



DIVISION OF
CORPORATION FINANCE

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

May 16, 2023

Iain Brown
Chief Financial Officer
Mural Oncology Ltd
10 Earlsfort Terrace
Dublin 2, D02 T380, Ireland

Re: Mural Oncology Ltd
Draft Registration Statement on Form 10
Submitted April 14, 2023
CIK No. 0001971543

Dear Iain Brown:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form 10 as Confidentially Submitted on April 14, 2023

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.

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.

Information Statement Summary, page 11

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.
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.

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 muscosal melanoma and Fast Track Designation for nemvaleukin for treatment of muscosal 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.

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.
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.

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.
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.

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.

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.

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.

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.

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.

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.

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.
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.

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.

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.

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.

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.

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.

Safety Observations, page 119

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.

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.

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.

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.

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.

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.

You may contact Franklin Wyman at 202-551-3660 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Robert E. Puopolo