



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

DIVISION OF
CORPORATION FINANCE

October 19, 2020

Peter (Peizhi) Luo
Chief Executive Officer
Adagene Inc.
4F, Building C14, No. 218
Xinghu Street, Suzhou Industrial Park
Suzhou, Jiangsu Province, 25125
People's Republic of China

Re: Adagene Inc.
Draft Registration Statement on Form F-1
Submitted September 22, 2020
CIK No.: 0001818838

Dear Mr. Luo:

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 Submitted on September 22, 2020

Prospectus Summary

Overview, page 1

1. Please substantially revise your narrative disclosures to more clearly explain in plain English your NEObody, SAFEbody, and POWERbody technologies, and how they are inter-connected and utilized for the building of your product pipeline. Also expand your explanations of the figures at the top of pages 2 and 3 (and in your Business sections), including with respect to the images in each of the three circles in the figure on page 3.

2. We refer to your statements on pages 4 and 6 and in your Business section comparing the safety of ADG126 with ipilimumab based on a separate study. As this comparison is not based on head-to-head studies, please delete these discussions, or advise.
3. Revise to limit your Summary discussion of your ongoing trials to serious adverse events, trial endpoints, and to the extent applicable, whether they were met. In the Business section discussion of preliminary efficacy assessments, clarify, if true, that the trials did not have efficacy endpoints.

Our Pipeline, page 4

4. With respect to your product candidates other than ADG106 and ADG104, revise your column headings to show "Phase II" as a separate column or otherwise advise. With respect to ADG106, please explain why the table does not show separate Phase I and Phase II columns when your narrative disclosure appears to refer to separate phases. In addition, based on your narrative disclosure regarding your status of development for ADG106, please shorten the arrows in your pipeline table to more precisely indicate the development status of such product candidate, or advise, and shorten your arrow for ADG116 to the end of the IND enabling column as it does not appear you have commenced your Phase 1 Australia trial yet based on your narrative disclosures, and it does not appear you are intending to rely on the paused U.S. trial.
5. Please revise your pipeline table to show the target indications of each included product candidate. In addition, please explain why it is appropriate for your pipeline table to include a row generally for "Preclinical Assets." Based on your discussion in the Business section, these assets appear to be in an early stage of development, and it does not appear that you have identified any specific preclinical candidates to pursue.

ADG106: Novel agonistic anti-CD137 NEObody candidate, page 5

6. We note your disclosure on page 5 and elsewhere in your prospectus that in preclinical and clinical trials, your product candidate has shown "robust anti-tumor activity," "was observed to balance between safety and efficacy of CD137 agonism," demonstrated "favorable safety results," "potent antitumor efficacy" and "preliminary clinical efficacy," and you also refer to "effective doses." Similar statements appear elsewhere in your prospectus, such as your statement on page 42 referring to the "significant safety margin" of ADG126, and your statement on page 151 that ADG126 "was observed to effectively inhibit tumor growth." Please revise your disclosures to remove all such statements suggesting that your product candidate is safe or effective, insofar as determinations as to safety and efficacy are within the sole authority of the FDA or comparable foreign regulatory authorities.

ADG116: Novel anti-CTLA-4 NEObody candidate, page 7

7. We note your disclosure that you have a Phase I clinical trial open in the United States for ADG116 as a monotherapy in patients with advanced/metastatic solid tumors, but that you

are not enrolling patients in the trial. Revise to disclose in your Summary that your Phase I trial was placed on clinical hold by the FDA following a death of a patient, as you explain on page 31, and that you intend to conduct your trial in Australia at higher starting doses than is currently permitted in the U.S.

Our Global Partnership and Collaborations, page 7

8. We note your statement that your recent partnerships are "validations of [y]our DPL platform and technologies as well as their potential broad application to a wide range of antibody modalities." Given the early stage of development of your product candidates derived from the platform and your partnerships and collaborations, such statements imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing such approval. Please delete such statements here and in the Business section. In addition, please qualify the fourth bullet on page 8 to state that you may not be able to enter into additional collaboration agreements beyond the ones with ADC Therapeutics and Guilin Sanjin.

Risk Factors, page 8

9. Please add a bullet to highlight that you may be classified as a PFIC for the current taxable year and the resulting consequence to investors.

Implications of Being an Emerging Growth Company, page 10

10. Please supplementally provide us with 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, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Risks Factors, page 18

11. We note your disclosure on page 224 that certain shareholders will possess board representation rights following the offering. Please add a risk factor discussing the board representation rights in sufficient detail so that investors can clearly understand the corporate governance, control of the company, and resulting conflicts of interest that may arise. For example, include in your revised disclosure that your CEO has such rights, and if true, that your sole supplier is also a significant shareholder with these rights. In addition, please also add appropriate disclosure in the summary risk factors disclosing that certain shareholders will have board representation rights.

Use of Proceeds, page 96

12. Please expand your bullet points to disclose the estimated proceeds to be allocated to each of your target indications and product candidates and clarify the stage of development you expect to be able to complete for each indication using the estimated proceeds. In addition, please add disclosure to the extent you will need additional funds to further

develop your material product candidates.

Capitalization, page 98

13. Please revise long-term borrowings to include the current portion of long-term borrowings.

Results of Operations, page 111

14. For research and development expenses, please separately present the costs incurred for preclinical testing from costs incurred for clinical trials. Please disclose the amount of costs incurred by program for each period presented.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Share-based Compensation, page 123

15. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

Our Pipeline

ADG106: Novel Agonistic Anti-CD137 NEObody Candidate

Mechanism of Action, page 136

16. Please include additional descriptive labels for the figures at the top of page 137. Specifically, please clearly label ADG106 in addition to the other objects depicted or otherwise revise the graphic to clarify this illustration.

Clinical Development Plan, page 147

17. We note your disclosure that you are conducting a Phase Ib cohort expansion for ADG106. In conjunction with your disclosure on page 139, revise to clarify the material details on the expansion trial, including the number of expected participants, trial design, endpoints and any protocols.

ADG116: Novel Anti-CTLA-4 NEObody Candidate, page 152

18. Expand your disclosure regarding your trials with ADG116 to describe the Phase I trial that occurred in the U.S. prior to its clinical hold. Please also revise to provide details for your planned Phase I trial in Australia, including the number of patients, dosage, duration, and endpoints.

Our Platform, page 161

19. Please revise to more clearly explain to investors the technology underlying your DPL platform, including by clarifying the "proven applications commonly used in the industry" and whether or not you have licenses to use these applications. In addition, please describe the underlying technology unique to your POWERbody technology so that investors can better understand this specific technology.

ADC Therapeutics Agreements, page 164

20. Please revise your disclosure regarding the ADC Therapeutics Agreements to disclose the aggregate payments received to date.

Sanjin Collaboration/ Out-Licensing Agreements, page 165

21. Please revise your disclosures regarding the Sanjin Greater China Agreement and Dragon Boat ROW Agreement to disclose the aggregate payments received to date. Also revise to specify the period Sanjin is required to pay the percentage of net sales.

Intellectual Property, page 167

22. Please expand the discussion of your intellectual property portfolio on page 167 to specify (i) the material patents and patent applications you have for each of your specific product candidates, and (ii) the type of patent protection granted or requested (composition of matter, use or process) for each patent or pending application. In addition, please revise your disclosure to specify the jurisdictions in Europe in which you have pending applications

Competition, page 169

23. We note that you cross-reference to "Market Opportunity and Competition" sections elsewhere in the prospectus where you disclose two advanced CD137 agonist antibodies in development and ipilimumab as competition to ADG106 and ADG126, respectively. Please revise your disclosure to enhance your description of the competitive business conditions you face in respect to your material product candidates, including disclosing the names of your main competitors, the stages of development for your competitors' candidates and if applicable competition from existing approved products.

Regulation, page 172

24. Please add a discussion regarding applicable regulation in Australia as you disclose that you intend to conduct clinical trials in Australia.

Related Party Transactions, page 212

25. Revise to clarify whether the transactions with WuXi Biologics included providing you

with manufacturing and quality control testing, as you state on page 169 that you rely on WuXi for your supply needs.

Notes to the Consolidated Financial Statements

10. Collaboration Arrangements, page F-29

26. Please expand your disclosures for the Dragon Boat Greater China Agreement to include the nature of the milestones along with the US dollar amount for the upfront fee and the total potential milestone payments. Refer to ASC 606-10-32.
27. For the ADCT Collaboration and License Agreements to address the following:
 - Clarify that the agreements are being combined for revenue recognition purposes, if appropriate, per ASC 606-10-25-9.
 - Clarify if you are required to perform research and development services in addition to providing a license along with whether the research and development services for the masked antibodies generated under the collaboration portion of the agreement is a separate performance obligation. Refer to ASC 606-10-25-14 through 25-22. Please also tell us how this impacts revenues recognition, if at all, in accordance with ASC 606-10-25-23 through 25-37.
 - Disclose the US dollar amount for each category of milestones that are to be met to receive payments.

18. Condensed Financial Information of the Parent Company, page F-40

28. We note that Adagene Inc., the parent company, is an offshore holding company. As such, please tell us why the parent company recognized revenues, contract liabilities, and research and development expenses. Please also provide footnote disclosures for the amounts due from related parties and amounts due to related parties. Please confirm that the changes in amounts due to related parties are reflected as cash financing transactions and the amounts due from related parties are reflected as cash investing transactions.

Exhibits

29. We note your disclosure on page 171 of various lease agreements for properties located in China and California. Please file your material lease agreements as exhibits to your registration statement or please advise. Refer to Item 8 of Form F-1 and Item 601(b)(10)(ii)(D) of Regulation S-K.

Peter (Peizhi) Luo
Adagene Inc.
October 19, 2020
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You may contact Tracey Houser at 202-551-3736 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Jason Drory at 202-551-8342 or Dorrie Yale at 202-551-8776 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Li He, Esq.