



DIVISION OF
CORPORATION FINANCE

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

January 18, 2023

Vicky Zhang
Chief Financial Officer
Adlai Nortye Ltd.
c/o PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands

Re: Adlai Nortye Ltd.
Draft Registration Statement on Form F-1
Submitted December 21, 2022
CIK No. 0001944552

Dear Vicky Zhang:

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 F-1

Cover Page

1. Please disclose whether your offering is contingent on final approval of your NASDAQ listing on your cover page. Ensure the disclosure is consistent with your underwriting agreement.
2. We note your statement on the cover page that Adlai Nortye Ltd. is "not an operating company but [y]our Cayman Islands holding company." Please revise this statement to specifically state that Adlai Nortye is not a Chinese operating company, but is a Cayman Islands holding company.

3. We note your disclosure on the cover page about the legal and operational risks associated with being based in or having the majority of the company's operations in China. Please revise this disclosure to make clear whether these risks could result in a material change in your operations and/or the value of your securities or could significantly limit or completely hinder your ability to offer securities to investors and cause the value of your securities to significantly decline or be worthless.
4. Please prominently disclose whether your auditor is subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act and related regulations will affect your company.
5. Clearly disclose how you will refer to the holding company and subsidiaries when providing the disclosure throughout the document so that it is clear to investors which entity the disclosure is referencing and which subsidiaries or entities are conducting the business operations. For example, disclose, if true, that your subsidiaries conduct operations in China. Disclose clearly the entity (including the domicile) in which investors are purchasing an interest.
6. We note your discussion of how cash is transferred through your organization on the cover page. Please further revise this disclosure to disclose your intentions to distribute earnings. State whether any transfers, dividends, or distributions have been made to date between the holding company, its subsidiaries, or to investors, and quantify the amounts where applicable. Please also address restrictions on your PRC subsidiary's ability to transfer funds, as disclosed elsewhere in the filing, and provide a cross-reference to the consolidated financial statements.

Prospectus Summary

Overview, page 1

7. Please revise your disclosure regarding your ongoing clinical trials for AN0025 and AN4005 to state the jurisdictions where such trials are taking place.
8. We note your statement used throughout the prospectus that you are actively advancing four in-house preclinical programs "considered to have high global commercial viability". Please provide support for this statement or revise to frame the statement as a belief or opinion.
9. Revise the summary to provide a clear description of how cash is transferred through your organization. Disclose your intentions to distribute earnings. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and its subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary have made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and your ability to transfer cash between entities, across borders, and to

U.S. investors. Describe any restrictions and limitations on your ability to distribute earnings from the company, including your subsidiaries, to the parent company and U.S. investors.

AN2025: the vanguard for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy, page 2

10. On page 2, you refer to AN2025 as “the vanguard” for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy. Please revise your use of the term in all places in which it appears to be expressed as a goal, belief or opinion. For instance, you may state, if accurate, that the Company aims to be the vanguard for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy.
11. On page 2, you reference studies demonstrating safety and efficacy. Similarly, on page 4, you reference that AN2025 demonstrated promising efficacy and safety data. Please revise these and similar statements throughout your prospectus to eliminate conclusions or predictions that the candidates are safe and effective, as determinations of safety and efficacy are solely within the authority of the FDA. You may provide an objective summary of the data that you used to draw such conclusions.
12. On page 3, we note your statement that you received Fast Track designation from the FDA for AN2025. Please balance this statement with the disclosure on page 43 that a Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that your drug candidates will receive marketing approval.
13. We note your references to the NMPA and the PMDA both here and throughout the document. Please revise your disclosure on page 3 where the terms are first used to indicate the jurisdiction of each authority.

Our company history and team, page 4

14. We note the last paragraph of the above referenced section on page 4. Please limit the disclosure of specific investors to those identified in the Principal Shareholder table on page 161. Additionally, indicate that prospective investors should not rely on the named investors’ investment decision, that these investors may have different risk tolerances and that the shares purchased in the referenced financings were conducted at a significant discount to the IPO price, if true.

Our strengths , page 4

15. Please balance your disclosure by adding a discussion of serious adverse events and deaths caused by treatment with AN2025.

Summary of risk factors, page 6

16. Please revise your summary risk factors relating to your operations in the PRC to disclose the risks that your corporate structure and being based in or having the majority of the company's operations in China poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks with cross-references to the more detailed discussion of these risks in the prospectus. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence your operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of the securities you are registering for sale. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

Conventions that apply to this prospectus, page 11

17. We note that your definition of China and the PRC excludes Hong Kong, Macau and Taiwan. Revise your definition and disclosure to clarify that the legal and operational risks associated with operating in China also apply to any operations in Hong Kong and/or Macau.

Risk Factors

Uncertainties with respect to the PRC legal system could materially and adversely affect us., page 61

18. Given the Chinese government's significant oversight and discretion over the conduct of your business, please revise to highlight separately the risk that the Chinese government may intervene or influence your operations at any time, which could result in a material change in your operations and/or the value of the securities you are registering. Also, given recent statements by the Chinese government indicating an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers, acknowledge the risk that any such action could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

Use of Proceeds, page 77

19. Although we note your statements that you intend to have broad discretion over the use of the net proceeds from the offering, please revise your use of proceeds disclosure to provide more granularity regarding the first bullet point, namely how far in the

development process you estimate that the proceeds will enable you to reach, including specific phases of clinical trials, if applicable. For example, please indicate if you expect to be able to fund the entirety of any ongoing or planned clinical trials or phases without raising additional capital. In this regard, we note your disclosure on pages 47 and 86 of the prospectus that while you believe, based on your current operating plan, that following the offering you will have sufficient cash on hand to fund operations for at least the next 12 months you will require substantial additional capital to support your business operations in the future.

Change in auditor, page 94

20. You state herein that you provided a copy of the change in auditor disclosure to Ernst & Young, and requested it to furnish you with a letter addressed to the SEC stating whether it agrees with the above statements, and if not, stating the respects in which it does not agree. Please revise your filing to indicate whether you ever obtained such a letter and, if so, to file it as an exhibit to your document.

Business

Phase Ia trial in patients with advanced solid tumors by Novartis, page 106

21. Per the table, it appears that 34.9% of patients treated with AN2025 experienced deaths and 43.4% experienced SAEs, for which 13.3% were drug related. Please provide clarification on the number of deaths determined to be drug-related, and identify the types of serious adverse events observed in the trials.

License and Collaboration Agreements, page 127

22. Please revise your disclosure to address the following:
- On page 127, quantify the upfront payment paid to Novartis in 2018.
 - On page 129, you state that Roche will supply its atezolizumab for use at no cost "unless otherwise provided in the clinical supply agreement supplement". Please revise to describe the payment terms and obligations of the agreement, including the referenced supplement.
 - On page 130, in relation to the Biotime collaboration agreement, include the payment amounts in USD in addition to RMB and summarize the term and termination provisions of the agreement.
23. Please file as exhibits your agreements with Roche, MSD and Biotime. Alternatively, please provide an analysis supporting your determination that such filing is not required. See Item 601(b)(10) of Regulation S-K.

Management

Employment agreements and indemnification agreements, page 158

24. Please revise your disclosure in this section to include a summary of the material terms of the employment agreement between the company and each named executive officer.

Compensation of directors and executive officers, page 158

25. We note your disclosure in this section. Please confirm that disclosure of compensation is not required on an individual basis in the company's home country and is not otherwise publicly disclosed by the company.

Principal Shareholders , page 161

26. Please identify any natural persons who have or share voting and/or dispositive power with respect to the shares owned by the entities listed in your table for Nortye Talent Limited, Nortye International Limited and UNIQUE MARK VENTURES LIMITED.

History of share capital, page 173

27. Please revise to disclose the nature of the relationship between you and Lucy Zhang, the only holder of ordinary shares.

Notes to the Consolidated Financial Statements

1. Corporate and Group Information, page F-8

28. You disclose that the Company and its subsidiaries now comprising the Group "underwent the reorganization as set out in the paragraph headed "Reorganization" in the section headed "History, Development and Corporate Structure" in the Document (the "Reorganization")." You make similar reference to such separate section on page F-9. However, we were unable to locate a paragraph entitled "Reorganization" and the "History, Development and Corporate Structure" section appears to be labeled "Corporate History and Structure". Please revise your disclosures hereunder accordingly.
29. We note your disclosure on page 63 regarding limitations on your PRC subsidiary's ability to pay dividends, which may impact your ability to pay dividends. Please tell us your consideration of providing the disclosures required by Rule 4-08(e) of Regulation S-X as well as the consolidated financial information of registrant (Schedule I) required by Rule 5-04.

4. Revenue, page F-25

30. We note that revenue of \$45.7 million for the year ended December 31, 2021 was derived from the sale of intellectual property to Xiamen Biotime Biotechnology Co., Ltd (Biotime) pursuant to a collaboration agreement entered into on November 15, 2021. Your accounting policy disclosure on page F-21 states that revenue from sales of intellectual property is recognized when you have sold the rights to the intellectual property and after there is no future performance obligation to be performed. Please explain how the potential milestone payments and sales-based royalties, as described on page 130, were considered in determining the transaction price for this collaboration agreement. To the extent that you determined that this variable consideration is fully constrained, please disclose that fact. Please also ensure that you have provided all of the

disclosures required by IFRS 15, particularly those required by paragraphs 119 and 126.

12. Financial Assets at FVTPL, page F-31

31. We note that your financial assets at fair value through profit or loss (FVTPL) consist of a wealth management product and a dual currency structured deposit. Please address the following:
- Revise your disclosure herein to clearly describe the nature and significant terms of these products. In this regard, describe the type of instrument (e.g., fixed-income security, equity investment, derivative instrument, etc.), key terms (e.g., maturity, yield, etc.) and any related risks.
 - Ensure that your accounting policy disclosure for financial assets at FVTPL relates to the type of financial assets actually held.
 - Revise your fair value disclosures in Note 24 to provide the disclosures required by paragraph 93 of IFRS 13 as they specifically relate to Level 3 fair value measurements.

15. Financial Liabilities at FVTPL, page F-34

32. We note your disclosure that upon the issuance of each series of convertible redeemable preferred shares, you designated Series B, C and D Preferred Shares and Series B Convertible Loans as financial liabilities measured at FVTPL and recognized Series A Preferred Shares as equity in accordance with the relevant IFRS. We further note your disclosure on page F-18 that financial liabilities are designated as FVTPL only if the criteria in IFRS 9 are satisfied. Please provide your analysis supporting the accounting for each of these instruments, including reference to the applicable IFRS guidance.

19. Share Incentive Plan, page F-40

33. It appears that your tabular disclosure on page F-41 presents a rollforward of the activity in your share-based awards for the periods presented, while the tables at the top of page F-42 indicate the amount of share-based awards outstanding at each period-end, segregated by weighted average exercise price. In the interest of clarity, please consider combining these tables into a single rollforward or revise the tables on page F-42 to clearly indicate the nature of each line item.

General

34. We note your statements on pages 8 and 59 that you have been advised by your PRC legal counsel that you are not currently required to make any filing or obtain any permissions or approval from the CSRC and CAC in the PRC for the listing of the ADSs on Nasdaq, nor are you required to submit an application to the CSRC for approval under the M&A Rules. We also note your disclosure under “Enforceability of Civil Liabilities” relating to advice provided by Maples and Calder (Hong Kong) LLP, your legal counsel as to Cayman Islands law, and Han Kun Law Offices, your legal counsel as to PRC law, on

Vicky Zhang
Adlai Nortye Ltd.
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matters governed by BVI and PRC law, respectively. Please revise your registration statement to comply with Item 10.G of Form 20-F in relation to the foregoing. See also Item 101(g)(2) of Regulation S-K and Rule 436 of Regulation C.

35. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Jenn Do at 202-551-3743 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Ke Geng