



DIVISION OF
CORPORATION FINANCE

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

December 16, 2022

Ryan Preblich
Chief Financial Officer
Indivior PLC
234 Bath Road, Slough, Berks, SL1 4EE
United Kingdom

Re: Indivior PLC
Amendment No. 1 to Draft Registration Statement on Form 20-F
Submitted November 22, 2022
CIK No. 0001625297

Dear Ryan Preblich:

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.

Amendment No. 1 to Draft Registration Statement on Form 20-F, submitted November 22, 2022

Glossary, page 1

1. We note your disclosure here and on page 29 that AEF0117 is a "first-in-class synthetic CB1 specific signaling inhibitor[.]" Please remove the references throughout your registration statement to "first-in-class" product candidates as these descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval.

About This Registration Statement, page 4

2. We note your disclosure that your registration statement "contains information regarding [y]our business and the industry in which [you] operate and compete, which [you] have

obtained from various third-party sources." Your disclosure also provides that you have "not independently verified and do not guarantee the accuracy and completeness of [] information [obtained from industry publications and surveys and from third-party sources.]" Please note that you are responsible for the entire content of the registration statement. It is not appropriate to directly or indirectly disclaim liability for statements in your registration statement. Please revise or specifically state that you take liability for these statements.

Item 3. Key Information

B. Capitalization and Indebtedness , page 8

3. Please remove "Cash and cash equivalents" from your "Total capitalization", as cash and cash equivalents are not a component of capitalization. Consider also including a double underline under "Cash and cash equivalents" to clarify that the amount is not included in total capitalization.

Item 3.D. Risk Factors

Risks Related to our Group and Its Business

Compliance with the terms and conditions of our Corporate Integrity Agreement..., page 11

4. We note your disclosure that in 2020, you entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of the Inspector General. Please disclose here and in other relevant sections, such as your "Legal proceedings" and "Material Contracts" sections, the allegations related to the criminal and civil charges that led to the execution of the Corporate Integrity Agreement.

We are currently, in the past have been, and in the future may be, subject to substantial litigation and ongoing litigation..., page 14

5. We note your disclosure that in 2019, the U.S. Attorney's Office for the Western District of Virginia brought an indictment against the Group in connection with your "marketing and promotional practices related to SUBOXONE Film and SUBOXONE Tablet[.]" We also note your disclosure that Indivior PLC entered into the Resolution Agreement in 2020 and "pleaded guilty to a single count of making a false statement relating to healthcare matters in 2012." Please provide further details regarding the factual allegations underlying the indictment brought against the Group in 2019.
6. We note your disclosure that in January 2022, the Group settled a securities law class action brought by holders of your Level 1 American Depositary Receipts related to "alleged misstatements regarding the marketing of SUBOXONE Film in the U.S. for approximately \$2 million." Please provide further details about the nature of the alleged misstatements at issue in that case and please disclose whether the parties entered into a written settlement agreement.
7. We note your disclosure that civil antitrust claims have been filed against you. Please

disclose the status of these claims, the venue in which these claims are being litigated, and the relevant parties associated with this matter.

We are subject to risks related to the manufacture and distribution of our products..., page 18

8. We note your disclosure that "[y]our manufacturing facilities also maintain high direct and indirect labor costs due to the complexity of [y]our manufacturing processes, often requiring specialized personnel." We also note your disclosure on page 11 that you rely "almost exclusively on third parties, including contract manufacturing organizations, to manufacture, package, test, and distribute [y]our products." Please revise your disclosure here to note whether you are referring to manufacturing facilities that you own and operate or facilities operated by third parties and whether the labor costs you are referring to are borne by you or your third party partners.

Item 4. Information on the Company

Merger Agreement, page 63

9. Please expand your disclosure to include the aggregate merger consideration for the acquisition of Opiant.

CVR Agreement, page 65

10. We note your disclosure that Indivior Inc. will have to pay certain milestone payments in relation to the CVR Agreement and that those payments are linked to "the period beginning with the first commercial sale of certain of Opiant's products." Please revise to specify which of Opiant's products would trigger the milestone payment period.
11. We note your disclosure that you estimate that total potential payments related to the CVR Agreement include an additional \$68 million over a period of up to 7 years from the date of the first commercial sales of a new "Olive product." Please explain your reference to an "Olive product."

Opioid use disorder ("OUD"), page 67

12. We note your disclosure that "[r]ecent data indicates that sustained high-plasma concentrations of buprenorphine . . . significantly reduced fentanyl-induced respiratory depression in opioid-tolerant participants." Please provide the basis for this statement.

Products of the Indivior Group

SUBLOCADE Long-acting injectable (buprenorphine) extended-release injection, page 73

13. We note your reference to your "RECOVER extension study." Please revise your disclosure to include the details of that study, including but not limited to, the selection criteria for participants, where the study was conducted, study parameters and whether there were any serious adverse events and if applicable, the number of participants who experienced them.

Cannabis Use Disorder, AEF0117 Synthetic CB1 Specific Signaling Inhibitor, page 78

14. We note your disclosure that upon commercialization of AEF0017, you would have to pay Aelis Farma a "double-digit tiered royalty" on net sales. Please revise your disclosure to specify a royalty rate or range not to exceed ten percentage points per tier.

Long term pipeline, page 78

15. Please revise your table with respect to Treatment for Cannabis Use Disorder (AEF0117) and Treatment for Substance Use Disorder (INDV-1000) to ensure that your bars do not appear to depict that Phase 2 has been completed for AEF0117 and pre-clinical work has been completed for INDV-1000. While AEF0117 is currently in a Phase 2B clinical trial it is not appropriate for the table to indicate that Phase 2 trials have been completed. Similarly, while INDV-1000 is still in the pre-clinical development phase, it is not appropriate for the table to indicate that pre-clinical development has been completed.
16. We note your disclosure that AEF0117 is currently in a Phase 2B clinical trial in treatment-seeking subjects with moderate to severe CUD. Please revise your disclosure to provide further details about this trial, including but not limited to, the selection criteria for participants, where the trial is being conducted, endpoints and whether there have been any serious adverse events to date and if applicable, the number of participants who experienced them.

Opioid Use Disorder, page 79

17. We note your disclosure that a "Phase 1, Single Ascending Dose study was completed and demonstrated good safety." Please revise your disclosure indicating or implying that your product is, or will be determined to be, safe and effective. Safety and efficacy determinations are solely within the authority of the FDA or similar regulators.

Additionally, please revise your disclosure to provide further details about the Single Ascending Dose study, including but not limited to, the selection criteria for participants, where the study was conducted, study parameters and whether there were any serious adverse events and if applicable, the number of participants who experienced them.

Intellectual Property , page 85

18. We note your disclosure that you own or license several patents and patent rights. You also state that you license or assign certain intellectual property rights to third parties. Revise your disclosure to specify whether the patents are owned or licensed. To the extent you have not done so, please add disclosure, where appropriate, of the material terms of your license agreements, including any upfront fees paid or received, aggregate potential milestone payments segregated by development and commercial milestones, royalty rate or range not to exceed ten percentage points, term and termination provisions.

Please also file such agreements as exhibits to your registration statement or tell us why you believe such filing is not required.

Item 5. Operating and Financial Review and Prospects

Results of operations, page 108

19. With respect to changes in net revenues for each period presented, please enhance your discussion to disclose the degree to which such changes were impacted by price changes as opposed to volume/market share.

Liquidity and Capital Resources

The Term Loan, page 120

20. Please disclose the names of the parties, including the lenders, to the Term Loan.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders, page 149

21. Please revise to identify the natural persons who have voting and/or investment control of the shares held by Scopia Capital Management LP and Two Seas Capital LP.

Item 9.C. Material Contracts, page 174

22. Please expand your disclosure to include the termination provisions under each of your Copacker Supply Agreement, Commercial Exploitation Agreement, Master Manufacturing Services Agreement and Master Development and Supply Agreement.

Item 18. Financial Statements

Consolidated Cash Flow Statement, page F-25

23. We note your reconciliation of operating cash flows begins with operating profit/(loss) instead of net income/(loss) for the year. Per paragraph 20 of IAS 7, cash flows from operating activities are determined by adjusting profit or loss. Paragraph 7 of IAS 1 defines profit or loss as the total of income less expenses, excluding the components of other comprehensive income. Please revise your presentation accordingly, or tell us why you believe no modification is necessary.

Note 27. Post Balance Sheet Subsequent Events

Opiant Pharmaceuticals Acquisition, page F-62

24. We note that you entered into a definitive agreement in November 2022 to acquire Opiant Pharmaceuticals and that you expect this transaction to close in the first quarter of 2023. Please revise to provide pro forma financial information in accordance with Article 11 of Regulation S-X as it relates to this acquisition or tell us why you believe it is not required. Please also explain your consideration of Rule 3-05 of Regulation S-X.

Ryan Preblich
Indivior PLC
December 16, 2022
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You may contact Eric Atallah at 202-551-3663 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Michael Levitt, Esq.