Adagene Reports Six Months 2025 Financial Results and Provides Corporate Updates

August 12, 2025

Muzastotug (ADG126) Phase 1b/2 in MSS CRC shows 19.4-month median OS (mOS) in 10 mg/kg dose cohorts; mOS for 20 mg/kg cohorts has not yet been reached

Alignment with FDA on Phase 2 and Phase 3 trial design elements. Company expects to begin enrolling patients in Phase 2 in 2H 2025

SAFEbody option exercised and up to US$25 million strategic investment by Sanofi, with cash runway extended into 2027

Sanofi will conduct a Phase 1b/2 trial in combination with ADG126 in over 100 patients

Strengthened leadership team with key additions

Partnered with ConjugateBio for development of bispecific ADCs

SAN DIEGO and SUZHOU, China, Aug. 12, 2025 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene" or the "Company") (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel antibody-based therapies, today reported financial results for the six months ended June 30, 2025, and provided corporate updates.

"The first half of 2025 was tremendously important for Adagene, as we shared the early overall survival benefit with ADG126 in combination with Merck's (known as MSD outside of the US and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) that exceeds standard of care and is highly competitive with data from other products in development. The safety and tolerability data from ADG126 in combination with pembrolizumab in our Phase 1b/2 study in microsatellite stable colorectal cancer contributes to a large body of growing evidence that the power of CTLA-4 inhibition can be harnessed more safely with our approach utilizing conditional activation in the tumor microenvironment. Grade 3 treatment-related adverse events were less than 20%, which is an outstanding achievement given that ADG126 was dosed 10 to 20 times higher than the approved CTLA-4 inhibitors, in order to drive dose-dependent depletion of regulatory T-cells at the desired level inside tumors," said Peter Luo, Ph.D., Chairman, CEO and President of R&D at Adagene. "Now that we have aligned with the FDA on Phase 2 and Phase 3 design elements, which do not require an ADG126 monotherapy arm, we have a clear line of sight into what will be required for regulatory approval. We look forward to initiating the Phase 2 study later this year."

PIPELINE HIGHLIGHTS

ADG126 - Phase 1b/2 data and regulatory update:

As presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting (Poster #248), mOS for the 10 mg/kg cohorts was 19.4 months in microsatellite stable colorectal cancer (MSS CRC) patients free of liver metastasis (NLM), comparing favorably with historical fruquintinib benchmarks of 10.8 months from the FRESCO[i] study and 12.1 months from the FRESCO-2[ii] study for the same NLM patient population. Only 1 out of 41 patients in the 10 mg/kg cohorts was censored due to early withdrawal within the first 12 months. Median OS for the 20 mg/kg cohorts has not yet been reached. ADG126 showed a 29% confirmed overall response rate (ORR) in MSS CRC. ADG126 can be dosed at 20 mg/kg Q6W in combination with KEYTRUDA® (200 mg, Q3W) with less than 20% Grade 3 adverse events having been observed. All six responders in the 20 mg/kg cohorts remain on treatment, with four patients on study for over one year.

As recently reported, Adagene has now gained alignment with the FDA on Phase 2 and Phase 3 trial design elements for ADG126, and the Company plans to begin enrollment in 2H 2025. In addition, Adagene has initiated evaluation of ADG126 plus pembrolizumab in combination with standard of care in MSS CRC patients, as approved by the Merck/Adagene joint development committee and supported by the 2021 supply agreement between the two partners.

MAJOR COLLABORATIONS

Sanofi: In July, Sanofi agreed to make a strategic investment of up to US$25 million in Adagene. The Company plans to use the proceeds to fund its research and development activities, including clinical development of ADG126, through a randomized Phase 2 trial in MSS CRC. To further explore the clinical potential of ADG126, Adagene will supply Sanofi with ADG126 to evaluate the safety, efficacy, pharmacokinetics and biomarker data in combination with other anticancer therapies in over 100 patients in a Phase 1b/2 clinical trial in advanced solid tumors. Adagene continues to own worldwide commercial rights to ADG126.

Sanofi has also exercised its option to select a third SAFEbody discovery program, utilizing Adagene's proprietary masking technology and antibody engineering expertise. The bispecific therapeutic, with undisclosed targets, will be engineered by Adagene and induces an option exercise fee, as well as milestones and royalties as per the 2022 partnership agreement.

Exelixis: Including upfront and other milestone payments, Adagene has received over US$18 million in total from Exelixis to date, under a technology license agreement to develop novel masked antibody-drug conjugate candidates.

ConjugateBio: In July 2025, Adagene entered into a partnering agreement with ConjugateBio to develop novel antibody drug conjugates. Adagene will provide ConjugateBio with a proprietary antibody for use in partner companies' bispecific ADC development programs.

CORPORATE UPDATES

In April, Adagene appointed John Maraganore, Ph.D. as Executive Advisor to provide strategic guidance, and to contribute to Adagene's growth, value

creation and benefit for patients.

In May, Mickael Chane-Du joined Adagene as Chief Strategy Officer to promote and advance Adagene's financing, internal strategic planning and external business development efforts.

FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents:
Cash and cash equivalents were US$62.8 million as of June 30, 2025, compared to US$85.2 million as of December 31, 2024. Total borrowings from commercial banks in China (denominated in RMB) decreased to US$6.6 million as of June 30, 2025 from US$18.2 million as of December 31, 2024. Further, the cash balance as of June 30, 2025 does not include any equity proceed received from Sanofi in July 2025.

Research and Development (R&D) Expenses:
R&D expenses were US$12.0 million for the six months ended June 30, 2025, compared to US$14.7 million for the same period in 2024. The decrease of approximately 18% in R&D expenses reflects clinical focus on and prioritization of the company's masked, anti-CTLA-4 SAFEbody ADG126.

Administrative Expenses:
Administrative expenses were US$3.7 million for the six months ended June 30, 2025, compared to US$3.6 million for the same period in 2024.

Net Loss:
Net loss attributable to Adagene Inc.'s shareholders was US$13.5 million for the six months ended June 30, 2025, compared to US$17.0 million for the same period in 2024.

Ordinary Shares Outstanding:
As of June 30, 2025, there were 58,914,087 ordinary shares issued and outstanding. Each American depository share, or ADS, represents one and one quarter (1.25) ordinary shares of the company.

Non-GAAP Net Loss:
Non-GAAP net loss, which is defined as net loss attributable to ordinary shareholders for the period after excluding share-based compensation expenses, was US$11.4 million for the six months ended June 30, 2025, compared to US$14.5 million for the same period in 2024. Please refer to the section in this press release titled "Reconciliation of GAAP and Non-GAAP Results" for details.

Non-GAAP Financial Measures:

The company uses non-GAAP net loss and non-GAAP net loss per ordinary share for the period, which are non-GAAP financial measures, in evaluating its operating results and for financial and operational decision-making purposes. The company believes that non-GAAP net loss and non-GAAP net loss per ordinary share for the period help identify underlying trends in the company's business that could otherwise be distorted by the effect of certain expenses that the company includes in its loss for the period. The company believes that non-GAAP net loss and non-GAAP net loss per ordinary share for the period provide useful information about its results of operations, enhances the overall understanding of its past performance and future prospects and allows for greater visibility with respect to key metrics used by its management in its financial and operational decision-making.

Non-GAAP net loss and non-GAAP net loss per ordinary share for the period should not be considered in isolation or construed as an alternative to operating profit, loss for the period or any other measure of performance or as an indicator of its operating performance. Investors are encouraged to review non-GAAP net loss and non-GAAP net loss per ordinary share for the period and the reconciliation to their most directly comparable GAAP measures. Non-GAAP net loss and non-GAAP net loss per ordinary share for the period here may not be comparable to similarly titled measures presented by other companies. Other companies may calculate similarly titled measures differently, limiting their usefulness as comparative measures to the company's data. The company encourages investors and others to review its financial information in its entirety and not rely on a single financial measure. Non-GAAP net loss and non-GAAP net loss per ordinary share for the period represent net loss attributable to ordinary shareholders for the period excluding share-based compensation expenses. Share-based compensation expense is a non-cash expense arising from the grant of stock-based awards to employees. The company believes that the exclusion of share-based compensation expenses from the net loss in the "Reconciliation of GAAP and Non-GAAP Results" assists management and investors in making meaningful period-to-period comparisons in the company's operating performance or peer group comparisons because (i) the amount of share-based compensation expenses in any specific period may not directly correlate to the company's underlying performance, (ii) such expenses can vary significantly between periods as a result of the timing of grants of new stock-based awards, and (iii) other companies may use different forms of employee compensation or different valuation methodologies for their share-based compensation. Please see the "Reconciliation of GAAP and Non-GAAP Results" included in this press release for a full reconciliation of non-GAAP net loss and non-GAAP net loss per ordinary share for the period to net loss attributable to ordinary shareholders for the period.

About Adagene

Adagene Inc. (Nasdaq: ADAG) is a platform-driven, clinical-stage biotechnology 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 globally unmet patient needs. The company has forged strategic collaborations with reputable global partners that leverage its SAFEbody® precision masking technology in multiple approaches at the vanguard of science.

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. The company's SAFEbody technology is designed to address safety and tolerability challenges associated with many antibody therapeutics by using precision masking technology to shield the binding domain of the biologic therapy. Through activation in the tumor microenvironment, this allows for tumor-specific targeting of antibodies in tumor microenvironment, while minimizing on-target off-tumor toxicity in healthy tissues.

Adagene's lead clinical program, ADG126 (muzastotug), is a masked, anti-CTLA-4 SAFEbody that targets a unique epitope of CTLA-4 in regulatory T cells (Tregs) in the tumor microenvironment. ADG126 is currently in phase 1b/2 clinical studies in combination with anti-PD-1 therapy, particularly

focused on Metastatic Microsatellite-stable (MSS) Colorectal Cancer (CRC). Validated by ongoing clinical research, the SAFEbody platform can be applied to a wide variety of antibody-based therapeutic modalities, including Fc empowered antibodies, antibody-drug conjugates, and bi/multispecific T-cell engagers.

For more information, please visit: https://investor.adagene.com.
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SAFEbody® is a registered trademark in the United States, China, Australia, Japan, Singapore, and the European Union.

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

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding certain clinical results of ADG126, the potential implications of clinical data for patients, and Adagene's advancement of, and anticipated preclinical 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. 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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[i] FRESCO: Li J.et al. JAMA. 2018;319(24):2486–2496
[ii] FRESCO-2: Garcia-Carbonero, R. et al. Annals of Oncology, 2024; Volume 35, S439

Unaudited Consolidated Balance Sheets

	December 31, 2024	June 30, 2025
	US$	US$
ASSETS		
Current assets:		
Cash and cash equivalents	85,194,502	62,828,156
Amounts due from related parties	8,309	2,449
Prepayments and other current assets	2,575,194	2,532,759
Total current assets	**87,778,005**	**65,363,364**
Property, equipment and software, net	1,125,389	901,383
Operating lease right-of-use assets	283,645	214,556
Other non-current assets	81,386	37,440
TOTAL ASSETS	**89,268,425**	**66,516,743**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	4,241,773	3,626,223
Amounts due to related parties	13,187,966	14,448,405
Accruals and other current liabilities	2,816,038	3,676,273
Income tax payable	5,265	4,121
Short-term borrowings	4,868,956	2,095,382
Current portion of long-term borrowings	12,923,599	4,539,994
Current portion of operating lease liabilities	141,341	125,851
Total current liabilities	**38,184,938**	**28,516,249**
Long-term borrowings	417,339	—

Operating lease liabilities	142,304	88,705
TOTAL LIABILITIES	**38,744,581**	**28,604,954**
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares (par value of US$0.0001 per share; 640,000,000 shares authorized, and 58,886,944 shares issued and outstanding as of December 31, 2024; and 640,000,000 shares authorized, and 58,914,087 shares issued and outstanding as of June 30, 2025)	5,889	5,891
Additional paid-in capital	362,220,445	364,254,280
Accumulated other comprehensive loss	(526,903)	(1,695,555)
Accumulated deficit	(311,175,587)	(324,652,827)
Total shareholders' equity	**50,523,844**	**37,911,789**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**89,268,425**	**66,516,743**

Unaudited Consolidated Statements of Comprehensive Loss

	For the Six Months Ended June 30, 2024	For the Six Months Ended June 30, 2025
	US$	US$
Revenues		
Licensing and collaboration revenue	—	—
Operating expenses and income		
Research and development expenses	(14,724,553)	(12,015,184)
Administrative expenses	(3,597,278)	(3,673,073)
Loss from operations	**(18,321,831)**	**(15,688,257)**
Interest and investment income	1,976,559	1,214,108
Interest expense	(428,328)	(318,422)
Other income, net	47,040	63,436
Foreign exchange gain (loss), net	(283,768)	1,252,353
Loss before income tax	**(17,010,328)**	**(13,476,782)**
Income tax expense	(1,388)	(458)
Net loss attributable to Adagene Inc.'s shareholders	**(17,011,716)**	**(13,477,240)**
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	500,285	(1,168,652)
Total comprehensive loss attributable to Adagene Inc.'s shareholders	**(16,511,431)**	**(14,645,892)**
Net loss attributable to Adagene Inc.'s shareholders	**(17,011,716)**	**(13,477,240)**
Net loss attributable to ordinary shareholders	**(17,011,716)**	**(13,477,240)**
Weighted average number of ordinary shares used in per share calculation:		
—Basic	55,213,051	58,891,864
—Diluted	55,213,051	58,891,864
Net loss per ordinary share		
—Basic	(0.31)	(0.23)
—Diluted	(0.31)	(0.23)

Reconciliation of GAAP and Non-GAAP Results

	For the Six Months Ended June 30, 2024	For the Six Months Ended June 30, 2025
	US$	US$
GAAP net loss attributable to ordinary shareholders	**(17,011,716)**	**(13,477,240)**
Add back:		
Share-based compensation expenses	2,477,108	2,030,335
Non-GAAP net loss	**(14,534,608)**	**(11,446,905)**
Weighted average number of ordinary shares used in per share calculation:		
—Basic	55,213,051	58,891,864
—Diluted	55,213,051	58,891,864

Non-GAAP net loss per ordinary share		
—Basic	(0.26)	(0.19)
—Diluted	(0.26)	(0.19)

Source: Adagene Inc.