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 July 2021

Commission File Number: 001-39997

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

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Xinghu Street, Suzhou Industrial Park
Suzhou, Jiangsu Province, 215123
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+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: July 22, 2021

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release titled “Adagene Announces Clinical Trial Collaboration With Merck to Advance Two Anti-CTLA-4 Monoclonal Antibody Programs (ADG116 and ADG126) in Combination Therapy with KEYTRUDA® (pembrolizumab)”

Exhibit 99.1

Adagene Announces Clinical Trial Collaboration With Merck to Advance Two Anti-CTLA-4 Monoclonal Antibody Programs (ADG116 and ADG126) in Combination Therapy with KEYTRUDA® (pembrolizumab)

- Two global clinical studies to evaluate NEObody™ product candidate, ADG116, and SAFEbody™ product candidate, ADG126, in combination with KEYTRUDA® (pembrolizumab) for patients with advanced/metastatic solid tumors-

SAN FRANCISCO, Calif. July 22nd, 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 that it has entered into the clinical trial collaboration and supply agreement with Merck (known as "MSD" outside the United States and Canada), the leader among top immuno-oncology (IO) drugs on the market. The agreement includes two open-label, dose escalation and expansion clinical studies to evaluate Adagene's anti-CTLA-4 monoclonal antibody (mAb) product candidates, ADG116 and ADG126, in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), for patients with advanced/metastatic solid tumors.

"This collaboration with Merck and the advancement of our global clinical studies represent an important milestone in our comprehensive CTLA-4 clinical development program," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "Our AI driven platforms have generated two highly differentiated CTLA-4 targeting molecules, ADG116 and ADG126. ADG116, our NEObody™ CTLA-4 candidate, is designed with strong antibody-dependent cellular cytotoxicity (ADCC) and softened T cell activation which combined, leading to increased potency with an improved safety profile. Our SAFEbody™ candidate ADG126 effectively limits on-target off-tumor toxicities in normal tissues and is designed for a superior systemic safety profile at efficacious dose levels with a significantly enhanced therapeutic window to overcome existing issues associated with current anti-CTLA-4 therapies."

Dr. Luo continued, "Although we believe that ADG116 and ADG126 have great promise as single agents, combining with KEYTRUDA may unleash the potential of dual PD-1/CTLA-4 blockade, overcoming the safety profile limitations seen historically with this combination while also modulating different T cell populations to drive new immune functions and synergies not achievable through conventional monotherapies. Our extensive preclinical and early strong clinical data support this strategy, and we look forward to combining our anti-CTLA-4 therapeutics with anti-PD-1 checkpoint inhibitors such as KEYTRUDA to fulfill the potential of this combination therapy approach. We are fortunate to have the opportunity to explore this combination with Merck and tackle two of the most potent immunotherapy targets."

"We are extremely pleased to partner with Merck to explore the therapeutic potential of ADG116 and ADG126 in combination with KEYTRUDA, as this collaboration represents an important milestone for Adagene, and for patients with advanced/metastatic solid tumors," said Steven Fischkoff, M.D., interim Chief Medical Officer of Adagene. "ADG116 program is at the 3 mg/kg dose level now which is where the commercial CTLA-4 therapy had been approved previously in mono and combination for specific indications. We expect to see differentiation going forward of our programs."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About CTLA-4 Clinical Development Program

ADG 116-P001: The Phase 1, open-label, dose escalation and cohort expansion study of ADG116 combined with KEYTRUDA in patients with advanced/metastatic solid tumors will be conducted at multiple sites in Asia and the United States. The study will evaluate the safety, tolerability, and recommended Phase 2 dose for ADG116 in combination with KEYTRUDA with dose escalation planned for up to 10 mg/kg. The study builds on encouraging signs of pharmacodynamic (PD) markers, favorable pharmacokinetic (PK) profile, strong early clinical data of the ADG116-1003 trial, extensive preclinical and safety tolerability data and successful Safety Review Committee meetings. In the ADG116-1003 trial, ADG116 has been well tolerated in 17 patients, with no dose-limiting toxicities or unexpected safety signals. No drug related Grade 2, Grade 3 or Grade 4 toxicities have been observed. Dosing for three additional patients has been completed in the 3 mg/kg cohort, for a total of 17 patients treated to date.

ADG 126-P001: The Phase 1, open-label, dose escalation and cohort expansion study of ADG126 combined with KEYTRUDA in patients with advanced/metastatic solid tumors will be conducted at multiple sites in Asia and the United States. It will evaluate the safety, tolerability, and recommended Phase 2 dose for ADG126 in combination with KEYTRUDA with dose escalation planed for up to 10 mg/kg. The study builds on encouraging preclinical data, demonstrating ADG126 was well tolerated at doses up to 200 mg/kg, with an encouraging antitumor response in multiple immune-competent mouse tumor models in a dose-dependent manner both as a single agent and in combination with anti-PD-1 and other therapies. In the ADG126-1001 trial, dose limiting toxicity (DLT) evaluation has been completed in six patients in the 0.1 and 0.3 mg/kg cohorts.

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, SAFEbody, and POWERbody 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.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding the therapeutic potential of ADG116 and/or ADG126 in combination with pembrolizumab to treat patients with advanced/metastatic solid tumors, data from the ADG116 and/or ADG126 clinical trials, clinical development plans of ADG116 and/or ADG126, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated clinical development, regulatory milestones and commercialization of ADG126. 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 the potential failure of the combination of ADG116 and/or ADG126 and pembrolizumab to demonstrate safety and/or efficacy in the Phase 1 open-label, dose escalation and expansion studies; the clinical results for Adagene's 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.

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