



New York  
Northern California  
Washington DC  
São Paulo  
London

Paris  
Madrid  
Hong Kong  
Beijing  
Tokyo

Davis Polk & Wardwell  
Hong Kong Solicitors  
The Hong Kong Club Building  
3A Chater Road  
Hong Kong

852 2533 3300 tel

**Resident Hong Kong Partners**

Karen Chan †	Martin Rogers †
Yang Chu †	Patrick S. Sinclair*
James C. Lin*	Miranda So*
Gerhard Radtke*	James Wadham†

*Hong Kong Solicitors*

\* Also Admitted in New York

† Also Admitted in England and Wales

January 19, 2021

**Re: Adagene Inc.**  
**Amendment No. 2 to Draft Registration Statement on Form F-1**  
**Submitted November 24, 2020**  
**CIK No.: 0001818838**

**Confidential**

Mr. Jason Drory  
Ms. Dorrie Yale  
Ms. Tracey Houser  
Mr. Terence O'Brien  
Office of Life Sciences  
Division of Corporation Finance  
U.S. Securities and Exchange Commission  
100 F Street, NE  
Washington, D.C. 20549

Dear Mr. Jason Drory, Ms. Dorrie Yale, Ms. Tracey Houser and Mr. Terence O'Brien:

On behalf of Adagene Inc. (the "**Company**"), a company incorporated under the laws of the Cayman Islands, we submit to the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") this letter setting forth the Company's responses to the comments contained in the Staff's letter dated December 9, 2020 on the Company's revised draft registration statement on Form F-1 confidentially submitted on November 24, 2020 (the "**Revised Draft Registration Statement**"). Concurrently with the submission of this letter, the Company is filing its registration statement on Form F-1 (the "**Registration Statement**") and certain exhibits via EDGAR to the Commission. The Company is, concurrently with the Registration Statement, filing the draft registration statement on Form F-1 initially confidentially submitted on September 22, 2020 and all amendments thereto that were previously submitted for the non-public review of the Staff, and plans to file a preliminary prospectus containing the estimated offering size and a price range on February 3, 2021, subject to market conditions and the review of the Staff. The Company confirms that its securities have not been previously sold pursuant to an effective registration statement under the Securities Act of 1933, as amended.

Davis Polk includes Davis Polk & Wardwell LLP and its associated entities.

---

To facilitate your review, we have separately delivered to you today four courtesy copies of the Registration Statement, marked to show changes to the Revised Draft Registration Statement, and two copies of the submitted exhibits.

The Company has responded to all of the Staff's comments by revising the Revised Draft Registration Statement to address the comments, by providing an explanation if the Company has not so revised the Revised Draft Registration Statement, or by providing supplemental information as requested. The Staff's comments are repeated below in bold, 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 the Registration Statement where the language addressing a particular comment appears.

Subject to the market conditions and the Staff's comments, the Company requests that the Staff declare the effectiveness of the Registration Statement on February 9, 2021. A registration statement on Form F-6 relating to the ADSs will be filed with the Commission in due course. The Company would greatly appreciate the Staff's continued assistance and support in meeting the timetable.

\* \* \* \*

**Draft Registration Statement on Form F-1 Submitted on November 24, 2020**

**Prospectus Summary**

**Overview**

**Our Pipeline, page 5**

- 1. We note your response to our prior comment 2 and your revised pipeline table that shows your trial 1001 for ADG126 has already commenced Phase Ia. However, your disclosures only indicate that you have received authorization to begin the trial from the Australian authorities, and from the FDA, subject to submission of a revised agreed-upon protocol, but not that the trial has commenced. Please reconcile your disclosures. In addition, please explain why it is appropriate to show Phase Ia and Phase Ib as two separate columns when your discussions for ADG126 and ADG116 only refer to "Phase I". Please also explain why it is appropriate to retain the US 1001 trial for ADG116 in the pipeline table when you do not currently plan to enroll patients in this clinical trial.**

In response to the Staff's comment, the Company respectfully submitted to the Staff that the first site of ADG126-1001 has been approved by the Australian authorities, investigational products have been released, and the site is ready to start patient screening. In addition, three potential patients have been identified for enrollment in the ADG126-1001 trial and the Company expects to commence patient enrollment by February. The Company has revised the disclosure on page 166 of the Registration Statement to reflect the update.

In addition, the Company has revised the pipeline chart on pages 6 and 140 of the Registration Statement to combined Phase Ia and Phase Ib columns in response to the Staff's comment.

With respect to ADG116-1001 US trial, the Company respectfully submits that although the Company currently is not enrolling patients in this clinical trial, ADG116-1001 nevertheless is an approved clinical trial by the FDA and the Company plans to initiate dose expansion phase in ADG116-1001 trial, pending results of ADG116-1003 trial. As the Company has disclosed on pages 166 and 172 of the Registration Statement, as of January 15, 2021, the Company has successfully completed the three dose escalation at 0.003 mg/kg, 0.01mg/kg and 0.03mg/kg. 0.03mg/kg was the dose that the Company had initiated a Phase I trial of ADG116 in the United States, and no treatment related adverse events have been observed in the three patients treated at 0.03 mg/kg in Australia. Therefore, the Company expects to resume ADG116-1001 trial in the United States pending on ADG116-1003 trial. The Company has revised the pipeline chart on pages 6 and 140 of the Registration Statement to clarify the Company's anticipated milestones accordingly.

**ADG126: Novel anti-CTLA-4 SAFEbody candidate, page 7**

- 2. We note your use of the phrase “potency” to describe certain preclinical observations. For example only, we note your revised disclosures here and elsewhere in your prospectus where you state that “ADG126 in addition to its potency for Treg depletion in TME suggests its potential for tolerable and potent monotherapies” and that “preclinical results support the further clinical evaluation of ADG116 both as tolerable and potent monotherapies and combination therapies for a wide range of tumor types.” As ADG126 is only in the preclinical stage, and as safety and efficacy determinations are solely within the FDA's authority and they continue to be evaluated throughout all phases of clinical trials, please remove these and any similar references. Where you deem appropriate, you may present objective data resulting from your trials without including your conclusions related to safety or efficacy.**

In response to the Staff's comment, the Company has revised the disclosure on pages 8, 9, 142, 168, 169 and 173 of the Registration Statement.

**Notes to the Consolidated Financial Statements**

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

- 3. Please disclose the amount of the restricted net assets for each subsidiary in accordance with Article 4-08(e)(3)(ii) of Regulation S-X. To the extent that restricted net assets of your consolidated subsidiaries does not exceed 25 percent of consolidated net assets as of December 31, 2019 in accordance with Article 5-04(c) of Regulation S-X, please disclose the purpose of presenting the parent company financial information.**

In response to the Staff's comment above regarding the amount of the restricted net assets for each subsidiary, the Company respectfully submits that there is only one subsidiary incorporated in the PRC with the restricted net assets, and it has added related disclosure on page F-39.

In response to the Staff's comment above regarding the purpose of presenting the parent company financial information, the Company respectfully advises the Staff that pursuant to Financial Reporting Manual 2810.4, since the Company has a consolidated shareholders' deficit, its net asset base for purposes of calculating the proportionate share of restricted net assets of consolidated subsidiaries should be zero. Therefore, the restricted net assets of the Company's consolidated subsidiaries exceed 25% of consolidated net assets of the Company, which triggers the requirement to provide parent company financial information (Note 18).

**4. Please disclose the related party transactions recognized in your statements of comprehensive loss and statements of cash flows in accordance with Article 4-08(k)(i) of Regulation S-K. In addition, disclose any intercompany profits or losses resulting from transactions with related parties and the effects of those transactions in accordance with Article 4-08(k)(ii) of Regulation S-X. As part of your response, tell us what services you provided and who the related party is for the revenue recognized for fiscal year 2019.**

In response to the Staff's comment above regarding the related party transactions recognized in the statements of comprehensive loss, the Company respectfully submits that it has revised its disclosure on pages F-4 and F-46. Moreover, the movements of amount due to/from related parties were in the statements of cash flows on F-6 and F-48.

In response to the Staff's comment above regarding intercompany profits or losses resulting from transactions with related parties and the effects of those transactions, the Company respectfully submits that it has added related disclosure on page F-44.

In response to the Staff's comment above regarding what services the Company provided and who the related party is for the revenue recognized for fiscal year 2019, the Company respectfully advises the Staff that the related party is Adagene Incorporated. In fiscal year 2019, Signal Pharmaceuticals LLC, a subsidiary of Celgene Corporation, made a purchase order to Adagene Incorporated for delivery of certain sequences. Because the intellectual properties relating to such sequences were held by the Company, the Company charged an R&D expenditure of US\$288,982 to Adagene Incorporated, which forms part of the Company's revenue in fiscal year 2019.

\* \* \* \*

If you have any questions regarding this submission, please contact Li He at +852 2533-3306 (li.he@davispolk.com) or Steve Wang at +852 2533-1092 (xuelin.wang@davispolk.com) or Raymond Tam, the Company's CFO, at +852 9873-6186 (raymond\_tam@adagene.com), or Alex Zhuang of PricewaterhouseCoopers Zhong Tian LLP at +86 21-2323 3701 (alex.zhuang@cn.pwc.com).

Thanks for your time and attention.

Yours sincerely,

/s/ Li He

---

cc: Mr. Peter (Peizhi) Luo, Chief Executive Officer and Chairman  
Mr. Raymond Tam, Chief Financial Officer  
Adagene Inc.

Benjamin Su, Esq., Partner  
Michael E. Sullivan, Esq., Partner  
Daying Zhang, Esq., Partner  
Latham & Watkins LLP

Alex Zhuang, Engagement Letter  
PricewaterhouseCoopers Zhong Tian LLP