

June 16, 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**  
**Draft Registration Statement on Form 10**  
**Submitted April 14, 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 Draft Registration Statement on Form 10 (the “**Draft Registration Statement**”) contained in the Staff’s letter dated May 16, 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. 1 to the Draft Registration Statement (“**Amendment No. 1**”) together with this response letter. Amendment No. 1 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 response to the comments as well as a summary of the responsive actions taken. We have included page numbers to refer to the location in Amendment No. 1 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. 1.

Cover Page

1. *We note that you intend to apply for listing of Mural's ordinary shares on the Nasdaq Global Market in connection with the distribution. Please revise the cover page and the Q&A as follows, and make conforming revisions throughout the Information Statement where appropriate:*
  - *State, if true, that no assurance can be given that your listing application will be approved.*
  - *State whether the distribution is contingent upon final approval of your NASDAQ listing.*
  - *Revise to clarify, if true, that the condition to obtain Nasdaq listing approval prior to the distribution may be waived by Alkermes in its sole discretion as you have on page 165.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and has revised the disclosure on the cover page and pages 6, 7, 69 and 166 of Amendment No. 1 accordingly.

Questions and Answers About the Separation and Distribution, page 3

2. *Please tell us when you expect to determine the distribution ratio. Please explain why you indicate that the distribution will be pro rata despite your plan to aggregate fractional shares into whole shares, sell the whole shares into the open market and distribute the aggregate proceeds.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and advises the Staff that, as of the date hereof, the distribution ratio remains under consideration by the Company and its board of directors. The Company and its board of directors expect to determine the distribution ratio in due course prior to effectiveness of the final registration statement and will include the distribution ratio in a future amendment once it has been determined.

Additionally, the Company advises the Staff that, as described on page 166 of Amendment No. 1 under the heading "The Separation and Distribution—The Number of Mural Ordinary Shares You Will Receive," the Company will issue ordinary shares to Alkermes shareholders pro rata to their respective holdings in Alkermes. As is common in separation transactions, Alkermes shareholders will only receive whole ordinary shares of the Company in the distribution and all fractional shares that would otherwise have been distributed will be aggregated into whole shares and sold by the Company's distribution agent, and the distribution agent will distribute the aggregate cash proceeds (net of discounts and commissions) of such sales pro rata (based on the fractional shares such holder would otherwise have been entitled to receive) to each Alkermes shareholder who otherwise would have been entitled to receive a fractional share in the distribution. Accordingly, immediately following the distribution, other than due to the treatment of fractional shares, each Alkermes shareholder will hold the same relative interest in Alkermes and in the Company.

3. *We note that your auditors have issued a going concern opinion regarding your operations. Please revise your disclosure throughout the Information Statement as follows:*
- *Expand and balance your Summary disclosure by including discussion regarding Mural's recurring operating losses, the expectation of continuing operating losses for the foreseeable future, the need to raise additional capital to finance your future operations, your agreements and obligations under the Tax Matters Agreement with Alkermes which may limit your ability to issue ordinary shares to raise capital during the four-year period beginning two years before and ending two years after the distribution, your reliance on an initial cash contribution from Alkermes for funding following the separation until you are able to access capital markets and other sources of capital, and the auditor's going concern opinion.*
  - *Disclose in both the Summary Risk Factors and Risk Factors that your ability to continue as a going concern is contingent upon the receipt of funding from Alkermes through the date of separation that will be contributed to Mural immediately prior to or in connection with the separation to cover Mural's capital needs following the separation until it is able to access capital markets and other sources of capital, as you have on page 97. Additionally, explain how this reliance on an initial contribution from Alkermes relates to the Tax Matters Agreement, which you state may limit Mural's ability to access capital on page 72. Disclose that if you cannot continue as a viable entity, your stockholders may lose some or all of their investment in your company.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and has revised the Summary Risk Factors on pages 15 and 16 of Amendment No. 1 to address the risks enumerated in the first bullet of the Staff's comment. The Company respectfully advises the Staff that the Company's operating losses, expectations of continued losses, need to raise additional capital to finance operations, restrictions under the Tax Matters Agreement and reliance on the initial cash contribution from Alkermes are already addressed throughout Amendment No. 1, including in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The Company respectfully advises the Staff that it has revised its disclosure on pages 15, 16, 23 and 24 of Amendment No. 1 to address bullet 2 of the Staff's comment. The Company respectfully advises the Staff that to preserve the tax-free treatment of the separation and distribution for U.S. federal income tax purposes, for the four-year period beginning two years before and ending two years after the distribution, the Company will be prohibited under the Tax Matters Agreement, except in specific circumstances, from certain actions, including entering into or approving any transaction involving the acquisition of outstanding or newly issued Company equity that, when combined with other non-excepted changes in ownership of our ordinary shares, results in a change in ownership of more than a specified percentage, as disclosed on page 73 of Amendment No. 1.

4. *Please revise the description of your ongoing trials to identify the trial phase in the text and define the term "registrational studies" and explain why your studies are "potentially" registrational. Your discussion should clarify the factors that will determine whether they are registrational and who will make such determination.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised its disclosure on pages 12, 13, 105, 106 and 107 of Amendment No. 1 accordingly. The Company believes Cohort 2 of the clinical trial ARTISTRY-6 (evaluating nemvaleukin as a monotherapy for the treatment of mucosal melanoma) and the clinical trial ARTISTRY-7 (evaluating nemvaleukin in combination with pembrolizumab for the treatment of PROC) are potentially registrational studies based on the Company’s communications with the FDA to date, including the FDA’s written minutes from Type C meetings held in 2021. These meeting minutes state that the data from these studies will determine whether these studies may be sufficient to support a submission for a Biologics License Application for nemvaleukin. The Company is currently blinded to the efficacy data being generated from these studies, and these data will not be available to the Company until future readouts as specified in each study’s protocol and statistical analysis plan. The Company respectfully submits to the Staff that it uses the term “potentially” to make clear that the FDA will ultimately determine whether these studies are registrational based on its review of the data from such studies once available.

Nemvaleukin Alfa, page 12

5. *Please revise pages 13 and 104 to briefly describe the significance of having obtained Orphan Drug Designation for nemvaleukin for the treatment of mucosal melanoma and Fast Track Designation for nemvaleukin for treatment of mucosal melanoma and to nemvaleukin in combination with pembrolizumab for the treatment of PROC. Additionally, explicitly state that fast track designation does not guarantee an accelerated review by the FDA. Provide similar disclosure on page 121 with respect to the accelerated approval pathway.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised its disclosure on pages 107 and 124 of Amendment No. 1 accordingly. The Company respectfully advises the Staff that the Company’s risk factor disclosure on page 30 specifies that the accelerated approval pathway may not lead to faster development or regulatory review or approval process.

6. *We note that your disclosures throughout this section, and a similar section on page 104, reference terms such as “durable and deepening responses,” “complete responses,” “partial responses,” “confirmed” responses, “disease control rate,” “overall response rate,” and “stable disease.” Please revise your discussion to describe the results of your clinical trials using objective terminology based on the clinical trial end points.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised its disclosure to provide explanations of such terms on pages 12 and 106-107 of Amendment No. 1 accordingly. The Company respectfully submits to the Staff that these terms are objective terms commonly used in oncology clinical trials that are relevant to the response-related endpoints in the ARTISTRY-1 clinical trial: one of the primary endpoints of ARTISTRY-1 is overall response rate (ORR), which is a measure that includes both complete responses and partial responses, and the secondary endpoints include disease control rate (DCR) and duration of response (DOR).

7. *With reference to the following non-exhaustive list of illustrative examples, please remove these and all other statements throughout the Information Statement that state or imply that your product candidates are safe or effective, as these determinations are solely within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies:*

- *“Our data has shown anti-tumor activity with nemvaleukin as a monotherapy in cancers for which high dose rhIL had proven efficacy, such as melanoma and renal cell carcinoma.” (page 12);*
- *Your statement of belief that features of nemvaleukin “may widen its potential therapeutic window compared to that of high-dose rhIL02, in terms of both safety and efficacy” (page 111);*
- *References to your belief that nemvaleukin’s molecular design may provide benefits over other IL-2 treatment options that may confer “enhanced efficacy” (table on page 112);*
- *Reference to the “initial efficacy signals” observed with nemvaleukin in combination with pembrolizumab in patients with PROC in the ARTISTRY-1 study (page 121).*

*You should include a discussion of your clinical trials that includes a description of the trials, the number of participants, the trial endpoints, serious adverse events, and whether the results were statistically significant, including p values.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised its disclosure on pages 12, 106, 107, 113, 114, 122, and 123 of Amendment No. 1 accordingly.

The Company respectfully advises the Staff that with respect to the first bullet point, the cited statement (“Our data has shown anti-tumor activity with nemvaleukin as monotherapy in cancers for which high dose rhIL had proven efficacy, such as melanoma and renal cell carcinoma”) is accurate and supported by the Company’s clinical trial data to date. The phrase “proven efficacy” reflects that Proleukin (aldesleukin), a human recombinant IL-2 product, is FDA-approved for the treatment of metastatic renal cell carcinoma and metastatic melanoma. The Company’s data to date from ARTISTRY-1 show that treatment with nemvaleukin has led to objective responses in melanoma and renal cell carcinoma (among other cancers), and such responses are evidence of nemvaleukin’s anti-tumor activity. Thus, it is scientifically accurate to state that nemvaleukin has shown anti-tumor activity, and that nemvaleukin has shown such anti-tumor activity in tumors in which high-dose rhIL-2 has proven efficacy. The Company respectfully submits that it acknowledges and agrees that the FDA will make the final determination of whether nemvaleukin meets the standards of safety and efficacy for regulatory approval, and this statement is not intended to state or imply that nemvaleukin has been found to be safe or effective for melanoma, renal cell carcinoma, or any other tumor type. In addition, the statement underscores the Company’s fundamental rationale for and approach to developing nemvaleukin—i.e., by focusing on evaluating nemvaleukin in those settings where another IL-2 product has been found to be safe and effective.

With respect to the Staff's request to supplement the discussion of the Company's clinical trials, the Company respectfully submits that it has revised its disclosure to include additional descriptive information, such as the number of participants, endpoints, and statistical methods for ARTISTRY-1, -6 and -7 on pages 12 and 106-107 of Amendment No. 1. The Staff has requested information about whether the results were statistically significant, including p-values; however, the Company respectfully submits that ARTISTRY-1 was not designed to generate comparisons, and as such, there are no p-values to disclose, and the Company remains blinded to the efficacy data being generated in the ongoing ARTISTRY-6 and -7 studies and therefore is not able to disclose results from those studies at this time. In the future, the Company intends to supplement its disclosure to include efficacy and safety data from ARTISTRY-6 and -7 after the Company is no longer blinded to these study data. The Company has incorporated information about treatment-related serious adverse events as of March 27, 2023 from Parts B and C of ARTISTRY-1 on page 122 of Amendment No. 1.

The Company respectfully acknowledges the Staff's request to include a description of "serious adverse events"; however, given the nature of the advanced cancers being evaluated in ARTISTRY-1, the Company advises the Staff that it is more relevant to disclose treatment-related serious adverse events, rather than all serious adverse events. Patients with advanced cancer who are participating in clinical trials can be expected to report numerous serious adverse events solely as a consequence of their disease. Thus, it is more informative to provide information about serious adverse events that have been determined to be related to treatment with nemvaleukin or nemvaleukin in combination with pembrolizumab. In light of the prevalence and severity of disease symptoms experienced by study subjects in ARTISTRY-1, the Company respectfully submits that it may be misleading to disclose all serious adverse events, and that it is more appropriate to disclose nemvaleukin treatment-related serious adverse events.

Risk Factors, page 21

8. *We note your discussion of the conditions to the distribution on page 165. Given that the Nasdaq listing condition pertaining to Mural's ordinary shares appears to be waivable, please include a risk factor reflecting that that this condition may be waived. Describe the consequences of not securing Nasdaq listing approval prior to the distribution.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 69 of Amendment No. 1 accordingly.

9. *With reference to your disclosure on page 184, please describe in an appropriate risk factor the risks related to:*

- *Your quorum requirements; and*
- *The allowable methods for which polls are to be taken at corporate meetings and the manner in which the votes are to be counted, including any material distinctions between such methods.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and has revised the disclosure on pages 82-83 of Amendment No. 1 accordingly.

We are conducting, and intend in the future to conduct, clinical trials for certain of our product candidates...., page 29

10. *We note your disclosure that you are conducting, and may continue to conduct, clinical trials outside the U.S. Please expand this risk factor disclosure to state the location(s) of current and planned trial sites located outside the U.S.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and has revised its disclosure on page 30 of Amendment No. 1 accordingly.

Side effects, serious adverse events, or other undesirable properties could arise from the use of our product candidates...., page 30

11. *Please revise to describe all serious adverse events that occurred in your clinical trials and quantify the number of occurrences.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment. As noted in response to Comment #7, the Company has included a description of treatment-related serious adverse events as of March 27, 2023 from Parts B and C of ARTISTRY-1 on page 122 of Amendment No. 1 and has revised its disclosure on pages 31 and 122 of Amendment No. 1 accordingly.

If we are a passive foreign investment company, there could be material adverse U.S. federal income tax consequences...., page 72.

12. *Please clarify whether the financial statements for the year ended December 31, 2022 would result in you being considered a PFIC.*

**RESPONSE:** The Company respectfully advises the Staff that the PFIC asset test is based on quarterly values, not year-end values. In addition, fair market value (not financial statement entries) is generally required under the Internal Revenue Code to be used to make a PFIC determination. The Company respectfully advises the Staff that it is therefore not possible to make a pro forma determination of PFIC status on the basis of financial statements. In addition, the 2022 financial statements do not include the cash to be contributed to the Company as part of the separation. Cash as a "passive asset" implicates the PFIC analysis, and the Company respectfully advises the Staff that it would therefore be unrepresentative and potentially misleading to use financial statements, which do not contain all necessary values, for a PFIC analysis.

The Company respectfully advises the Staff that as stated in Amendment No. 1, PFIC determinations cannot be made until after the end of the applicable taxable year. The Company respectfully notes that fair market value of residual assets, such as goodwill, cannot be determined until after a separate public trading price for the Company has been established; as a result, it is not possible to predict the PFIC status of the Company for 2023.

The Company respectfully advises the Staff that, in similarly structured transactions, no statements regarding PFIC status were made. See, as examples, the information statement filed as exhibit 99.1 to the Form 8-K filed by Allegion plc on November 15, 2013 and the information statement filed as exhibit 99.1 to the Form 8-K/A filed by nVent Electric plc on April 11, 2018.

Irish law differs from the laws in effect in the U.S. and might afford less protection...., page 79

13. *We note that your Articles of Association will provide that the Irish courts have exclusive jurisdiction to determine the outcome of certain litigation, including derivative actions*
- *Please disclose in your Risk Factors and Description of Share Capital section whether this provision applies to actions arising under the Exchange Act and the Securities Act. If so, please address the 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. If the provision does not apply to actions arising under the Exchange Act and the Securities Act, please also ensure that the disclosure in your Risk Factors and Description of Share Capital sections and the exclusive forum provision in your Articles of Association state this clearly, or confirm that you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act.*
  - *Additionally, please expand this risk factor to highlight the material impact and risks to shareholders related to this exclusive forum provision. Such risks may include, but are not limited to, increased costs to bring a claim and that these provisions can discourage claims or limit investors' ability to bring a claim in a judicial forum that they find favorable.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments. With respect to the first bullet, the Company notes that actions arising under the Exchange Act and Securities Act are expressly carved out from this provision, as set out in the dispute resolution section of the Company's Constitution, which the Company expects to file with a future amendment. With respect to the second bullet, the Company has revised the disclosure on page 80 of Amendment No. 1 accordingly.

Unaudited Pro Forma Combined Financial Statements, page 87

14. *On page 85, you state that immediately following the separation and distribution, Mural's unconsolidated balance sheet will show shareholders' equity comprised of share capital and share premium equal to the "aggregate value of the oncology business at the time of transfer to Mural less the share capital." Please explain how this aggregate value of the oncology business will be determined. In addition, explain how you plan to present Mural's shareholders' equity following the distribution and related internal restructuring transactions in your pro forma presentation. Refer us to the technical guidance upon which you intend to rely and revise your pro forma presentation accordingly.*



**RESPONSE:** The Company respectfully acknowledges the Staff’s comments. With respect to the “aggregate value of the oncology business at the time of transfer to Mural less the share capital,” the aggregate value of the oncology business will represent the book value at the time of separation and distribution. The information disclosed in the second paragraph under “Dividend Policy—Creation of Distributable Reserves” on page 86 of Amendment No. 1 is specific to disclosure required under Irish law and would only appear in such statements.

The Company respectfully advises the Staff that it plans to present Mural’s shareholders’ equity following the distribution in accordance with ASC 805-50-30-5, which indicates that the transferred assets and liabilities shall be measured based on the historical cost of the parent. The shareholders’ equity following distribution presented under “Unaudited Pro Forma Combined Financial Statements” will be presented in accordance with such guidance.

Management’s Discussion and Analysis of Financial Condition and Results of Operations Results of Operations

Research and Development Expenses, page 93

15. *We note your disclosure on page 109 that nemvaleukin is being developed across multiple indications and on page 113 that you have several ongoing clinical studies of nemvaleukin including ARTISTRY-1, ARTISTRY-2, ARTISTRY-3, ARTISTRY-6, ARTISTRY-7.*

*Please break out the external research and development expense line item for nemvaleukin by indication or by study. If you do not track this information, please disclose this fact. In addition, you disclose that other external R&D expense increased primarily due to increased spend on the IL-12 and IL-18 early-stage oncology development programs.*

*Please break out external R&D expense separately for these programs or disclose that you do not track this information.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised its disclosure on page 95 of Amendment No. 1 to break out the external research and development expense for the ARTISTRY program by study. With respect to its IL-12 and IL-18 early-stage oncology development programs, due to the early-stage and immaterial spending on these individual programs, the Company has not individually broken out the external research and development expense for such programs.

Business, page 103

16. *Many of your graphics throughout the Business section include text within the graphic and in footnotes that are too small to be legible. Please revise your graphics to ensure that all text is legible.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comment and has revised the graphics throughout Amendment No. 1 accordingly.

17. *With respect to all completed clinical trials discussed in this section, please revise your disclosure to provide results within proper context. Please disclose the primary and any secondary endpoints, the number of trial participants, the results observed relative to the endpoints, any serious adverse events and whether statistical significance was demonstrated, including supporting p-values. If no statistical analysis was performed, please state as such. Remove all statements indicating that the trial demonstrated anti-tumor activity or proven efficacy.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments. None of the clinical trials discussed in this section (ARTISTRY-1, ARTISTRY-6, or ARTISTRY-7) are complete at this time; however, the Company has supplemented the discussion of these clinical trials on pages 12, 106-107, and 113-114 of Amendment No. 1 in response to Comment #7 and respectfully refers the Staff to that response.

Our Strategy, page 105

18. *Please remove your statement that nemvaleukin is "a potentially first-in-class" IL-2 variant. Such term suggests that your lead product candidate is effective and likely to be an approved therapeutic for oncology. You may discuss how your candidate differs from that used by competitors.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and has revised its disclosure on page 108 of Amendment No. 1 in response to the Staff's comment. The Company respectfully advises the Staff that it believes nemvaleukin is a potentially first-in-class IL-2 variant, or has the potential to be first-in-class, given the Company's understanding of the state of clinical development of other IL-2 variant immunotherapies and its belief that, if approved by the FDA, nemvaleukin would be the first IL-2 variant of its class to be approved. The Company also notes that the Food and Drug Administration's Center for Drug Evaluation and Research has defined "first-in-class" drugs to include, for example, those that use a new and unique mechanism of action for treating a medical condition. As such, the Company respectfully submits that the use of "potentially first-in-class" as a description of nemvaleukin is accurate.

Our Strategy, page 105

19. *Based on your disclosure on pages 39 and 116, it appears that you may be pursuing accelerated development pathways from foreign regulatory agencies, such as the United Kingdom's Innovative Licensing and Access Pathway ("ILAP"), which you state has granted an Innovation Passport designation for nemvaleukin for the treatment of mucosal melanoma. If material, please expand this section to provide context for these references and briefly explain your development strategy for nemvaleukin in the UK.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 40 of Amendment No. 1 accordingly.

Nemvaleukin Program ,page 110

20. *With respect to your description of cell expansion analyses from your ARTISTRY-1 clinical trial, you indicate in the narrative and graphic on page 112 that nemvaleukin showed similar or greater levels of cancer fighting cell expansion than observed historically with high-dose rhIL-2, with lower levels of Treg expansion. Please remove all statements indicating that treatment candidates that are not FDA approved are as effective or superior to approved immunotherapies. You may present objective result of clinical trials but such results should not be compared to alternative treatment products unless head-to-head studies were conducted.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments and has revised its disclosure on page 114 of Amendment No. 1 accordingly.

ARTISTRY-1, page 113

21. *Please explain the term "clinically meaningful" as used to describe responses observed with nemvaleukin monotherapy in patients with RCC and melanoma in the ARTISTRY-1 trial. Similarly, explain the reference on page 118 to "clinically meaningful disease control" observed when nemvaleukin was used as both monotherapy and in combination with pembrolizumab.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comments. The Company respectfully submits that "clinically meaningful" is used on page 116 of Amendment No. 1 to describe responses observed with nemvaleukin monotherapy in patients with RCC and melanoma in the ARTISTRY-1 trial in the context of the high unmet medical need in this patient population. The Company considers it "clinically meaningful" that it observed any responses at all, given the lack of effective treatment options, particularly for patients who have exhausted or progressed on standard of care therapies such as checkpoint inhibitors. In addition, the Company respectfully submits that the number of responses it observed in these tumor settings was favorable relative to the response rates that would be expected with the current standard of care. Similarly, "clinically meaningful disease control" observed when nemvaleukin was used as both monotherapy and in combination with pembrolizumab as used on page 120 of Amendment No. 1 refers to the Company's observation of any responses at all in heavily pre-treated patients who had previously failed on checkpoint inhibitor therapy (including pembrolizumab), as well as the disease control rate that the Company observed in ARTISTRY-1 relative to the disease control rate typically observed with the current standard of care.

IV Nemvaleukin Monotherapy Response Summary in Melanoma (Part B), page 116

22. *Please revise to ensure that each acronym used in the first column of this table is defined. In this regard, we note that it is not evident from your preceding disclosure what "PD" or "ORR" refers to.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and has revised the disclosure on page 117 of Amendment No. 1 accordingly.

23. *Please revise to clarify that Grade 4 TRAE are serious adverse events and confirm that you have disclosed all serious adverse events and quantified the number of incidents, as opposed to the majority or most frequent categories.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and has revised its disclosure on page 122 of Amendment No. 1 to include the treatment-related serious adverse events of special interest, including neutropenia, and respectfully refers the Staff to the Company's response to Comment #7. However, the Company respectfully advises the Staff that Grade 4 TRAEs are not always considered serious adverse events, and thus has not made that revision to Amendment No. 1.

ARTISTRY-7, page 121

24. *We note your disclosure that your ongoing Phase 3 clinical trial of IV nemvaleukin in combination with pembrolizumab is being conducted in collaboration with various partners, including Gynecologic Oncology Group, European Network of Gynecological Trial groups and MSD. Please describe the material terms of the collaboration agreements. File the agreements as exhibits or tell us why you believe you are not required to file it in accordance with Item 601(b)(10) of Regulation S-K.*

**RESPONSE:** The Company respectfully advises the Staff that it does not believe its collaboration and other agreements with Gynecologic Oncology Group and European Network of Gynecological Trial groups (the "**Trial Group Service Agreements**") and MSD (the "**MSD Collaboration Agreement**", and together with the Trial Group Service Agreements, the "**Agreements**") are material contracts under Item 601(b)(10) of Regulation S-K. The Company's consideration of Item 601(b)(10) of Regulation S-K is summarized below.

Item 601(b)(10)(i) of Regulation S-K defines a "material contract" as a contract made outside of the ordinary course of business which is material to the registrant. Item 601(b)(10)(ii) of Regulation S-K states that "[I]f the contract is such as ordinarily accompanies the kind of business conducted by the registrant and its subsidiaries, it will be deemed to have been made in the ordinary course of business and need not be filed unless it falls within one or more of the following categories, in which case it shall be filed except where immaterial in amount or significance."

Subsection (B) of Item 601(b)(10)(ii) states that a contract entered into in the ordinary course of business would be a "material contract" if such contract is a "contract upon which the registrant's business is substantially dependent, as in the case of continuing contracts to sell the major part of registrant's products or services or to purchase the major part of registrant's requirements of goods, services or raw materials or any franchise or license or other agreement to use a patent, formula, trade secret, process or trade name upon which registrant's business depends to a material extent."

The Company respectfully advises the Staff that the Agreements were not entered into outside the ordinary course of business. As described in Amendment No. 1, the Company is a clinical-stage oncology business focused on discovering and developing immunotherapies that may meaningfully improve the lives of patients with cancer. As such, it has and plans to continue to enter into service and/or collaborations agreements from time to time to advance and validate its product candidates and conduct its clinical trials. Such service and/or collaboration agreements among developers of immunotherapies are common. In addition, the Company respectfully advises the Staff that its business is not “substantially dependent” on any individual Agreement.

With regard to the Trial Group Service Agreements, such agreements involve no financial payments between the parties, and there are no royalties or other similar financial terms included in the agreements and, as such, each Trial Group Service Agreement is immaterial in amount and significance to the Company’s product development and financial condition. Furthermore, the Company submits that if either of such agreements were terminated, it could continue to conduct its clinical trials, and/or enter into additional collaborations, without material harm to its clinical trials.

With regard to the MSD Collaboration Agreement, MSD has agreed pursuant to such agreement to provide the Company with pembrolizumab at no cost for the ARTISTRY-7 clinical trial for the duration of the trial. 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 all data and intellectual property rights relating to each party’s respective compounds is retained by each party.

The Company respectfully advises the Staff that its business is not “substantially dependent” on the MSD Collaboration Agreement, nor does the MSD Collaboration Agreement constitute a license or other agreement to use a patent, formula, trade secret, process or trade name upon which the Company’s business depends to a material extent. The MSD Collaboration Agreement involves no financial payments between the parties, and there are no royalties or other similar financial terms other than the savings that the Company benefits from under the agreement as a result of the pembrolizumab that is provided by MSD. The MSD Collaboration Agreement therefore is immaterial in amount and significance to the Company’s financial condition. Furthermore, in the event that the MSD Collaboration Agreement was terminated, the Company believes that it could purchase adequate quantities of pembrolizumab for its ARTISTRY-7 clinical trial without material harm to the Company given that pembrolizumab is commercially available.

For the reasons set forth herein, the Company respectfully advises the Staff that it does not believe filing the Agreements as exhibits would provide meaningful information to investors beyond that which has already been summarized in Amendment No. 1. The Company respectfully advises the Staff that it will continue to evaluate in future periods whether any individual Agreement rises to the level of substantial dependence or otherwise falls within the definition of a “material contract” under Item 601(b)(10) of Regulation S-K.

Intellectual Property, page 131

25. *We note your disclosure that Mural and Alkermes may enter into an intellectual property license agreement prior to or concurrently with the completion of the separation. In relation to the intellectual property described, please clarify whether the patents and patent applications will be owned by Mural or licensed to mural by Alkermes or a third party.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comment and has revised the disclosure on pages 132 and 161 of Amendment No. 1 accordingly.

Certain Relationships and Related Person Transactions, page 156

26. *Please file the “Form of” Separation Agreement, Tax Matters Agreement, Employee Matters Agreement, and Intellectual Property License Agreement with your next amendment. We may have additional comments once we have had an opportunity to review these agreements.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comment and advises the Staff that it expects to file these forms of agreements with a future amendment once these agreements are available.

Material U.S. Federal Income Tax Consequences of the Distribution, page 168

27. *We note your disclosure that the distribution is intended to be generally tax-free for U.S. federal income tax and Irish tax purposes to Alkermes’ shareholders. We also note that the disclosed tax consequences in this section assume that the Distribution, together with certain related transactions, so qualifies. Please revise the disclosure in this section, and elsewhere as appropriate, to remove language stating that “generally” certain tax consequences will apply and express a firm opinion for each material tax consequence. If there is uncertainty regarding the tax treatment of the transaction, counsel may issue a “should” or “more likely than not” opinion to make clear that the opinion is subject to a degree of uncertainty and explain why it cannot give a firm opinion.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comments and has revised the disclosure on the cover and pages 4, 6, 8, 16, 71-73, 94, 160, 161, 163, 167 and 170-172 of Amendment No. 1 accordingly.

Voting, page 184

28. *We note your disclosure that your Constitution provides that the board of directors or the chairman “may determine the manner in which the poll is to be taken at each meeting and the manner in which the votes are to be counted.” Please expand this disclosure to describe the allowable methods for taking a poll and for counting votes, and describe any material distinctions between such methods. File your Constitution as an exhibit.*

**RESPONSE:** The Company respectfully acknowledges the Staff’s comment and has revised the disclosure on page 186-187 of Amendment No. 1 accordingly.

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Sincerely,

/s/ Stephanie Richards

Stephanie Richards

cc: Robert E. Puopolo, *Goodwin Procter LLP*