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 December 2021

Commission File Number: 001-39997

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

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(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 o

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): o

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): o

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: December 14, 2021

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release titled “Adagene Presents Preclinical Data Showcasing Best-in-Class Profiles for ADG153, an Anti-CD47 SAFEbody® and ADG152, a CD20xCD3 Bispecific T-cell Engager POWERbody™”

Exhibit 99.1

Adagene Presents Preclinical Data Showcasing Best-in-Class Profiles for ADG153, an Anti-CD47 SAFEbody® and ADG152, a CD20xCD3 Bispecific T-cell Engager POWERbody™

- Posters presented at the 63rd American Society of Hematology Annual Meeting -

SAN DIEGO and SUZHOU, China, December 13, 2021 – Adagene Inc. ("Adagene") (Nasdaq: ADAG), a biopharmaceutical company committed to transforming the discovery and development of novel antibody-based immunotherapies, today announced preclinical data demonstrating the compelling differentiation of ADG153, an anti-CD47 monoclonal antibody (mAb), and ADG152, a CD20xCD3 bispecific T-cell engager (TCE). The data were presented in two poster presentations at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition taking place December 11-14, 2021, which are available in the Publications section of the company's website at www.adagene.com.

"Our novel anti-CD47 antibody and CD20xCD3 bispecific TCE programs successfully leverage SAFEbody technology for precision masking to decouple efficacy from the toxicities that are often associated with therapeutic modalities for these two important targets on the forefront of clinical development for hematologic malignancies," said Peter Luo, Ph.D., Co-founder, Chief Executive Officer and Chairman of Adagene. "Our preclinical evaluation shows the desirable target product profiles of these two transformative programs emerging from our deep, broad and differentiated pipeline. In particular, we are very excited about our highly differentiated anti-CD47 SAFEbody in IgG1 format, which introduces IgG1-mediated effects for potent tumor killing with a compelling safety profile and 8-fold prolonged half-life. Our first POWERbody CD20xCD3 bispecific TCE with precision masking on our tailor-made anti-CD3 arm is highly differentiated, engineered for potent and sustained tumor killing with more than 100-fold cytokine release control and 2-3-fold prolonged half-life in comparison with a benchmarked antibody in clinical development. Together, these two programs highlight the strength of our AI-powered antibody platform, paving the way for explosive growth of our pipeline."

ADG153 (Anti-CD47 SAFEbody)

Key findings from the poster (#3342) titled "ADG153, an Anti-CD-47 Monoclonal Antibody Prodrug, Has Strong *In Vivo* Anti-Tumor Activity, Minimal RBC-Related and Antigen Sink Liabilities, and Extended Half Life in Comparison with Benchmark Clinical Antibodies of the Same IgG Subclass" include:

- Given the dose-limiting hematologic toxicity and antigen sink liability associated with current anti-CD47 antibodies in clinical development, Adagene has developed an anti-CD47 SAFEbody with precision masking for preferential binding on CD47 overexpressed on tumor versus normal cells. To realize the full potential of anti-CD47 therapy for both hematologic and solid malignancies, the SAFEbody technology enables IgG1-mediated strong effector functions for potent tumor killing, while minimizing antigen sink and red blood cell (RBC) depletion with an approximately 8-fold prolonged half-life for convenient drug dosing and administration.

- An anti-CD47 ADG153-G4 SAFEbody was designed for benchmarking and evaluated in preclinical studies in comparison with its parental antibody, and analogs of magrolimab (Hu5F9) and lemzoparlimab (TJC4) in IgG4 format with the following findings:
    - ADG153-G4 parental antibody and its activated SAFEbody can block the CD47 signal by targeting a unique epitope of CD47 with high affinity and minimal RBC hemagglutination.

- In preclinical studies in monkeys, ADG153-G4 showed a significantly less decrease in RBCs and hemoglobin at the 10, 30 and 60 mg/kg dose levels compared to Hu5F9 at 10 mg/kg, addressing the hematologic toxicities inherent in current anti-CD47 therapies in development.
- ADG153-G4 SAFEbody also showed its 8-fold prolonged half-life by overcoming the antigen sink observed with other anti-CD47 therapies in development.
- Only antibody-dependent cellular phagocytosis (ADCP) effector function was detected for anti-CD47 antibodies in IgG4 isotype via CD47-mediated phagocytosis by macrophage.

· An anti-CD47 ADG153-G1 SAFEbody was designed to maximize tumor killing via IgG1-mediated effector functions unlike many other anti-CD47 therapies in development:
  - ADG153-G1 induced potent antibody-dependent cellular cytotoxicity (ADCC); as expected, none was observed for the IgG4 benchmark antibodies.
  - ADG153-G1 induced stronger ADCP activity than the IgG4 benchmark antibodies.

· Preclinical results concluded that the ADG153-G1 can achieve potent anti-CD47 efficacy with a well-tolerated safety profile, providing a strong rationale to advance this candidate into clinic. Currently, no other known anti-CD47 antibodies using the IgG1 isotype are in clinical development.
  - Notably, ADG153-G1 was well tolerated at 10 mg/kg, with only an 8 percent decrease in RBCs, compared to a 49 percent decrease with Hu5F9 in IgG4 format. For reference, it has been reported in the literature that another IgG1 anti-CD47 antibody can cause more than a 40 percent decrease in RBCs at 1 mg/kg.
  - After a single intravenous dose, ADG153-G1 demonstrated an approximately 8-fold longer apparent half-life and 5-fold higher area under the curve (AUC) at 10mg/kg than Hu5F9.

· Taken together, these preclinical findings suggest that the ADG153-G1 SAFEbody integrates safety (by precision masking) and efficacy (by IgG1-mediated ADCC and ADCP) into one single modality for a best-in-class product profile, presenting the exciting opportunity to maximize potential of anti-CD47 therapy - ultimately aimed for solid malignancies.

ADG152 (CD20xCD3 POWERbody)

Key findings from the poster (#1204) titled “ADG152, a Novel CD20xCD3 T-Cell Engager Prodrug with Enhanced Therapeutic Index, Demonstrates Strong Anti-Tumor Activity with Improved Safety” include:

· ADG152 is a bispecific CD20xCD3 T-cell engager POWERbody that integrates SAFEbody precision masking technology to minimize cytokine release syndrome (CRS) and on-target/off-tumor toxicities for an increased therapeutic index.

  - The anti-CD20 arm of ADG152 has enhanced the binding to CD20, while its anti-CD3 arm has tailor made affinity for CD3 using SAFEbody technology.

· At a 100-fold higher dose, ADG152 at 30 mg/kg resulted in significantly less cytokine induction (as measured by IFN-γ and IL-2 levels) than an analog of plamotamab at 0.3 mg/kg.

· In preclinical models, ADG152 resulted in dose-dependent anti-tumor activity with almost complete tumor growth inhibition when dosed at 1.5 mg/kg.

- ADG152 induced strong and sustained B-cell depletion across different dose levels.

- ADG152 also demonstrated improved pharmacokinetics in monkeys versus the plamotamab analog, with approximately a 2-fold longer half-life (7-13 days at 0.3 - 30mg/kg) and approximately an 8-fold higher AUC after a single intravenous injection.

“CRS has been a longstanding challenge of T-cell engagers and has limited the ability to safely provide high levels of activity during initial dosing,” said Stanley Frankel, M.D., a clinical advisor who contributed to development and approval of blinatumomab (Blincyto®) while working at Micromet and Amgen. “I am encouraged that the preclinical profile of ADG152 offers potential to provide a way to simplify treatment by avoiding step dosing and pretreatment with steroids, while also enhancing efficacy of this POWERbody to engage T-cells to attack tumor targets.”

Both ADG153 and ADG152 are potential Investigational New Drug candidates from Adagene’s growing portfolio of preclinical discovery programs, five of which are in IND-enabling studies. The preclinical data presented at ASH provide a strong rationale for advancing these potentially best-in-class candidates into clinical development.

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 Dynamic Precision Library (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.

SAFEbody® is a registered trademark in the United States, China, Australia, Japan, Singapore, and the European Union.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding the potential implications of preclinical results, and Adagene’s advancement of, and anticipated clinical activities, clinical development and regulatory milestones of its product candidates. 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.

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