms of the 2024 Registration Rights Agreement, we agreed to keep the registration statement effective at all times until the shares are no longer considered "Registrable Securities" under the 2024 Registration Rights Agreement and if we fail to keep the registration statement effective, subject to certain permitted exceptions, we will be required to pay liquidated damages to the investors in an amount of up to 10% of the invested capital, excluding interest. We also agreed, among other things, to indemnify the selling holders under the registration statement from certain liabilities and to pay all fees and expenses incident to our performance of or compliance with the 2024 Registration Rights Agreement.

During the year ended December 31, 2024, 23,660 common shares were issued upon the vesting and settlement of restricted stock units and 117,000 common shares were issued upon the exercise of stock options for gross proceeds of $256,000.

Shares reserved

Common shares reserved for future issuance are as follows:

	December 31, 2025
Employee and non-employee stock options	6,864,854
Common shares issuable upon settlement of deferred stock units	174,515
Shares available for grant under the Amended and Restated 2019 Omnibus Incentive Plan	948,666
Shares available for grant under the 2021 Employment Inducement Incentive Plan	653,125
Total	8,641,160

13. Share-Based Compensation

Amended and Restated 2019 Omnibus Incentive Plan

The DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan (as amended from time to time, the 2019 Plan) was adopted by the Board of Directors (Board) on March 14, 2019 and approved by our shareholders at our 2019 Annual General Meeting of Shareholders held on May 22, 2019. Subsequent amendments to the plan, comprised principally of increasing the authorized shares under the plan, were approved by our shareholders at our 2022 and 2024 Annual General Meetings of Shareholders.

The 2019 Plan permits the Board, or a committee or subcommittee thereof, to grant to the Company's eligible employees, non-employee directors and certain consultants non-statutory and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units (RSUs), deferred stock units (DSUs), performance awards, non-employee director awards and other share-based awards. We grant options to purchase common shares under the 2019 Plan at no less than the fair market value of the underlying common shares as of the date of grant. Options granted to employees and non-employee directors have a maximum term of ten years and generally vest over one to four years. Options granted to non-employees have a maximum term of five years and generally vest over one year. Subject to adjustment as provided in the 2019 Plan, the maximum number of the Company's common shares authorized for issuance under the 2019 Plan is 7,000,000 shares. As of December 31, 2025, options to purchase an aggregate of 5,402,444 common shares were outstanding and 164,770 common shares were reserved for issuance upon settlement of DSUs under the 2019 Plan.

2021 Employment Inducement Incentive Plan

On December 3, 2021, the Board adopted the DiaMedica Therapeutics Inc. 2021 Employment Inducement Incentive Plan (Inducement Plan) to facilitate the granting of equity awards as an inducement material to new employees joining the Company. The Inducement Plan was adopted without shareholder approval pursuant to Nasdaq Listing Rule 5635(c)(4) and is administered by the Compensation Committee of the Board of Directors. The Board reserved 1,000,000 common shares of the Company for issuance under the Inducement Plan, which permits the grant of non-statutory options, stock appreciation rights, restricted stock awards, restricted stock units, performance awards and other share-based awards, to eligible recipients. The only persons eligible to receive awards under the Inducement Plan are individuals who are new employees and satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4) or 5635(c)(3), as applicable. Also, on December 3, 2021, the Compensation Committee adopted a form of notice of option grant and option award agreement for use under the Inducement Plan, which contains terms substantially identical to the form of notice of option grant and option award agreement for use under the shareholder-approved 2019 Plan. The Inducement Plan has a term of 10 years. The share reserve under the Inducement Plan may be increased at the discretion of and approval by the Board and, on July 31, 2025, the Board increased the number of common shares reserved for issuance under the plan to 2,000,000. As of December 31, 2025, options to purchase an aggregate of 1,100,000 common shares were outstanding under the Inducement Plan.

Prior stock option plan

Our Board of Directors ceased granting awards under the DiaMedica Therapeutics Inc. Stock Option Plan, Amended and Restated November 6, 2018 (Prior Plan) upon receipt of the shareholder approval of the 2019 Plan. Awards outstanding under the Prior Plan remain outstanding in accordance with and pursuant to the terms thereof. Options granted under the Prior Plan have terms similar to those used under the 2019 Plan. As of December 31, 2025, options to purchase an aggregate of 362,410 common shares were outstanding under the Prior Plan.

Prior deferred stock unit plan

Our Board of Directors ended participation in the DiaMedica Therapeutics Inc. Amended and Restated Deferred Stock Unit Plan (Prior DSU Plan) upon receipt of the shareholder approval of the 2019 Plan. Awards outstanding under the Prior DSU Plan remain outstanding in accordance with and pursuant to the terms thereof. As of December 31, 2025, there were 9,745 common shares reserved for issuance upon settlement of DSUs outstanding under the Prior DSU Plan.

Stock options

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

	December 31, 2025	December 31, 2024
General and administrative	$ 2,526	$ 1,464
Research and development	1,320	621
Total share-based compensation	$ 3,846	$ 2,085

We recognize share-based compensation for options awards 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 options that actually vest.

A summary of option activity is as follows (in thousands except share and per share amounts):

	Shares Underlying Options	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Balances as of December 31, 2023	3,871,013	$ 3.61	$ 832
Granted	1,864,775	3.03	
Forfeited	(531,350)	2.96	
Expired/cancelled	(395,000)	5.08	
Exercised	(117,000)	2.19	
Balances as of December 31, 2024	4,692,438	$ 3.33	$ 10,243
Granted	3,433,416	4.88	
Forfeited	(830,747)	3.80	
Exercised	(415,253)	2.43	
Expired/cancelled	(15,000)	5.02	
Balances as of December 31, 2025	6,864,854	$ 4.11	$ 26,479

A summary of the status of our unvested shares underlying options during the year ended and as of December 31, 2025 is as follows:

	Shares Underlying Options	Weighted Average Grant Date Fair Value Per Share
Unvested as of December 31, 2024	2,371,983	$ 2.18
Granted	3,433,416	3.30
Vested	(1,143,530)	2.28
Forfeited	(801,372)	2.57
Unvested as of December 31, 2025	3,860,497	$ 3.06

Information about stock options outstanding, vested and expected to vest as of December 31, 2025, is as follows:

	Outstanding, Vested and Expected to Vest			Options Vested and Exercisable	
Per Share Exercise Price	Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Exercisable	Weighted Average Remaining Contractual Life (Years)
$1.00 - $1.99	51,443	7.1	$ 1.64	42,989	1.66
$2.00 - $2.99	2,278,895	6.7	2.73	1,515,350	2.70
$3.00 - $3.99	311,893	4.7	3.56	247,519	3.66
$4.00 - $4.99	2,917,069	7.7	4.32	808,626	4.51
$5.00 - $5.99	549,287	7.6	5.16	256,787	5.03
$6.00 - $16.00	756,267	8.5	7.14	133,086	7.97
	6,864,854	7.3	$ 4.11	3,004,357	3.68

The cumulative grant date fair value of employee options vested during the years ended December 31, 2025 and 2024 was $2.6 million and $1.5 million, respectively. A total of 415,253 and 117,000 options were exercised during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, total compensation expense related to unvested employee stock options not yet recognized was $10.6 million, which is expected to be allocated to expenses over a weighted-average period of 3.1 years.

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, 2025 and 2024:

	2025	2024
Common share fair value	$4.07 – $8.67	$2.40 – $5.38
Risk-free interest rate	3.7 – 4.4%	3.8 – 4.5%
Expected dividend yield	0%	0%
Expected option life (years)	5.0 – 5.6	5.5 – 5.7
Expected stock price volatility	75.7 – 83.3%	83.0 – 124.1%

Deferred stock units and restricted stock units

Under our non-employee director compensation program, non-employee directors may elect to receive RSUs or DSUs in lieu of all or a portion of the annual cash retainers payable to such director. Each RSU or DSU represents the right to receive one common share. These recipients receive a number of RSUs or DSUs equal to the amount of the elected portion of the annual cash retainers divided by the 10-trading day average closing sale price of our common shares as determined on the third business day prior to the anticipated grant date of the award. These annual RSU and DSU grants vest quarterly over one year, conditioned on continuous service. The cost of the RSUs and DSUs is measured and recognized based on the fair market value of our common shares on the date of grant. RSUs will be settled immediately upon vesting and DSU awards will be settled following a separation from service by such director.

There were 174,515 and 284,886 vested DSUs outstanding under our share-based compensation plans as of December 31, 2025 and 2024, respectively. During 2025, 35,215 common shares were issued upon the vesting and settlement of RSUs. During 2024, 23,660 common shares were issued upon the vesting and settlement of RSUs. There were no unvested DSUs or RSUs as of December 31, 2025 and 2024.

14. Employee Benefit Plan

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

We have recorded contribution expenses of $234,000 and $166,000 under the 401(k) Plan for the years ended December 31, 2025 and 2024, respectively.

15. Segment Information

An operating segment is identified as a component of an enterprise that engages in business activities about which separate discrete financial information and operating results is regularly reviewed by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company's CODM is the Chief Executive Officer. The Company operates in a single operating segment focused on the development of its drug product candidate DM199 for the treatment of severe ischemic disease. The CODM manages and allocates resources to the operations of the Company on a total company basis. Further, the CODM reviews and utilizes functional expenses (i.e., research, development and general and administrative) at the consolidated level to manage the Company's operations. Other segment items included in consolidated net loss are revenues, share-based compensation, interest income, other expense, net, and income tax expense, which are reflected in the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The following table presents financial information, including significant segment expenses, which are regularly provided to the CODM and included within segment and consolidated net loss:

	Year Ended December 31,	
	2025	2024
Operating expenses, excluding share-based compensation		
Research and development	$ 23,294	$ 18,436
General and administrative	7,257	6,160
Total operating expenses, excluding share-based compensation	30,551	24,596
Share-based compensation		
Research and development	1,320	621
General and administrative	2,526	1,464
Total share-based compensation	3,846	2,085
Operating loss	(34,397)	(26,681)
Interest income	1,669	2,301
Other expense, net	(10)	(34)
Income tax expense	(28)	(30)
Segment and consolidated net loss	$ (32,766)	$ (24,444)

16. Income Taxes

The domestic and foreign components of gain (loss) from continuing operations before provision for income taxes are as follows:

	Year Ended December 31,	
	2025	2024
Domestic (Canada)	$ (33,119)	$ (24,452)
Foreign	381	38
Loss before income tax expense	$ (32,738)	$ (24,414)

The Company has computed its provision for income taxes based on the actual effective tax rate for the year as the Company believes this is the best estimate for the annual effective tax rate. The Company is subject to income taxes in Canada, the United States and Australia.

Significant judgment is required in evaluating the Company's uncertain tax positions and determining the provision for income taxes. The Company recognizes benefits from uncertain tax positions based on the cumulative probability method whereby the largest benefit with a cumulative probability of greater than 50% is recorded. An uncertain tax position is not recognized if it has less than a 50% likelihood of being sustained.

The provision for income taxes consists of:

	December 31,	
	2025	2024
Current		
Federal	$ 24	$ 28
State	—	—
Foreign	4	2
Total current	$ 28	$ 30
Deferred		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total deferred	$ —	$ —
Total income tax expense	$ 28	$ 30

The following table reconciles the expected Canadian statutory federal income tax to the actual income tax expense:

	December 31, 2025		December 31, 2024	
	Amount	Percent	Amount	Percent
Loss before income tax expense	$ (32,738)		$ (24,414)	
Canadian federal statutory rate	(4,911)	15.0%	(3,662)	15.0%
Canadian provincial and local income tax rate	(3,640)	11.1%	(2,719)	11.1%
Foreign tax effects	(74)	0.2%	13	(0.1)%
Nontaxable or nondeductible items				
Share-based compensation	515	(1.6)%	273	(1.1)%
Share issuance costs	(149)	0.5%	(8)	0.1%
Other	(4)	0.0%	—	0.0%
Changes in valuation allowance	8,291	(25.3)%	6,133	(25.1)%
Actual income tax expense	$ 28	(0.1)%	$ 30	(0.1)%

As the operations of the Company are predominantly conducted through its Canadian parent company, the Company has prepared the tax rate table using the Canadian federal tax rate of 15%.

The principal component of deferred taxes are as follows:

	December 31,	
	2025	2024
Deferred tax assets (liabilities):		
Non-capital losses carried forward	$ 40,316	$ 32,240
Research and development expenditures	817	817
Patents and other	460	400
Share-based compensation	419	284
Share issue costs	379	275
Accruals	92	256
Property and equipment	(71)	(89)
Total deferred tax asset, net	42,412	34,183
Valuation allowance	(42,412)	(34,183)
Net deferred tax asset	$ —	$ —

The following table presents a reconciliation of the valuation allowance:

	December 31, 2025	December 31, 2024
Balance at beginning of the year	$ 34,183	$ 28,039
Increase based on tax positions related to current period	8,229	6,144
Increase based on tax positions related to prior periods	—	—
Balance at end of the year	$ 42,412	$ 34,183

The Company assesses available positive and negative evidence to estimate if it is more likely than not to use certain jurisdiction-based deferred tax assets including net operating loss carryovers. On the basis of this assessment, the Company continues to maintain a valuation allowance on its net deferred tax assets for the year ended December 31, 2025.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss ("NOL") and credit carryforwards may be limited by statute because of a cumulative change in ownership of more than 50%. Pursuant to Sections 382 and 383 of the IRC, the annual use of the Company's NOLs and credit carryforwards would be limited if there is a cumulative change of ownership (as that term is defined in Section 382(g) of the IRC of greater than 50% in a three-year period). Management has not performed an analysis to determine if the Company has had a cumulative change in ownership of greater than 50%.

Net operating losses and tax credit carryforwards as of December 31, 2025, are as follows:

	Amount (In thousands)	Expiration Years
Non-capital income tax losses, net – domestic	$ 145,679	Beginning 2027
Non-capital income tax losses, net – foreign	—	
Research and development expense carry forwards	3,027	Indefinitely
Tax credits	473	Beginning 2026

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 our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

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

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

This annual report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that exempt smaller reporting companies from the auditor attestation requirement.

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, 2025 that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Plan and Non-Rule 10b5-1 Trading Arrangement Adoptions, Terminations, and Modifications

During the three months ended December 31, 2025, none of our directors or "officers" (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) and 408(c) respectively of SEC Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers

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

Code of Ethics

We have adopted a code of business conduct and ethics applicable to all of our directors, officers and employees, in accordance with Section 406 of the Sarbanes-Oxley Act, the rules of the SEC promulgated thereunder, and the Nasdaq Listing Rules. The code of business conduct and ethics is posted on our website at www.diamedica.com. We intend to disclose on our website any amendment to or waiver from any provision of the code of business conduct and ethics that applies to our principal executive, financial or accounting officers, and that relates to any element of the code identified in Item 406(b) of Regulation S-K, as promulgated by the SEC. Such disclosure will be provided promptly following the date of the amendment or waiver. We are not including the information contained on our website as part of, or incorporating it by reference into, this report or any other filing or document submitted to the SEC.

Additional Information

The additional information required by this Item is incorporated herein by reference to the information under the headings "Voting Proposal One – Election of Directors," "Corporate Governance," "Stock Ownership – Insider Trading Policy," and, if any, under "Delinquent Section16(a) Reports" appearing in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual General Meeting of Shareholders (Annual Proxy Statement).

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information under the headings "Director Compensation," "Executive Compensation," "Corporate Governance – Compensation Committee" appearing in the Annual Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the information under the headings "Stock Ownership" and "Equity Compensation Plan Information," appearing in the Annual Proxy Statement.

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

The information required by this Item is incorporated herein by reference to the information under the headings "Related Person Relationships and Transactions," "Corporate Governance—Director Independence," "Corporate Governance—Audit Committee" and "Corporate Governance—Compensation Committee" appearing in the Annual Proxy Statement

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated herein by reference to the information under the headings "Audit Fees" and "Audit Committee Pre-Approval Policies and Procedures" under "Voting Proposal Two—Appointment of Baker Tilly US, LLP as our Independent Registered Public Accounting Firm and Authorization to Fix Remuneration" appearing in the Annual Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

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

Financial Statement Schedules

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

Exhibits

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

A copy of any of the exhibits listed or referred to herein will be furnished at a reasonable cost to any person who is a shareholder upon receipt from any such person of a written request for any such exhibit. Such request should be sent to: Mr. Scott Kellen, Chief Financial Officer and Corporate Secretary, DiaMedica Therapeutics Inc., 301 Carlson Parkway, Suite 210, Minneapolis, Minnesota 55305, Attn: Shareholder Information.

Item No.	Item	Method of Filing
3.1	Notice of Articles of DiaMedica Therapeutics Inc. dated May 20, 2025	Incorporated by reference to Exhibit 3.1 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 (File No. 001-36291)
3.2	Amended and Restated Articles of DiaMedica Therapeutics Inc. Effective May 17, 2023	Incorporated by reference to Exhibit 3.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 18, 2023 (File No. 001-36291)
4.1	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	Incorporated by reference to Exhibit 4.1 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-36291)
4.2	Specimen Certificate representing Voting Common Shares of DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 4.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 4, 2019 (File No. 001-36291)
4.3	Registration Rights Agreement dated as of September 28, 2021 among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	Incorporated by reference to Exhibit 4.5 to DiaMedica's Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on October 5, 2021 (File No. 333-260066)
4.4	Registration Rights Agreement dated as of June 23, 2023 among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	Incorporated by reference to Exhibit 4.6 to DiaMedica's Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on June 30, 2023 (File No. 333-273068)
4.5	Form of Registration Rights Agreement by and among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	Incorporated by reference to Exhibit 10.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 26, 2024 (File No. 001-36291)
4.6	Form of Registration Rights Agreement by and among DiaMedica Therapeutics Inc. and the Purchasers party thereto dated as of July 23, 2025	Incorporated by reference to Exhibit 10.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 21, 2025 (File No. 001-36291)

Item No.	Item	Method of Filing
10.1#	DiaMedica Therapeutics Inc. Amended and Restated 2019 Omnibus Incentive Plan (Effective May 22, 2024)	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 23, 2024 (File No. 001-36291)
10.2#	Form of Option Award Agreement under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan	Incorporated by reference to Exhibit 10.2 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-36291)
10.3#	Form of Deferred Stock Unit Award Agreement under the DiaMedica Therapeutics Inc. 2019 Omnibus Incentive Plan	Incorporated by reference to Exhibit 10.1 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 (File No. 001-36291)
10.4#	DiaMedica Therapeutics Inc. Amended and Restated 2021 Employment Inducement Incentive Plan	Incorporated by reference to Exhibit 10.3 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025 (File No. 001-36291)
10.5#	Form of Inducement Option Award Agreement under the DiaMedica Therapeutics Inc. 2021 Employment Incentive Plan	Incorporated by reference to Exhibit 10.6 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-36291)
10.6#	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)
10.7#	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)
10.8#	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)
10.9#	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)
10.10#	DiaMedica Therapeutics Inc. Short-Term Incentive Plan	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2019 (File No. 001-36291)
10.11#	Form of Indemnification Agreement between DiaMedica Therapeutics Inc. and Each Director and Officer	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 24, 2025 (File No. 001-36291)
10.12#	Employment Agreement effective as of September 12, 2018 between DiaMedica USA, Inc. and Rick Pauls	Incorporated by reference to Exhibit 10.6 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)

Item No.	Item	Method of Filing
10.13#	Employment Agreement effective as of September 12, 2018 between DiaMedica USA, Inc. and Scott Kellen	Incorporated by reference to Exhibit 10.7 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2018 (File No. 001-36291)
10.14#	Employment Agreement effective as of August 11, 2025, between DiaMedica USA, Inc. and Julie Krop, M.D.	Incorporated by reference to Exhibit 10.5 to DiaMedica's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025 (File No. 001-36291)
10.15	301 Carlson Parkway Office Lease dated June 22, 2022 between Medica Services Company, LLC and DiaMedica USA Inc.	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2022 (File No. 001-36291)
10.16	Lease Guaranty Agreement dated June 22, 2022 by DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 10.2 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2022 (File No. 001-36291)
10.17(1)	GPEx® - Derived Cell Line Sale Agreement dated February 2, 2012 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.12 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.18	First Amendment to GPEx® Development and Manufacturing Agreement dated April 10, 2017 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.13 to DiaMedica's Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on November 9, 2018 (File No. 333-228313)
10.19	Second Amendment to GPEx® Development and Manufacturing Agreement dated as of October 22, 2018 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.19 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2019 (File No. 001-36291)
10.20	Third Amendment to GPEx® Development and Manufacturing Agreement dated as of April 11, 2022 between DiaMedica Therapeutics Inc. and Catalent Pharma Solutions, LLC	Incorporated by reference to Exhibit 10.23 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-36291)
10.21	Securities Purchase Agreement dated as of September 26, 2021 among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	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 September 27, 2021 (File No. 001-36291)
10.22#	Securities Purchase Agreement dated as of June 21, 2023 among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2023 (File No. 001-36291)
10.23#	Form of Securities Purchase Agreement, dated as of June 25, 2024, by and among DiaMedica Therapeutics Inc. and the Purchasers Party Thereto	Incorporated by reference to Exhibit 10.1 to DiaMedica's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 26, 2024 (File No. 001-36291)
10.24*	Form of Securities Purchase Agreement, dated as of July 21, 2025, by and among DiaMedica Therapeutics Inc. and the Purchasers party thereto	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 July 21, 2025 (File No. 001-36291)
10.25	Sales Agreement between DiaMedica Therapeutics Inc. and TD Securities (USA) LLC, dated August 12, 2025	Incorporated by reference to Exhibit 1.2 to DiaMedica's Registration Statement on Form S-3 filed with the Securities and Exchange Commission on August 12, 2025 (File No. 001-36291)

Item No.	Item	Method of Filing
19.1	DiaMedica Therapeutics Inc. Insider Trading Policy	Incorporated by reference to Exhibit 19.1 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2024 (File No. 001-36291)
21.1	Subsidiaries of DiaMedica Therapeutics Inc.	Incorporated by reference to Exhibit 21.1 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2019 (File No. 001-36291)
23.1	Consent of Baker Tilly US, LLP	Filed herewith
24.1	Powers of Attorney	Included on Signature Page
31.1	Certification of President and Chief Executive Officer Pursuant to SEC Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of President and Chief Executive Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
97.1#	DiaMedica Therapeutics Inc. Clawback Policy	Incorporated by reference to Exhibit 97.1 to DiaMedica's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-36291)
101	The following materials from DiaMedica Therapeutics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2025, formatted in Inline 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, (vi) Notes to Consolidated Financial Statements, and (vii) the information under Part II, Item 9B of this Annual Report on Form 10-K.	Filed herewith
104	Cover Page Interactive Data File	Embedded within the Inline XBRL document

# 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.

* Certain exhibits and schedules have been omitted pursuant to Item 601 of Regulation S-K. A copy of any omitted exhibit can be furnished to the Commission upon its request

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 30, 2026

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

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Rick Pauls and Scott Kellen, or either of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and any documents related to this report and filed pursuant to the Securities Exchange Act of 1934, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney shall be governed by and construed with the laws of the State of Minnesota and applicable U.S. federal securities laws.

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

Name	Title	Date
/s/ Rick Pauls Rick Pauls	President, Chief Executive Officer and Director (principal executive officer)	March 30, 2026
/s/ Scott Kellen Scott Kellen	Chief Financial Officer and Secretary (principal financial and accounting officer)	March 30, 2026
/s/ James Parsons James Parsons	Chairman of the Board, Director	March 30, 2026
/s/ Michael Giuffre, M.D. Michael Giuffre, M.D.	Director	March 30, 2026
/s/ Richard Kuntz, M.D., M.Sc. Richard Kuntz, M.D., M.Sc.	Director	March 30, 2026
/s/ Tanya N. Lewis Tanya N. Lewis	Director	March 30, 2026
/s/ Daniel J. O'Connor Daniel J. O'Connor	Director	March 30, 2026
/s/ Charles Semba, M.D. Charles Semba, M.D.	Director	March 30, 2026

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-260066, 333-273068, 333-280744, 333-289159, 333-278146 and 333-289542) and Form S-8 (File Nos. 333-228821, 333-231717, 333-263543, 333-266789, 333-279710 and 333-291508) of DiaMedica Therapeutics Inc. of our report dated March 30, 2026, relating to the consolidated financial statements, which appears in this Form 10-K for the year ended December 31, 2025.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
March 30, 2026

Exhibit 31.1

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

I, Rick Pauls, certify that:

1. I have reviewed this annual report on Form 10-K of DiaMedica Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2026

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

Exhibit 31.2

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

I, Scott Kellen, certify that:

1. I have reviewed this annual report on Form 10-K of DiaMedica Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2026

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K for the year ended December 31, 2025 of DiaMedica Therapeutics Inc. (the Company) 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 30, 2026

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K for the year ended December 31, 2025 of DiaMedica Therapeutics Inc. (the Company) 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 30, 2026