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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16
OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of May 2021

Commission File Number: 001-39997

Adagene Inc.
(Exact Name of Registrant as Specified in Its Charter)

4F, Building C14, No. 218
Xinghu Street, Suzhou Industrial Park
Suzhou, Jiangsu Province, 215123
People's Republic of China
+86-512-8777-3632
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Adagene Inc.

By: /s/ Peter (Peizhi) Luo
Name: Peter (Peizhi) Luo
Title: Chief Executive Officer

Date: May 19, 2021

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release titled “Adagene Presents Clinical Data from NEObody™ Program, ADG106, Anti-CD137 Agonist, in an Abstract at ASCO 2021 Annual Meeting”

Exhibit 99.1

Adagene Presents Clinical Data from NEObody™ Program, ADG106, Anti-CD137 Agonist, in an Abstract at ASCO 2021 Annual Meeting

-Identified a predictive biomarker and two pharmacodynamic biomarkers that correlate with clinical efficacy and target engagement

-ADG106, a fully human, ligand-blocking, agonistic anti-CD137 antibody demonstrated a favorable safety profile

SAN FRANCISCO, Calif. and SUZHOU, China, May 19, 2021 – Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biopharmaceutical company committed to transforming the discovery and development of novel antibody-based immunotherapies, today announced clinical data from its ADG106 NEObody™ program. Results from Phase I, open-label, dose-escalation, single center (NCT03802955) and multicenter (NCT03707093) studies of ADG106 in subjects with advanced or metastatic solid tumors and/or relapsed/refractory non-Hodgkin lymphoma were presented in an abstract at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting. In these Phase I trials, ADG106 monotherapy exhibited a favorable safety profile and demonstrated promising clinical efficacy in biomarker positive patients. ADG106 is a fully human, ligand-blocking, agonistic anti-CD137 IgG4 antibody (mAb) engineered using Adagene's proprietary NEObody platform technology.

"We are very pleased with the original finding of a predictive biomarker for our anti-CD137 agonist and its association with tumor shrinkage," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "ADG106 has been well tolerated in dose escalation and extensive expansion cohorts at dosage of up to 5 mg/kg, which exceeds that of other anti-CD137 agonists. Further, this clinical data demonstrates the power of our proprietary NEObody platform designed to generate antibodies with novel mechanisms of action by targeting unique and highly conserved epitopes. We believe these results, together with analyses of PK and PD data from around 100 patient population, support the recommended dose regimen for ongoing clinical development of ADG106 as monotherapy and in combination with anti-PD-1 and other therapies. We look forward to multiple upcoming studies as we continue to advance our ADG106 clinical program."

"Predictive biomarkers for patient stratification are critical to advances in precision immuno-oncology. It's compelling to identify a predictive biomarker for anti-CD137 agonism that shows a strong correlation between ADG106 treatment and tumor shrinkage," said Hua Gong, M.D. Ph.D., Chief Operating Officer and Head of Precision Medicine of Adagene. "In an upcoming global Phase Ib/II trial (ADG106-2001), we plan to enrich for populations expressing our predictive biomarker in order to demonstrate a clinical benefit to ADG106 therapy. Our predictive biomarker has the potential to optimize favorable treatment options and enable oncologists to preselect cancer patients who are likely to benefit from ADG106 treatment. In our continuing commitment to the development of precision immunotherapies, Adagene has established a center of excellence for precision medicine in San Diego with cutting-edge technologies to support biomarker-guided clinical trials."

Interim data for the ongoing Phase 1 clinical trial includes:

- **Biomarker studies:** In a retrospective analysis, 75% of biomarker positive patients demonstrated more than 30% tumor shrinkage after ADG106 treatment.
    - Tumor shrinkage was not significant among biomarker negative patients. There was a strong negative correlation (100%) between biomarker absence and clinical response.
    - A tissue microarray study confirmed biomarker expression in a variety of tumor types suggesting a broad indication for ADG106 therapy.
- **Target engagement:** Target engagement upon ADG106 treatment was demonstrated with dose-dependent increases in NK cells in ADG106-mediated anti-tumor activities and in dose-dependent induction of soluble CD137 over baseline.

- **Safety and efficacy:** ADG106 demonstrated a disease control rate of 56% and exhibited a favorable safety profile at 3mg/kg and 5mg/kg with dose escalation up to 10mg/kg.

ADG106-1001 and ADG106-1002 Phase I trials have successfully completed enrollment of nearly 100 patients with advanced solid tumors and/or non-Hodgkin's lymphoma in the US and China, respectively. Limited TEAEs, i.e., liver toxicity or hematologic abnormalities, were observed. Following a productive end-of-phase I (EOP1) meeting about our ADG106 biomarker-stratified trial design with the FDA, Adagene made a new submission (ADG106-2001) to stratify patients using the predictive biomarker prior to treatment with ADG106 as monotherapy and its combination with anti-PD-1 therapy. In March 2021, Adagene initiated patient enrollment in China for ADG106-1008 (NCT04775680) a multicenter, open-label, Phase Ib/II study of ADG106 in combination with PD-1 antibody in advanced solid tumors and relapsed/refractory non-Hodgkin lymphoma. Preparations are underway for the ADG106-1003 trial in Australia to evaluate ADG106 in combination with other therapies in advanced solid tumors and hematological malignancies.

About Adagene

Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biopharmaceutical company committed to transforming the discovery and development of novel antibody-based cancer immunotherapies. Adagene combines computational biology and artificial intelligence to design novel antibodies that address unmet patient needs. Powered by its proprietary DPL platform, composed of NEObody^{TM}, SAFEbody^{TM}, and POWERbody^{TM} technologies, Adagene's highly differentiated pipeline features novel immunotherapy programs. Adagene has forged strategic collaborations with reputable global partners that leverage its technology in multiple approaches at the vanguard of science.

For more information, please visit: https://investor.adagene.com.

About ADG106

ADG106, is a fully human ligand-blocking, agonistic anti-CD137 Immunoglobulin G4, or IgG4, mAb, being developed for the treatment of advanced solid tumors and non-Hodgkin's lymphoma, or NHL. CD137 stimulates the immune system to attack cancer cells and is a key driver for long-lasting T-cell proliferation and survival. In preclinical studies, we observed that ADG106 had robust antitumor activity and was well tolerated as a single agent and in combination with the existing standard-of-care and other immuno-oncology therapies. ADG106 activates CD137 in a native ligand-like fashion, blocks reverse signaling of CD137 ligand, and has potent cross-linking via Fc receptor. Because of this novel mechanism of action, ADG106 was observed to favorably balance CD137-induced toxicity and CD137 agonism, which we believe has potential to address the limitations of other existing anti-CD137 therapies.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding data from the ADG106 Phase I clinical trial, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of ADG106. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to Adagene's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or regulatory approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of Adagene's drug candidates; Adagene's ability to achieve commercial success for its drug candidates, if approved; Adagene's ability to obtain and maintain protection of intellectual property for its technology and drugs; Adagene's reliance on third parties to conduct drug development, manufacturing and other services; Adagene's limited operating history and Adagene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; Adagene's ability to enter into additional collaboration agreements beyond its existing strategic partnerships or collaborations, and the impact of the COVID-19 pandemic on Adagene's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in Adagene's filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Adagene, and Adagene undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Investors Contact:
Raymond Tam
Adagene
86-512-8777-3626
ir@adagene.com

Bruce Mackle
LifeSci Advisors
646-889-1200
bmackle@lifesciadvisors.com

Media Contact:
Annie Starr
6 Degrees
973-768-2170
astarr@6degreespr.com