
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 January 2022

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):

Explanatory Note

Senior management of Adagene Inc. (the “Company”) plan to present the information in the presentation slides attached hereto as Exhibit 99.1 at various investor and analyst meetings scheduled during the week of January 12, 2021 and from time to time.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the presentation is summary information that is intended to be considered in the context of more complete information included in the Company’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that the Company has made and may make from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC or through other public disclosures.

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: January 12, 2022

EXHIBIT INDEX

Exhibit

Description

[99.1](#)

[Company Presentation](#)



Company Overview

January 2022

ADAGENE

Disclaimer and Cautionary Note on Forward-Looking Statements

The following presentation has been prepared by Adagene Inc. ("Adagene" or the "Company") solely for informational purposes and should not be construed to be, directly or indirectly, in whole or in part, an offer to buy or sell and/or an invitation and/or a recommendation and/or a solicitation of an offer to buy or sell any security or instrument or to participate in any investment or trading strategy, nor shall any part of it form the basis of, or be relied on in connection with, any contract or investment decision in relation to any securities or otherwise. This presentation does not contain all relevant information relating to the Company or its securities, particularly with respect to the risks and special considerations involved with an investment in the securities of the Company. Nothing contained in this document shall be relied upon as a promise or representation as to the past or future performance of the Company. Past performance does not guarantee or predict future performance. You acknowledge that any assessment of the Company that may be made by you will be independent of this document and that you will be solely responsible for your own assessment of the market and the market position of the Company and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of the business of the Company.

This document contains certain statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, with respect to the Company's future financial or business performance, anticipated clinical activities and development, strategies or expectations. These statements typically contain words such as "believe," "may," "will," "could," "expects" and "anticipates" and words of similar import. Any statement in this document that is not a statement of historical fact is a forward-looking statement and involves known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by such forward-looking statements. Such forward-looking statements including statements regarding the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated clinical activities, clinical development, regulatory milestones, and commercialization 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. There can be no assurance that the results and events contemplated by the forward-looking statements contained herein will in fact occur. None of the future projections, expectations, estimates or prospects in this document should be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such future projections, expectations, estimates or prospects have been prepared are correct or exhaustive or, in the case of assumptions, fully stated in the document. The Company also cautions that forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time and which may be beyond the Company's control.

This presentation concerns product candidates that are or have been under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration, European Medicines Agency, The China National Medical Products Administration, or other foreign regulatory authorities. These product candidates are currently limited by U.S. Federal law to investigational use, and no representations are made as to their safety or effectiveness for the purposes for which they are being investigated.

This document speaks as of January 12, 2022. Neither the delivery of this document nor any further discussions of the Company with any of the recipients shall, under any circumstances, create any implication that there has been no change in the affairs of the Company since that date. 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.

We are leveraging our AI-powered Dynamic Precision Library (DPL) to bring highly differentiated antibody-based drugs to cancer patients worldwide

Our Story: AI-Powered Adaptation Rooted in Science

Ada

- Ada Lovelace is the mathematician who invented the first computational algorithm



Gene

- Gene inherited through millions of years of evolution for survival

✓ **Adaptation** by AI-Powered Directed Evolution for Prosperity

to engage dynamically between antibody and antigen

to target the conserved epitope of a target across different species

to enable seamless animal to human studies for accelerated development

Highlights

AI Powered DPL Platform

Three-Body Technologies
NEObody, SAFEbody, POWERbody

NEObody™

ADG106, ADG116

SAFEbody®

ADG126, anti-CD47 (IgG1)
in IND-enabling



Leadership

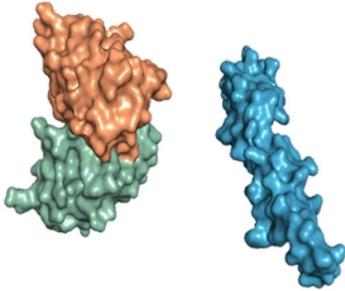
Partnerships

POWERbody™

4 in IND-enabling, including a
CD20xCD3 bispecific T-Cell Engager
(TCE) and a solid tumor target xCD3

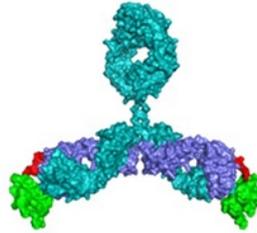
Disruptive Technologies For Tailor-Made Antibody Therapeutics

NEObody™



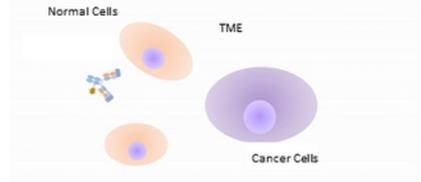
Adaptive Binding between
CD137 and ADG106

SAFEbody®



Precision Masking for
Antibody Safety

POWERbody™



Empowered SAFEbody in
different modalities

A Robust, Transformative Pipeline of Wholly-Owned Assets*

Program & Technology	Target	Development stage					Rights
		Discovery	IND Enabling	Ph 1	Ph 2	Pivotal	
ADG106 NEO	CD137						Global
ADG116 NEO	CTLA-4						Global
ADG126 SAFE	CTLA-4						Global
ADG152 POWER	CD20xCD3						Global
ADG153 SAFE	CD47						Global
3 Undisclosed POWER	Various						Global
>50 Undisclosed	Various						Global

* Two additional candidates derived from Adagene's AI-powered antibody platform are in development by other entities. These include ADG104, an anti-PD-L1 antibody in phase 2 development by Sanjin, and ADG125, an antibody targeting CSF-1R in phase 1 development by Dragon Boat BioPharmaceutical.

2021 Progress

- ✓ Advanced two anti-CTLA-4 programs (ADG116/126) through monotherapy dose escalation and started cohort expansion across multiple regions and countries
- ✓ Demonstrated early signs of efficacy with anti-CTLA-4 NEObody™ (ADG116) and SAFEbody® (ADG126) in treatment-resistant tumors
- ✓ Advanced anti-CD137 (ADG106) program in combination with anti-PD-1 therapy in China, and initiated investigator collaboration in Singapore with nivolumab for advanced NSCLC with exploratory biomarker studies in response to ADG106 combination treatment
- ✓ Finalized clinical agreements and protocols with Merck to conduct combination trials with anti-PD-1, pembrolizumab
- ✓ Presented preclinical data on two highly differentiated new transformative programs: CD20XCD3 (ADG152) and anti-CD47 (ADG153-IgG1)
- ✓ Advanced SAFEbody candidates in Exelixis collaboration, triggering \$3M milestone payment
- ✓ Second partnered program (ADG125) advanced into clinic by Dragon Boat Biopharmaceutical



2022 Expected Milestones & Outlook

- Demonstrate single-agent activity for anti-CTLA-4 programs (ADG116/126) in warm and cold tumors in heavily pre-treated patients
- Demonstrate safety and preliminary efficacy for anti-CTLA-4 programs with anti-PD-1 therapy
- Establish safety profile for novel combination of wholly-owned anti-CTLA-4 and anti-CD137 (ADG106)
- Show synergistic effect of anti-CD137 with anti-PD-1 therapy in biomarker-enriched tumors
- Submit filings to advance two or more candidates to clinic, and expand programs into IND-enabling phase
- Continue efficient discovery operations, with >50 projects underway
- Complete a potential major collaboration

5
Clinical
Programs
(2 partnered)

5
Programs in
IND-enabling
studies

>50
Programs in
Discovery

Three Wholly-Owned, Tailor-Made Antibodies in Clinic

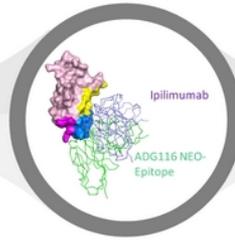
ADG106: CD137



NEObody™

- Unique epitope binding aims to balance safety and efficacy
- >100 patients enrolled for Ph1 mono and Ph1b/2 combo with toripalimab
- Two additional Ph1b/2 combos with nivolumab and pembrolizumab
- Novel combo with ADG116/126

ADG116: CTLA-4



NEObody™

- Unique epitope triggers a softer ligand blocking and stronger regulatory T-cell depletion
- ~31 patients in Ph1 dose escalation; dosing at 10 mg/kg complete
- Cohort expansion increased to 10 mg/kg
- Ph1b/2 combos with toripalimab and pembrolizumab

ADG126: CTLA-4

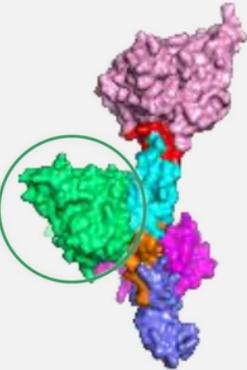


SAFEbody®

- Adds mask to epitope binding site, further enhancing safety
- ~18 patients in Ph1 dose escalation; dosing at 10 mg/kg complete
- Cohort expansion at 10 mg/kg
- Ph1b/2 combos with toripalimab and pembrolizumab

ADG106: Anti-CD137 NEObody Program

Targeting a unique epitope of CD137/4-1BB pathway validated by CAR-T



ADG106 (Adagene)

Anti-CD137 mAb A

Anti-CD137 mAb B

Competitor A:
Inflammatory liver toxicity, despite initial signs of efficacy



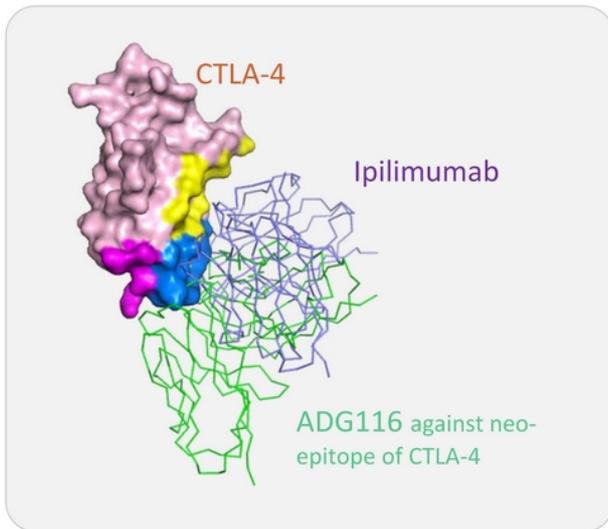
Competitor B:
Improved safety profile, but less potent

- ✓ Well-tolerated with cohort expansion at 3 & 5mg/kg and at 300mg and 400mg flat doses in US and China
- ✓ Single agent clinical efficacy with 56% disease control rate (45 of 81 patients evaluated), including PR for a solid tumor patient R/R to PD-L1 therapy
- ✓ Proprietary biomarker identified with tumor shrinkage in 75% of biomarker positive patients
- ✓ Dose-dependent PD biomarkers: T and NK cells, sCD137
- ✓ Combination trials with anti-PD-1 ramping up targeting biomarker-enriched indications
- ✓ PD biomarker analyses of ongoing clinical trial with toripalimab showed a 2-fold greater immune activation than ADG106 alone*

* Data presented at ESMO-IO 2021 and summarized in press release issued December 6, 2021

ADG116: Anti-CTLA-4 NEObody Program

Targeting a unique epitope of CTLA-4 to overcome longstanding toxicity challenges



- ✓ ADG116 targets a unique epitope with broad species cross-reactivity
- ✓ Novel MOA:
 - ✓ Potent Treg depletion via strong ADCC
 - ✓ Safer T-cell activation via softer blocking
- ✓ 5x more potent than commercially-approved CTLA-4 in head-to-head preclinical comparison and better safety with HNSTD of 30 mg/kg in monkey GLP Tox
- ✓ Phase 1b/2 data show strong single agent safety profile and early signs of efficacy in treatment resistant tumors such as ovarian and pancreatic*

* Data presented on 25 patients at ESMO-IO 2021 and summarized in press release issued December 6, 2021

Building a Deep, Broad and Differentiated Pipeline, with 5 Candidates in IND-Enabling Studies and >50 in Discovery

- >50 programs across stages of discovery
- 5 POWERbody and SAFEbody programs in IND-enabling studies, including two presented at ASH 2021
- All 5 IND-enabling programs have a robust CMC profile with encouraging preclinical safety and efficacy data
- On track to submit more than 10 INDs or equivalent applications in the next three to five years

Multiple Antibody-based Modalities for Tailor Made Therapeutics



Novel
Monoclonal



Bispecific T-cell
engagers



Fc Empowered
SAFEbody



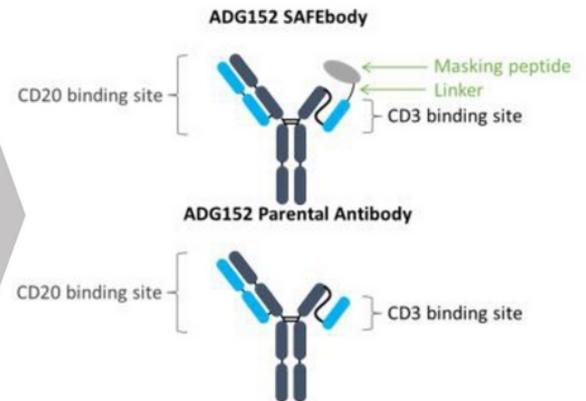
Anti-CD47 (IgG1)
SAFEbody



SAFEbody Antibody
Drug Conjugates

ADG152: Anti-CD20xCD3 is First Bispecific T-cell engager from POWERbody™ Platform

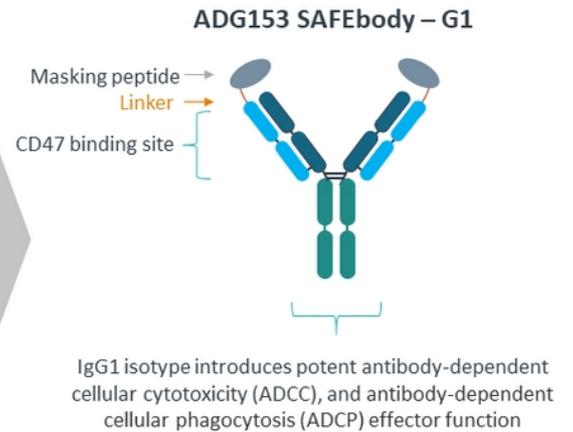
- Integrates SAFEbody precision masking technology to **minimize cytokine release syndrome** (CRS) and on-target/off-tumor toxicities for an **increased therapeutic index** (~10-fold higher)
- Enhanced binding to CD20; anti-CD3 arm has tailor-made affinity for CD3 with SAFEbody technology
- ✓ **Potency:** Antitumor activity as a single agent in the mouse xenograft tumor model
- ✓ **Safety:** ~100-fold less CRS than a plamotamab analog in monkeys
- ✓ **PK:** Improved half-life and area under the curve than a plamotamab analog in monkeys



* Data presented at ASH 2021 and summarized in press release issued December 13, 2021

ADG153: A Highly Differentiated IgG1 Anti-CD47 SAFEbody®

- Anti-CD47 antibody with **IgG1-mediated** strong effector functions for potent tumor killing, while **minimizing antigen sink and red blood cell (RBC) depletion**
- Integrates safety and efficacy into one single modality
- ✓ **Potency:** Maximize tumor killing via **IgG1-mediated** ADCC and ADCP unlike other anti-CD47 antibodies in clinic
- ✓ **Safety:** Reduced RBC-related and antigen sink liabilities
 - ✓ Well-tolerated at 10 mg/kg, with an 8% decrease in RBCs, versus a 49% decrease for Hu5F9 analog in IgG4
- ✓ **PK:** ~8-fold prolonged half-life for convenient dosing and administration



* Data presented at ASH 2021 and summarized in press release issued December 13, 2021

Global Partnerships and Collaborations Validate Our Platform

Clinical Collaborations

- Three Ph 1b/2 trials with pembrolizumab 
- Ph 1b/2 trial of ADG106 and nivolumab in advanced NSCLC in Singapore   

SAFEbody ADC Development

- \$11M upfront, up to \$780M in milestones, plus royalties; \$3M milestone achieved* 
- Licensing fee, up to \$166M milestones, plus royalties and certain right to Greater China 
- Development of an ADC against a solid tumor target 

DPL Discovery

- Antibodies targeting HERV associated with RCC 
- Generate antibodies targeting novel antigens  
- Antibodies against multi-transmembrane targets 

Validation by Other Entities

- Two programs: an anti-PD-L1 (ADG104), and a novel anti-CSF-1R (ADG125 / BC006) 
- Discovered cross-reactive agonistic antibody for IO 

* Successful nomination of SAFEbody candidates announced December 2021

Financial Summary

	As of June 30, 2021	As of December 31, 2021
Cash and cash equivalents (unaudited)	US\$208 million	Approximately US\$174 million

ADAGENE

Thank you