New York Northern California Washington DC São Paulo London Paris Madrid Hong Kong Beijing Tokyo

# **Davis Polk**

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

CERTAIN PORTIONS OF THIS LETTER HAVE BEEN OMITTED FROM THE VERSION FILED VIA EDGAR. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS. INFORMATION THAT WAS OMITTED IN THE EDGAR VERSION HAS BEEN NOTED IN THIS LETTER WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[\*\*\*]".

# FOIA CONFIDENTIAL TREATMENT REQUESTED

The entity requesting confidential treatment is

Adagene Inc.
4F, Building C14, No. 218,
Xinghu Street, Suzhou Industrial Park
Suzhou, Jiangsu Province, 25125
People's Republic of China
+86-512-8777-3632

**Rule 83 Confidential Treatment Request** 

January 25, 2021

Re:

## **BY Secured Electronic Transmission and EDGAR**

Office of Life Sciences Division of Corporation Finance U.S. Securities and Exchange Commission 100 F Street, N.E.

Washington, D.C. 20549-7561 Attention: Mr. Jason Drory Ms. Dorrie Yale Ms. Tracey Houser

Mr. Terence O'Brien

Adagene Inc. (CIK No. 0001818838)

Registration Statement on Form F-1 Filed January 19, 2021

(Registration Statement No. 333-252210)

### Ladies and Gentlemen:

We are submitting this letter on behalf of Adagene Inc. (the "**Company**") in connection with the review by the staff (the "**Staff**") of the Securities and Exchange Commission (the "**Commission**") of the Company's Registration Statement on Form F-1 (File No. 333-252210) initially filed January 19, 2021 (the "**Registration Statement**").

Because of the commercially sensitive nature of the information contained herein, the Company respectfully requests that the specified information contained in this letter be treated as confidential information and that the Commission provide timely notice to Mr. Raymond Tam, Chief Financial Officer of the Company, before it permits any disclosure of the bracketed information in this letter.

The Company respectfully advises the Staff that, based on discussions with the Company's board of directors and preliminary input provided by the underwriters for this offering, the Company anticipates that the price range for this offering will be [\*\*\*] per ordinary share (the "Estimated IPO Price Range"). The indicative Estimated IPO Price Range assumes the implied valuation range of the Company's market capitalization prior to the Company's initial public offering at [\*\*\*] million and [\*\*\*] million (the "Estimated Pre-Money IPO Market Cap Range"). The indicative Estimated IPO Price Range represents an estimate of the fair value of the unrestricted, freely tradable shares that would be sold in the public market without liquidity and marketability discounts. The Company will include the actual price range in an amendment to the Registration Statement shortly before the commencement of the Company's management roadshow. That price range will be subject to then-current market conditions, continuing discussions with the underwriters and certain other factors affecting the Company or this offering.

# Summary of recent equity awards and issuance of Series C-3 convertible preferred shares

The Company has determined fair value per ordinary share of the share options of its Second Amended and Restated Share Incentive Plan (the "Share Options") granted on August 15, 2020 and August 27, 2020 (each, a "Valuation Date"), respectively, to be [\*\*\*]. The valuation of the Company's ordinary shares was based on the valuation performed by an independent valuation firm (the "Independent Valuation Firm") using market approach valuation by making reference to (a) the Company's latest equity financing transaction of Series C-3 convertible preferred shares closed on December 19, 2019 and (b) discount for lack of marketability ("DLOM"). DLOM reflects the fact that the Company's shares were privately-held shares. DLOM was quantified by Finnerty option pricing model. Under this method, the cost of the put option, which could be used to hedge the price change before the privately held shares can be sold, was considered as a basis to determine the DLOM. This option pricing method is one of the methods commonly used in estimating DLOM. The key assumptions of such model includes estimated dividend yields, timing of a liquidity event, and estimated volatility of our shares. The further the valuation date is from an expected liquidity event, the higher the put option value and thus the higher the implied DLOM. The lower DLOM is used for the valuation, the higher is the determined fair value of the ordinary shares.

The valuation of the Company's Share Options on each Valuation Date was determined based on the valuation performed by the Independent Valuation Firm using Hull-White ESO Binomial tree model by making reference to, among various factors, fair value of the Company's ordinary shares on each Valuation Date, the expected volatility based on stock price performances of 12 comparable publicly listed companies in the same industry, the exercise multiples and the risk-free rate. Both market approach valuation and binominal tree model are commonly used valuation methods introduced in the AICPA Audit and Accounting and Valuation Guide, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation" (the "Guide").

A detailed description of the valuation method used for the assessment of the fair value of the share options of the Company is set forth on pages 131 and 132 of the Registration Statement.

In October 2020, the Company granted certain number of Share Options to newly joined executive officer and members of mid-level management (the "October Grant"). Given the fact that the date of the October Grant was subsequent to the balance sheet date of the Company's latest unaudited financial statements included in the Registration Statement, the Company did not engage the Independent Valuation Firm to perform a fair value assessment as of the date of the October Grant.

On January 16, 2021, the Company granted certain number of Share Options to its founder team (the "January Grant"). The exercise price of the Company's Share Options granted on January 16, 2021 was determined to be US\$13.85, which was estimated after considering, among other things, the Company's financial and operating performance, and current economic conditions as well as then implied valuation of the Company's market capitalization, which is close to the Estimated Pre-Money IPO Market Cap Range. Because the grant date of such Share Options was subsequent to the balance sheet date of the Company's latest unaudited financial statements included in the Registration Statement, the Company did not engage the Independent Valuation Firm to perform a fair value assessment as of a more recent date since the latest Valuation Date.

## Difference between recent valuations leading up to the offering and estimated offering price

According to the Company's Independent Valuation Firm's valuation model, assuming (i) a 60% likelihood of the Company's initial public offering and (ii) no preferred rights associated with the ordinary shares converted from the Series C-3 convertible preferred shares, such as liquidation preference, the fair value of ordinary shares as of each Valuation Date was derived to be [\*\*\*] per share, representing an approximately [\*\*\*] discount to the issue price of Series C-3 convertible preferred shares. The difference between the mid-point of Estimated IPO Price Range and the fair value of the ordinary shares under the valuation model is approximately [\*\*\*] per share, representing a [\*\*\*] increase from the fair value of ordinary shares as of each Valuation Date. Furthermore, the difference between the fair value per ordinary share as of each Valuation Date and the high end of the Estimated IPO Price Range is approximately [\*\*\*] or approximately [\*\*\*].

Among the factors that were considered in setting the Estimated IPO Price Range were the following: (a) the Company's stage of development, (b) progress of Company's research and development efforts, (c) the impact of significant corporate events or milestones, (d) the general conditions of the securities market and the recent market prices of, and the demand for, publicly traded common stock of comparable companies; (e) the Company's financial condition and prospects; (f) estimates of business potential and earnings prospects for the Company and the industry in which it operates; and (g) recent performance of initial public offerings of companies in the sector.

In particular, since Valuation Date, the Company has achieved several milestones:

- · ADG106 Since the latest Valuation Date, the Company has achieved significant progress in the clinical development of one of its lead product candidates, ADG106, including:
  - As of the November 30, 2020, the Data Cut-off Date, the Company has completed the Phase Ia dose escalation in each of its Phase I studies of ADG106 in both the United States and China as a monotherapy in patients with advanced or metastatic solid tumors and/or NHL. ADG106 was dose escalated up to 10 mg/kg and is well tolerated at dose expansion at 3 mg/kg, 5 mg/kg and at 300mg and 400 mg flat doses. A total number of 92 patients have been dosed. Both clinical trials, namely ADG106-1001 and ADG106-1002, have limited treatment emergent adverse events, or TEAEs, liver toxicity or hematologic abnormalities. One patient with a solid tumor who previously failed chemotherapies, radiotherapy, and an anti-PD-L1 antibody treatment showed a partial response to ADG106 treatment with a 40% tumor size reduction after two treatment cycles. In addition, two NHL patients showed more than a 30% tumor size reduction after one and two ADG106 treatment cycles, respectively. Furthermore, biomarker studies showed target engagement with specific pharmacodynamics biomarkers indicative of immune system activation, and clinical response correlated with changes in CD137 target engagement. These data are encouraging given that the enrolled population was not preselected and was heavily pretreated.
  - The Company also identified a potential predictive biomarker which correlates with patient response to ADG106 treatment from a retrospective analysis of the ongoing Phase I clinical trial. Based on this finding, the Company is in the process of preparing an additional Phase II trial which the Company expects to initiate in 2021 and for which the Company intends to stratify and preselect patients using this predictive biomarker to potentially enhance clinical response of patients to ADG106 treatment. The Company also plans to pursue potential registrational trials evaluating ADG106 in biomarker enriched patient populations.
  - The Company has received the National Medical Product Administration, or the NMPA, approval for the ADG106-1008 study in China, which is a Phase Ib/II combination trial of ADG106 with anti-PD-1 in advanced solid tumors and hematological malignancies. The Company is also in the preparation for a submission of a Clinical Trial Notification, or CTN, for its ADG106-1003 clinical trial in Australia, which will combine ADG106 with anti-PD-1, and other therapies in advanced solid tumors and hematological malignancies.

### · ADG126

• The Company obtained authorization from the Australian Therapeutic Goods Administration, or the ATGA, under a CTN for ADG126-1001 for a Phase I trial in Australia. 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.

· U.S. Food and Drug Administration, or the FDA, authorized the Company to proceed with its ADG126-1001 Phase I trial in the United States in 2021.

### ADG116

• Subsequent to the CTN authorization obtained from the ATGA in July 2020, the Company has successfully completed dose escalation at the first three doses in our ADG116-1003 clinical trial in Australia, including a dose level at 0.03mg/kg, which was the dose level used for the first patient in the ADG116 Phase I trial in the United States. As of January 15, 2021, no dose limiting toxicity or treatment related serious adverse events have been observed in any of the patients treated. There was no treatment induced liver toxicity and all three patients treated at 0.03mg/kg showed normal liver enzyme level post ADG116 treatment.

# Collaboration with Sanjin

- · With the collaboration effort from the Company's partner, Sanjin, ADG104 has progressed to Phase Ib and Phase II trials concurrently in China. In addition, Sanjin and its affiliates have recently filed an IND application for the second monoclonal antibody that the Company is collaborating with Sanjin, which has been accepted by the NMPA.
- · Expansion of Leadership to support strategic growth
  - The Company expanded its leadership team with the appointment of multiple executive officers and independent director nominees. Dr. Gong's contributions to securing regulatory approval for seven precision oncology drugs, Dr. Xu's extensive oncology drug discovery and translational medicine experience and Dr. Zhao's expertise in manufacturing will support the Company's continued efforts on the discovery and design of novel antibodies and advancement of its immunotherapy clinical programs. Mr. Andy Cheung's contributions as an independent director nominee and an audit committee chairman as well as Dr. Min Li's expertise and industry insights will further support the Company's improvement of its corporate governance and compliance with heightened standards as a publicly listed company.
- · Establishing a center of excellence for precision medicine in San Diego, United States
  - The Company recently secured laboratory and office space in San Diego to building out its team in San Diego with a focus on precision medicine and translational studies to support the acceleration of its Dynamic Precision Library platform for its partners and pipeline.
- · Increased probability of an IPO and substantially enhanced liquidity and marketability of the Company's ordinary shares

• The Estimated IPO Price Range represents a future price for ordinary shares that, if issued in the IPO, assumes a 100% probability of the consummation of the IPO and that, if issued in the IPO, the shares will be immediately freely tradable in a public market, whereas the estimated fair value of the ordinary shares as of the latest Valuation Date represents a contemporaneous estimate of the fair value of shares that were then illiquid and might never become liquid. This illiquidity accounts for a substantial difference between the estimated fair values of the ordinary shares through the date hereof and the Estimated IPO Price Range. At the time of the latest Valuation Date, the Company had not yet confidentially submitted its draft registration statement to the Commission.

Accordingly, the Company considers that the difference between the fair value of ordinary share per share in August 2020 and the Estimated IPO Price Range is not unreasonable.

\* \* \* \*

If you have any questions regarding this submission, please contact Li He at +852 2533-3306 (<u>li.he@davispolk.com</u>) or Steve Wang at +852 2533-1092 (<u>xuelin.wang@davispolk.com</u>).

Thanks for your time and attention.

Yours sincerely,

By: /s/ Li He Li He

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

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

Alex Zhuang, Engagement Partner PricewaterhouseCoopers Zhong Tian LLP

[Signature page to Cheap Stock Letter]