



Adagene Reports Full Year 2025 Financial Results and Provides Corporate Update

April 1, 2026

In 2025, muzastotug showed 29% confirmed overall response rate (ORR) among 21 patients with MSS CRC in the 20 mg/kg dose cohorts

Median overall survival (OS) for the 10 mg/kg cohorts was 19.4 months, with a median follow-up of 17.8 months

4% overall discontinuation rate, no dose limiting toxicities, and no Grade 4 or 5 treatment-related adverse events (TRAEs) across 67 patients in all dose cohorts supports improved tolerability profile of muzastotug

Randomized Phase 2 trial enrollment ahead of plan, with potential updates in 2026 and results expected in 1H 2027; registration trial expected to begin once optimal dose regimen has been established

Cash and cash equivalents of \$74.5 million as of December 31, 2025, plus proceeds raised from the ATM Offering in 2026 year-to-date, anticipated to provide cash runway into early 2028

SAN DIEGO, Calif. and SUZHOU, China, April 01, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (Nasdaq: ADAG), a platform-driven, clinical-stage biotechnology company transforming the discovery and development of novel anti-body-based therapies, today reported financial results for the full year 2025 and provided corporate updates.

"Our clinical data for muzastotug plus pembrolizumab consistently demonstrate potent, dose-dependent efficacy," said Peter Luo, Ph.D., Chairman and President of R&D at Adagene. "The 10 mg/kg data reported at ASCO have now matured into the classic long survival tail of CTLA-4 inhibition. By significantly mitigating severe toxicities, patients remain on therapy longer, allowing CTLA-4-mediated intratumoral Treg depletion, alongside PD-1-mediated reinvigoration and CTLA-4-mediated priming of effector T cells, to drive durable disease control. Importantly, these data provide a clear, de-risked read-through to the 20 mg/kg dose, which already shows an encouraging 29% ORR with median duration of response not yet reached.

"Supported by Fast Track Designation and FDA alignment under Project Optimus, we are on track to finalize the optimal combination dose regimen for a potential MSS colorectal cancer registrational trial. The expanded therapeutic window also helps to establish muzastotug as a foundational combination backbone. At AACR, we will showcase this potential with data from triplet regimens—combining with fruquintinib in 3L+ MSS CRC, alongside results from the Morpheus Liver study evaluating a triplet of muzastotug, atezolizumab, and bevacizumab versus atezolizumab and bevacizumab alone in first-line HCC. These readouts underscore our ability to safely unlock deeper responses in hard-to-treat tumors."

2026 OBJECTIVES & CASH RUNWAY INTO EARLY 2028

- Data update from the ongoing Phase 1b/2 study of muzastotug in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in 3L+ MSS CRC, including 41 patients in the 10 mg/kg cohorts and 26 patients in the 20 mg/kg cohorts
- Complete enrollment of the ongoing randomized Phase 2 dose-optimization study with muzastotug, which is being conducted in alignment with FDA Project Optimus, and designed to allow dose regimen selection for Phase 3.
- Provide preliminary clinical data, including pathological responses, to inform future development from investigator-initiated Phase 2 trial for neoadjuvant muzastotug + pembrolizumab in colorectal cancer.
- Provide initial clinical data from a new cohort of patients in the ongoing Phase 1b/2 study of muzastotug + pembrolizumab in combination with standard of care (fruquintinib) in MSS CRC patients.
- Share results of the clinical trial collaboration with Roche, which evaluates muzastotug in triplet combination with atezolizumab and bevacizumab in first-line treatment of locally advanced or metastatic hepatocellular carcinoma (HCC; liver cancer).
- Establish additional collaboration/licensing agreements.

With cash and cash equivalents of \$74.5 million as of December 31, 2025, plus proceeds raised from the ATM Offering in 2026 year-to-date, Company expects a cash runway extending into early 2028.

PIPELINE HIGHLIGHTS

ADG126- Phase 1b/2 data:

- As presented at ASCO 2025, muzastotug showed 29% (6/21) confirmed overall response rate (ORR) in the combined 20 mg/kg dose cohorts.
- Among 41 patients in the combined 10mg/kg dose cohorts, median overall survival (mOS) was 19.4 months with a 17.8-month median follow-up, which compares favorably to 11-12 month mOS from fruquintinib Phase 3 trials in the same population¹
- Across 67 patients in all cohorts, a low 4% overall discontinuation rate, no dose limiting toxicities, and no Grade 4 or 5 treatment-related adverse events (TRAEs); Grade 3 TRAEs were 15% in the 10 mg/kg cohorts and 27% in the 20 mg/kg

cohorts, which were generally transient and manageable.

- Updated data demonstrate the durability of response and further support the optimized therapeutic index profile of muzastotug, which overcomes well-known dose-limiting toxicities of other CTLA-4 inhibitors at 10-20-fold higher doses², to provide potentially improved efficacy.
- Randomized Phase 2 trial enrollment ongoing, with results expected in 1H 2027; registration trial expected to begin once optimal dose regimen has been established

AMERICAN ASSOCIATION FOR CANCER RESEARCH 2026 PRESENTATIONS

The following abstracts have been selected for presentation at AACR 2026:

- 1) Title: Ph1b evaluation of ADG126 (muzastotug, an anti-CTLA-4 masking antibody) pembrolizumab (Pembro) IO doublet in combination with fruquintinib (Fruq) in advanced and metastatic microsatellite stable colorectal cancer

This poster will provide initial clinical data from a new cohort of patients in the ongoing Phase 1b/2 study of muzastotug + pembrolizumab in combination with standard of care (fruquintinib) in MSS CRC patients.

- 2) Title: Results from the phase 1b/2 Morpheus Liver study in patients with unresectable locally advanced or metastatic hepatocellular carcinoma (HCC): Muzastotug (ADG126: masked anti-CTLA-4 Ab) combination arm

This poster will share results of the clinical trial collaboration with Roche, which evaluates muzastotug in triplet combination with atezolizumab and bevacizumab in first-line treatment of liver cancer.

- 3) Title: Preclinical characterization of XB404, a masked anti-ROR1/2 antibody-drug conjugate

Partner Exelixis will present preclinical data from antibody-drug conjugate, XB404, built with Adagene's SAFEbody masking technology and designed to deliver a cytotoxic payload to ROR1/2-expressing tumors while minimizing on-target, off-tumor side effects.

ONGOING COLLABORATIONS

- Sanofi: Invested up to \$25 million to support muzastotug's randomized Phase 2 study. Separately, Adagene will supply Sanofi with muzastotug to evaluate the safety, efficacy, pharmacokinetics and biomarker data in combination with Sanofi's SAR445877 (PD-1 x IL-15 fusion protein) in over 100 patients in a Phase 1/2 clinical trial in advanced solid tumors. Sanofi also exercised its option for a third SAFEbody® discovery program.
- Third Arc Bio: Partnered to develop two masked CD3 T cell engagers, expanding SAFEbody® into next-generation T cell therapies.
- Exelixis: Advanced a third masked ADC against a solid tumor target, building on the 2021 collaboration.
- ConjugateBio: Collaborated on bispecific ADCs using Adagene-derived antibody, further demonstrating scalable platform potential.
- Roche: Roche is sponsoring and conducting a phase 1b/2 multi-national trial to evaluate ADG126 in a triple combination with atezolizumab and bevacizumab in first-line hepatocellular carcinoma (HCC).

FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents:

Cash and cash equivalents were US\$74.5 million as of December 31, 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\$6.1 million as of December 31, 2025 from US\$18.2 million as of December 31, 2024. The associated loan proceeds were primarily used to pay for the company's R&D activities in China.

Net Revenue:

Net revenue was US\$7.7 million for the year ended December 31, 2025, compared to US\$0.1 million in 2024. The increase of approximately 7,333% reflects net revenue recognized upon fulfillment of certain performance obligations associated with the collaboration and technology licensing agreements with Sanofi, ConjugateBio and Third Arc Bio, respectively.

Research and Development (R&D) Expenses:

R&D expenses were US\$22.0 million for the year ended December 31, 2025, compared to US\$28.8 million in 2024. The decrease of approximately 23% 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\$7.1 million for the year ended December 31, 2025, compared to US\$7.3 million in 2024. The decrease was mainly a result of cost-control measures.

Net Loss:

Net loss attributable to Adagene Inc.'s shareholders was US\$17.6 million for the year ended December 31, 2025, compared to US\$33.4 million in 2024.

Ordinary Shares Outstanding:

As of December 31, 2025, there were 59,231,993 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\$13.9 million for the year ended December 31, 2025, compared to US\$28.5 million 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 shares for the year, 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 shares for the year 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 year. The company believes that non-GAAP net loss and non-GAAP net loss per ordinary shares for the year 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 shares for the year should not be considered in isolation or construed as an alternative to operating profit, loss for the year 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 shares for the year and the reconciliation to their most directly comparable GAAP measures. Non-GAAP net loss and non-GAAP net loss per ordinary shares for the year 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 shares for the year represent net loss attributable to ordinary shareholders for the year 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 shares for the year to net loss attributable to ordinary shareholders for the year/period.

¹ Qin S, Xu RH, Shen L, Et Al. Subgroup Analysis By Liver Metastasis In The FRESKO Trial Comparing Fruquintinib Versus Placebo Plus Best Supportive Care In Chinese Patients With Metastatic Colorectal Cancer. *Onco Targets Ther.* 2021;14:4439-; Garcia-Carbonero R, Dasari NA, Eng C, et al. 520P Efficacy and safety of fruquintinib in patients with refractory metastatic colorectal cancer with and without liver metastasis: A subgroup analysis of the phase III FRESKO-2 trial. *Ann Onc* 2024;35:S439

² (i) CheckMate 511 (Phase IIIb/IV): This study compared nivolumab 3 mg/kg plus ipilimumab 1 mg/kg Q3W x 4 versus the standard nivolumab 1 mg/kg plus ipilimumab 3 mg/kg Q3W x 4 in patients with advanced melanoma. The trial demonstrated similar efficacy with a significantly lower incidence of Grade 3-5 treatment-related adverse events (34% vs. 48%); and (ii) Lebbé C, et al. (2019). Evaluation of two dosing regimens for nivolumab in combination with ipilimumab in patients with advanced melanoma: Results from the Phase IIIb/IV CheckMate 511 trial. *Journal of Clinical Oncology*, 37(11):867-875.

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, while minimizing on-target off-tumor toxicity in healthy tissues.

Adagene's lead clinical program, muzastotug (ADG126), is a masked, anti-CTLA-4 SAFEbody with FDA Fast Track designation that targets a unique epitope of CTLA-4 in regulatory T cells (Tregs) in the tumor microenvironment. Muzastotug is currently in Phase 1b/2 and Phase 2 clinical studies in combination with anti-PD-1 therapy, particularly focused on microsatellite stable (MSS) metastatic 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/multi-specific T-cell engagers.

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

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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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Unaudited Consolidated Balance Sheets

	December 31, 2024	December 31, 2025
	US\$	US\$
ASSETS		
Current assets:		
Cash and cash equivalents	85,194,502	74,523,782
Amounts due from related parties	8,309	17,349
Prepayments and other current assets	2,575,194	2,834,034
Total current assets	87,778,005	77,375,165
Property, equipment and software, net	1,125,389	717,374
Operating lease right-of-use assets	283,645	145,535
Other non-current assets	81,386	25,223
TOTAL ASSETS	89,268,425	78,263,297
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	4,241,773	2,884,507
Contract liabilities	—	3,462,683
Amounts due to related parties	13,187,966	10,347,200
Accruals and other current liabilities	2,816,038	2,790,794
Income tax payable	5,265	410,198
Warrant liabilities	—	205,146
Short-term borrowings	4,868,956	4,268,154
Current portion of long-term borrowings	12,923,599	711,359
Current portion of operating lease liabilities	141,341	92,055
Total current liabilities	38,184,938	25,172,096
Long-term borrowings	417,339	1,138,174
Operating lease liabilities	142,304	53,480
TOTAL LIABILITIES	38,744,581	26,363,750
Commitments and contingencies		
Mezzanine equity:		
Series A non-voting contingently redeemable convertible preferred shares (par value of US\$0.0001 per share; nil authorized, issued and outstanding as of December 31, 2024; and 1,062,500 shares authorized, issued and outstanding as of December 31, 2025)	—	16,550,000
Total mezzanine equity	—	16,550,000
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 59,231,993 shares issued and outstanding as of December 31, 2025)

	5,889	5,923
Additional paid-in capital	362,220,445	366,043,455
Accumulated other comprehensive loss	(526,903)	(1,914,831)
Accumulated deficit	(311,175,587)	(328,785,000)
Total shareholders' equity	50,523,844	35,349,547
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY	89,268,425	78,263,297

Unaudited Consolidated Statements of Comprehensive Loss

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2025
	US\$	US\$
Revenues		
Licensing and collaboration revenue	103,204	7,670,902
Operating expenses and income		
Research and development expenses	(28,781,412)	(22,033,573)
Including external related parties	(1,943,523)	(1,580,387)
Administrative expenses	(7,273,335)	(7,075,624)
Loss from operations	(35,951,543)	(21,438,295)
Interest and investment income	3,801,345	2,303,990
Interest expense	(851,874)	(463,132)
Other income, net	466,620	323,988
Foreign exchange gain (loss), net	(906,212)	1,318,235
Change in fair value of warrant liabilities	—	47,941
Loss before income tax	(33,441,664)	(17,907,273)
Income tax benefit	17,553	297,860
Net loss attributable to Adagene Inc.'s shareholders	(33,424,111)	(17,609,413)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	1,273,185	(1,387,928)
Total comprehensive loss attributable to Adagene Inc.'s shareholders	(32,150,926)	(18,997,341)
Net loss attributable to Adagene Inc.'s shareholders	(33,424,111)	(17,609,413)
Net loss attributable to ordinary shareholders	(33,424,111)	(17,609,413)
Weighted average number of ordinary shares used in per share calculation:		
—Basic	56,287,903	59,006,129
—Diluted	56,287,903	59,006,129
Net loss per ordinary share		
—Basic	(0.59)	(0.30)
—Diluted	(0.59)	(0.30)

Reconciliation of GAAP and Non-GAAP Results

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2025
	US\$	US\$
GAAP net loss attributable to ordinary shareholders	(33,424,111)	(17,609,413)
Add back:		
Share-based compensation expenses	4,909,573	3,741,548
Non-GAAP net loss	(28,514,538)	(13,867,865)
Weighted average number of ordinary shares used in per share calculation:		
—Basic	56,287,903	59,006,129
—Diluted	56,287,903	59,006,129
Non-GAAP net loss per ordinary share		
—Basic	(0.51)	(0.24)
—Diluted	(0.51)	(0.24)

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Source: Adagene Inc.