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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 13, 2021**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Two Carlson Parkway, Suite 260 **Minneapolis, Minnesota**	**55447**
(Address of principal executive offices)	(Zip Code)

(763) 312-6755
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☒

Item 7.01. Regulation FD Disclosure.

On September 13, 2021, DiaMedica Therapeutics Inc. (the "Company") announced the initiation of the first site for its pivotal ReMEDy2 trial, a Phase 2/3 clinical study of DM199 for the treatment of acute ischemic stroke ("AIS"), as described in more detail under Item 8.01 of this Current Report on Form 8-K. A copy of the press release announcing the initiation of the ReMEDy2 trial is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference and constitutes a part of this report.

Also, on September 13, 2021, in connection with the announcement of the initiation of the ReMEDy2 trial and management's participation in several upcoming investor conferences, the Company made available an investor presentation (the "Investor Presentation"), a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K, and the information set forth therein is incorporated herein by reference and constitutes a part of this Item 7.01. Representatives of the Company intend to make presentations at investor conferences and in other forums and these presentations may include the information contained in the Investor Presentation. The Company intends to disclose the information contained in the Investor Presentation, in whole or in part, and with updates and possibly modifications, in connection with presentations to investors, analysts and others and on its corporate website.

The information furnished under this Item 7.01 and the exhibits hereto shall not be deemed "filed" for the purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any other filing by the Company under the Exchange Act or the United States Securities Act of 1933, as amended, except as otherwise expressly stated in such filing.

The information contained in this Current Report on Form 8-K and the exhibits hereto is summary information that is intended to be considered in the context of the Company's United States Securities and Exchange Commission (the "SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report and the exhibits hereto, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. By filing this report and furnishing this information, the Company makes no admission as to the materiality of any information contained in this report, including the exhibits hereto.

Item 8.01. Other Events.

As described under Item 7.01 above, on September 13, 2021, the Company announced the initiation of the first site for its pivotal ReMEDy2 trial, a Phase 2/3 clinical study of DM199 for the treatment of acute ischemic stroke.

The ReMEDy2 trial is a randomized, double-blind, placebo-controlled Phase 2/3 adaptive trial designed to enroll 350 patients at 75 sites in the United States. Patients enrolled in the study will be treated with either DM199 or placebo within 24 hours of the onset of AIS symptoms. The study excludes patients treated with tissue plasminogen activator ("tPA") and those with large vessel occlusions. The study population is representative of the 80% of AIS patients who do not have treatment options today, primarily due to the short treatment window of 4.5 hours required for administration of tPA.

The ReMEDy2 trial has two primary endpoints and is powered for success with either endpoint: 1) recovery from stroke as measured by the well-established modified Rankin Scale ("mRS") at day 90, and 2) the rate of ischemic stroke recurrence at day 30. Recurrent strokes represent 25% of all ischemic strokes, often occur in the first few weeks after an initial stroke and are typically more disabling, costly, and fatal than initial strokes. Secondary endpoints for the study will evaluate participant deaths, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity) and additional standard stroke scores (NIHSS and Barthel Index scores).

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated September 13, 2021 announcing initiation of the ReMEDy2 trial for acute ischemic stroke (furnished herewith)
99.2	Investor Presentation issued by DiaMedica Therapeutics, Inc. in connection with the initiation of the ReMEDy2 trial for acute ischemic stroke (furnished herewith)
104	The cover page from this Current Report on 8-K, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DIAMEDICA THERAPEUTICS INC.

By: /s/ Scott Kellen
Scott Kellen
Chief Financial Officer and Secretary

Dated: September 13, 2021

DiaMedica Therapeutics Initiates Pivotal Trial of DM199 for the Treatment of Acute Ischemic Stroke

- ***The ReMEDy2 Trial Will Assess the Potential of DM199 to Both Improve Recovery After a Stroke and Prevent Stroke Recurrence***
- ***Opportunity to Expand Therapeutic Treatment Window and Eligible Patient Population for Acute Ischemic Stroke for the First Time in Decades***

Minneapolis, Minnesota – September 13, 2021 (Business Wire)– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and kidney diseases, today announced the initiation of the first site for its pivotal ReMEDy2 Trial, a Phase 2/3 clinical study of DM199 for the treatment of acute ischemic stroke (AIS).

The ReMEDy2 Trial is a randomized, double-blind, placebo-controlled Phase 2/3 adaptive trial designed to enroll 350 patients at 75 sites in the United States. Patients enrolled in the study will be treated with either DM199 or placebo within 24 hours of the onset of AIS symptoms. The study excludes patients treated with tissue plasminogen activator (tPA) and those with large vessel occlusions. The study population is representative of the 80% of AIS patients who do not have treatment options today, primarily due to the short treatment window of 4.5 hours required for administration of tPA.

The ReMEDy2 trial has two primary endpoints and is powered for success with either endpoint: 1) recovery from stroke as measured by the well-established modified Rankin Scale (mRS) at day 90, and 2) the rate of ischemic stroke recurrence at day 30. Recurrent strokes represent 25% of all ischemic strokes, often occur in the first few weeks after an initial stroke and are typically more disabling, costly, and fatal than initial strokes. Secondary endpoints for the study will evaluate participant deaths, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity) and additional standard stroke scores (NIHSS and Barthel Index scores).

“Our investigators are enthusiastic to study a promising new therapy for their patients with the flexibility of a 24-hour treatment window, particularly given the challenges in emergency medicine today,” said Rick Pauls, DiaMedica’s Chief Executive Officer. “By either or both improving overall recovery and reducing the risk of a recurrent stroke, DM199 could be the first new therapeutic in 25 years that could meaningfully change outcomes for stroke patients. Stroke represents a significant, unmet medical need for approximately 700,000 patients annually in the U.S. and millions more globally.”

“KLK1 has been shown to stabilize plaque and reduce blood pressure, both important factors in stroke patient recovery and prevention of additional strokes,” said Scott Kasner, M.D., ReMEDy2 National Principal Investigator and Professor of Neurology and Director of the Comprehensive Stroke Center, University of Pennsylvania. “KLK1’s mechanistic activity, clinical data from Asia using the endogenous form of KLK1 in stroke patients and the results from the ReMEDy Phase 2 AIS study provide overwhelming support for our community to study whether a recombinant KLK1 such as DM199 can significantly improve and prolong the lives of our patients.”

About DM199

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (KLK1). KLK1 is a serine protease (protein) that plays an important role in the regulation of diverse physiological processes including blood flow, inflammation, fibrosis, oxidative stress and neurogenesis via a molecular mechanism that, among other things, increases production of nitric oxide and prostaglandin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as stroke, chronic kidney disease, retinopathy, vascular dementia and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a pharmaceutically active recombinant form of the KLK1 protein. The KLK1 protein, in forms produced from porcine pancreas and human urine, has been used to treat patients in Japan, China and Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke and chronic kidney disease.

About Acute Ischemic Stroke and Stroke Recurrence

Stroke is characterized by the rapidly developing loss of brain function due to a blockage of blood flow in the brain. As a result, the affected tissues of the brain becomes inactive and may eventually die. AIS is characterized by interruption of the blood supply by a blood clot (ischemia). 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.

According to the U.S. Centers for Disease Control:

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

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality for the treatment of acute ischemic stroke and chronic kidney disease. For more information visit our website at www.diamedica.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and forward-looking information that are based on the beliefs of management and reflect management's current expectations. When used in this press release, the words "estimate," "believe," "anticipate," "intend," "expect," "plan," "continue," "look forward," "will," "may" or "should," the negative of these words or such variations thereon or comparable terminology and the use of future dates are intended to identify forward-looking statements and information. The forward-looking statements and information in this press release include statements regarding the anticipated clinical benefits and success of DM199, the timing and requirements of its clinical programs, including its anticipated Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes will commence in Summer 2021 after an FDA review completion in mid-May and has the potential to serve as a pivotal registration study of DM199 in that patient population, and enrollment, clinical results and ability to achieve clinical milestones, including the timing of completion of enrollment and readout of results in its REDUX trial, and cash runway timing. Such statements and information reflect management's current view and DiaMedica undertakes no obligation to update or revise any of these statements or information. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements, or other future events, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Applicable risks and uncertainties include, among others, the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of AIS and CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on DiaMedica's business; DiaMedica's reliance on collaboration with third parties to conduct clinical trials; DiaMedica's ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for AIS and CKD, and the risks identified under the heading "Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2020. The forward-looking information contained in this press release represents the expectations of DiaMedica as of the date of this press release and, accordingly, is subject to change after such date. Readers should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While DiaMedica may elect to, it does not undertake to update this information at any particular time except as required in accordance with applicable laws.

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Exhibit 99.2

DiaMedica THERAPEUTICS

Investor Presentation

September 2021

Cautionary Note Regarding Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and forward-looking information that are based on the beliefs of management and reflect our current expectations. When used in this presentation, the words "estimate," "believe," "anticipate," "intend," "expect," "plan," "continue," "look forward," "will," "may," "potential" or "should," the negative of these words or comparable terminology and the use of future dates are intended to identify forward-looking statements. The forward-looking statements in this presentation include statements regarding the anticipated clinical benefits and success of DM199, potential study result scenarios and potential labels and indications for DM199, the safety and efficacy of DM199, the timing, requirements and anticipated outcomes of our clinical programs, including our Phase 2/3 trial for DM199 in patients with acute ischemic stroke (AIS), which we believe has the potential to serve as a pivotal registration study of DM199 in that patient population, and our ongoing REDUX study. Such statements reflect management's current view and we undertake no obligation to update or revise any of these statements. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements, or other future events, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Applicable risks and uncertainties include, among others, the possibility of unfavorable results from our ongoing or future clinical trials of DM199, including our Phase 2/3 trial for DM199 in patients with AIS which we just initiated and the fact that the interim REDUX study data we released remains preliminary and future interim and final results may differ materially from the data released; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the possibility of unfavorable results from subsequent analysis of existing or future data from our studies of DM199; our plans to develop, obtain regulatory approval for and commercialize our DM199 product candidate for the treatment of AIS and chronic kidney disease (CKD) and our expectations regarding the benefits of DM199; our ability to conduct successful clinical testing of DM199 and within anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on our business; our reliance on collaboration with third parties to conduct clinical trials; our ability to continue to obtain funding for our operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for AIS and CKD, and the risks identified under the heading "Risk Factors" in our annual report on Form 10-K for the fiscal year ended December 31, 2020 and our subsequent U.S. Securities and Exchange Commission (SEC) filings. The forward-looking information contained in this presentation represents our expectations as of the date of this presentation and, accordingly, is subject to change after such date. Investors should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we do not undertake to update this information at any particular time except as required in accordance with applicable laws.

Potential New Standard of Care for Acute Ischemic Stroke (AIS)

Unique Opportunity to Address AIS Market

- Treatment window within 24 hours of stroke
- Opportunity to address both stroke recovery and stroke recurrence
- ~700K AIS patients in US
- 80% of AIS patients have no treatment options

Strong Supporting Data from Asia

- KLK1 improves blood flow, lowers inflammation and believed to stabilizes plaque
- KLK1 forms extracted from human urine/porcine approved to treat stroke and other diseases in Asia
- Millions of patients safely and effectively treated

1st Recombinant KLK1 Product - DM199

- Efficacy – DM199 Phase 2 results comparable to endogenous forms in Asia
- Safety/tolerability – excellent profile in 250+ patients
- Strong IP and low-cost manufacturing

Two Paths to Fast Approval in Stroke

- Fast path to data – 350 patient study, 90-day endpoint
- Potential for FDA approval in stroke for either primary endpoint: recovery or recurrence

Stroke Represents a Large, Underserved Market

Gaps in Treatment Lead to Significant Disability and Stroke Recurrence

Acute Ischemic Stroke (AIS)

Blockage of blood flow in brain

- Leading cause of adult disability
- 2nd leading cause of death WW

Stroke Recurrence

- 25% of all strokes
- More disabling, fatal and costly[1]

15 million strokes per year globally

800,000 strokes per year in US

87% acute ischemic strokes

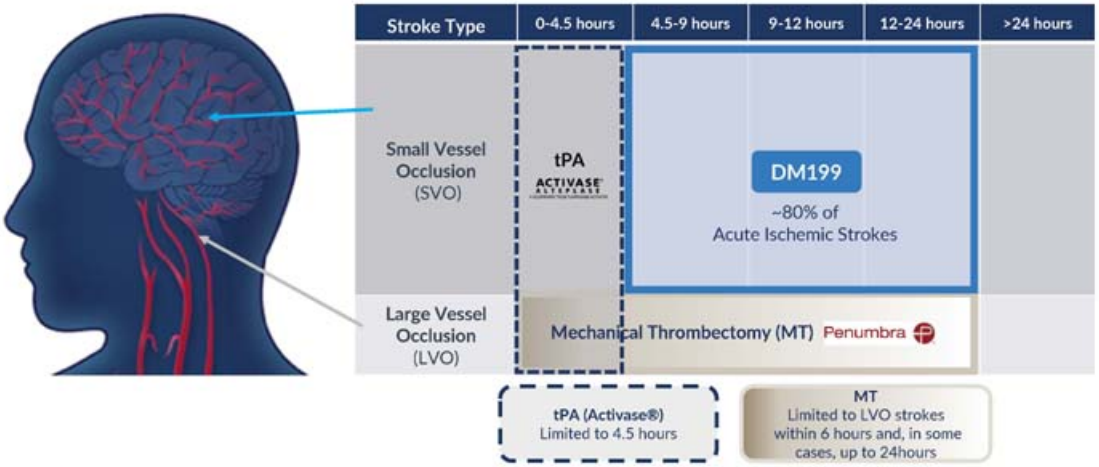
>500,000: DM199 initial US target market

>$10B estimated annual U.S. revenue opportunity

1. https://theconversation.com/one-in-three-stroke-survivors-have-another-attack-the-nhs-could-do-more-to-prevent-it-77196

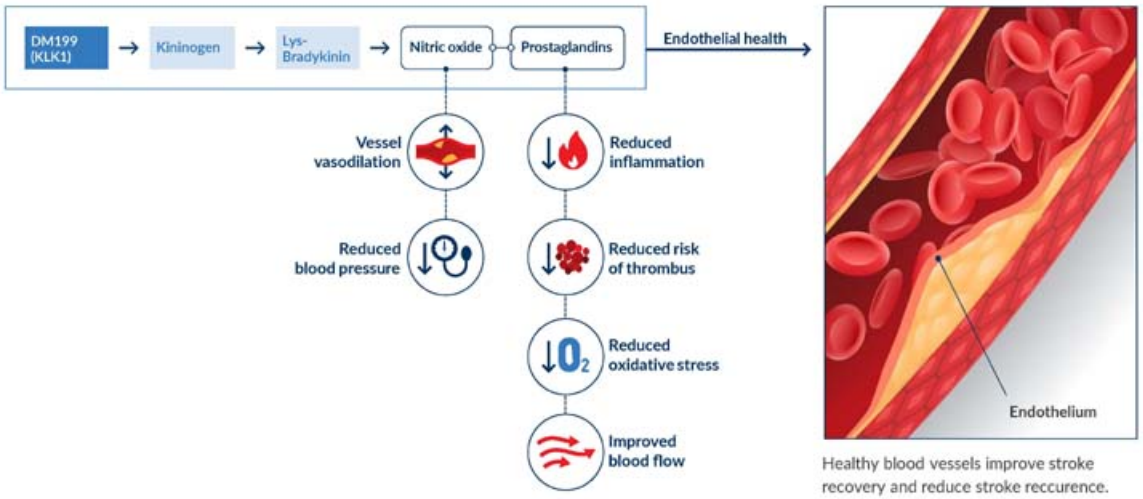
80% of Ischemic Stroke Patients Lack Treatment Options

DM199 Addresses This Gap by Expanding the Treatment Window to 24 Hours Post Stroke



DM199 Improves Endothelial Health

Differentiated Mechanism Addresses Both Recovery and Prevention of Recurrent Strokes



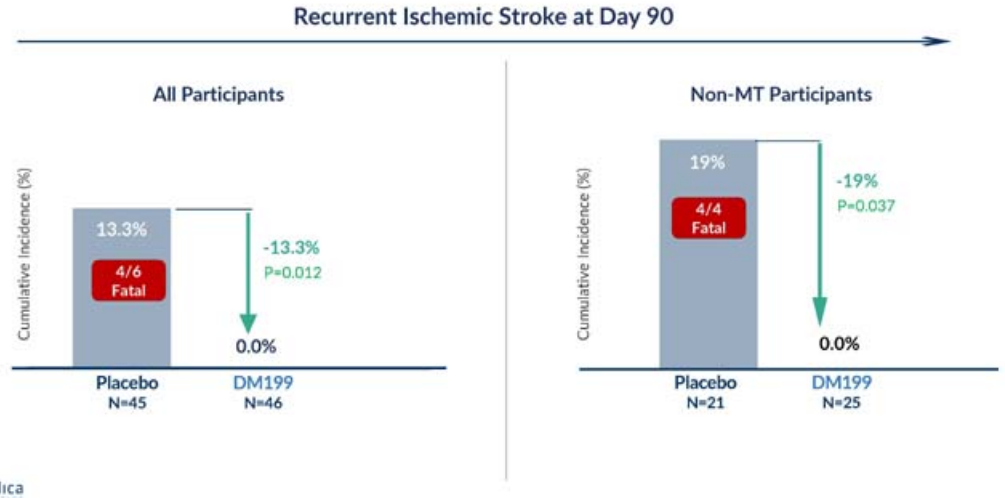
Healthy blood vessels improve stroke recovery and reduce stroke reccurence.

Profound Treatment Effect in Stroke with Marketed Urinary KLK1 in Asia

Improves Recovery and Reduces Risk for Recurrent Stroke

DM199 Prevented Ischemic Stroke Recurrences in Phase 2 Trial

Even More Pronounced in Non-Mechanical Thrombectomy Participants



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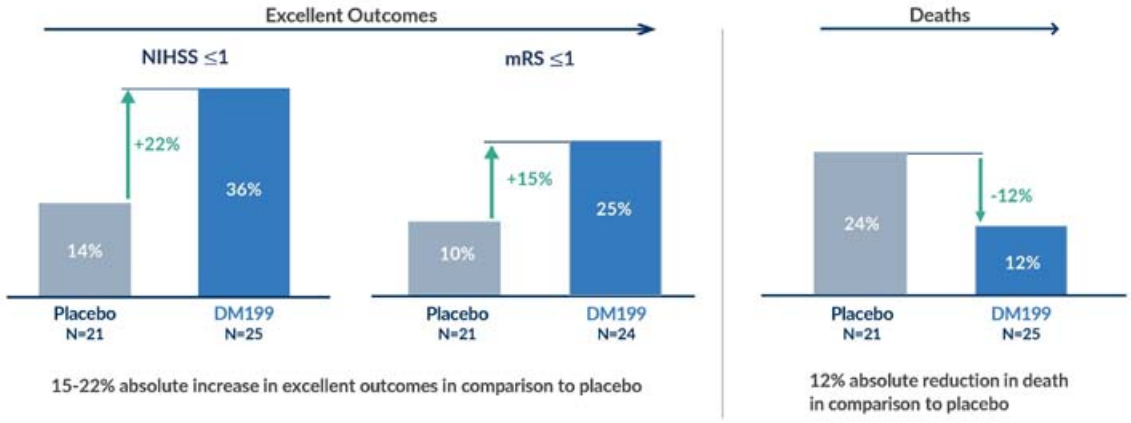
Improvement in Stroke Recovery and Lower Death Rate vs Placebo in Phase 2

Potential to Increase Patients with Full or Nearly Full Recovery and to Resume Normal Lives

Stroke Outcomes and Deaths at Day 90
Non-MT Participants

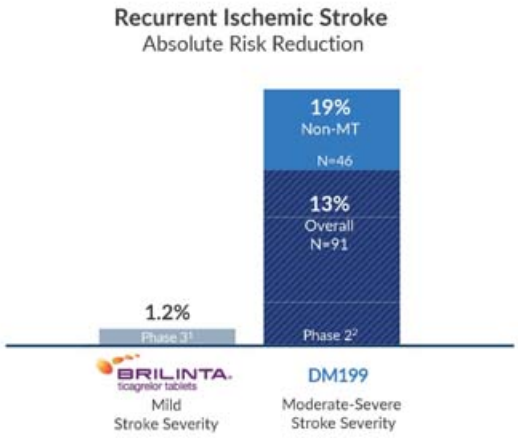


15-22% absolute increase in excellent outcomes in comparison to placebo

12% absolute reduction in death in comparison to placebo

Potential Benefit Much Greater Than Recently Approved Drug For Recurrence

Modest Benefit by Brilinta® Led to Label Expansion in 2020 For Preventing Stroke Recurrence



1. Mild-moderate stroke severity patients, P=0.015 at 30 days. Severe bleeding increased by 0.4%, no-MT. www.brilintahcp.com/content/dam/physician-services/us/523-hcp-brilinta-redesign/pdf/brilinta-thales-study-results.pdf.
2. Moderate stroke severity patients, P=0.012 at 30 and 90 days; Phase 2 ReMEDy study.

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DM199 Shows Potential Best-in-Class Improvement in Stroke Recovery

Improved Excellent Outcomes (NIHSS ≤1) vs Placebo
All Studies Excluded MT

1. New England Journal Med 1995; 333:1581-1588; and N Engl J Med 2008 Sep 25;359(13):1317-2; associated with 5.8% absolute increase in intracranial hemorrhage, Phase 3 N=333.
2. New England Journal Med 2008 Sep 25;359(13):1317-2; associated with 9.4% absolute increase in intracranial hemorrhage, N=821.
3. Brain and Behavior, 2020; 10:e01461. https://pubmed.ncbi.nlm.nih.gov/31793238

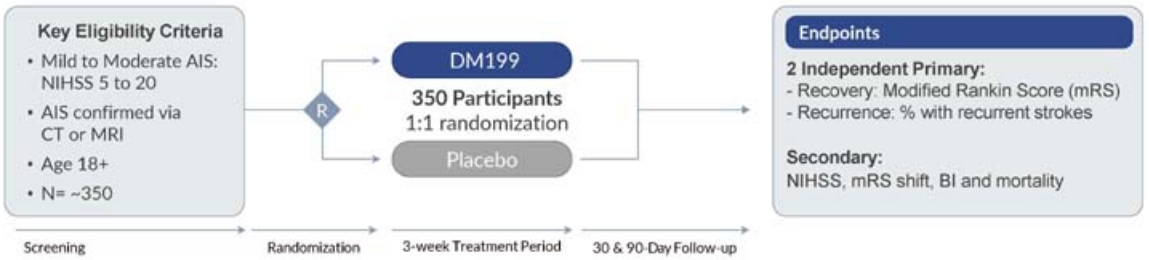
DM199 Excellent Safety Profile

Consistent with Earlier DM199 Studies and Approved Human Urinary Forms of KLK1

- 250+ participants dosed with DM199 in studies including stroke, kidney disease and healthy volunteers
  - 2,000+ doses administered
- No serious adverse events related to DM199
- No discontinuations or dosing interruptions due to tolerability
- No hypotension difference compared to placebo
- 1 severe hemorrhagic stroke in Phase 2 stroke study, patient also received tPA
- Most common related adverse events observed - all of which self-resolved:
  - Constipation
  - Nausea
  - Headache

ReMEDy2 DM199 Pivotal P2/3 Trial Design Enables Two Shots on Goal

Two Independent Primary Endpoints with Interim Analysis: Stroke Recovery & Stroke Recurrence



Exclusion Criteria

- Hemorrhagic stroke
- Large vessel occlusion (MT eligible)
- tPA (Activase®)

Treatment: 24-hour Window

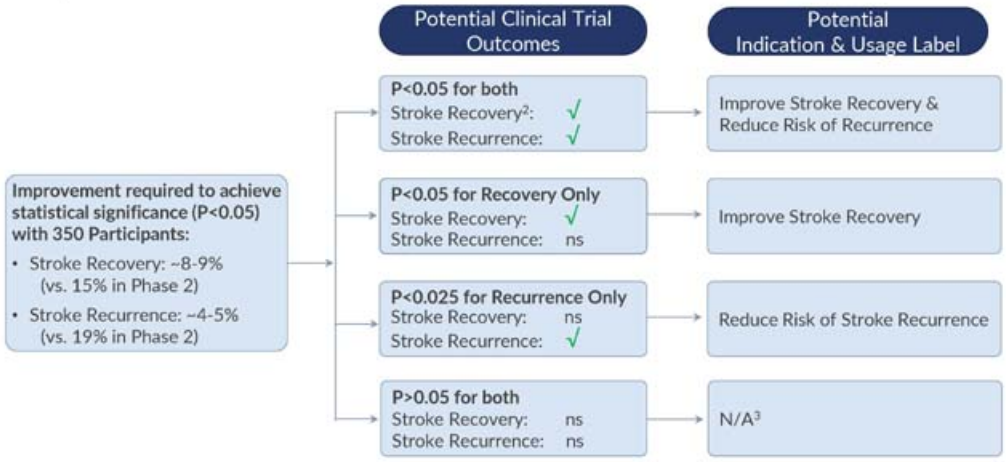
- 1st dose within 24-hours of stroke onset
  - DM199 IV (1 µg/kg) or placebo
- 3-weeks treatment, 2x week
  - DM199 SC (3 µg/kg) or placebo

Blinded DSMB Interim Analysis

- After ~140 participants complete study, potential to increase study sample size if deemed appropriate

ReMEDy2 Successful if it Achieves ~Half of the Effect Observed in Phase 2

Three potential labels with Recovery / Recurrence



1. FDA Multiple Endpoints in Clinical Trials Guidance for Industry. www.fda.gov/files/drugs/published/Multiple-Endpoints-in-Clinical-Trials-Guidance-for-Industry.pdf, .
2. Stroke Recovery: excellent outcomes, mRS=0-1
3. N/A = not statistically significant

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DiaMedica Pipeline

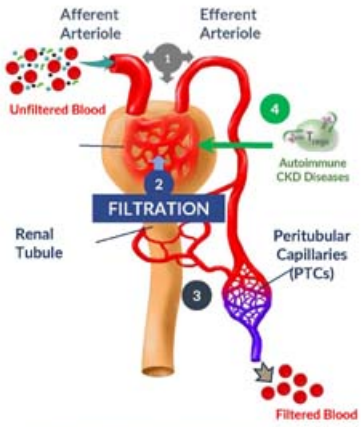
Focus on Pivotal Study in AIS and Completion of Phase 2 Kidney Studies

	Program	Product	Preclinical	Phase I	Phase 2	Pivotal	Milestones
Neuro	**Acute Ischemic Stroke (AIS):** Stroke Recovery & Recurrence Reduction	DM199 IV/SC	ReMEDy2 Pivotal Phase 2/3				Trial opened for enrollment (September 2021) Blinded interim analysis by early 2023
Renal	IgA Nephropathy	DM199 SC	REDUX Phase 2				Interim update Nov 2021
	Hypertensive African Americans with CKD	DM199 SC	REDUX Phase 2				Interim update Nov 2021
Other	Recombinant protein	DM300	Preclinical				Ongoing development

Pipeline:
Future CKD opportunity

DM199 Mechanism Applies to Improving Kidney Health

KLK1 Is Predominately Produced in Kidneys & Regulates Multiple Interrelated Mechanisms



KLK1 predominantly produced in renal tubules

DM199 Potential Kidney Benefits

1. **Regulate blood flow (↑ eGFR):**
   - Improve micro vascularization blood flow
2. **Improve glomerular function (↓ UACR):**
   - Reduce inflammation, oxidative stress and fibrosis
   - Prevent or reduce thickening of glomerular basement membrane
   - Inhibit mesangial cell proliferation
   - Improve podocyte health
3. **Regulate epithelial sodium channel (ENaC):**
   - Regulate salt & water reabsorption and excretion
   - Control blood pressure
4. **Increase Tregs (halt autoimmune attack)**
   - Halt pathological autoimmune attack on glomerulus
   - Potential to be disease modifying

DM199 for IgA Nephropathy and Hypertensive African Americans

Areas for Potential Label Expansion After Stroke

IgA Nephropathy	Hypertensive African Americans with CKD
A rare and devastating cause of kidney disease with prevalence of ~140K in US, ~200K in EU, ~180 in Japan and ~2M in China	~6 million African Americans with CKD
Up to 50% of patients progress to end stage renal disease (ESRD) within 10-20 years	KLK1 levels significantly lower than Caucasians[1] 3x – 4x more kidney failure than Caucasians
Proteinuria reduction recognized by FDA as surrogate endpoint for accelerated approval with full approval based on kidney function (eGFR)	APOL1 gene mutation = higher risk of ESRD Potential rare disease
No approved treatment options	No approved treatment options

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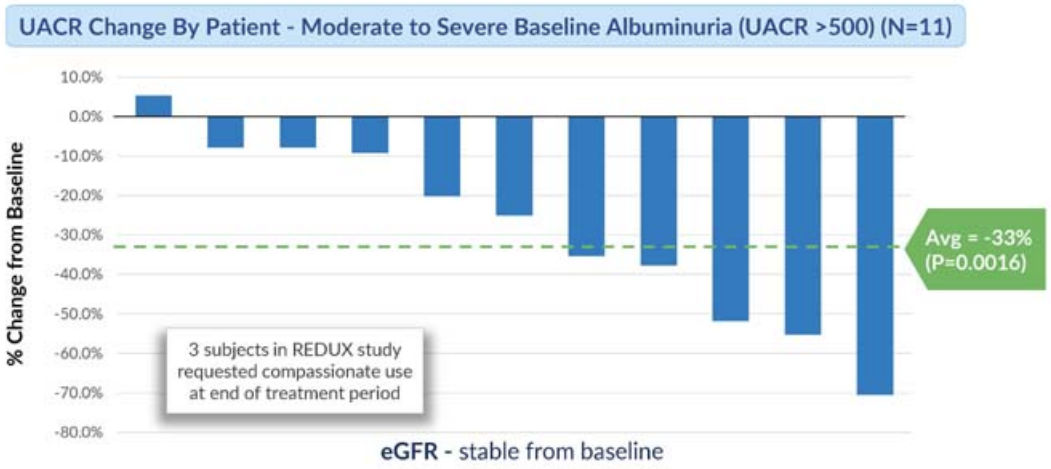
1. The Journal of Clinical Investigation Volume 60 July 1977 *129-138

IgA Nephropathy – Interim Analysis REDUX Phase 2 CKD, after 95 days Treatment

KOLs Excited By Significant Reductions Seen in Moderate/Severe Patients - Warrants Further Study



Corporate Summary

DiaMedica THERAPEUTICS

DM199 Multi-layered IP Position, Potential for Regulatory Exclusivity

Patents & Regulatory Exclusivity

Patents

- **Composition of matter**
  - issued (2033)[1]
- Subcutaneous and improved PK
  - issued (2033)
- Dosing, route of delivery and formulation
  - pending (2038)

Regulatory exclusivities - biologics

- FDA: up to 12 years
- EMA: up to 10 years

Manufacturing & Trade Secrets

Produced at up to 250L

- Planned commercial scale
- High-efficiency production based on proprietary cell line technology for creating and growing cells that release large amounts of KLK1
  - Exclusivity with manufacturer
- Proprietary expression system, composition & know-how

Key CMC Challenges Solved: 1) protein activity and 2) economical/scalable manufacturing

DiaMedica THERAPEUTICS

1. Eligible for regulatory patent term extension up to five years

Leadership

Rick Pauls, MBA
President & CEO
CEO of DiaMedica since 2010. Former venture investor and financial analyst.

Scott Kellen, CPA
CFO & VP Finance
25+ years in life sciences industry. CPA (inactive), held senior leadership roles including CFO and COO for several private and pubic (Nasdaq) companies.

Harry Alcorn Jr., Pharm.D
SVP Clinical Operations
30+ years biopharma experience. Principle Investigator of over 150+ clinical studies and investigator on 300+ studies. Former Chief Scientific Officer at DaVita Clinical Research.

Sydney Gilman, Ph.D.
VP Regulatory Affairs
30+ years regulatory and drug develop experience with multiple products through product approval. Positions with Elan, Amylin and Bristol Myers Squibb. Also spent 6 years as FDA reviewer.

Clinical Advisory Boards

Stroke/Cardiovascular

Philip Bath, M.D., DSC
Stroke Association Professor of Stroke Medicine, and Chair and Head of the Division of Clinical Neuroscience at the University of Nottingham.

Scott Kasner, M.D.
Professor of Emergency Medicine and Director of Comprehensive Stroke Center at the University of Pennsylvania.

Pooja Khatri, M.D.
Professor of Neurology and Director of Acute Stroke at the University of Cincinnati.

John Volpi, M.D.
Co-Director of the Eddy Scurlock Stroke Center at Houston Methodist and Associate Professor of Clinical Neurology at the Institute for Academic Medicine.

Paolo Madeddu, M.D.
Chair of Experimental Cardiovascular Medicine, University of Bristol. KLK1 expert, over 310 publications including over 55 related to KLK1.

Kidney Diseases

George Bakris, M.D.
Professor of Medicine and Director of the American Heart Association Comprehensive Hypertension Center at the University of Chicago.

Rajiv Agarwal, M.D.
Tenured Professor of Medicine at Indiana University School of Medicine. Published 250 original papers and reviews in Nephrology.

Glenn Chertow, M.D.
Chief, Division of Nephrology at Stanford University School of Medicine, Norman S. Coplon Satellite Healthcare Professor of Medicine and (by courtesy) of Health Research and Policy.

Charles Herzog, M.D.
Professor of medicine at the University of Minnesota, and cardiologist at Hennepin County Medical Center "HCMC" for 34 years.

Aldo Peixoto, M.D.
Professor of Medicine in the Section of Nephrology at the Yale University School of Medicine.

Stock and Financial Information

NASDAQ (DMAC)	
Recent Price (September 1, 2021)	$4.30
Market Capitalization	$81M
Shares Outstanding	19M
Fully Diluted Shares Outstanding	20.5M
Cash and Investments (June 30, 2021)	$21M
Debt	$0

Summary

Unique Opportunity to Address AIS Market

- Treatment window within 24 hours of stroke
- Opportunity to address both stroke recovery and stroke recurrence
- ~700K AIS patients in US
- 80% of AIS patients have no treatment options

Strong Supporting Data from Asia

- KLK1 improves blood flow, lowers inflammation and believed to stabilizes plaque
- KLK1 forms extracted from human urine/porcine approved to treat stroke and other diseases in Asia
- Millions of patients safely and effectively treated

1st Recombinant KLK1 Product - DM199

- Efficacy – DM199 Phase 2 results comparable to endogenous forms in Asia
- Safety/tolerability – excellent profile in 250+ patients
- Strong IP and low-cost manufacturing

Two Paths to Fast Approval in Stroke

- Fast path to data – 350 patient study, 90-day endpoint
- Potential for FDA approval in stroke for either primary endpoint: recovery or recurrence

DiaMedica THERAPEUTICS

Thank you!

NASDAQ: DMAC

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