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October 18, 2018

# CONFIDENTIAL SUBMISSION VIA EDGAR

Office of Healthcare and Insurance Division of Corporation Finance U.S. Securities and Exchange Commission 100 F Street, N.E.

Washington D.C. 20549

Attention: Franklin Wyman, Angela Connell, Irene Paik and Mary Beth Breslin

Re: DiaMedica Therapeutics Inc.

Amendment No. 1 to Draft Registration Statement on Form 10-12B

Submitted September 17, 2018

CIK No. 0001401040

#### Ladies and Gentlemen:

This letter is confidentially submitted on behalf of DiaMedica Therapeutics Inc. (the "Company") in response to comments of the staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") with respect to the Company's Amendment No. 1 to Draft Registration Statement on Form 10-12B, as amended, confidentially submitted on September 17, 2018 ("Amendment No. 1"), as set forth in the Staff's letter dated October 15, 2018 to Rick Pauls, Chief Executive Officer (the "Comment Letter"). The Company is concurrently confidentially submitting Amendment No. 2 to the Draft Registration Statement ("Amendment No. 2"), which includes changes to reflect a response to the Staff's comment and other updates. In addition to addressing the comments raised by the Staff in the Comment Letter, the Company has included other revisions and updates to its disclosure in Amendment No. 2.

For the convenience of the Staff, the numbering of the paragraphs below corresponds to the numbering of the comments in the Comment Letter, the text of which we have incorporated into this response letter for convenience in italicized type and which is followed by the Company's response. In the responses below, page number references are to Amendment No. 2.

				A Pennsylv	ania Limit	ed Liabilit	y Partnership		
California		Colorado		Delaware		District of Columbia		Florida	Illinois
Minnesota	Nev	ada	New	Jersey	New	York	Pennsylvania	Texas	Washington



In addition to confidentially submitting this letter via EDGAR, we are sending via Federal Express three (3) copies of each of this letter and Amendment No. 2 (marked to show changes from Amendment No. 1).

# Amendment No. 1 to Form 10 submitted September 17, 2018

#### Item 1. Business

# Overview, page 1

1. We note your disclosure on page 24 that you have not yet filed an IND to initiate a clinical trial for DM199 in the United States. Please revise the Overview section to disclose this fact. In addition, where appropriate, please disclose the locations of your clinical trials and the foreign jurisdictions from which you have received approval to initiate clinical trials. To the extent you plan to submit DM199 for marketing approval in Australia, please also revise the Regulatory Approval section to describe the Australian drug approval process.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure under the Overview section of Amendment No. 2 to note that the Company has not yet filed an IND to initiate a clinical trial for DM199 in the United States and, where appropriate, to disclose the locations of the Company's clinical trials and the foreign jurisdictions from which the Company has received approval to initiate clinical trials. See page 2 of Amendment No. 2.

The Company respectfully informs the Staff that the Company plans to focus initially for the next several years on seeking U.S. regulatory approval for DM199 for the treatment of acute ischemic stroke and chronic kidney disease and once such approval has been obtained will then decide in which other countries to seek marketing approval. Accordingly, the Company does not believe that a description of the Australian drug approval process is necessary.

#### Acute Ischemic Stroke, page 3

2. Please explain the basis for your belief that the annual market opportunity for DM199 could be over \$20 billion. Your response should include your material assumptions underlying this prediction. In addition, please revise your disclosure to clarify whether you are referring to the market opportunity for DM199 for the treatment of acute ischemic stroke.



**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 4 of Amendment No. 2 to delete the reference the \$20 billion annual market opportunity for DM199 for the treatment of acute ischemic stroke.

# DM199 Clinical Studies, page 11

3. Please revise your disclosure regarding the clinical studies of DM199 you have conducted to date to provide information, to the extent available, regarding the dosages studied, the primary and secondary endpoints, any adverse events and any other resulting objective data.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on pages 10 and 11 of Amendment No. 2 to provide additional information regarding the clinical studies of DM199 that the Company has conducted to date, including information, to the extent available, regarding the dosages studied, the primary and secondary endpoints, any adverse events and any other resulting objective data.

4. We note your disclosure on page 24 that you have been unable to obtain the complete study records for the two clinical studies in patients with Type 2 diabetes and that this may delay your ability to obtain the acceptance of an investigational new drug application. Please revise your disclosure to provide additional information about these studies, including to which indication these studies relate, what phase of development these clinical studies were intended to be, what the primary and secondary endpoints were and whether the results are needed to proceed in the development of the drug.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 24 of Amendment No. 2 to provide additional information about the two clinical studies in patients with Type 2 diabetes, including to which indication these studies relate, what phase of development these clinical studies were intended to be, what the primary and secondary endpoints were and whether the results are needed to proceed in the development of the drug.



5. Regarding the trial in which secondary efficacy endpoints were not met, please revise to clarify the basis for your belief that this was the result of serious execution errors by the contract research organization conducting the trial.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 24 of Amendment No. 2 to clarify the basis for the Company's belief that the trial in which secondary efficacy endpoints were not met was the result of serious execution errors by the contract research organization conducting the trial.

# Intellectual Property, page 17

6. We note your disclosure on page 18 that you exclusively license patents from your manufacturing partner for the production of DM199 or any human KLK1 protein. Please disclose the material terms of this license agreement and file it as an exhibit to the registration statement, or tell us why you do not believe this is required. See Item 601(b)(10) of Regulation S-K.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 18 of Amendment No. 2 to describe the material terms of the agreement with Catalent Pharma Solutions, LLC and has filed this agreement as an exhibit to the registration statement. The Company supplementally informs the Staff that the Company has submitted an application for confidential treatment relating to this exhibit.

#### Item 2. Financial Information

# Commitments and Contingencies, page 50

7. We note that you are party to a research, development and license agreement under which you are required to make milestone and royalty payments. Please expand your disclosure to describe the material terms of this agreement, including the counter-party, the rights and obligations of each party, the royalty term and term and termination provisions. In addition, please file the agreement as an exhibit to the registration statement, or tell us why you do not believe this is required. See Item 601(b)(10) of Regulation S-K.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 53 of Amendment No. 2 to describe the material terms of the agreement with Catalent Pharma Solutions, LLC, including the counter-party, the rights and obligations of each party, the royalty term and term and termination provisions. In addition, as previously mentioned, the Company has filed this agreement as an exhibit to the registration statement and has submitted an application for confidential treatment relating to this exhibit.



# Item 8. Legal Proceedings, page 63

8. Please disclose the information required under Regulation S-K Item 103 with respect to the litigation referenced on page 24, or tell us why you do not believe it is required. We note your disclosure that failure to obtain the reports from the study that is the subject of the litigation could result in delay or prevention of clinical development or regulatory approval of your lead candidate, DM199.

**RESPONSE**: In response to the Staff's comment, the Company has revised the disclosure on page 66 of Amendment No. 2 to disclose the information required under Regulation S-K Item 103 with respect to the litigation referenced in the Risk Factors section.

We hope the foregoing answers are responsive to your comments. Please do not hesitate to contact me by telephone at (612) 607-7287 with any questions or comments regarding this correspondence.

Very truly yours,

Amy E. Culbert

cc: Rick Pauls, President and Chief Executive Officer of the Company Scott Kellen, Chief Financial Officer of the Company