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): **November 13, 2023**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

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

301 Carlson Parkway, Suite 210 **Minneapolis, Minnesota**	**55305**
(Address of principal executive offices)	(Zip Code)

(763) 496-5454
(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 2.02. Results of Operations and Financial Condition.

On November 13, 2023, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the three and nine-month periods ended September 30, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and the information set forth therein is incorporated herein by reference and constitutes a part of Item 2.02 of this report.

The information contained in Item 2.02 of this report and Exhibit 99.1 to this report shall not be deemed to be "filed" with the Securities and Exchange Commission (the "SEC") for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be incorporated by reference into any filings made by the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

Also on November 13, 2023, the Company made available an investor presentation in connection with its announcement of protocol amendments to the Company's ReMEDy2 Phase 2/3 clinical trial studying DM199 in the treatment of acute ischemic stroke (the "Investor Presentation"). The Investor Presentation 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 use the Investor Presentation in connection with presentations at investor conferences, meetings and in other forums. 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 contained in Item 7.01 of this report and Exhibit 99.2 to this report is summary information that is intended to be considered in the context of the Company's 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 exhibit 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 exhibit hereto.

The information contained in Item 7.01 of this report and Exhibit 99.2 to this report shall not be deemed to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any registration statement or other document filed by the Company under the Securities Act or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated November 13, 2023 providing a business update and announcing third quarter 2023 financial results (furnished herewith)
99.2	ReMEDy2 Updates Investor Presentation issued by DiaMedica Therapeutics Inc. issued on November 13, 2023 (furnished herewith)
104	The cover page from this Current Report on Form 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: November 13, 2023

Exhibit 99.1

DiaMedica Therapeutics Provides a Business Update and Announces Third Quarter 2023 Financial Results

Conference Call and Webcast November 14 at 8:00 AM Eastern Time / 7:00 AM Central Time

- **Updated Amendment to Phase 2/3 ReMEDy2 AIS Protocol Aimed at Enhancing Patient Enrollment and Increasing Probability of Study Success, 30-Day FDA Review Period Passed Without Comment**
- **ReMEDy2 Initial Activation of Clinical Sites Expected in November and December**
- **$56 Million Cash with Runway to 2026**

Minneapolis, Minnesota – November 13, 2023 (Business Wire)– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal disease, today provided a business update and financial results for the quarter ended September 30, 2023. Management will host a conference call Tuesday, November 14, 2023, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and third quarter 2023 financial results.

ReMEDy2 Phase 2/3 AIS Clinical Developments

Following in-depth discussions of the ReMEDy2 Phase 2/3 protocol design with global stroke experts, the scientific advisory board and current investigators, the Company has made several important amendments to the protocol. These changes were submitted to the U.S. Food and Drug Administration (FDA) in early October and the Company is proceeding with use of the amended protocol as the FDA did not issue any comments during the 30-day review period which ended on November 3, 2023.

These study modifications include focusing participant eligibility to those subjects with only moderate acute ischemic strokes in the anterior circulation. Moderate strokes are commonly defined as those stroke patients having a baseline National Institute of Health Score (NIHSS) of 5-15. Moderate severity strokes frequently result from occlusions in small vessels, and if diagnosed after the tPA treatment window has closed, typically have limited treatment alternatives as they are generally not candidates for mechanical thrombectomy. The exclusion of posterior circulation (PC) strokes aligns with enrollment criteria used by Techpool Bio-Pharma, the marketer of urinary-derived KLK1, called KAILIKANG®, in their registration studies in China. Given the ReMEDy2 primary endpoint of modified Rankin score (mRS) of 0-1 (excellent outcome), the Company believes that focusing on strokes of moderate severity will maximize the potential performance improvement in participants treated with DM199 vs. placebo, meaning that this change should increase the number of participants receiving DM199 achieving an excellent outcome as compared to the placebo group. This change is also consistent with results from the Company's Phase 2, ReMEDy1 stroke trial, where the subgroup of participants with moderate strokes, not receiving mechanical thrombectomy prior to enrollment, showed a greater percentage of patients on DM199 achieving an mRS of 0-1 compared to placebo, recognizing that the trial had a relatively small number of participants.

“The revisions we are implementing to the ReMEDy2 trial protocol reflect the feedback we’ve received from clinical sites and stroke key opinion leaders and follows more closely the clinical studies with KAILIKANG® in China," said Jordon Dubow, M.D., DiaMedica’s Interim Chief Medical Officer. "With these changes, we aim to leverage new insights and data to optimize our trial execution, accelerate the involvement of new clinical sites, and ultimately, enhance the robustness of our study findings."

For more information about the ReMEDy2 AIS Phase 2/3 clinical trial, please visit (www.remedytrial.com). DiaMedica also released a more comprehensive presentation describing this information in a Current Report on Form 8-K submitted to the U.S. Securities and Exchange Commission (SEC) concurrent with this press release. This presentation is available on both the DiaMedica website (www.diamedica.com) and on the SEC’s website (www.sec.gov).

DiaMedica has been working closely with PPD Development, L.P., its contract research organization (CRO), on the re-initiation of the study in parallel to the FDA protocol amendment review period. The Company anticipates that the initial clinical study sites in the United States will be activated in November and December 2023. These initial sites enrolled participants prior to the clinical hold and have elected to continue. The bulk of the U.S. sites are expected to be activated in the first half of 2024 and the Company is also preparing to expand globally to further accelerate enrollment in ReMEDy2.

At this time, based upon enrollment rates in recent stroke trials and discussions with multiple CROs, the Company believes that full enrollment for the interim analysis can be completed in 2024.

“We are thrilled to be reengaging with doctors and hospitals to work towards developing DM199 as a significant advance for the treatment of ischemic stroke patients,” commented Rick Pauls, DiaMedica’s Chief Executive Officer. “The updates to our clinical trial protocol are expected to provide the most reliable read on the potential for DM199 to improve outcomes for stroke patients.”

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $56.2 million, current liabilities of $2.2 million and working capital of $45.7 million as of September 30, 2023, compared to total cash, cash equivalents and investments of $33.5 million, $2.2 million in current liabilities and $31.7 million in working capital as of December 31, 2022. The increases in cash and investments and in working capital were due primarily to the $36.8 million of net proceeds from the June and April 2023 private placements, partially offset by cash used to fund operating activities during the nine months ended September 30, 2023.

Net cash used in operating activities for the nine months ended September 30, 2023 was $14.9 million compared to $8.7 million for the nine months ended September 30, 2022. The increase in cash usage relates primarily to the increased net loss in the current year period over the prior year period and increased amortization of discounts on marketable securities, partially offset by non-cash share-based compensation and the effects of changes in operating assets and liabilities in the current year period.

Financial Results

Research and development (R&D) expenses increased to $3.3 million for the three months ended September 30, 2023, up from $1.6 million for the three months ended September 30, 2022. R&D expenses increased to $9.4 million for the nine months ended September 30, 2023, up from $5.6 million for the nine months ended September 30, 2022. The increase for the nine-month comparison was driven principally by costs incurred for the in-use studies performed to address the recently lifted clinical hold on the Company’s ReMEDy2 AIS trial, costs incurred for the Phase 1C study determining the DM199 blood concentration levels achieved with the IV dose of DM199 and increased manufacturing and process development costs. Also contributing to the increase were increased personnel costs associated with expanding the clinical team. These increases were partially offset by decreased costs incurred for the Phase 2/3 ReMEDy2 AIS trial as activity was limited prior to the June 2023 lift of the clinical hold.

General and administrative (G&A) expenses were $1.9 million for the three months ended September 30, 2023, up from $1.5 million for the three months ended September 30, 2022. G&A expenses were $6.0 million for the nine months ended September 30, 2023, up from $4.5 million for the nine months ended September 30, 2022. The increase for the nine-month comparison was primarily due to increased legal fees incurred in connection with our lawsuit against PRA Netherlands and increased personnel costs incurred in conjunction with expanding the team. Increased cost for patent prosecution and non-cash share-based compensation also contributed to the increase.

Other income, net, was $693 thousand for the three months ended September 30, 2023, up from $76 thousand for the three months ended September 30, 2022. Other income, net, was $1.2 million for the nine months ended September 30, 2023, up from $0.1 million for the nine months ended September 30, 2022. The increase for the nine-month comparison was due to increased interest earned on marketable securities.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and third quarter 2023 financial results on Tuesday, November 14, 2023, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Tuesday, November 14, 2023
Time:	8:00 AM ET / 7:00 AM CT
Web access:	https://app.webinar.net/OVpdLmgYMDE
Dial In:	(877) 550-1858
Conference ID:	1754341

Interested parties may access the conference call by dialing in or listening to the simultaneous webcast. Listeners should log on to the website or dial in 15 minutes prior to the call. The webcast will remain available for playback on the Company's website, under investor relations - events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until November 21, 2023, by dialing (800) 645-7964 (US Toll Free) and entering the replay passcode: 2125#.

About ReMEDy2 Trial

The ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial studying the use of the Company's product candidate, DM199, to treat acute ischemic stroke (AIS) patients. The trial is intended to enroll approximately 350 patients at up to 100 sites in the United States with planned global expansion. Patients enrolled in the trial will be treated for three weeks with either DM199 or placebo, beginning within 24 hours of the onset of AIS symptoms, with the final follow-up at 90 days. The trial excludes patients treated with tissue plasminogen activator (tPA) and/or mechanical thrombectomy. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

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 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 and clinically studied a recombinant form of the KLK1 protein. The KLK1 protein, produced from the pancreas of pigs and human urine, has been used to treat patients in Japan, China and South Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke (AIS). In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of AIS.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases with a focus on acute ischemic stroke. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality in Asia for the treatment of acute ischemic stroke and other vascular diseases. For more information visit the Company's 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 "anticipates," "believes," "look forward," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "hope," "should," or "will," 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 Company's expectations regarding the effect of the protocol amendments to increase the probability of clinical success and streamline the site selection and activation process, timing for site activations and geographic locations thereof and enrollment in the ReMEDy2 trial, anticipated clinical benefits and success of DM199, and cash runway into early 2026. 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, uncertainties relating to the effects of the protocol amendments, timing of site activations and enrollment, regulatory applications and related filing and approval timelines; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; 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 acute ischemic stroke and cardio-renal disease and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, enrollment numbers, costs and timeframes; the adaptive design of the ReMEDy2 trial and the possibility that the targeted enrollment and other aspects of the trial could change depending upon certain factors, including additional input from the FDA and the blinded interim analysis; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of COVID-19, hospital and medical facility staffing shortages, and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including its ability to meet its site activation and enrollment goals; 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 acute ischemic stroke and cardio-renal disease, 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, 2022 and subsequent U.S. Securities and Exchange Commission filings, including DiaMedica's quarterly report on Form 10-Q for the quarterly period ended September 30, 2023. 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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DiaMedica Therapeutics Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 3,272	$ 1,640	$ 9,433	$ 5,569
General and administrative	1,885	1,488	5,986	4,459
Operating loss	(5,157)	(3,128)	(15,419)	(10,028)
Other income:				
Other income, net	693	76	1,220	124
Loss before income tax expense	(4,464)	(3,052)	(14,199)	(9,904)
Income tax expense	(7)	(7)	(21)	(21)
Net loss	(4,471)	(3,059)	(14,220)	(9,925)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(64)	5	(53)	(111)
Net loss and comprehensive loss	$ (4,535)	$ (3,054)	$ (14,273)	$ (10,036)
Basic and diluted net loss per share	$ (0.12)	$ (0.12)	$ (0.46)	$ (0.38)
Weighted average shares outstanding – basic and diluted	37,949,422	26,443,067	30,751,329	26,443,067

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

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,232	$ 4,728
Short term marketable securities	44,233	28,774
Prepaid expenses and other assets	1,111	251
Amounts receivable	310	82
Total current assets	47,886	33,835
Non-current assets:		
Long term marketable securities	9,746	—
Operating lease right-of-use asset, net	372	424
Property and equipment, net	135	136
Total non-current assets	10,253	560
Total assets	$ 58,139	$ 34,395
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 863	$ 734
Accrued liabilities	1,227	1,365
Operating lease obligation	78	63
Finance lease obligation	2	6
Total current liabilities	2,170	2,168
Non-current liabilities:		
Operating lease obligation, non-current	337	396
Finance lease obligation, non-current	3	4
Total non-current liabilities	340	400
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 37,953,711 and 26,443,067 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Paid-in capital	166,153	128,078
Accumulated other comprehensive loss	(127)	(74)
Accumulated deficit	(110,397)	(96,177)
Total shareholders' equity	55,629	31,827
Total liabilities and shareholders' equity	$ 58,139	$ 34,395

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (14,220)	$ (9,925)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,227	1,091
Amortization of discount on marketable securities	(856)	118
Non-cash lease expense	52	47
Depreciation	22	19
Changes in operating assets and liabilities:		
Amounts receivable	(228)	55
Prepaid expenses and other assets	(860)	(134)
Accounts payable	129	355
Accrued liabilities	(182)	(371)
Net cash used in operating activities	(14,916)	(8,745)
Cash flows from investing activities:		
Purchase of marketable securities	(64,537)	(35,895)
Maturities of marketable securities	40,135	42,758
Purchases of property and equipment	(21)	(49)
Net cash (used in) provided by investing activities	(24,423)	6,814
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	36,848	—
Principal payments on finance lease obligations	(5)	(5)
Net cash provided by (used in) financing activities	36,843	(5)
Net decrease in cash and cash equivalents	(2,496)	(1,936)
Cash and cash equivalents at beginning of period	4,728	4,707
Cash and cash equivalents at end of period	$ 2,232	$ 2,771
Supplemental disclosure of non-cash transactions:		
Cash paid for income taxes	$ 26	$ 10
Assets acquired under financing lease	$ —	$ 446

Exhibit 99.2

ReMEDy2 Updates

November 13, 2023

Summary of ReMEDy2 Trial Protocol Key Changes

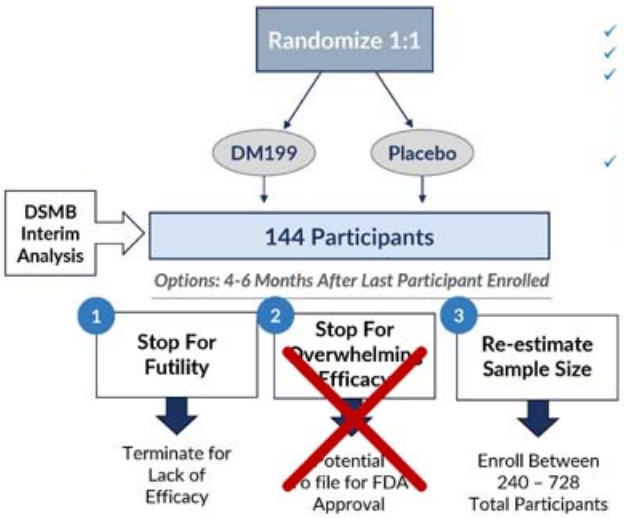
Inclusion Criteria Guided by Recent Insights from KOLs & the Marketer of Urinary KLK1 in China

- **Changes to inclusion criteria aimed at enhancing the probability of clinical success:**
  - Modified NIHSS baseline inclusion criteria to 5-15 (6-25 in ReMEDy1; see slides 4 & 5 for rationale)
    - Estimate a net reduction of approximately 45,000 potential participants in the US (~6% of all AIS patients)
  - Excluded posterior circulation strokes (see slide 6 for rationale)
  - ***Modifications not expected to meaningfully prolong enrollment timetable***
- **Eliminate the option to stop for overwhelming efficacy at the interim analysis**
  - Reduces statistical alpha penalty which enhances probability of success
  - Provides larger safety data set and increases probability of achieving statistical significance on secondary endpoints
  - By the time the interim analysis is available, enrollment should already be near 240 participants – minimal benefit to overall timeline
    - 240 participants is the bottom end of the sample size readjustment range of 240 – 728 participants (see slide 3)
- **DiaMedica is confident that targeting moderate strokes is the fastest path to approval with the greatest likelihood of success. Post-approval further label expansion studies:**
  - Mild and severe strokes (different study endpoints)
  - Adjuvant therapy with thrombolytics

Change to ReMEDy2 Clinical Trial Interim Analysis Plan

Eliminating option 2, stopping for overwhelming efficacy at the interim analysis (IA), but adaptive design framework remains in place

Adaptive design allows for an adjustment in the sample size based on treatment effect



Rationale

- ✓ Reduce statistical alpha penalty
- ✓ Larger safety database
- ✓ Increases PoS* of winning on secondary endpoints which would provide more robust efficacy for the BLA package
- ✓ Enrollment should already be near 240 participants at completion of IA, the bottom end of re-estimate range

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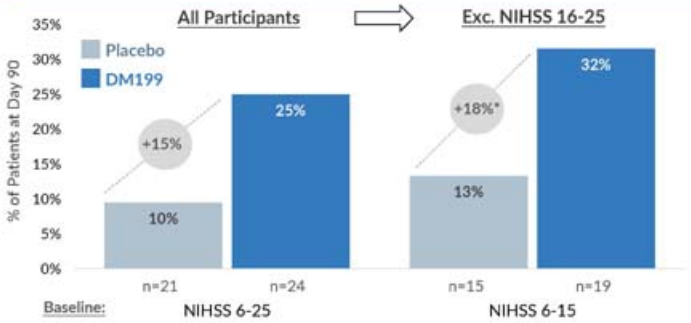
* Probability of Success

Potential Benefit Of Excluding Baseline NIHSS 16-25 Participants

~3% Absolute/18% Relative Increase in mRS 0-1 in ReMEDy1 Phase 2 Post Hoc Analysis

- Percentage of DM199 participants achieving mRS 0-1 relative to placebo increased when more severe strokes (NIHSS 16-25) were excluded
- Achieving mRS 0-1 from above baseline NIHSS 15 is a high bar, and no participants in ReMEDy1 Phase 2 (Non-MT) achieved mRS 0-1
- Potential to enhance primary endpoint measure and interim analysis powering by excluding NIHSS 16-25 from ReMEDy2 Phase 2/3

% of ReMEDy1 Participants with mRS 0-1 at 90 Days (Non-MT subgroup)[1,2]



Primary Endpoint Improvement Excl. 16-25

Absolute Increase	18 - 15% = +3%
Relative Increase*	(18 - 15%) / 15% = +18%*

* Slight % variances due to rounding

1. One participant on DM199 did not have a day 90 follow-up visit. This participants had a day 22 NIHSS of 1 and has been excluded from the analysis
2. Post hoc analysis of participants not receiving mechanical thrombectomy (MT) prior to enrollment in the ReMEDy1 trial

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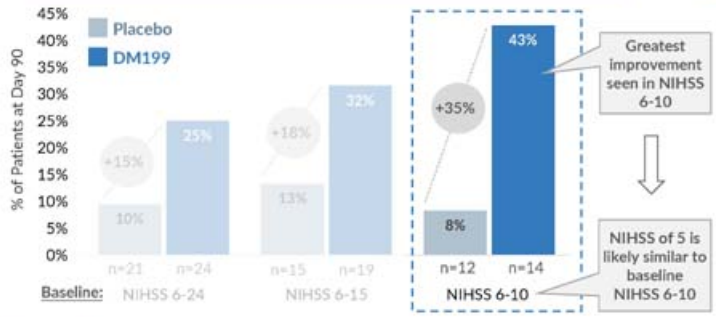
Potential Benefit of Adding NIHSS 5 to the ReMEDy2 Study

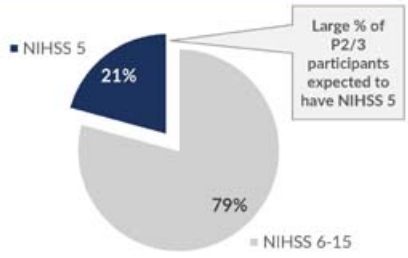
Large Pool of Eligible Patients with NIHSS 5 with Potential to Improve Performance vs. Placebo

- Greatest improvement in the primary endpoint was observed in participants with baseline NIHSS 6-10 in the ReMEDy1 Phase 2 (non-MT)
- By incorporating participants with baseline NIHSS 5 into ReMEDy2, we believe we will capture more of these high responding participants
- Stroke patients with NIHSS of 5 represent approximately 20% of all moderate strokes
- Including mild strokes (NIHSS < 5) may erode treatment effect due to high placebo response

% of ReMEDy1 Participants with mRS 0-1 at 90 Days (Non-MT, Post Hoc Analysis of NIHSS 6-10 Baseline) [1,2]



Distribution of Moderate Strokes[1]



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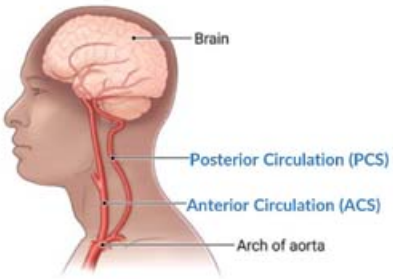
1. Saber et al. "Distributional Validity and Prognostic Power of the National Institutes of Health Stroke Scale in US Administrative Claims Data". JAMA Neurol. 2020
2. Post hoc analysis of participants not receiving mechanical thrombectomy (MT) prior to enrollment in the ReMEDy1 trial

Potential Benefit of Excluding Posterior Circulation Strokes (PCS)

Consistent with Urinary KLK1 Inclusion/Exclusion Criteria of KLK1 Studies in China

- It has been observed that approximately 80% of ischemic strokes are attributed to the anterior circulation (ACS), while around 20% are associated with the posterior circulation[1]
- Additionally, it is estimated that approximately 70%[2] of PCS present in patients with a baseline NIHSS ≤ 4
  - Since ReMEDy2 enrollment criteria is 5-15, the overall reduction to the eligible patient pool is minimized
- Recent feedback from Chinese KOLs familiar with urinary KLK1 (uKLK1) supports excluding PCS, and this was corroborated by US KOLs
- **Importantly**, PCS were excluded in the original uKLK1 Chinese approval study and the recent 2021 RESK study (1,200 participants on uKLK1)[4]



Additional Rationale For Excluding PCS

1. NIHSS is strongly weighted towards deficits caused by anterior circulation strokes (ACS), hence **PCS severity may be understated by NIHSS**[1]
2. Eliminate the potential for randomization imbalances, ensuring a more homogenous study population and consistent therapeutic outcome
3. PCS was associated with worse outcomes compared with ACS in patients arriving later than 4.5 hours at hospital – Vast majority of DM199 patients expected to be dosed after 4.5 hours[3]

1. Alemseged et al (2022). Posterior NIHSS Improves Prognostic Accuracy in Posterior Circulation Stroke. Stroke. 2022;53:1247–1255. DOI:10.1161/STROKEAHA.120.034019
2. Siniscalchi, et al (2017). The National Institutes of Health Stroke Scale: Its Role in Patients with Posterior Circulation Stroke, Hospital Topics, 95:4, 79-81, DOI: 10.1080/00185868.2017.1322888
3. Sommer et al (2018). Is Functional Outcome Different in Posterior and Anterior Circulation Stroke? Stroke 2018. DOI: 10.1161/STROKEAHA.118.021785
4. CNS Neurosci Ther. 2021;27:1493–1503