

goodwinlaw.com +1 617 570 1000



July 14, 2023

VIA EDGAR AND FEDERAL EXPRESS

United States Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F Street, N.E. Washington, D.C. 20549

Attention: Franklin Wyman, Vanessa Robertson, Lauren Hamill, and Suzanne Hayes

Re: Mural Oncology Limited

Amendment No. 1 to Draft Registration Statement on Form 10

Submitted June 16, 2023 CIK No. 0001971543

Dear Ladies and Gentlemen:

On behalf of our client, Mural Oncology Limited (the "Company"), we are responding to the comments from the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") relating to the Company's confidential Amendment No. 1 Draft Registration Statement on Form 10 (the "Draft Registration Statement") contained in the Staff's letter dated June 30, 2023 (the "Comment Letter"). In response to the comments set forth in the Comment Letter, the Company has revised the Draft Registration Statement and is confidentially submitting Amendment No. 2 to the Draft Registration Statement ("Amendment No. 2") together with this response letter. Amendment No. 2 also contains certain additional updates and revisions.

Set forth below are the Company's responses to the Staff's comments in the Comment Letter. The responses and information below are based on information provided to us by the Company. For convenience, the Staff's comments are repeated below in italics, followed by the Company's responses to the comments as well as summaries of the responsive actions taken. We have included page numbers to refer to the location in Amendment No. 2 submitted herewith where the revised language addressing a particular comment appears. Capitalized terms used but not defined herein are used herein as defined in Amendment No. 2.

Amendment No. 1 to Registration Statement on Form 10 as Confidentially Submitted on June 16, 2023

<u>Information Statement Summary, page 11</u>

1. We note your response to prior comment 3, which we reissue in part. Please revise the Summary to provide to disclose your reliance on the initial cash contribution from Alkermes.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 16-17 of Amendment No. 2 accordingly.

Nemvaleukin Alfa, page 12

2. We note your response to prior comment 6, which we reissue in part. Please revise to eliminate the use of terms implying efficacy to describe your trial results. Determinations of efficacy are within the sole authority of the FDA or equivalent foreign regulator. Define terms such as "complete response," "partial response rate" and "stable disease" the first time they are used, so it is clear that the terms are based on objective criteria and are not determinations of efficacy. Explain how the overall response rate and disease control rate are calculated.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company has revised its disclosure to remove and/or modify the use of terms implying efficacy on pages 12, 106, 108, 111, 113, 117, 131 and 133 of Amendment No. 2. The Company has also revised its disclosure to include definitions of "complete response," "partial response" and "stable disease" where such terms are first used on page 12 of Amendment No. 2 to clarify that the terms are based on objective criteria and are not determinations of efficacy. Finally, the Company has revised its disclosure to provide additional context for how "overall response rate" and "disease control rate" are calculated upon their first usage on page 12 of Amendment No. 2.

- 3. We note your response to comment 7.
 - With respect to your statements of "anti-tumor activity" revise your statements to describe the observations in objective terms without indicating a cause and effect. It is in the sole authority of the FDA to determine if your product candidate is solely responsible for the trial observations.
 - Explain the terms overall response rate, partial responses, and disease control rate the first time they are used.
 - Describe the Response Evaluation Criteria in Solid Tumors guidelines version 1.1 the first time it is referenced.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company has revised its disclosure to remove and/or modify references to "anti-tumor activity" on pages 12, 106, 108, 117, and 129 of Amendment No. 2. The Company has also revised its disclosure to include definitions of "overall response rate", "partial response", and "disease control rate" where such terms are first used on page 12 of Amendment No. 2, and has provided a description of the Response Evaluation Criteria in Solid Tumors ("RECIST") guidelines version 1.1 the first time it is referenced on page 12 of Amendment No. 2.

Irish law differs from the laws in effect in the U.S. and might afford less protection..., page 80

- 4. We note your response to prior comment 13, which we reissue in part. You state on page 80 that your Constitution will provide that the federal district courts of the United States shall be the sole and exclusive forum for resolving any disputes arising under the Securities Act and the Exchange Act. As such, please revise your disclosure as follows:
 - On both page 80 and in the Description of Mural's Share Capital section, describe your exclusive forum provision and the carve out for actions arising under the Exchange Act and Securities Act. State that there is uncertainty as to whether a court would enforce such provision, and state that shareholders will not be deemed to have waived the company's compliance with federal securities laws and the rules and regulations thereunder. In this regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.
 - Further revise your risk factor on page 80 to explain that your exclusive forum provision may result in increased costs to bring a claim and/or limit investors' ability to bring a claim in a judicial forum that they find favorable.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 79, 80 and 200 of Amendment No. 2 accordingly.

Dividend Policy

Creation of Distributable Reserves, page 86

- 5. We acknowledge the information provided in your response to prior comment 14 but continue to have difficulty in understanding how distributable reserves will be created, given Mural's negative net parent investment of \$21.6 million at December 31, 2022. Please describe and quantify the expected capital structure of Mural, following the Separation and Distribution and then following subsequent approval of the resolution by the High Court of Ireland. Also, describe in greater detail the sequence of events that will be necessary to establish a distributable reserve and the expected sources for funding this reserve. In addition, provide the following information to facilitate our understanding of your discussion on page 86.
 - Explain the difference between the merger reserve and the distributable reserves.
 - Describe the nature and expected timing for planned "internal restructuring transactions" to create sufficient capital to fund the distributable reserves.
 - Quantify the expected "share premium" in the unconsolidated balance sheet immediately following the separation and distribution that you state will equal the "aggregate historical book value of the oncology business at the time of its transfer to Mural less the share capital."
 - Describe and quantify capital and other transactions that are expected to create a positive book value for the oncology business prior to the separation and distribution compared to the apparent negative book value for the oncology business reported at December 31, 2022.

• Explain your statement that "the pre-distribution shareholder of Mural is expected to pass a resolution that would create distributable reserves following the distribution by converting to distributable reserves up to all of our share premium." In this regard, quantify the expected amount of "our share premium" to be converted to distributable reserves.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company respectfully advises the Staff that the Company's proposed procedure to create distributable reserves is a standard one under Irish law for Irish public companies, including those seeking a listing as a result of a spin-off transaction. The purpose of this procedure is to provide companies with the ability under Irish law to make distributions (such as the payment of dividends and repurchases of own shares) if and when they are profitable in the future. This is a forward-looking mechanism; the proposed creation of distributable reserves at this time is not being effected so that the Company can make distributions when it is loss-making and unprofitable.

As a matter of Irish law, any amount paid for shares in excess of the par value of such shares will generally be placed in the company's share premium account. Similarly, where an Irish company acquires the entire issued share capital of another body corporate in consideration for the issuance of shares of the acquiring company (which the Company will do at the time of the separation when it acquires the oncology business from Alkermes), a merger reserve is created that is equal to the market value of the acquiring company's shares as issued, less their aggregate par value. However, under Irish law, neither a company's share premium account nor its merger reserve is distributable absent shareholder approval and court action as set forth below.

The Company's proposed procedure to create distributable reserves involves, as a first step, capitalizing the merger reserve that will result from the separation and distribution to convert it into share premium. In order to capitalize the merger reserve and convert it into share premium, upon completion of the separation, the Company will issue one bonus preference share (which is then immediately surrendered back to the Company and cancelled) with a share premium (market value as issued *less* par value) equal to the merger reserve.

The second step is then creating distributable reserves by way of reduction of the converted share premium. Such reduction requires shareholder approval (which will be given by the existing shareholders in the Company) and approval of the High Court of Ireland. Following such shareholder approval being obtained and subsequent court approval to reduce the share premium account in this manner, the Company will have distributable reserves equal to the amount by which the share premium account is reduced. The Company will thereby have the necessary Irish legal structure in place to give the Company maximum flexibility in respect of any future distributions, when and if the Company becomes profitable in the future.

Business, page 105

- 6. We note your response to prior comment 16. However, many of your graphics continue to include text printed in type that is too small to read. For example:
 - Notes to the Artistry Development Program on page 115;
 - Part C and notes to Artistry-1 Trial Design and Dosing Regimen on page 115;
 - Line items on the x and y axes in many of your tables; and
 - Notes to the Artistry-7 Trial Design Table and sections labeled "Pembrolizumab dosing" and "Nemvaleukin dosing" on page 124.

Please further review and revise the formatting in your graphics throughout to use font size that is clearly readable without the need for magnification.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 116, 118, 120, 121 and 126 of Amendment No. 2 accordingly.

Nemvaleukin Alfa, page 106

7. We note your response to comment 7, which indicates "Artistry-1 was not designed to generate comparisons, and as such, there are no p-values to disclose." While we understand that the trials are currently ongoing, and therefore you have not been able to perform any statistical analyses, please confirm that you will disclose the results of any statistical analyses, including the p-values. If your trials are not designed to generate data that is statistically significant, please provide further explanation.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company intends to supplement its disclosure to include updated efficacy and safety data from ARTISTRY-1 in the future once the trial is completed. However, the Company respectfully clarifies that because ARTISTRY-1 was not designed to generate comparisons and the study protocol specifies that the clinical trial endpoints will be summarized descriptively, the Company will not conduct statistical analyses to generate p-values for such study. P-values reflect the degree of statistical significance of a difference between the endpoint results of a product candidate and placebo (or another control or comparator arm). In accordance with its protocol, ARTISTRY-1 is not designed to evaluate nemvaleukin compared to placebo (or another control or comparator). Rather, the primary outcome measure for ARTISTRY-1 is the overall response rate (ORR) in patients with melanoma or renal cell carcinoma (Part B) and in combination with pembrolizumab in patients with advanced solid tumors (Part C).

The Company also intends to supplement its disclosure to include efficacy and safety data from ARTISTRY-6 and ARTISTRY-7 upon completion of these trials and after the Company is no longer blinded to the study data. ARTISTRY-6 is not designed to evaluate nemvaleukin compared to placebo (or another control or comparator). The primary outcome measures for ARTISTRY-6 are centrally-assessed ORR (Cohorts 1 and 2) and investigator-assessed ORR (Cohort 3). The ARTISTRY-6 study protocol specifies that these endpoints will be summarized descriptively and, as such, the Company will not conduct statistical analyses to generate p-values for such study. The primary outcome measure for ARTISTRY-7 is progression-free survival ("PFS") as assessed by the investigator. The treatment difference in PFS and overall survival, a secondary outcome measure, will be assessed by the stratified log- rank test, and p-values will be reported. This statistical comparison will be conducted between the nemvaleukin-pembrolizumab combination arm and the chemotherapy arm of the trial, as defined in the study protocol.

Our Strategy, page 108

8. We note your response to prior comment 18, which we reissue. We continue to object to the reference to your belief that nemvaleukin, if approved by the FDA, has the potential to be a "first-in-class" IL-2 variant. This statement is speculative in light of the current regulatory status of your product candidates and the uncertainty involved in clinical development. Further, the use of such term may be read to imply that your lead product candidate is effective or likely to be approved, and such determinations are solely within the authority of the FDA and comparable regulatory bodies. Please revise your disclosure accordingly.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 108 of Amendment No. 2 accordingly.

Establish an integrated development and commercial capability, page 109

9. We note your response to prior comment 19. You state on page 40 that the "first step" under the UK's ILAP is receipt of an "Innovation Passport" allowing for enhanced engagement with the MHRA and its partner agencies, and that you were granted this designation for nemvaleukin for the treatment of mucosal melanoma in January 2023. Please further revise this section to briefly explain any additional material steps that you will need to complete as you continue the application process of designating nemvaleukin under the ILAP.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 40 of Amendment No. 2 accordingly.

Safety Observations, page 121

10. Please revise your disclosure to define the acronym "AESIs" on page 122.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has removed the disclosure on page 122 of Amendment No. 2; accordingly, no definition is needed.

11. Your letter states in response to prior comment 23 that Grade 4 treatment related adverse events are not always considered serious adverse events. Please identify for us any classification system used by the Company with respect to grading of adverse events and explain the differences in severity grades.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company utilizes the National Cancer Institute's Common Terminology Criteria for Adverse Events ("CTCAE") for grading the severity of adverse events in ARTISTRY-1, per the trial protocol. The Company utilized CTCAE Version 4.03 when the trial commenced and adopted CTCAE Version 5.0 when such revised guidelines were published. The CTCAE provides unique clinical descriptions of severity for each adverse event, with general grading guidelines as follows:

- Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- <u>Grade 2</u>: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental Activities of Daily Living (ADL).
- <u>Grade 3</u>: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.
- <u>Grade 4</u>: Life-threatening consequences; urgent intervention indicated.
- Grade 5: Death related to AE.

As noted on page 123 of Amendment No. 2, the most frequent Grade 3-4 nemvaleukin-related adverse event in ARTISTRY-1 as of March 27, 2023 was neutrophil count decrease/neutropenia. Per CTCAE Version 5.0, neutrophil count decrease events are graded on a unique scale based on laboratory test results, as follows:

- <u>Grade 1</u>: <LLN 1500/mm3; <LLN 1.5 x 10e9 /L.
- Grade 2: <1500 1000/mm3; <1.5 1.0 x 10e9 /L.
- Grade 3: <1000 500/mm3; <1.0 0.5 x 10e9 /L.
- Grade 4: <500/mm3; <0.5 x 10e9 /L.
- <u>Grade 5</u>: Not specified.

As the Staff has noted, there is a distinction between severity of an adverse event, as graded by CTCAE, and seriousness of an adverse event, as defined by regulatory authorities. An adverse event is considered serious by the FDA when the event is associated with a patient outcome of death, life-threatening condition, initial/prolonged hospitalization, disability or permanent damage, congenital anomaly/birth defect, or other important medical event that may jeopardize the patient and require medical or surgical intervention to prevent one of the aforementioned outcomes.

The Grade 3-4 neutrophil count decreased/neutropenia events described on page 123 did not, in all instances, meet the definition of a serious adverse event because a Grade 3-4 neutrophil decreased/neutropenia event, based on laboratory test results, does not always result in the type of patient outcome, as described above, that would lead the event to be considered a serious adverse event.

ARTISTRY-7, page 123

12. Please revise your description of the Artisty-7 Phase 3 trial to describe GOG's and ENGOG's roles in the trial. Additionally, clarify that MSD will jointly own any clinical data, inventions and patents resulting from the combined use of nemvaleukin and pembrolizaumab in the ARTISTRY-7 clinical trial.

RESPONSE: The Company respectfully acknowledges the Staff's comment. The Company has revised its disclosure on page 125 of Amendment No. 2 to describe the roles of the Gynecologic Oncology Group ("GOG"), the European Network for Gynecological Oncological Trials Group ("ENGOT"), and the Asia-Pacific Gynecologic Oncology Trials Group ("APGOT") in the ARTISTRY-7 clinical trial. In addition, the Company has clarified that each of the Company and MSD will jointly own any clinical data and inventions (including patents that cover such inventions) that result from the combined use of nemvaleukin and pembrolizumab in the ARTISTRY-7 clinical trial, but will retain all data and intellectual property rights relating solely to each party's respective compound.

Material U.S. Federal Income Tax Consequences of the Distribution, page 170

13. We note that the tax consequences described in this section continue to assume that the Distribution, together with certain related transactions, will qualify as tax-free for U.S. federal income tax purposes. If there is uncertainly regarding the tax consequences, please revise the disclosure in this section, and elsewhere as appropriate, to clarify the reason(s) for the uncertainty.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 8 and 176 of Amendment No. 2 accordingly.

Voting, page 186

- 14. We note the revisions made in response to prior comments 9 and 28, which we reissue in part. Please further revise your disclosure here, and as appropriate in your risk factors, to clarify the allowable methods for which votes may be taken at corporate meetings and the manner in which the votes may be counted, including any material distinctions between such methods.
 - Please revise your disclosure to briefly explain what a "poll" or "poll voting" means.

RESPONSE: The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 192 and 193 of Amendment No. 2 accordingly.

- Please reconcile your disclosures regarding poll voting. In this regard, we note your disclosure that your Constitution provides that "at any general meeting all resolutions put to the vote of the meeting shall be decided on a poll" is seemingly at odds with disclosure appearing to indicate that a poll vote must be "demanded." Indicate who may demand a poll under Irish law and/or your Constitution.
- Disclose what manner of voting and vote counting may be used in the absence of a demand for a poll. If appropriate, include an explanation of any impact on shareholders' procedural or substantive rights associated with a demand, or lack thereof, for poll voting.

RESPONSE: The Company respectfully acknowledges the Staff's comment and respectfully advises the Staff that the statement on page 192 that "at any general meeting a resolution put to the vote of the meeting shall be decided on a poll," does not conflict with the disclosure describing a shareholder's ability to demand a poll on other questions that arise.

Pursuant to Regulation 96 of the Constitution, in addition to a poll being used to decide a resolution put to the vote of the meeting, a poll can also be demanded at a meeting on any other question that may arise. A poll demanded in relation to either (i) the election of the Chairperson of the board of directors or (ii) a question of adjournment, shall be taken immediately. A poll demanded in relation to any other question shall be taken within 10 days after the date of the meeting at which the poll is demanded, as the Chairperson of the meeting directs.

The Company respectfully advises the Staff that it has revised the disclosure on pages 192 and 193 of Amendment No. 2 in response to the Staff's comment.

General

15. We note your disclosure on page 156 that on June 1, 2023, you entered into an employment agreement with Dr. Caroline Loew. Please file the Loew Employment Agreement as an exhibit to the Information Statement.

RESPONSE: The Company respectfully acknowledges the Staff's comment and respectfully submits that it plans to file the employment agreement with Dr. Caroline Loew as Exhibit 10.10 to a subsequent amendment to the Registration Statement.

Sincerely,

/s/ Stephanie Richards

Stephanie Richards

cc: Robert E. Puopolo, Goodwin Procter LLP