



Adagene Reports Six Months 2026 Financial Results and Provides Corporate Updates

August 12, 2026

Randomized Phase 2 trial in microsatellite stable colorectal cancer (MSS CRC) ongoing, with results expected in 1H 2027; potential registration trial expected in 2027 once recommended dose regimen has been established

Data reported at AACR from triple combination therapy in 1L hepatocellular carcinoma (HCC) and late-line MSS CRC highlights muzastotug's potential as a backbone combination treatment for multiple tumor types across all lines of therapy

Initiated dosing in a global Phase 1/2 basket trial evaluating muzastotug in combination with a next-generation investigational IO agent through a clinical collaboration with Sanofi

Investigator-initiated Phase 2 trial of muzastotug in neoadjuvant setting for colorectal cancer is ongoing

Cash and cash equivalents of \$127.9 million include proceeds of public offering in April 2026; provide runway into late 2028

SAN DIEGO and SUZHOU, China, Aug. 12, 2026 (GLOBE NEWSWIRE) -- Adagene Inc. ("Adagene") (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, 2026, and provided corporate updates.

"The first half of 2026 was a period of meaningful advances for the company, as our lead program, muzastotug, a masked, anti-CTLA-4 SAFEbody, continues to demonstrate compelling efficacy and a favorable safety profile in MSS CRC and HCC," said Peter Luo, Ph.D., CEO and President of R&D at Adagene. "The strength of muzastotug as a potential backbone therapy continues to be recognized with recent collaborations and the clinical data to date demonstrates the enhanced safety of muzastotug relative to legacy CTLA-4 therapies, even at approximately ten times higher doses. This enhanced safety allows muzastotug to be used as a potential backbone therapy in combination with pembrolizumab and/or other standard of care therapies, such as fruquintinib. We remain encouraged by the durable benefit we are seeing."

"We also welcomed Peter Lebowitz to our Scientific and Strategic Advisory Board, further strengthening the clinical expertise guiding our programs," continued Dr. Luo. "The equity offering in April brought in new investors and extended our cash runway into late 2028, allowing us to accelerate our pipeline and deliver on our mission to transform cancer immunotherapy for patients."

PIPELINE HIGHLIGHTS

Muzastotug (ADG126) Phase 1b/2 study in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with advanced microsatellite stable colorectal cancer (MSS CRC) with no liver metastases.

- Updated data announced in April 2026 highlighted clinical results from patients that have been treated with a muzastotug dose of either 10 mg/kg or 20 mg/kg, in combination with pembrolizumab.
 - In the combined 10 mg/kg cohorts, muzastotug achieved an overall response rate (ORR) of 13%. The median progression-free survival (PFS) was 4.8 months, and median overall survival (OS) was 19.8 months.
 - In patients dosed with 10 mg/kg of muzastotug every 6 weeks (Q6W), the ORR was 0% (0/10) and median PFS was 4.5 months.
 - In patients dosed with 10 mg/kg of muzastotug every 3 weeks (Q3W), the ORR was 17% (5/29) and median PFS was 4.8 months.
 - In the combined 20 mg/kg cohorts, muzastotug achieved a confirmed ORR of 31%. The median PFS was 6.7 months, and median OS was not yet reached.
 - In patients dosed with 20 mg/kg of muzastotug every 6 weeks (Q6W), the ORR was 25% (3/12) and median PFS was 4.9 months.
 - In the 20 mg/kg loading dose cohort (20 mg/kg, followed by 10 mg/kg Q3W), the ORR was 36% (5/14) and median PFS was 15.4 months.
- 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 38% in the 20 mg/kg cohorts, which were generally transient and manageable.
- Enrollment into the randomized Phase 2 trial is well on-track, and results are expected in 1H 2027. The Phase 2 trial is enrolling patients into two arms designed to allow dose regimen selection for the Phase 3 trial. Both arms include an induction phase to drive early efficacy and a maintenance phase to prolong overall survival.
 - Arm A: Patients receive 10 mg/kg induction dose of muzastotug plus 200 mg pembrolizumab Q3W for 4 doses followed by one 200 mg dose of pembrolizumab; the maintenance phase doses 10 mg/kg muzastotug Q6W plus 400 mg of pembrolizumab Q6W.
 - Arm B: Patients receive 20 mg/kg induction dose of muzastotug Q6W plus 400 mg pembrolizumab Q6W for 2 doses; the maintenance phase doses muzastotug at 15 mg/kg Q6W plus 400 mg pembrolizumab Q6W.
- A potential registration trial is expected to begin once the recommended dose regimen has been established, supported by

the Fast Track Designation and FDA alignment under Project Optimus.

Triple combination Phase 1b/2 study of muzastotug, atezolizumab and bevacizumab, in patients with first-line HCC:

- Data presented at the American Association for Cancer Research (AACR) annual meeting in April 2026 included results from the study which is evaluating the triple combination of muzastotug, atezolizumab and bevacizumab compared to atezolizumab and bevacizumab as an active control arm. Interim results from six patients in the muzastotug arm (18.8 months median duration of follow-up) demonstrated a 66.7% ORR (4/6) using HCC-specified modified RECIST v1.1 criteria. ORR was 50.0% (3/6) using RECIST v1.1 criteria. The median PFS was 8.2 months (same for both RECIST criteria) and the median OS was not yet reached at the data cut but was greater than 22 months.
- These results compared favorably to the 40 patients in the active control arm (17.2 months median duration of follow-up) that demonstrated an ORR of 32.5% (13/40) using HCC-specified modified RECIST v1.1 criteria, median PFS of 5.5 months, and median OS of 17.5 months. Using RECIST v1.1 criteria, the ORR was 17.5% (7/40) and the median PFS was 4.3 months.
- The triplet regimen of muzastotug, atezolizumab and bevacizumab was well-tolerated with safety data comparable to the doublet active control arm of atezolizumab and bevacizumab. Grade 3 or greater TRAEs were 50% (3/6) in the muzastotug arm and 45% (18/40) in the active control arm, which supports the potential for continuous dosing with muzastotug. Ongoing muzastotug plus atezolizumab treatment after bevacizumab discontinuation suggests potential flexibility to modify individual agents during safety-related interruptions while preserving durable clinical benefit from the muzastotug and atezolizumab doublet for an extended period of time.

Triple combination Phase 1b/2 study of muzastotug, pembrolizumab and fruquintinib in patients with advanced or metastatic MSS CRC:

- In data presented at AACR, interim results from the study demonstrated a 25% confirmed ORR (1/4) among patients at a dose of 10 mg/kg every 6 weeks (Q6W) of muzastotug (6.7 months median follow-up), and a 40% ORR (2/5) among patients at a dose of 15 mg/kg Q6W of muzastotug (5.9 months median follow-up). The triplet regimen was well-tolerated with no new safety signals, relative to known CTLA-4, PD-1, and fruquintinib monotherapy and combination safety data. There were no dose-limiting toxicities, 25 – 60% Grade 3 TRAEs, and no Grade 4 or Grade 5 TRAEs.

Investigator-initiated Phase 2 trial of muzastotug in the neoadjuvant setting, in combination with pembrolizumab, for the treatment of MSS CRC:

- Patients in this study received muzastotug up to 20 mg/kg in combination with pembrolizumab prior to surgery. Using paired tumor biopsies collected before and after treatment, the study evaluates muzastotug's pharmacokinetic profile in tumor tissue and its pharmacodynamic effects on the immune landscape of the tumor microenvironment. These analyses are designed to further elucidate muzastotug's unique mechanism of action and its potential to deliver an enhanced therapeutic index.
- Additionally, the trial's primary endpoint is the rate of Major Pathologic Response (MPR), defined as $\leq 10\%$ residual viable tumor in the surgical specimen, and is being evaluated in up to 20 patients. Secondary endpoints include complete pathological response, disease-free survival, and safety/tolerability. Preliminary clinical data will inform future development of muzastotug in the neoadjuvant setting.

COLLABORATION UPDATES

- **Sanofi:** A global Phase 1/2 basket trial evaluating muzastotug in combination with a next-generation investigational IO agent in patients with advanced solid tumors is being sponsored and conducted by Sanofi as part of an external clinical collaboration.
- **Incyte:** Established clinical collaboration to evaluate muzastotug in combination with Incyte's TGF β R2xPD-1 bispecific antibody (INCA33890), a leading PD-1-based bispecific program which has demonstrated promising clinical efficacy and safety data as a monotherapy in immune checkpoint sensitive and insensitive cancers, including MSS CRC with and without liver metastases. A Phase 1 combination study in 3L MSS CRC patients with and without liver metastases, sponsored and conducted by Incyte, is expected to begin later this year.
- **Exelixis:** Preclinical data was presented at AACR 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. XB404 demonstrated dose-related tumor growth inhibition and improved survival in cell line models. Investigational New Drug (IND)-enabling studies are ongoing.
- **ConjugateBio:** The collaboration is ongoing with bispecific ADCs utilizing an Adagene-derived antibody, further demonstrating scalable platform potential.

CORPORATE UPDATES

- Added Peter Lebowitz, M.D., Ph.D., former Global Head of Oncology R&D for Johnson & Johnson, to the Scientific and Strategic Advisory Board (SAB), who is helping guide the clinical development of muzastotug, including strategies to advance the program into registration studies.
- Completed underwritten public offering of American depositary shares in April 2026 with approximately \$70 million in gross proceeds.

FINANCIAL HIGHLIGHTS

Cash and Cash Equivalents:

Cash and cash equivalents were US\$127.9 million as of June 30, 2026, compared to US\$74.5 million as of December 31, 2025. Cash and cash equivalents included proceeds received from the ATM offering and underwritten public offering completed in April 2026. The company expects a cash runway extending into late 2028.

Total borrowings from commercial banks in China (denominated in RMB) decreased to US\$5.7 million as of June 30, 2026 from US\$6.1 million as of December 31, 2025. The associated loan proceeds were primarily used to pay for the company's R&D activities in China.

Net Revenue:

Net revenue was US\$1.6 million for the six months ended June 30, 2026, compared to nil for the same period in 2025. The increase reflects net revenue recognized upon fulfillment of certain performance obligations associated with the collaboration and technology licensing agreements with Sanofi and Exelixis, respectively.

Research and Development (R&D) Expenses:

R&D expenses were US\$14.0 million for the six months ended June 30, 2026, compared to US\$12.0 million for the same period in 2025. The increase of approximately 16.2% in R&D expenses reflects continued clinical focus and development of muzastotug, the company's masked, anti-CTLA-4 SAFEbody ADG126.

Administrative Expenses:

Administrative expenses were US\$4.2 million for the six months ended June 30, 2026, compared to US\$3.7 million for the same period in 2025. The increase was mainly due to increase in both personnel and office-related expenses.

Net Loss:

Net loss attributable to Adagene Inc.'s shareholders was US\$16.4 million for the six months ended June 30, 2026, compared to US\$13.5 million for the same period in 2025.

Ordinary Shares Outstanding:

As of June 30, 2026, there were 83,929,180 ordinary shares issued and outstanding. Each American depositary 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\$14.2 million for the six months ended June 30, 2026, compared to US\$11.4 million for the same period in 2025. 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 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 shares 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 shares 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 shares 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 shares for the period and the reconciliation to their most directly comparable GAAP measures. Non-GAAP net loss and non-GAAP net loss per ordinary shares 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 shares 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 shares 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, 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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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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Unaudited Consolidated Balance Sheets

	December 31, 2025	June 30, 2026
	US\$	US\$
ASSETS		
Current assets:		
Cash and cash equivalents	74,523,782	127,909,840
Accounts receivable, net	—	150,000
Amounts due from related parties	17,349	3,025
Prepayments and other current assets	2,834,034	4,345,758
Total current assets	77,375,165	132,408,623
Property, equipment and software, net	717,374	716,616
Operating lease right-of-use assets	145,535	390,535
Other non-current assets	25,223	59,794
TOTAL ASSETS	78,263,297	133,575,568
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	2,884,507	15,538,937
Contract liabilities	3,462,683	2,182,770
Amounts due to related parties	10,347,200	—

Accruals and other current liabilities	2,790,794	2,580,704
Income tax payable	410,198	—
Warrant liabilities	205,146	1,178,702
Short-term borrowings	4,268,154	4,404,704
Current portion of long-term borrowings	711,359	293,647
Current portion of operating lease liabilities	92,055	181,733
Total current liabilities	25,172,096	26,361,197
Long-term borrowings	1,138,174	1,027,764
Operating lease liabilities	53,480	183,189
TOTAL LIABILITIES	26,363,750	27,572,150
Commitments and contingencies		
Mezzanine equity:		
Series A non-voting contingently redeemable convertible preferred shares (par value of US\$0.0001 per share; 1,062,500 shares authorized, issued and outstanding as of December 31, 2025 and June 30, 2026, respectively)	16,550,000	16,550,000
Total mezzanine equity	16,550,000	16,550,000
Shareholders' equity:		
Ordinary shares (par value of US\$0.0001 per share; 640,000,000 shares authorized, and 59,231,993 shares issued and outstanding as of December 31, 2025; and 640,000,000 shares authorized, and 83,929,180 shares issued and outstanding as of June 30, 2026)	5,923	8,393
Additional paid-in capital	366,043,455	436,768,742
Accumulated other comprehensive loss	(1,914,831)	(2,159,885)
Accumulated deficit	(328,785,000)	(345,163,832)
Total shareholders' equity	35,349,547	89,453,418
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY	78,263,297	133,575,568

Unaudited Consolidated Statements of Comprehensive Loss

	For the six months ended June 30, 2025	For the six months ended June 30, 2026
	US\$	US\$
Revenues		
Licensing and collaboration revenue	—	1,619,913
Operating expenses and income		
Research and development expenses	(12,015,184)	(13,964,667)
Administrative expenses	(3,673,073)	(4,241,785)
Loss from operations	(15,688,257)	(16,586,539)
Interest and investment income	1,214,108	1,376,774
Interest expense	(318,422)	(140,344)
Other income, net	63,436	46,697
Foreign exchange gain (loss), net	1,252,353	(169,880)
Change in fair value of warrant liabilities	—	(973,556)
Loss before income tax	(13,476,782)	(16,446,848)
Income tax benefit (expense)	(458)	68,016
Net loss attributable to Adagene Inc.'s shareholders	(13,477,240)	(16,378,832)
Other comprehensive income (loss)		
Foreign currency translation adjustments, net of nil tax	(1,168,652)	(245,054)
Total comprehensive loss attributable to Adagene Inc.'s shareholders	(14,645,892)	(16,623,886)
Net loss attributable to Adagene Inc.'s shareholders	(13,477,240)	(16,378,832)
Net loss attributable to ordinary shareholders	(13,477,240)	(16,378,832)
Weighted average number of ordinary shares used in per share calculation:		
—Basic	58,891,864	70,773,769
—Diluted	58,891,864	70,773,769
Net loss per ordinary share		
—Basic	(0.23)	(0.23)
—Diluted	(0.23)	(0.23)

Reconciliation of GAAP and Non-GAAP Results

For the six months ended	For the six months ended
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	June 30, 2025	June 30, 2026
	US\$	US\$
GAAP net loss attributable to ordinary shareholders	(13,477,240)	(16,378,832)
Add back:		
Share-based compensation expenses	2,030,335	2,131,758
Non-GAAP net loss	(11,446,905)	(14,247,074)
Weighted average number of ordinary shares used in per share calculation:		
—Basic	58,891,864	70,773,769
—Diluted	58,891,864	70,773,769
Non-GAAP net loss per ordinary share		
—Basic	(0.19)	(0.20)
—Diluted	(0.19)	(0.20)



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Source: Adagene Inc.