DualityBio (9606 HK)

Emerging as a global leader in ADC innovation with next-gen platforms and strategic collaborations

- Differentiated ADC product pipeline. DualityBio has a robust pipeline of in-house discovered antibody-drug conjugate (ADC) candidates which is a testament to the Company's prowess in ADC innovation. DB-1303/BNT323 (HER2 ADC)'s first indication (HER2-expressing EC) is projected to file FDA accelerated approval as early as 2025 as per the management. DB-1311/BNT324 (B7-H3 ADC) is under development both as monotherapy and in combination with immunotherapy for SCLC, CRPC, among others. Early results showed that for 3L+ SCLC patients, DB-1311 (9mg/kg) achieved 70.4%, guite competitive compared to other B7-H3 ADC peers. For heavily pre-treated CRPC patients, DB-1311 showed a rPFS of 8.3 months, supporting further investigations. DB-1310 (HER3 ADC) has adopted a differentiated development strategy focused on EGFRm NSCLC in combination with osimertinib, and KRASm NSCLC. Meanwhile, DB-1310 monotherapy demonstrated promising mPFS results of 8.3 months for heavily pre-treated 4L+ EGFR-TKI resistant NSCLC, highlighting the potential of the drug candidate as a monotherapy. DB-1305/BNT325 (TROP2 ADC) targets indications currently under-explored by other TROP2 ADC candidates, such as OC. Moreover, to harness the potent anti-tumor activity of ADCs along with the sustained benefit of next-generation IO, DualityBio/BioNtech are conducting Ph1/2 trials of DB-1311/DB-1305 + BNT327 (PD-L1/VEGF bsAb) across tumor types as an early mover in this promising ADC + next-gen IO space.
- Eye on global markets with a replicable partnership model. In line with its global strategy, DualityBio has established a number of strategic partnerships to accelerate the development of its pipeline across key global markets. Incorporated in 2019, with a relatively short operating history, DualityBio's innovative ADC assets have attracted global biopharmaceutical companies, resulting in multiple strategic partnerships with BioNTech (collaborations on B7-H3 ADC, HER2 ADC, and TROP2 ADC), BeiGene (collaboration on B7-H4 ADC), Adcendo (collaboration on the DITAC platform), GSK (collaboration on DB-1324 and certain ADCs), and Avenzo (collaboration on EGFRxHER3 BsADC). These partnerships have generated a total deal value exceeding US\$6.0bn. DualityBio strives to be the partner-of-choice for global biopharma companies seeking innovative ADC programs. DualityBio's high-profile partnerships serve as industry validation of its platform and pipeline assets. The replicability of DualityBio's partnership model creates a sustainable path for future innovation.
- Initiate at BUY: We expect DualityBio's total revenue to reach RMB2.0bn/ 1.5bn/ 1.5bn in FY25E/ 26E/ 27E, mainly from license and collaborations revenue. We expect the Company to book product sales revenue in 2027E. We derive our target price of HK\$270.34 based on a DCF valuation (WACC: 11.04%, terminal growth rate: 2.5%).

Earnings Summary

(YE 31 Dec)	FY23A	FY24A	FY25E	FY26E	FY27E
Revenue (RMB mn)	1,787	1,941	1,992	1,487	1,547
YoY growth (%)	111,558.8	8.7	2.6	(25.4)	4.0
Net profit (RMB mn)	(357.5)	(1,050.4)	(674.9)	(592.3)	(617.9)
EPS (Adjusted) (RMB cents)	0.00	0.00	(766.60)	(672.76)	(701.83)
R&D expenses (RMB)	(559)	(837)	(920)	(1,012)	(851)
Admin expenses (RMB mn)	(63)	(159)	(200)	(268)	(232)
Courses Company data Bloomha	THE CHARLEN	atimataa			

Source: Company data, Bloomberg, CMBIGM estimates



BUY (Initiate)

Target PriceHK\$270.34Up/Downside24.4%Current PriceHK\$217.40China HealthcareJill WU, CFA(852) 3900 0842

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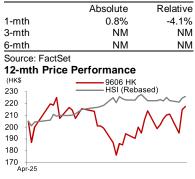
Stock Data

Mkt Cap (HK\$ mn)	19,139.1
Avg 3 mths t/o (HK\$ mn)	166.1
52w High/Low (HK\$)	165.5/234.6
Total Issued Shares (mn)	88.0
Source: FactSet	

Shareholding Structure

LAV Fund	19.0%
King Star Med Lp	7.5%
Source: HKEx	

Share Performance



Source: FactSet

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Investment thesis

Incorporated in 2019, DualityBio has been one of the leading global players in ADC innovation despite having a short operating history, and dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. DualityBio knows how to create differentiated ADCs. DualityBio has built a pipeline of 12 in-house discovered ADC candidates, targeting B7-H3, HER3, HER2, TROP2, B7-H3xPD-L1, EGFRxHER3, etc. DualityBio's innovative ADC assets have attracted leading global biopharmaceutical companies and reached several global partnerships to date, including that with BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US\$6.0bn in total deal value.

Differentiated ADC product pipeline

DualityBio strives to be at the forefront of ADC technologies and development strategies. DualityBio's pipeline of 12 in-house discovered ADC candidates is a testament to the Company's prowess in ADC innovation, comprising: (i) seven clinical-stage ADCs with potential in a broad range of indications, each ranking among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan; (ii) two next-generation bispecific ADCs (BsADCs); and (iii) multiple other preclinical ADCs. DualityBio employs a tiered strategy in ADC development, placing it at the forefront of ADC innovation:

- First wave: Empowered by DualityBio's DITAC platform, these assets serve as proof of concept. This wave includes ADC candidates with clinically validated targets for differentiated indications (e.g., DB-1303, a HER2 ADC, and DB-1305, a TROP2 ADC) and ADC candidates for high-potential targets and underexplored indications (e.g., DB-1311, a B7-H3 ADC, and DB-1310, a HER3 ADC). Leveraging the expertise and resources of its partner, DualityBio is actively exploring the potential of combining ADCs with the next-generation IO.
- Second wave: Leveraging DIBAC and DIMAC platforms, this wave comprises next-generation ADCs with novel formats and components for front-line or difficult-to-treat settings and new therapeutic areas. Examples include BsADCs (DB-1419 (B7-H3xPD-L1 BsADC), DB-1418/AVZO-1418 (EGFRxHER3 BsADC), and DB-1421) and immune-modulating ADCs for autoimmune diseases (e.g., DB-2304, a BDCA2 ADC).
- **Third wave:** Enabled by the DUPAC platform, this wave focuses on novel ADC payload and linker technologies to potentially disrupt the ADC modality, targeting hard-to-treat tumors and overcoming acquired resistance to existing ADCs.

<u>DB-1303/BNT323</u> is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing breast cancer (BC), with potential for extension to other underserved cancer indications. DualityBio formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value.

DB-1311/BNT324 is a clinically advanced **B7-H3 ADC** candidate under global development. DualityBio, in collaboration with BioNTech, is actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown encouraging antitumor activity and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC, and multiple other solid tumors. Besides SCLC and CRPC, DualityBio is also investigating DB-1311's treatment potential in HNSCC,



HCC, CC, and melanoma. Early results showed that among 3L+ SCLC patients, the ORR in the 9mg/kg SCLC cohort (n=34) reached 70.4%, quite competitive compared to other B7-H3 ADC peers. Updated ASCO 2025 data of DB-1311 in heavily pre-treated CRPC patients showed a rPFS of 8.3 months, supporting further clinical investigation of the candidate in this setting. In collaboration with BioNTech, the parties are also conducting phase 1/2 studies of DB-1311 plus BNT327 (PD-L1/VEGF bsAb) across multiple solid tumors, to explore the potential of ADC in combination with next-generation IO, as an early mover in this promising space.

DB-1310 is one of the world's most clinically advanced **HER3 ADC** candidates, for which DualityBio holds global rights. DualityBio has adopted a differentiated clinical development strategy focused on maximizing commercial potential in carefully selected indications. For EGFRm NSCLC, while competitors are exploring HER3 ADCs as second-line or later monotherapy, DualityBio is investigating DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI therapy, with the possibility of first-line treatment covering a broader patient population. Meanwhile, the DB-1310 monotherapy has demonstrated promising mPFS results of 8.3 months for heavily pre-treated 4L+ EGFR-TKI resistant NSCLC, highlighting the potential of the drug candidate as a monotherapy. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRASm NSCLC. Additionally, DualityBio is exploring DB-1310's efficacy in various other solid tumors, including BC, CRPC, HNSCC, ESCC, and BTC.

DB-1305/BNT325 is a **TROP2 ADC** candidate with a global development strategy. DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. DualityBio believes this wellrounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, DualityBio is advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed. The study of DB-1305 plus BNT327 (PD-L1/VEGF bsAb) is also ongoing, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators.

Eye on global markets with a replicable partnership model

DualityBio has set its sights on the global market and aspires to treat patients worldwide. The Company has designed its ADC drug candidates to be competitive with, or differentiated from, those of the leading global ADC players. Five of DualityBio's clinical-stage assets had obtained IND approvals from both the FDA and the NMPA as of the Feb 2025. Duality Bio has seven ongoing global MRCTs across 17 countries and over 230 trial sites, with over 2,000 patients (more than 50% located in the US, EU, and Australia) enrolled as of the Feb 2025.

In line with its global strategy, DualityBio has established a number of strategic partnerships to accelerate the development of its pipeline across key global markets, expand its global clinical development capabilities, and fuel its future innovation and long-term growth. In its short operating history, DualityBio's innovative ADC assets have attracted global biopharmaceutical companies, forming multiple strategic partnerships with BioNTech (collaborations on B7-H3 ADC, HER2 ADC, and TROP2 ADC), BeiGene (collaboration on B7-H4 ADC), Adcendo (collaboration on the DITAC platform), GSK (collaboration on DB-1324 and certain ADCs), and Avenzo (collaboration on EGFRxHER3 BsADC). These partnerships have generated a total deal value exceeding US\$6.0bn, in which DualityBio received approximately US\$400mn as of the Feb 2025.

DualityBio strives to be the partner-of-choice for global biopharmaceutical companies seeking innovative ADC programs. DualityBio's high-profile partnerships serve as industry validation of its platform technologies and pipeline assets. The replicability of DualityBio's partnership model creates a sustainable path for future innovation. Cash



flows generated from partnerships contribute to its agile pipeline development strategy, sustaining its R&D engine. Additionally, DualityBio has structured its partnerships to provide strong commercial upside and visibility. For example, it has preserved the opportunity to capture the commercial upside of DB-1311 (B7-H3 ADC) by retaining optin rights to co-develop and co-commercialize this asset with BioNTech in the US. The partnership with Adcendo includes an exclusive option to license the Greater China rights for the development and commercialization of Adcendo's novel ADC candidates arising from this collaboration after they have completed proof-of-concept trials.

Initiate at BUY with TP of HK\$270.34

We derive our target price of HK\$270.34 based on an 11-year DCF model (WACC: 11.04%, terminal growth rate 2.5%).

Investment risks

Risks relating to (1) research and development of drug candidates; (2) dependence on third parties; and (3) operations.



An innovative ADC company empowered by extensive global partnerships

Incorporated in 2019, being one of the leading global players in ADC innovation, DualityBio dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. Duality Bio knows how to create differentiated ADCs. From target selection, ADC design to clinical development, Duality Bio builds on the extensive experience of major players in the ADC space and has accumulated deep knowledge in this rising modality. This expertise has allowed Duality Bio to stand out among the pioneers in this domain, harnessing proprietary next - generation ADC platform technologies and addressing unmet medical needs worldwide, according to Frost & Sullivan.

DualityBio has built a pipeline of 12 in-house discovered ADC candidates, targeting B7-H3, HER3, HER2, TROP2, B7-H3xPD-L1, EGFRxHER3, etc. DualityBio's innovative ADC assets have attracted leading global biopharmaceutical companies, and formed several global partnerships to date, including that with BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US\$6.0bn in total deal value (of which approximately US\$400mn have been received as of the Feb 2025.

Innovative in-house discovered pipeline

DualityBio has built a pipeline of 12 in-house discovered ADC candidates, comprising: (i) seven clinical-stage ADCs with potential in a broad range of indications, each ranking among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan; (ii) two next-generation BsADCs; and (iii) multiple other preclinical ADCs. Three of DualityBio's clinical-stage assets—its Core Products DB-1303 (HER2 ADC) and DB-1311 (B7-H3 ADC), and key product DB-1305 (TROP2 ADC)—have received Fast Track Designation from the FDA. DB-1303 has also received Breakthrough Therapy Designations from both the FDA and the NMPA for certain indications. DualityBio employs a tiered strategy in ADC development, placing it at the forefront of ADC innovation:

- First wave: Empowered by DualityBio's DITAC platform, these assets serve as proof of concept. This wave includes ADC candidates with clinically validated targets for differentiated indications (e.g., DB-1303, a HER2 ADC, and DB-1305, a TROP2 ADC) and ADC candidates for high-potential targets and underexplored indications (e.g., DB-1311, a B7-H3 ADC, and DB-1310, a HER3 ADC). Leveraging the expertise and resources of its partner, DualityBio is actively exploring the potential of combining ADCs with the next-generation IO.
- Second wave: Leveraging DIBAC and DIMAC platforms, this wave comprises next-generation ADCs with novel formats and components for front-line or difficult-to-treat settings and new therapeutic areas. Examples include BsADCs (DB-1419 (B7-H3xPD-L1 BsADC), DB-1418/AVZO-1418 (EGFRxHER3 BsADC), and DB-1421) and immune-modulating ADCs for autoimmune diseases (e.g., DB-2304, a BDCA2 ADC).
- **Third wave:** Enabled by the DUPAC platform, this wave focuses on novel ADC payload and linker technologies to potentially disrupt the ADC modality, targeting hard-to-treat tumors and overcoming acquired resistance to existing ADCs.



Figure 1: DualityBio's pipeline

DITAC - Leading	TOPIS ADC Platf	Larm.														
DTIAC - Leading	i or in Abe i lau		Mone	Single-arm, Potential Regis	trational Study			FDA, NMPA	Global	NCT05150691	Trial completion: 2027					
		HER2-expressing EC (2L+)	Mono	Planned Phase 3 Confirmat				FDA, NMPA	Global	NCT06340568	Trial completion: 2029					
→ DB-1303		HR+/HER2-low BC (chemo naïve)	Mono		1	1		FDA, NMPA	Global	NCT06018337	Trial completion: 2028	Mainland China,				
★ DB-1303 /BNT323	HER2	HERZ+ BC (2L+)	Mono			1		NMPA	China	NCT06265428	Trial completion: 2026	Hong Kong, Macau	BIONTE			
		HER2+ BC (1L)	+ Pertuzumab					FDA, NMPA	Global							
		Solid Tumors (OC, CRC, esophageal cancer, etc.)	Mono					FDA, NMPA	Global	NCT05150691	Trial completion: 2027					
		SCLC (2L+)	Mono					FDA, NMPA	Global							
DB-1311	B7-H3	CRPC (late line)	Mono					FDA, NMPA	Global			Mainland China, Hong Kong,				
/BNT324	87-03	ESCC (2L+)	Mono					FDA, NMPA	Global	NCT05914116	Trial completion: 2026 (U.S.: 0 prion to Co-develop and Co-commercialize)		BIONTE			
		NSCLC (2L+)	Mono					FDA, NMPA	Global							
		Solid Tumors (HNSCC, HCC, CC, melanoma, etc)	Mono					FDA, NMPA	Global			co-connectance)				
		EGFRm NSCLC (TKI-resistant)	+ Osimertinib					FDA, NMPA	Global	NCT05785741						
DB-1310	HER3	KRASm NSCLC (2L+)	Mono					FDA, NMPA	Global		NCT05785711	NCT05785741	Trial completion: 2026	11 Trial completion: 2026	Trial completion: 2026	Global
M DB-1310	in the second se	HER2+ BC (Post-Enhertu)	+ Trastuzumab					FDA, NMPA	Global	102103703741	This competition, 2020	Groom				
		Solid Tumors	Mono					FDA, NMPA	Global							
		OC (2L+)	Mono					FDA, NMPA	Global		Trial completion: 2025					
DB-1305 /BNT325	TROP2	NSCLC (2L+)	Mono					FDA, NMPA	Global	NCT05428220		Frial completion: 2025 Mainland China, Macau	BIONTEC			
/BNT325	TROF2	NSCLC, OC, CC, TNBC (multiple lines)	+PD-L1xVEGF bsAb					FDA, NMPA	Global	4	That completion: 2025					
		Solid Tumors (CC, TNBC, etc.)	Mono					FDA, NMPA	Global							
DB-1312 /BG-C9074	B7-H4	Solid Tumors	Mono/ + Tislelizumab		**			FDA, NMPA	Global	NCT06233942	Trial completion: 2027	/	🧾 BeiGe			
DB-1314	Undisclosed	Solid Tumors	Mono					N.A.	1	1	IND submission: 2026	Global				
DB-1317	Undisclosed	Solid Tumors	Mono					N.A.	1	1	IND submission: 2025	Global				
DB-1324	Undisclosed	Solid Tumors	Mono					N.A.	1	/		Mainland China, Hong Kong, Macau	GSK			
DIBAC - Leading	Bispecific ADC Pl	latform														
🔆 DB-1419	B7-H3 x PD-L1	Solid Tumors	Mono					FDA, NMPA	Global	NCT06554795	Trial completion: 2027	Global				
DB-1418 /AVZO-1418	EGFR x HER3	Solid Tumors	Mono					N.A.	1	1	IND submission: 2025	Greater China	AVENZ			
DB-1421	Undisclosed	Solid Tumors	Mono					N.A.	1	1	IND submission: 2026	Global				
DUPAC - Unique ?	ovel MOA Paylo	ad ADC Platform														
DB-1316	Undisclosed	Solid Tumors	Mono					N.A.	1	1	IND submission: 2026	Global				
DIMAC - Leading	Immune-modulat	ting ADC Platform														
📩 DB-2304	BDCA2	SLE, CLE	Mono		•			FDA, NMPA	Global	NCT06625671	Trial completion: 2026	Global				
							*	Core Products	Key Products	FDA Breakthrough Therapy Designation	NMPA Breakthrough Therapy Designation	FDA Fast Track Designation	n Ba Gran			

(2) For each drug candidate, Based on the results from these phase 1/2 trials, we determine which indications to prioritize for advancement into later-stage clinical development to candidate. Based on the results from these phase 1/2 trials, we determine which indications to prioritize for advancement into later-stage clinical development later later stage clinical by the NMPA. Eccept for DB-1033 phase 3 trial in HER2+BC patients, which is conduced solely in China and regulated by the NMPA. BioNTech was the sponse of this global trial is of the Later Practicable Date.

BeiGene was serving as the sponsor of this trial as of the Latest Practicable Date.

<u>DB-1303/BNT323</u> is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study. The first indication (HER2-expressing EC) is projected to be filed for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2.

According to Frost & Sullivan, DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing breast cancer (BC), with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and strong medical needs for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, ovarian cancer (OC), colorectal cancer (CRC) and esophageal cancer, supported by global clinical data from patients across the US, China and Australia to date. To further advance DB-1303, DualityBio formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value.

DB-1311/BNT324 is a clinically advanced **B7-H3 ADC** candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a

Source: Company data, CMBIGM



broad range of tumor types, including SCLC, NSCLC, BC, CRPC, ESCC, and HNSCC. Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload and Fc-silenced mAb, potentially translates into a favorable safety profile and a wide therapeutic window.

DualityBio, in collaboration with BioNTech, is actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown encouraging antitumor activity and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC, and multiple other solid tumors. Preliminary data from this trial were presented in an oral session at the 2024 ESMO Asia. As of 27 September 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%. As of the same date, among patients with SCLC (n=73) who previously received median 2.0 lines of treatments, the uORR was 56.2%, with the ORR in the 9mg/kg SCLC cohort (n=34) reaching 70.4%, quite competitive compared to other B7-H3 ADC peers. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0%; rPFS data were not yet mature, with a median rPFS of 7.2 months. Updated results in CRPC (n=43) was released at ASCO 2025, with the rPFS increasing to 8.3 months for heavily pre-treated CRPC patients, warranting further study of the drug candidate in CRPC.

Besides SCLC and CRPC, DualityBio is also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC. Additionally, to explore the potential of DB-1311 in combination with next-generation IO, BioNTech has started a phase 1/2 trial of DB-1311 in combination with BNT327 (PD-L1/VEGF bsAb) in NSCLC and SCLC, while DualityBio is starting a phase 2 trial of DB-1311 in combination with BNT327 in multiple solid tumors, including HCC, CC, HNSCC and NSCLC.

DB-1310 is one of the world's most clinically advanced **HER3 ADC** candidates, for which DualityBio holds global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. Despite the growing research and clinical interest in HER3, it remains under-explored and has faced two decades of drug development challenges due to the complexity in achieving signaling inhibition and the potential for escape pathway activation. Guided by DualityBio's team of leading experts in HER3 research, they have built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

HER3 ADCs offer opportunities to treat a broad patient population without relying heavily on biomarker-based patient selection, potentially overcoming resistance to standard of care. DualityBio has adopted a differentiated clinical development strategy focused on maximizing commercial potential in carefully selected indications. For EGFRm NSCLC, while competitors are exploring HER3 ADCs as second-line or later monotherapy, DualityBio is investigating DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI therapy, with the possibility of first-line treatment covering a broader patient population. Meanwhile, the DB-1310 monotherapy has demonstrated promising mPFS results of 8.3 months for heavily pre-treated 4L+ EGFR-TKI resistant NSCLC, highlighting the potential of the drug candidate as a monotherapy. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRASm NSCLC. Additionally, DualityBio is exploring DB-1310's efficacy in various other solid tumors, including BC, CRPC, HNSCC, ESCC, and BTC.



<u>DB-1305/BNT325</u> is a TROP2 ADC candidate with a global development strategy. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. To date, several TROP2 ADCs have been approved globally, indicated for advanced triple-negative breast cancer (TNBC), urothelial cancer (UC) and HR+/HER2- BC, according to Frost & Sullivan. The global TROP2 ADC market is expected to increase from US\$1.1bn in 2023 to US\$7.7bn by 2028, representing a CAGR of 48.8%.

DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. DualityBio believes this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, DualityBio is advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed. The study of DB-1305 plus BNT327 (PD-L1/VEGF bsAb) is also ongoing, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators.

<u>DB-1419</u> is a potential first-in-class **B7-H3xPD-L1 BsADC** candidate with a DNA topoisomerase I inhibitor, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. The simultaneous action of delivering the toxin to tumor cells and modulating T cell activation provides a potential synergistic anti-tumor effect. Combining payload-mediated cytotoxicity with antibody-mediated immunotherapy activity, DB-1419 provides an innovative approach for cancer treatment. DualityBio has obtained IND approval from the FDA for DB-1419 and initiated DB-1419's phase 1/2a global trial in September 2024.

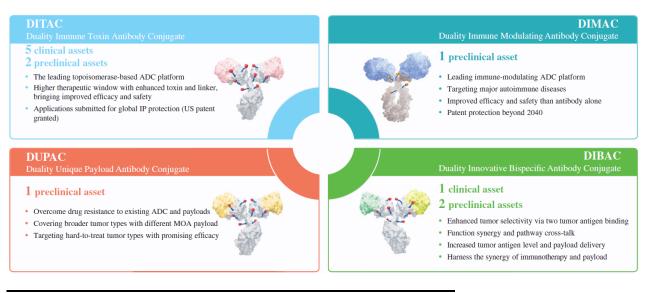
DB-2304 is a potential first-in-class **BDCA2 ADC** candidate for systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE), being one of the most advanced BDCA2 ADCs in terms of development progress, according to Frost & Sullivan. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system. DualityBio believes DB-2304 holds promise to substantially improve upon the standard of care for SLE and CLE, such as glucocorticoids and immunosuppressants, and represents a major step in the innovation of autoimmune ADCs. DualityBio initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. It has submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expects to complete DB-2304's phase 1 global trial in 2026.

Cutting-edge technology platforms to push the boundaries of ADC treatment

Leveraging its experienced R&D team, deep insights into ADC design, and strong execution capabilities, DualityBio has established four cutting-edge ADC technology platforms: DITAC, DIBAC, DIMAC, and DUPAC, to push the boundaries of ADC treatment. These platforms serve as the foundation for continuous and sustained innovation and value creation. Their value and versatility have been validated by DualityBio's pipeline assets and recognized by global MNC partners.



Figure 2: DualityBio's technology platform



Source: Company data, CMBIGM estimates

Duality Immune Toxin Antibody Conjugate (DITAC), a proprietary topoisomerase inhibitor-based ADC platform, is validated by the global clinical data from over 2,000 patients across the US, China, Europe, Australia and other major markets. This platform is developed by screening and optimizing a library of proprietary ADC components, including DualityBio's proprietary payloads P1003 and P1021, through meaningful technological improvements. As such, DITAC provides critical flexibility to design ADCs with improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance.

Duality Innovative Bispecific Antibody Conjugate (DIBAC), one of a few BsADC platforms in the world, is leading a new wave of ADC innovation. By incorporating two distinct binding moieties in a single therapeutic entity, BsADCs can potentially offer meaningful advantages over traditional monospecific ADCs and combination therapies. While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing, setting a high entry barrier. DualityBio's innovative DIBAC platform features its deep understanding in disease and target biology, rich experience in bispecific antibody engineering, and artificial intelligence-empowered target selection and antibody design.

Duality Immune-Modulating Antibody Conjugate (DIMAC), empowered by its proprietary immune-modulating payload, holds the potential to open the ADC modality to a significant white-space market in autoimmune and other therapeutic areas. Many patients with chronic autoimmune diseases, such as SLE and CLE, are currently treated with therapies that often lead to severe side effects. The long-term use of glucocorticoids, for example, is commonly associated with increased risks of bone fractures, weight gains, diabetes, immune system suppression, and other chronic conditions. ADCs can reshape the treatment paradigm of autoimmune diseases by offering a targeted treatment with low systemic exposure, enhanced efficacy and reduced side effects. Molecules designed under the DIMAC platform have demonstrated potent and broad anti-inflammatory activity, long duration of action, sustained stability, and low systemic exposure in preclinical studies.

Duality Unique Payload Antibody Conjugate (DUPAC) reflects the Company's visionary foresight into the future landscape of ADC innovation. DualityBio is building DUPAC to develop linker-payload complexes with novel mechanisms of action beyond traditional cytotoxic agents to combat growing drug resistance and hard-to-treat tumors. The Company has made promising progress in a number of unique payload mechanism



and has obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies.

A tailored differentiated clinical development strategy

DualityBio takes a differentiated clinical development strategy to accelerate the global expansion of its drug programs and maximize their impact on patients worldwide, taking into account its unique features in ADC design, acumen in indication selection, and understanding of unmet clinical needs and the market landscape. DualityBio's development strategies are carefully tailored by drug and target indication, following the general principles below:

• **First-to-market approach**. To maximize the global competitiveness of its pipeline, DualityBio will select and address initial target indications that are commercially attractive and often underserved, which enable it to demonstrate key asset differentiation and rapidly enter and establish a strong presence in the global market. For example, DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels, according to Frost & Sullivan. DualityBio and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

• Fast-to-commercial approach. Complementing its first-to-market strategy, DualityBio utilizes a fast-to-commercial approach to accelerate access to its differentiated assets for a wider addressable population of patients in need. For instance, DB-1303 is a leading candidate for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 is undergoing a phase 3 global registrational trial in HR+/HER2-low metastatic BC patients who are chemo-naïve with the first patient dosed in January 2024. Furthermore, DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan.

· Combination and indication expansion strategy, especially with next-generation IO. DualityBio adopts combination therapy strategies to unlock the frontline and backbone potential for its assets and offer improved clinical benefits to patients. For instance, DB-1310 is a global clinical-stage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments through combination with osimertinib. Together with BioNTech, DualityBio is actively exploring the TROP2 ADC DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, CC, and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to evaluate the combination of DB-1305 and BNT327 (PD-L1/VEGF bsAb) aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. In October 2024, in China, DualityBio received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with latestage/metastatic solid tumors. For DB-1311 (B7-H3 ADC), BioNTech has started a phase 1/2 trial of DB-1311 + BNT327 in NSCLC and SCLC (NCT06892548), while DualityBio is starting a phase 2 trial (NCT06953089) of DB-1311 + BNT327 in multiple solid tumors, including HCC, CC, HNSCC and NSCLC.

Robust competitive strengths as an ADC powerhouse

Global ADC powerhouse with insights and strong execution capabilities to lead ADC innovation

Being a global player in ADC innovation, DualityBio dedicated to developing nextgeneration therapeutics in this rapidly expanding drug modality to treat cancer, autoimmune diseases, and other conditions. ADCs are revolutionizing oncology treatment, becoming a new backbone therapy and moving toward early-line treatment, potentially replacing existing standards of care and broadening coverage to pan-tumors



and pan-expression. Beyond oncology, ADCs hold promise as an optimal modality in other therapeutic areas, such as autoimmune, metabolic, and cardiovascular diseases.

According to Frost & Sullivan, DualityBio is a key player in the global ADC landscape, empowered by innovative research, clinical and regulatory insights, and strong execution capabilities. In four years, DualityBio has established four globally innovative ADC technology platforms for next-generation ADC research. The Company has designed and executed development strategies for its ADC drug candidates to be competitive with, or differentiated from, those of leading global ADC players. Leveraging comprehensive global R&D capabilities, DualityBio has multiple ongoing global MRCTs across 17 countries and over 230 trial sites, with over 2,000 patients enrolled (more than 50% located in the US, EU, and Australia) as of the Feb 2025.

With its insights and know-how, supported by four leading technology platforms and strong global clinical development experience, DualityBio has achieved these feats with industry-leading speed and quality. DualityBio's core product, DB-1303, reached a FDA EOP2 meeting just 20 months after first-patient-in and is projected to file for accelerated approval with the FDA within four years of the first patient dosing. According to Frost & Sullivan, the average time for an innovative drug to advance from IND filing to NDA approval by the FDA is over eight years. DualityBio's ADC candidates have received three FDA Fast Track Designations, two Breakthrough Therapy Designations from the FDA and NMPA, and two FDA Orphan Drug Designations since its inception. Recognizing the clinical and commercial value of DualityBio's platforms and pipeline, it has established several global partnerships with a total deal value exceeding US\$6.0bn, accelerating the delivery of its ADC drugs to patients worldwide.

DualityBio strives to remain at the innovation forefront of the rising ADC modality to unlock its full potential. Meaningful advancements are being made to enhance and innovate all three ADC components — the payload, the linker, and the antibody — to improve efficacy and reduce toxicity, and potentially extend ADCs to front-line or difficult-to-treat settings, including relapsed patients with drug resistance to current standard-of-care treatments. In addition to cancer treatment, innovative ADCs are also being developed for a broader spectrum of non-oncology indications. Driven by continued innovation, the global ADC market is expected to surpass US\$110bn by 2032. In the pursuit of next-generation ADCs, China has emerged as a global innovation center, where over 45% of the world's clinical trials conducted for ADCs since 2023 took place. With growing global competency in drug discovery, biotech companies in China are leading the research of novel targets such as HER3 and B7-H3 and new modalities like BsADCs, achieving a record-breaking US\$35bn in ADC deals with global MNCs since 2022. Guided by its "CP2" formula, DualityBio aims to continue to achieve breakthroughs in ADC technology and drug development that propel it to the forefront of the industry.

Clinically advanced ADC assets with promising global data as validation of its DITAC

DualityBio has developed a pipeline of novel ADCs led by seven clinical-stage assets, each ranked among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan. These assets leverage both well-validated targets, such as HER2 and TROP2, and emerging targets, such as B7-H3 and HER3, with broad indication opportunities. As DualityBio rapidly advances these assets towards regulatory approval and commercialization, it has established a global leading position in addressable markets with vast clinical and commercial potential.

DualityBio's clinical-stage assets share roots in DITAC, its proprietary topoisomerasebased ADC platform. DITAC is validated by global clinical data from over 2,000 patients. Compared to ADCs with earlier-generation payloads such as monomethyl auristatin E (MMAE), topoisomerase-based ADCs can target a broader range of tumor types. The bystander effect of topoisomerase-based ADCs enhances efficacy by impacting neighboring tumor cells that may not express the target antigen.



DITAC employs a holistic ADC design approach, demonstrating improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance, potentially translating to a significantly improved therapeutic window. DualityBio has developed a library of proprietary linkers and payloads with technological improvements, providing optionality in optimizing each ADC component for a broad range of target indications.

Innovator in ADC development powered by versatile platforms to target underserved therapeutic areas

DualityBio pushes the boundaries of ADC innovation through the continued development and iteration of three cutting-edge technology platforms: DIBAC, DIMAC, and DUPAC. Building on the successful DITAC platform, DualityBio developed DIBAC, DIMAC, and DUPAC based on its accumulated expertise in antibody engineering, linker chemistry, and toxin technologies, as well as deep insights into disease biology and targets. These platforms are designed to explore next-generation ADC formats, mechanisms of action, and diseases within and beyond oncology.

DualityBio's technology platforms drive continuous innovation and value creation by empowering its cutting-edge R&D and strategic collaborations with global partners. In addition to its clinical-stage assets, DualityBio is advancing multiple preclinical programs, including five anticipated to enter clinical trials by the end of 2026.

Strategic and value-enhancing partnerships to sustain long-term global development

DualityBio has set its sights on being a global ADC powerhouse from day one. In line with its global strategy, DualityBio has established an array of strategic partnerships to accelerate the development of its pipeline across key global markets, expand its global clinical development capabilities, and fuel its future innovation and long-term growth. In its short operating history, DualityBio has entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US\$6.0bn in total deal value (of which approximately US\$400mn have been received as of Feb 2025). Its proven partnership model has the following advantages:

- Validation of industry-leading innovation: DualityBio's high-profile partnerships serve as industry validation of its platform technologies and pipeline assets. Since deal signings, consistent and timely achievement of R&D and clinical milestones has solidified and deepened collaborations with partners. These partnerships have elevated DualityBio's strengths, particularly in executing global trials and managing multicenter studies, expanding its cross-border clinical development capabilities and enabling exploration into new R&D programs. DualityBio strives to be the partner-of-choice for global biopharmaceutical companies seeking innovative ADC programs.
- Strong commercial upside: DualityBio have received approximately US\$400mn in upfront and milestone payments from collaboration partners as of Feb 2025, providing significant capital support for its R&D and operations. DualityBio has structured its partnerships to provide strong commercial upside and visibility. For example, it has preserved the opportunity to capture the commercial upside of DB-1311 (B7-H3 ADC) by retaining opt-in rights to co-develop and co-commercialize this asset with BioNTech in the US. The partnership with Adcendo includes an exclusive option to license the Greater China rights for the development and commercialization of Adcendo's novel ADC candidates arising from this collaboration after they have completed proof-of-concept trials.
- Fueling future innovation: The replicability of DualityBio's partnership model creates a sustainable path for future innovation. Cash flows generated from partnerships contribute to its agile pipeline development strategy, sustaining its R&D engine. Through external collaboration, DualityBio creates flexible deal



structures to leverage each other's strengths to accelerate the development of drug candidates valued by patients and the biopharmaceutical industry. DualityBio believes its partnership model creates a virtuous business cycle that drives its long-term value creation and generates future partnership opportunities.



DB-1311/BNT324, a B7-H3 ADC candidate with global market potential

Unlocking the potential of B7-H3 ADC in oncology

DB-1311 is DualityBio's in-house discovered, clinically advanced B7-H3 ADC candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a broad range of tumor types, including SCLC, NSCLC, CRPC, ESCC, and HNSCC. Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload, and Fc-silenced mAb, potentially translates into a favorable safety profile and a wide therapeutic window.

Opt-in rights to co-develop and co-commercialize in the US. In collaboration with BioNTech, DualityBio is actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. Under DualityBio's collaboration agreement with BioNTech, it has retained an option to co-develop and co-commercialize DB-1311 in the US. If DualityBio elects to exercise this option, it will become eligible to share the profits/losses and costs from DB-1311's development and commercialization in this major market. This strategic partnership demonstrates DualityBio's confidence in and commitment to DB-1311's global development and allows it to leverage BioNTech's complementary strengths and resources while capturing the asset's significant economic interest and upside potential overseas. Thus, DualityBio is well-positioned to efficiently navigate the complex global market landscape and accelerate DB-1311's entry into both domestic and international markets.

DB-1311 is designed with three key components: a Fc-silenced, humanized anti-B7-H3 IgG1 mAb, a cleavable linker, and a proprietary DNA topoisomerase I inhibitor (P1021). The core components of DB-1311 are illustrated below.

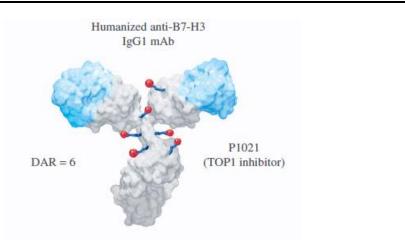


Figure 3: Drug design of DB-1311

Source: Company data, CMBIGM

DB-1311 is designed to deliver potent tumor killing while reducing off-target toxicities. Conjugated at a higher DAR value of 6, DB-1311 showed more potent antitumor activities compared to DS-7300 in vitro and in vivo in both high and medium B7-H3 expression models, based on preclinical results published at the 2023 AACR Annual Meeting. DB-1311 demonstrated high selectivity by targeting the 4IgB7-H3 isoform, which is predominantly found on B7-H3-overexpressing tumor cells, with over 1,000-fold greater



affinity compared to the 2lgB7-H3 isoform commonly expressed on normal cells. This high selectivity differentiates DB-1311 and aims to enable the delivery of DB-1311's payload directly into tumor cells. Meanwhile, DB-1311's Fc-silenced mAb is designed to reduce unwanted immune responses. In preclinical studies, DB-1311 has shown a significantly higher highest non-severely toxic dose (HNSTD) and better binding to B7-H3-expressing lung cancer cells compared to DS-7300.

As of Jun 2025, there were no approved B7-H3-targeted therapies, including ADCs, globally or in China. To compete effectively in the B7-H3 ADC market, DualityBio is actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, with a strategic focus on SCLC and CRPC, potentially expanding to NSCLC and other solid tumors, like HNSCC, HCC, etc.

Lung cancer is the most common cancer and the leading cause of cancer death worldwide. SCLC represents 10-15% of all lung cancer cases globally. Chemotherapy is still the mainstay for SCLC treatment. However, SCLC patients often develop resistance to chemotherapy and the disease often relapses within one year. Relapsed SCLC patients often have worse prognosis, with limited treatment options available. While immunotherapies such as PD-(L)1 inhibitors are recommended in frontline settings for extensive stage SCLC patients, there remains a significant unmet need for new and more effective treatments for SCLC patients.

CRPC is a severe form of prostate cancer that exhibits resistance to treatments aiming to reduce testosterone levels. Among the subtypes of CRPC, mCRPC is particularly advanced and challenging. The current treatment paradigm for CRPC remains limited in its ability to provide durable and effective long-term control. Drug resistance remains a critical challenge in the treatment of mCRPC. While androgen deprivation therapy (ADT) like enzalutamide and abiraterone provide initial benefits, most patients eventually develop resistance, leading to disease progression, underscoring the potential of innovative targeted therapy to address this unmet needs.

Besides SCLC and CRPC, DualityBio is also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC. Additionally, to explore the potential of DB-1311 in combination with next-generation IO, BioNTech has started a phase 1/2 trial of DB-1311 in combination with BNT327 (PD-L1/VEGF bsAb) in NSCLC and SCLC (NCT06892548), while DualityBio is starting a phase 2 trial (NCT06953089) of DB-1311 in combination with BNT327 in multiple solid tumors, including HCC, CC, HNSCC and NSCLC.

Leading B7-H3 ADC for SCLC and CRPC with global potential and combination therapy opportunities

Key player in the global B7-H3 ADC landscape for SCLC and CRPC. Despite the current absence of approved B7-H3-targeted therapies, B7-H3 ADCs have demonstrated encouraging clinical efficacy, notably in SCLC patients, sparking substantial interest and high-profile licensing deals in the field. These developments underscore the potential of B7-H3 ADCs to improve cancer patient outcomes. DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC.

SCLC is an aggressive form of lung cancer characterized by rapid growth and high rates of recurrence with a five-year survival rate of less than 7%, compared to 28% for NSCLC. However, available treatments for SCLC remain limited, primarily to chemotherapy and PD-L1 inhibitors, with only a few targeted therapies approved globally for this indication to date.

DualityBio is also investigating DB-1311's potential in treating CRPC patients, another highly underserved cancer population. To date, Daiichi/MSD's DS-7300/I-DXd only



recently entered phase 3 registrational trial for CRPC (NCT06925737). In June 2024, DB-1311 was granted Fast Track Designation by the FDA for the treatment of patients with advanced/unresectable or metastatic CRPC who have progressed on or after standard systemic regimens, in recognition of DB-1311's potential for the treatment of this challenging tumor type. While patients with metastatic prostate cancer initially respond to hormone therapy, most patients progress after 18-24 months and develop mCRPC, leading to a poor prognosis.

Novel design with the potential to enable tumor killing and wide therapeutic window. DB-1311 is designed to deliver potent tumor killing while reducing off-target toxicities. Conjugated at a higher DAR value of 6, DB-1311 showed more potent antitumor activities compared to DS-7300 *in vitro* and *in vivo* in both high and medium B7-H3 expression models, based on preclinical results published at the 2023 AACR Annual Meeting. DB-1311 demonstrated high selectivity by targeting the 4IgB7-H3 isoform, which is predominantly found on B7-H3-overexpressing tumor cells, with over 1,000-fold greater affinity compared to the 2IgB7-H3 isoform commonly expressed on normal cells. This high selectivity differentiates DB-1311 and aims to enable the delivery of DB-1311's payload directly into tumor cells. Meanwhile, DB-1311's Fc-silenced mAb is designed to reduce unwanted immune responses. In preclinical studies, DB-1311 has shown a significantly higher HNSTD and better binding to B7-H3-expressing lung cancer cells compared to DS-7300.

Promising clinical efficacy and manageable safety profile observed in phase 1/2a trial. DB-1311 showed encouraging antitumor activity in its phase 1/2a global trial in advanced solid tumors. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia. As of 27 September 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0%; rPFS data were not yet mature, with a median rPFS of 7.2 months. Updated results in CRPC (n=43) was released at ASCO 2025, with the rPFS increasing to 8.3 months for heavily pre-treated CRPC patients, warranting further study of the drug candidate in CRPC.

DualityBio is also investigating DB-1311's treatment potential in several prevalent cancer types underexplored by other clinical-stage B7-H3 ADCs. Preliminary data from DB-1311's phase 1/2a global trial also showed an acceptable and manageable safety profile, with low rates of treatment-related adverse events (TRAEs) leading to drug discontinuation, dose reduction, drug interruption, or death.

Combination potential as frontline treatment for prevalent cancers. DualityBio believes that the combination of DB-1311 with immunotherapy holds therapeutic promise, as the direct cytotoxic effects of this B7-H3 ADC synergize with the immune-activating properties of immunotherapies, potentially leading to a more powerful anti-tumor response and improved patient outcomes. DualityBio is actively exploring DB-1311's combination potential to expand into earlier treatment lines in various solid tumors, such as CRPC, SCLC, and NSCLC. BioNTech has started a phase 1/2 trial of DB-1311 in combination with BNT327 (PD-L1/VEGF bsAb) in NSCLC and SCLC (NCT06892548), while DualityBio is starting a phase 2 trial (NCT06953089) of DB-1311 in combination with BNT327 in multiple solid tumors, including HCC, CC, HNSCC and NSCLC.

Pivotal studies to start in 2025

DualityBio initiated a phase 1/2a global trial for DB-1311 for patients with advanced/metastatic solid tumors in September 2023. DualityBio completed the phase 1 study of this phase 1/2a trial in March 2024. Phase 2a dose expansion study is currently ongoing. DualityBio is focused on DB-1311's strategic positioning as one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC. Leveraging DB-1311's Fast Track Designation from the FDA, DualityBio



is also actively exploring DB-1311's potential in CRPC. DualityBio and BioNTech will continue to advance the phase 2a dose expansion study of DB-1311's phase 1/2a trial in cancer types underexplored by other clinical-stage B7-H3 ADC candidates. We expect the Company to initiate pivotal studies in 2025.

Encouraging activity with a manageable safety profile for SCLC and CRPC

Phase 1/2a Clinical Trial in Patients with Advanced/Metastatic Solid Tumors (*NCT05914116*)

Trial Design. This is a phase 1/2a study of DB-1311 in patients with advanced/metastatic solid tumors who progressed on previous standard therapies or for whom no standard therapy is available. This trial consists of two parts: phase 1 dose escalation study and phase 2a dose expansion study. Phase 1 adopts an accelerated titration at first dose level (3 mg/kg) followed with classic "3+3" design (6, 9, 12 and 15 mg/kg) given intravenous Q3W to identify the MTD and/or RP2D. Phase 2a is a dose expansion phase to confirm the safety, tolerability and explore efficacy in selected malignant solid tumors treated with DB-1311 as monotherapy.

Trial Progress. The phase 1 dose escalation study was initiated in September 2023 completed in March 2024, with all primary endpoints met. Phase 2a dose expansion study is currently ongoing. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia. As of 27 September 2024, the data cut-off date for 2024 ESMO Asia, there were 277 evaluated patients across various solid tumor types including SCLC, NSCLC, CRPC, and squamous cell carcinoma of the head and neck (SCCHN). About 75% of participants had an ECOG performance status of 1, and approximately 61% had undergone two or more lines of therapy.

Efficacy Data. DB-1311 shows encouraging antitumor activity across heavily pre-treated patients with locally advanced or metastatic solid tumors. As of 27 September 2024, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4% and the DCR was 82.4%.

Among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. The majority of patients with SCLC received 6 mg/kg and 9 mg/kg of DB-1311, with no significant difference in uORR between the two dose groups (54.5% and 58.8%, respectively).

Most patients with NSCLC had non-squamous histology (n=41), exhibiting a uORR of 22.0%, while patients with squamous NSCLC (n=25) had a uORR of 16.0%.

Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%. rPFS data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.

In other tumor types, including CC (n=4), HCC (n=12), HNSCC (n=3), and melanoma (n=11), DB-1311 also exhibited antitumor activity with uORRs of 75.0%, 25.0%, 100.0%, and 36.4%, respectively.

Safety Data. DB-1311 showed a manageable safety profile across all evaluated patients and tumor types (n=277) as of 27 September 2024. The most common TRAEs reported included nausea, neutrophil count decreased, anemia, white blood cell count decreased, decreased appetite, and platelet count decreased.

The updated results of this phase 1/2 trial in the heavily pre-treated CRPC patients (post docetaxel/hormonal therapy) were reported at 2025 ASCO. The dose optimization cohorts randomized patients to receive 6 mg/kg or 9 mg/kg Q3W DB-1311 until progression or unacceptable toxicity. As of 3 Jan 2025, of 393 patients treated with DB-1311, there were 65 patients with pre-treated CRPC. 49%/34%/14% were White/Asian/Black, and 29% had bone only disease. Median number of prior lines was 3



(range 1 – 14) and 28% had \geq 5 prior lines. Most patients received prior docetaxel (93.8%) and hormonal therapy (96.9%); other therapies included PARP inhibitors (PARPi, 15.4%), Lutetium-177 (Lu-177, 15.4%), immunotherapy (IO, 13.8%).

Among 43 response-evaluable patients, best overall response was PR in 12 pts for an unconfirmed ORR of 27.9% (8 confirmed). Median DOR was not reached (95% CI 4.2, NE). After a median follow-up of 5.7 months, median rPFS (N=57) was 8.3 months (95% CI 6.7, NE) with a 6-month rate of 86.6% (95% CI 67.8, 94.8). Outcomes were similar by dose (6 mg/kg [ORR 26.3%, 6-m rPFS rate 88.7%], 9 mg/kg [ORR 29.2%, 6-m rPFS rate 80.0%]), by line of treatment (\leq 3L [ORR 33.3%, DCR 77.8%], \geq 4L [ORR 26.7%, DCR 100%]), and by type of prior treatment (ORR: Lu-177 [25.0%], IO [33.3%], albeit lower for PARPi [16.7%]).

The CRPC safety profile (N=65) is supported by the safety in the larger overall population (N=393). TRAEs occurred in 56 (86.2%) and 343 (87.3%) pts and were Grade \geq 3 (G \geq 3) in 26 (40.0%) and 156 (39.7%) pts, respectively. TRAEs led to dose reduction in 8 (12.3%) and 39 (9.9%) pts, to discontinuation in 4 (6.2%) and 23 (5.9%) pts, and to death in 0 and 2 (0.5%) pts, respectively. Nausea and hematological events, primarily G1–2, were the most common TRAEs. Hematological TRAEs occurred more frequently with 9 mg/kg vs 6 mg/kg, both in the CRPC and overall populations.

As of 4 March 2025, as updated at the ASCO 2025, with 73 heavily pre-treated CRPC patients enrolled in the study, DB-1311 demonstrated that outcomes appear better in earlier treatment lines, while encouraging antitumor activity was also observed in later lines and regardless of number of prior NHTs, type of prior treatment, or metastatic site (caveat small sample size).

	Overall	Line where DB-1311/BNT324 administered†		Number of prior NHTs		Prior treatment [‡]			Site of metastasis [‡]		
	(N=73)	2–3L (n=13)	≥4L (n=57)	1 (n=38)	≥2 (n=32)	Cabazitaxel (n=29)	Lu-177 (n=16)	Platinum (n=15)	Liver (n=17)	Lung (n=16)	Bone (n=64)
Evaluable for response, n	52	12	38	28	22	24	6	11	16	16	43
ORR,* % [95% CI]	42.3 [28.7, 56.6]	58.3 [27.7, 84.8]	39.5 [24.0, 56.6]	53.6 [33.9, 72.5]	27.3 [10.7, 50.2]	37.5 [18.8, 59.4]	50.0 [11.8, 88.2]	36.4 [10.9, 69.2]	62.5 [35.4, 84.8]	43.8 [19.8, 70.1]	41.9 [27.0, 57.9]
DCR, % [95% Cl]	90.4 [79.0, 96.8]	83.3 [51.6, 97.9]	94.7 [82.3, 99.4]	89.3 [71.8, 97.7]	90.9 [70.8, 98.9]	91.7 [73.0, 99.0]	100 [54.1, 100]	100 [71.5, 100]	87.5 [61.7, 98.5]	75.0 [47.6, 92.7]	93.0 [80.9, 98.5]
Evaluable for rPFS, n	68	13	52	35	31	25	12	14	16	16	59
6-month	60.0	100	60.6	74.6	50.7	56.0	50.0	62 5	70.0	40.6	19 (bone only) 69.8
rPFS rate, %	69.8	100	60.6	71.6	58.7	56.9	58.9	63.5	78.0	49.6	82.0 (bone only)

Figure 4: DB-1311 outcomes in CRPC by prior treatment and metastatic site

Source: Company data, 2025 ASCO slides, CMBIGM

Recall that for CRPC patients in a similar setting, DS-7300 showed an mPFS of 5.3 months (link), and 177-Lu-PSMA-617 delivered mPFS of 8.7 months (link). The early efficacy signal of DB-1311 of 8.3 month of PFS for heavily pre-treated patients warrants further investigation of the drug candidate. In addition, the Company is also evaluating DB-1311 in the post Lu-177 CRPC and in taxane-naïve CRPC.

Strategic collaboration with BioNTech

DualityBio and BioNTech entered into a license and collaboration agreement on 31 March 2023. BioNTech received an exclusive license to develop, manufacture, and



commercialize DB-1311 globally, excluding mainland China, Hong Kong, and Macau. DualityBio retains full rights for DB-1311 in these regions. The agreement also includes a license for BioNTech to exploit certain patents and know-how related to DB-1311's B7-H3 antibody sequences, which were in-licensed from WuXi Biologics.

Under the agreement, BioNTech granted DualityBio an option to share development and commercialization costs and profits/losses for the first DB-1311 product in the US. DualityBio can exercise this option after completing the first phase II trial. BioNTech paid an upfront payment and will reimburse DualityBio for trial-related expenses.

DualityBio is eligible for milestone payments of up to \$901mn and tiered royalties on net sales. To date, \$24mn in milestone payments have been made. The royalties range from high single-digit to low double-digit percentages, subject to adjustments based on the cost-sharing option.

On 26 May 2022, DualityBio licensed from WuXi Biologics the exclusive global rights to research, develop, manufacture, and commercialize products containing a B7-H3-targeted antibody (the "B7-H3 Antibody") for all uses, including ADCs and other biologics. DB-1311 is currently the only product under this agreement. DualityBio has sole authority over global regulatory activities for the licensed products. In return, DualityBio paid an upfront fee and a US\$12mn sublicensing fee after out-licensing DB-1311 to BioNTech. WuXi Biologics is also eligible for milestones up to US\$56.75mn for ADC use and US\$39.725mn for each other modality, with US\$4.75mn paid to date. Upon commercialization, WuXi Biologics will receive low single-digit royalties on net sales.

DB-1310, one of the most advanced HER3 ADC candidates with combination potential

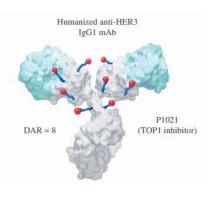
A differentiated HER3 ADC approach for EGFRm/KRASm NSCLC and other solid tumors

DB-1310 is DualityBio's self-discovered HER3 ADC and one of the world's most clinically advanced HER3 ADC candidates, according to Frost & Sullivan, for which DualityBio holds global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. DualityBio has built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

DB-1310 is a HER3-targeted ADC designed with a highly potent topoisomerase I inhibitor payload P1021, a cleavable linker containing tetrapeptide and a novel humanized anti-Her3 IgG1 monoclonal antibody. DB-1310 is designed with a DAR of 8, enabling a high concentration of the cytotoxic agent to be delivered to the tumor cell. In preclinical studies, DB-1310's mAb demonstrated higher affinity for HER3 compared to patritumab (the antibody used in U3-1402) and was more effectively internalized.



Figure 5: Drug design of DB-1310



Source: Company data, CMBIGM

HER3 ADCs present opportunities to cover a broad patient population with limited reliance on biomarker-based patient selection and overcome resistance to standard of care. As of Jun 2025, there were no approved HER3-directed therapies, including ADCs, globally or in China. DualityBio is currently developing DB-1310 for multiple subtypes of NSCLC and BC and may further expand to other solid tumors such as CRPC.

DualityBio has developed a rational and differentiated clinical development strategy for DB-1310 focused on carefully selected indications that maximize its commercial potential. For EGFRm NSCLC, while DualityBio's peers explore HER3 ADCs as a second-line or later monotherapy, DualityBio has taken a differentiated strategy to investigate DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI therapy, with opportunity as first-line treatment to cover a broader patient population. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRASm NSCLC. The Company is also exploring the efficacy signals of DB-1310 in various other solid tumors, including BC, CRPC, HNSCC, ESCC and BTC.

For BC treatments, while HER2 is a well-established target, approximately 15-40% of all BC cases are HER2 null, which show limited response to current HER2-targeted therapies. In addition, HER2-expressing BC cases commonly exhibit co-expression and activation of HER3. Inhibition of HER2 can lead to a compensatory upregulation or activation of HER3, which can limit the efficacy of HER2-targeted therapies, including HER2 ADCs such as Enhertu®. This feedback loop between the two receptors highlights the importance of developing HER3-targeted therapies to overcome potential resistance to HER2-targeted therapies. The Company is also planning studies of DB-1310 in post-Trodelvy TNBC and in combo with trastuzumab in post-Enhertu HER2+ BC.

Differentiated clinical strategy

Differentiated EGFRm NSCLC combination strategy. DB-1310 is a global clinicalstage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments. The DB-1310 monotherapy has demonstrated promising mPFS results of 8.3 months for heavily pre-treated 4L+ EGFR-TKI resistant NSCLC, highlighting the potential of the drug candidate as a monotherapy. DualityBio is also strategically developing DB-1310 in combination with osimertinib based on its translational medicine research that EGFR inhibition synergistically promotes HER3 ADC internalization and efficacy. Preclinical studies demonstrate more potent anti-tumor activity from DB-1310 and osimertinib combination therapy than either DB-1310 or osimertinib as monotherapy. DualityBio is enrolling patients in its phase 1 global dose escalation study for this combination therapy in China and the US.



Unique coverage of KRASm NSCLC. KRAS mutations are estimated to occur in approximately 30% of NSCLC cases. There are currently no global registrational trials for HER3 ADC candidates specifically targeting KRASm NSCLC, highlighting the potential of DB-1310 in this underserved area. Patients with KRASm NSCLC typically experience rapid disease progression after KRAS TKI treatments, and those who develop drug resistance face severely limited subsequent treatment options. DualityBio has observed preliminary efficacy in KRASm NSCLC patients, including partial response in dose expansion, in DB-1310's phase 1/2a global trial.

Encouraging efficacy in multiple BC subtypes. DB-1310 has demonstrated efficacy signals across multiple BC subtypes, including in TNBC patients with prior Trodelvy® treatment. DB-1310 has significant potential to treat HER2+ BC patients, including those with prior Enhertu® treatment, given HER3's critical role in drug resistance and pathway synergies with HER2.

Treatment potential for CRPC. HER3 protein is frequently overexpressed in prostate cancer, correlating with faster progression to castration resistance and reduced overall survival. In preclinical studies, DB-1310 has demonstrated significant antitumor activity against prostate cancer, indicating its potential as a promising treatment for this cancer type. DualityBio is currently recruiting patients with CRPC in DB-1310's phase 1/2a trial.

Promising preliminary data in NSCLC to support further development

DualityBio received IND approvals from the FDA and NMPA in March 2023 and May 2023, respectively, and commenced DB-1310's first-in-human global MRCT phase 1/2a clinical trial for advanced/metastatic solid tumors. The results of phase 1/2a trial in patients with advanced/metastatic solid tumors (NCT05785741) was reported at 2025 ASCO.

This is a phase 1/2a study to assess DB-1310 in patients with advanced/metastatic solid tumors who failed previous standard therapies or no standard therapy is available, regardless of HER3 expression. This trial consists of two parts: a phase 1 dose escalation study and phase 2a dose expansion study. The phase 1 study has three arms: (i) DB-1310 monotherapy (solid tumors), using a classic "3+3" design with six dose levels from 1.5 to 6.5 mg/kg, Q3W, (ii) DB-1310 combo-therapy A (HER2+ BC), combining DB-1310 with trastuzumab, and (iii) DB-1310 combo-therapy B (NSCLC with EGFR Ex19del or L858R mutation), combining DB-1310 with osimertinib. Each arm of the phase 1 study adopts a "3+3" dose escalation design to identify: the MTD and/or RP2D of DB-1310 as monotherapy, the recommended combination dose A ("RCD_A") of DB-1310 in combination with osimertinib. The phase 2a study expands into multiple cohorts of advanced/metastatic solid tumors, each exploring specific subtypes and/or combinations, to further assess the efficacy and safety of DB-1310.

As of 11 Apr2025, 172 patients were enrolled and treated with DB-1310 monotherapy in Ph1 (White, 29.1%, Asian, 65.1%; NSCLC, 62.8%, EGFRm NSCLC, 36.0%; brain metastasis, 14.0%).

Of the 62 patients with EGFRm NSCLC, 86% had previously received 3rd generation EGFR TKI, 92% had received platinum-based chemotherapy, and 39% had received immune checkpoint inhibitors. The median prior lines of systemic therapy was 3 (range, 1-11). Of the 46 efficacy-evaluable patients, the mPFS was 7.0 months overall, while the mPFS reached 8.3 months in the 5mg/kg cohort (n=16) for the 4L+ heavily pre-treated EGFRm NSCLC patients.



Figure 6: Baseline and efficacy of DB-1310 mono in heavily pre-treated EGFRm NSCLC

		Overall (N=62)*	5 mg/kg (n=16)	5.5 mg/kg (n=27)
Age, years	Median (range)	56.5 (36, 79)	60.0 (43, 72)	54.0 (36, 73)
Sex, n(%)	Male	32 (51.6%)	10 (62.5%)	12 (44.4%)
	Female	30 (48.4%)	6 (37.5%)	15 (55.6%)
Race , n(%)	Asian	49 (79.0%)	12 (75.0%)	25 (92.6%)
	White	10 (16.1%)	3 (18.8%)	1 (3.7%)
	Black	1 (1.6%)	0 (0.0%)	1 (3.7%)
ECOG PS, n(%)	0	7 (11.3%)	3 (18.8%)	0 (0.0%)
	1	55 (88.7%)	13 (81.3%)	27 (100.0%)

		Overall (N=62)*	5 mg/kg (n=16)	5.5 mg/kg (n=27)
Metastases at baseline, n(%)	Brain	17 (27.4%)	6 (37.5%)	5 (18.5%)
	Liver	11 (17.7%)	3 (18.8%)	4 (14.8%)
EGFR	19Del	35 (56.5%)	4 (25.0%)	17 (63.0%)
Mutations, n(%)	L858R 23 (23 (37.1%)	11 (68.8%)	8 (29.6%)
Prior lines	Median (range)	3.0 (1, 11)	3.0 (1, 11)	3.0 (1, 9)
Prior 3rd G TKI		53 (85.5%)	15 (93.8%)	21 (77.8%)
Prior PBC	Yes, n(%)	57 (91.9%)	13 (81.3%)	25 (92.6%)
Prior ICI		24 (38.7%)	6 (37.5%)	8 (29.6%)

	Overall (N=46)*	5 mg/kg (n=16)	5.5 mg/kg (n=12)
mFU, mo (Min, Max)	7.52 (1.7, 18.9)	9.97 (1.7, 12.5)	4.24 (3.4, 9.4)
ORR , n(%)	20 (43.5%)	6 (37.5%)	8 (66.7%)
Confirmed, n(%)	13 (28.3%)	6 (37.5%)	4 (33.3%)
Pending confirmation, n	3†	0	2†
DoR, mo (95%CI)	5.80 (2.73, NE)	6.93 (3.48, NE)	2.78 (2.73, NE)
DCR, n(%)	42 (91.3%)	14 (87.5%)	11 (91.7%)
mPFS, mo (95%CI)	7.03 (4.14, 8.41)	8.28 (2.96, NE)	4.11 (2.73, NE)
mOS, mo (95%CI)	18.89 (11.63, NE)	NR (7.10, NE)	NR (NE, NE)

⁺Response confirmations were pending for three patients, which were confirmed post DCO.

Source: Company data, 2025 ASCO, CMBIGM. Note: The median follow-up for the 5.5mg/kg was immature with just 4.24 months.



Figure 7: Manageable safety profile of DB-1310 mono in EGFRm NSCLC

n(%)	Overall (N=62)*	3 mg/kg (n=7)	4.5 mg/kg (n=9)	5 mg/kg (n=16)	5.5 mg/kg (n=27)	6 mg/kg (n=2)	6.5 mg/kg (n=1)
Any TEAE	59 (95.2%)	6 (85.7%)	9 (100.0%)	15 (93.8%)	26 (96.3%)	2 (100.0%)	1 (100.0%)
Grade ≥3 TEAE	29 (46.8%)	2 (28.6%)	6 (66.7%)	9 (56.3%)	10 (37.0%)	1 (50.0%)	1 (100.0%)
Any TRAE	57 (91.9%)	5 (71.4%)	9 (100.0%)	15 (93.8%)	25 (92.6%)	2 (100.0%)	1 (100.0%)
Grade ≥3 TRAE	22 (35.5%)	1 (14.3%)	4 (44.4%)	6 (37.5%)	9 (33.3%)	1 (50.0%)	1 (100.0%)
TRAE leading to:							
Interruption	13 (21.0%)	1 (14.3%)	2 (22.2%)	1 (6.3%)	8 (29.6%)	1 (50.0%)	0 (0.0%)
Dose reduction	6 (9.7%)	0 (0.0%)	1 (11.1%)	2 (12.5%)	3 (11.1%)	0 (0.0%)	0 (0.0%)
Discontinuation	2 (3.2%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (3.7%)	0 (0.0%)	0 (0.0%)

Source: Company data, 2025 ASCO, CMBIGM

The 8.3 months of mPFS of DB-1310 for 4L+ EGFRm TKI-resistant NSCLC with only 35.5% Grade \geq 3 TRAEs was quite competitive, in our view. Recall that sac-TMT demonstrated an mPFS of 6.9 months (HR=0.30, vs docetaxel) in the OptiTROP-Lung03 trial. Dato-DXd and HER3-DXd both reported 5.8 months of mPFS in the Ph2 TROPION-Lung05 and Ph3 HERTHENA-Lung02 trials, respectively. AK112 (PD-1/VEGF) + chemotherapy showed 7.1 months in the HARMONi-A trial (both 2L and 3L patients enrolled in the study), and amivantamab (EGFR/cMET) + chemotherapy demonstrated 6.3 months in the Ph3 MARIPOSA-2 trial, also in a mixed 2L/3L population. These benchmarks highlight DB-1310's strong efficacy profile in later-line setting as a monotherapy. Meanwhile, DualityBio is also strategically developing DB-1310 in combination with osimertinib for EGFRm NSCLC.



DB-1303/BNT323, a late clinical-stage HER2 ADC asset targeting differentiated indications

A differentiated HER2 ADC targeting HER2-expressing endometrial and HER2-low breast cancers

DB-1303 is an in-house discovered, late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2. The global HER2 ADC market is expected to increase from US\$4.8bn in 2023 to US\$18.5bn by 2028, representing a CAGR of 30.8%, according to Frost & Sullivan.

DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and a strong medical need for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, OC, CRC and esophageal cancer, supported by global clinical data from patients across the US, China and Australia to date.

To further advance DB-1303, DualityBio formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value. DualityBio has granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by DualityBio to develop, manufacture, commercialize or otherwise exploit DB-1303 and pharmaceutical products comprising DB-1303 (together "DB-1303 Products") for all uses worldwide except Mainland China, Hong Kong and Macau (the "Territory"). DualityBio retains the full rights to develop, manufacture, commercialize and otherwise exploit DB-1303 and DB-1303 Products in Mainland China, Hong Kong and Macau.

In partial consideration for granting these licenses and rights, DualityBio received an upfront payment from BioNTech. Additionally, BioNTech agreed to fund and reimburse DualityBio for reasonable costs and expenses incurred in the Territory related to conducting the DB-1303 ongoing clinical trial on behalf of BioNTech, subject to the applicable cap in the agreement. DualityBio is also eligible to receive payments upon achieving specified development, regulatory, and commercial milestones, potentially up to a total of US\$857.5mn. To date, milestone payments of US\$21.0mn have been made under this agreement. BioNTech further agreed to pay tiered royalties, ranging from single-digit to double-digit percentages, on the annual net sales of all DB-1303 Products in the Territory (subject to certain royalty reduction adjustments).

In January 2025, DualityBio appointed 3SBio as its strategic partner in Mainland China, Hong Kong, and Macau to promote DB-1303 for various indications. 3SBio will also provide related commercialization services to support DB-1303's commercial activities. DualityBio will continue to be responsible for advancing the clinical development and registration of DB-1303 before and after commercial launch, and will pay 3SBio service fees. 3SBio has paid DualityBio an upfront payment of US\$25mn and will pay DualityBio



additional up to US\$42mn milestone payments upon the achievement of specified development, regulatory, and sales-based milestones.

DB-1303 is a HER2-targeted ADC designed with a humanized anti-HER2 immunoglobulin G1 (IgG1) mAb, covalently linked to a proprietary topoisomerase I inhibitor payload (P1003) via a maleimide tetrapeptide-based cleavable linker, with a DAR of 8.

DB-1303's anti-HER2 IgG1 mAb has the same amino acid sequence as Herceptin (trastuzumab), a clinically proven HER2 mAb. Designed with a cleavable linker that is stable in plasma, DB-1303 travels through the bloodstream upon IV administration with low free payload in the system, translating to a potentially favorable safety profile. Upon selectively binding to HER2 on the surface of tumor cells, DB-1303 is endocytosed into the tumor cell, where the tetrapeptide-based linker is cleaved by lysosomal enzymes preferentially expressed in tumor cells, releasing the highly potent P1003 payload. P1003, a derivative of exatecan, leads to apoptosis of the target tumor cells via the inhibition of topoisomerase I. DB-1303 is also expected to exhibit HER2-specific antitumor activity through antibody-dependent cellular cytotoxicity (ADCC) activity and bystander killing effect.

As of Jun 2025, Kadcyla®, Aidixi®, Enhertu® and SHR-A1811 were the only HER2 ADCs approved globally or in China. DualityBio faces fierce competition in the HER2 ADC market from existing and future ADCs directed against the same molecular targets and indicated for the same indications. Such competition may become more intense due to future collaborations, mergers and acquisitions in the biopharmaceutical industry.

To compete effectively in the HER2 ADC markets, DualityBio is driving the clinical development of DB-1303 with a differentiated strategy focused on under-served indications, such as HER2-expressing EC and HER2 low-expressing BC, where existing treatments fail to offer satisfactory clinical benefits to patients. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2.

In addition to the indications described above, DB-1303's antitumor activity has been observed in a range of tumors, including OC, CRC and esophageal cancer, signifying its potential for indication expansion.

Most clinically advanced HER2 ADC globally for EC patients across HER2expression levels. EC is known to be one of the most common gynecological malignancies globally. Both the reported incidence and mortality of EC have increased in the last decade, especially in younger women, with approximately 400,000 new cases reported worldwide in 2023, according to Frost & Sullivan. Approved first- and secondline standard-of-care treatments for EC, including chemotherapy and targeted therapies, have shown limited efficacy in advanced or metastatic EC patients, highlighting an unmet medical need. The five-year survival rate for EC patients with advanced, metastatic or recurrent disease is estimated at only 18%. The global EC drug market is expected to increase from US\$5.3bn in 2023 to US\$9.0bn by 2028, representing a CAGR of 11.2%, according to Frost & Sullivan.

DualityBio aims to improve treatment for EC patients across HER2-expression levels. To date, Enhertu, the only approved HER2 ADC available for EC patients globally is indicated for pan-HER2+ solid tumors and hence covers only HER2+ (IHC 3+) EC, which is estimated to account for around 17-30% of the EC patient population. Beyond this small subset of patients, approximately 47-53% of EC patients are HER2 low-expressing with very limited treatment options, according to Frost & Sullivan.



DB-1303 is differentiated by observed anti-tumor activity across both HER2-low (IHC 1+ and IHC 2+) and HER2+ EC patients, which potentially expands its suitability to over 70% of the EC patient population. Notably, DB-1303 demonstrated an ORR of 58.8% and DCR of 94.1% in heavily pre-treated HER2-expressing EC patients (IHC 1/2/3+ or ISH-positive), including those with prior immunotherapy or anti-HER2 antibody treatments, in its phase 1/2a trial, preliminary data of which were published at the 2023 ESGO.

DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. DualityBio and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

Potential treatment for chemo-naïve HR+/HER2-low BC patients. BC is known to be the second largest cancer type in the world by incidence, according to Frost & Sullivan, with approximately 2.4mn new cases reported in 2023 of which HER2-low patients accounted for approximately 50%. The global HER2-low BC drug market is expected to increase from US\$17.2bn in 2023 to US\$25.9bn by 2028, representing a CAGR of 8.5%, according to Frost & Sullivan. DualityBio is advancing, in collaboration with BioNTech, a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC patients with the first patient dosed in January 2024.

HR+/HER2-low BC is the most prevalent subtype of BC, accounting for approximately 50% of total BC cases. Endocrine therapies (ET), such as aromatase inhibitors and a selective estrogen receptor degrader, represent the cornerstone of standard 1L and 2L treatment options for advanced HER2-low BC in China and the US. However, the recurrence rate after using ET is approximately 40-50%. Limited effective treatment options are available for recurrent patients, leaving a need for effective non-endocrine therapy-based treatment. Trastuzumab deruxtecan (Enhertu®, HER2 ADC) is recommended as 2L+ treatment for HER2-low BC patients in China and the US. As of Jun 2025, only one HER2 ADC, Enhertu®, was approved for HR+/HER2-low BC in phase 2 clinical development or beyond globally.

Phase 3 topoisomerase-based ADC for HER2+ BC in China. HER2+ BC is an aggressive type of BC, representing approximately 15-30% of total BC cases. About 20-25% of HER2+ BC patients present with advanced disease at the time of diagnosis, and 20% of early-stage patients eventually develop advanced disease. The treatment paradigm for HER2+ BC in China and the US primarily comprises combination therapy of taxane-based chemotherapy plus HER2 mAbs such as pertuzumab and trastuzumab, HER2 ADCs and other targeted therapy options. With the approval of effective treatments such as HER2 ADCs in recent years, HER2+ BC patients have experienced increased progression free survival (PFS) and overall survival (OS). However, there is still a risk of acquired resistance and need for safer treatments for long-term use. Kadcyla®, for example, carries a black box warning issued by the FDA for hepatic, cardiac and embryofetal toxicities. These limitations highlight a need for safer treatments that can prolong the survival for relapsed or refractory patients. As of Jun 2025, Kadcyla® and Enhertu® were the only two HER2 ADCs indicated for HER2+ BC approved both in the US and in China. As of the same date, there were more than a dozen HER2 ADCs targeting HER2+ BC in phase 2 clinical development or beyond globally.

DualityBio plans to complete its phase 3 China's registrational trial in 2026 for DB-1303 versus T-DM1 (trastuzumab emtansine) in patients with HER2+ unresectable and/or metastatic BC previously treated with trastuzumab and taxane and file a BLA with the NMPA by the end of 2025.



Multiple (potential) registrational studies ongoing

Based on the IND approvals from the FDA and NMPA, DualityBio initiated a phase 1/2a global trial for DB-1303 in advanced or metastatic solid tumors in January 2022. As the first-in-human study for DB-1303, this phase 1/2a clinical trial provides foundational data that informs DualityBio's regulatory discussions with the competent authorities and shapes its late-stage clinical development strategy. DualityBio completed the phase 1 dose escalation study of the phase 1/2a global trial in January 2023, and initiated the phase 2a dose expansion study of this trial in the same month. DB-1303 is being investigated in multiple cohorts for various solid tumors in an ongoing phase 2a dose expansion study and has advanced into two registrational trials (one global trial and one in China) and one potential global registrational study.

In collaboration with BioNTech, DualityBio is advancing DB-1303 towards the market with the first indication projected to file for accelerated approval with the FDA as early as 2025:

First-to-market approach. DualityBio strategically adopts a first-to-market approach for DB-1303 as a potential treatment for EC across all HER2-expression levels (IHC 3+, 2+, 1+, or ISH-positive) to rapidly establish a presence in the global market. As of Jun 2025, patient enrollment had been completed for DB-1303's registrational cohort in HER2-expressing patients with advanced/recurrent EC, with a confirmatory phase 3 trial planned to commence in 2025. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations by the FDA and Breakthrough Therapy Designation by the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. Subject to the results of this potential registrational study, DualityBio and BioNTech plan to file for accelerated approval with the FDA as early as 2025.

Fast-to-market approach. DualityBio is advancing, in collaboration with BioNTech, a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC patients, with the first patient dosed in January 2024. DualityBio plans to develop DB-1303 for other prevalent tumor types, including HER2+ BC. DualityBio is conducting a phase 3 registrational trial in China for unresectable and/or metastatic BC patients previously treated with trastuzumab and taxanes and plans to file a BLA with the NMPA for this indication by the end of 2025. Building on DB-1303's clinical data from its ongoing trials, DualityBio plans to further explore its combination potential as an early line treatment, including for HER2-low BC.

No	Indication (lines of treatment)	Mono/Combo -therapy	Trial phase	Regio n	Trial status	(Planned) Trial start date	(Planned) Trial completio n date
1	Advanced or metastatic solid tumors	Mono/Combo	Phase 1/2a	Global	Phase 1: complete d Phase 2a: ongoing	January 2022	(2027)
2	HER2- expressing EC (2L+)	Mono	Potential registration al study	Global	Ongoing	Septembe r 2023	(2025)
3	HR+/HER2- low BC (chemo naive) DYNASTY- Breast02/ NCT0601833 7	Mono	Phase 3 registration al trial	Global	Ongoing	January 2024	(2028)
4	HER2+ BC (2L+) DYNASTY- Breast01/ NCT0626542 8	Mono	Phase 3 registration al trial	China	Ongoing	January 2024	(2026)

Figure 8: Key clinical trials of DB-1303



5	HER2- expressing EC (2L+) NCT0634056 8	Mono	Planned phase 3 confirmator y trial	Global	Planned	(2025)	(2029)
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Source: Company data, CMBIGM

Encouraging signals in HER2-expressing EC with manageable safety profile Potential Registrational Study for HER2 Expressing EC (*NCT05150691*)

This is a potential registrational study conducted as part of DB-1303's phase 1/2a global trial in advanced/metastatic solid tumors. This study is a multicenter, open-label, nonrandomized study to assess DB-1303 for use as a potential treatment for patients with advanced EC who have progressed on or after standard systemic treatment. Based on communications with the FDA and NMPA in September 2023 and April 2024, respectively, results from this potential registrational study will be used to support the application for accelerated approval (in the US) and conditional approval (in China) for HER2-expressing EC. A phase 3 confirmatory trial for DB-1303 in HER2-expressing EC patients is required for full marketing approval post accelerated/ conditional approval.

Study Design. Patients with advanced/unresectable, recurrent, or metastatic HER2expressing (IHC 1/2/3+ or ISH+) EC have been enrolled and are treated with DB-1303, including subjects with or without prior immune checkpoint inhibitor (ICI) treatments.

Study Progress. This study is currently ongoing. DualityBio published the preliminary data from DB-1303's dose escalation and expansion studies in patients with HER2-expressing advanced/metastatic EC at the 2023 ESGO. As of May 8, 2023, the data cut-off date for the 2023 ESGO, 32 patients with EC received 7 or 8 mg/kg doses of DB-1303. The median treatment duration was 2.6 (range, 0.7-10.4) months with 29 patients (90.6%) remaining on treatment. Median number of prior regimens for metastatic disease was 2 (range, 1-10). Nineteen patients (59.4%) had prior immunotherapy therapy.

Efficacy Data. DB-1303 demonstrated promising antitumor activity with high disease control in patients with advanced/metastatic EC, including serous and carcinosarcomas. As of May 8, 2023, 17 patients were evaluable for response. Ten patients (58.8%) had objective partial tumor response per RECIST v1.1. The ORRs for patients at 7 and 8 mg/kg dose were 50.0% (2/4) and 61.5% (8/13), respectively. The overall DCR was 94.1%. The table below sets forth a summary of the efficacy data as of 8 May 2023.

Response Type	Dose Escalation	Dose Escalation	Dose Expansion	Pooled	Total
	7 mg/kg (n=4)	8 mg/kg (n=4)	8 mg/kg (n=9)	8 mg/kg (n=13)	n=17
Best Overall Response,	n (%)				
PR	2 (50.0)	4 (100)	4 (44.4)	8 (61.5)	10 (58.8)
SD	2 (50.0)	0	4 (44.4)	4 (30.8)	6 (35.3)
PD	0	0	1 (11.1)	1 (7.7)	1 (5.9)
Unconfirmed ORR, n (%)	2 (50.0)	4 (100)	4 (44.4)	8 (61.5)	10 (58.8)
Confirmed ORR, n (%)	1 (25.0)	3 (75.0)	0	3 (23.1)	4 (23.5)
Pending Confirmation ORR, n (%)	1 (25.0)	1 (25.0)	4 (44.4)	5 (38.5)	6 (35.3)
Unconfirmed ORR By Hi	stology, n/N (%)			
Serous Carcinoma	1/1 (100)	4/4 (100)	2/3 (66.7)	6/7 (85.7)	7/8 (87.5)
Adenocarcinoma	1/2 (50.0)		0/1	0/1	1/3 (33.3)
Carcinosarcoma			1/2 (50.0)	1/2 (50.0)	1/2 (50.0)
Mixed Adenocarcinoma			1/2 (50.0)	1/2 (50.0)	1/2 (50.0)
Unconfirmed DCR, n (%)	4 (100)	4 (100)	8 (88.9)	12 (92.3)	16 (94.1)

Figure 9: Efficacy results of DB-1303 in HER2-expressing EC

Source: Company data, CMBIGM

Safety Data. DB-1303 showed a manageable safety profile. As of 8 May 2023, no TEAEs leading to death or dose discontinuation occurred. No adverse event of special interest (AESI) occurred, and no DLT was observed in dose escalation. The following table sets forth a summary of the safety data as of 8 May 2023.

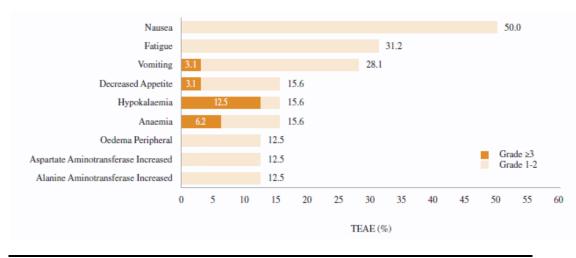
Figure 10: Safety results of DB-1303 in HER2-expressing EC

Response Type	Dose Escalation	Dose Escalation	Dose Expansion	Pooled	Total
	7 mg/kg (n=4)	8 mg/kg (n=4)	8 mg/kg (n=9)	8 mg/kg (n=13)	n=17
TEAEs	4 (100)	4 (100)	22 (91.7)	26 (92.9)	30 (93.8)
Study treatment related	4 (100)	4 (100)	18 (75.0)	22 (78.6)	26 (81.2)
Grade ≥ 3 TEAEs	2 (50.0)	1 (25.0)	7 (29.2)	8 (28.6)	10 (31.2)
Study treatment related Serious TEAEs	1 (25.0) 1 (25.0)	0 0	4 (16.7) 3 (12.5)	4 (14.3) 3 (10.7)	5 (15.6) 4 (12.5)
TEAEs associated with dose reduction	0	0	1 (4.2)	1 (3.6)	1 (3.1)
Study treatment related	0	0	1 (4.2)	1 (3.6)	1 (3.1)
TEAEs associated with dose interruption	0	0	3 (12.5)	3 (10.7)	3 (9.4)
Study treatment related	0	0	2 (8.3)	2 (7.1)	2 (6.2)
TEAEs associated with dose discontinuation	0	0	0	0	0

Source: Company data, CMBIGM

The most frequent TEAEs of any grade were nausea (16 grade 1-2; 0 grade \geq 3), fatigue (10 grade 1-2; 0 grade \geq 3) and vomiting (8 grade 1-2; 1 grade \geq 3). The chart below sets forth the TEAEs occurring in \geq 10% of the participants. No interstitial lung disease occurred.

Figure 11: The most TEAEs of DB-1303 in HER2-expressing EC



Source: Company data, CMBIGM



DB-1305/BNT325, a TROP2 ADC candidate with potential as a frontline backbone therapy

A differentiated TROP2 ADC with combination potential

DB-1305 is an in-house discovered TROP2 ADC candidate with a global development strategy. DB-1305 is a TROP2-targeted ADC designed with a humanized anti-TROP2 lgG1 mAb, a cleavable linker, and a proprietary DNA topoisomerase I inhibitor (P1021) conjugated at a DAR value of 4. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. The global TROP2 ADC market is expected to increase from US\$1.1bn in 2023 to US\$7.7bn by 2028, representing a CAGR of 48.8%, according to Frost and Sullivan.

DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC, and TNBC. DualityBio believes this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, DualityBio is advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed.

DualityBio entered into a license and collaboration agreement with BioNTech in August 2023, where DualityBio granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by DualityBio to develop, manufacture, commercialize or otherwise exploit DB-1305 and pharmaceutical products comprising DB-1305 (together "DB-1305 Products") for all uses worldwide except Mainland China, Hong Kong and Macau. DualityBio retains the full rights to develop, manufacture, commercialize and otherwise exploit DB-1305 and DB-1305 Products in Mainland China, Hong Kong and Macau.

In partial consideration of DualityBio's granting of the licenses and rights to BioNTech under the DB-1305 License and Collaboration Agreement, DualityBio had received an upfront payment from BioNTech. In addition, BioNTech agreed to reimburse DualityBio for the reasonable costs and expenses incurred in the Territory in relation to DualityBio conducting the DB-1305 Planned Trials. DualityBio is also eligible to receive payments upon the achievement of specified development, regulatory and commercial milestones, potentially up to an aggregate of US\$826.0mn. To date, no milestone payments have become due under this agreement. BioNTech further agreed to pay tiered royalties between single-digit to double-digit percentage on the annual net sales of all DB-1305 Products in the Territory (subject to certain royalty reduction adjustments).

As of Jun 2025, Trodelvy®, SKB264 (brand name: $\pounds \& \bar{\&} \&$ ®) and Datroway® were the only three TROP2 ADCs approved globally or in China. As of the same date, there were multiple TROP2 ADCs indicated for OC under clinical development globally and TROP2 ADCs in combination with immunotherapies in phase 1/2 clinical development or beyond globally. The global TROP2 ADC market reached US\$1.1bn in 2023.

DualityBio faces fierce competition in the TROP2 ADC market from existing and future ADCs directed against the same molecular targets and indicated for the same indications. Such competition may become more intense by future collaborations, mergers and acquisitions in the biopharmaceutical industry.

To compete effectively in the TROP2 ADC markets, DualityBio is developing DB-1305 by strategically targeting indications previously under-explored by other TROP2 ADC candidates, such as OC. DualityBio is also exploring the combination potential as backbone therapy in multiple solid tumors, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. DualityBio and BioNTech



are actively exploring DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, CC and TNBC.

OC. OC is the third most common cancer of the female reproductive system worldwide. High expression of TROP2 is reported in about 83% of OC patients. Chemotherapy represents the mainstay of standard treatments for advanced OC in China and the US, which involves platinum-based and taxane-based chemotherapy with or without antiangiogenic mAb bevacizumab. However, the disease often recurs in a more resistant form even after initial successful treatment with surgery and chemotherapy. Patients with persistent disease or progression during 1L treatment are treated with 2L approaches, primarily consisting of bevacizumab and PARP inhibitors, such as olaparib and niraparib, and platinum-based or non-platinum-based chemotherapy, depending on whether they are platinum-sensitive or platinum-resistant. Immunotherapy biomarkers who have no satisfactory alternative treatment options. However, immunotherapies, while promising, has shown limited effectiveness in OC when used as a monotherapy. This limited efficacy and high recurrence rate underscores the need for more effective and durable treatment options that can improve long-term survival outcomes for patients.

Traditionally, ADC development has focused on FR-positive OC patients, who constitute a limited subset of the OC population. Given that TROP2 is overexpressed in the majority of OC patients and the under-exploration of OC as an indication for other TROP2 ADC candidates, TROP2 ADCs targeting OC patients represent a promising therapeutic strategy with vast potential. In addition, TROP2 ADCs can potentially bypass platinum resistance, providing a novel therapeutic option when standard platinum-based chemotherapy is no longer effective. They can also be used in combination with or as a complement to standard platinum-based chemotherapy, potentially enhancing treatment efficacy.

NSCLC. TROP2 is broadly overexpressed in NSCLC, making TROP2 ADCs a promising modality for treating advanced NSCLC regardless of driver mutation status. The treatment paradigm of advanced NSCLC in China and the US can be broadly classified based on the presence or absence of driver mutations. For driver mutation-positive advanced NSCLC, the 1L treatment options include TKIs directed against specific actionable driver mutations. However, most of these patients eventually acquire resistance to this treatment. For patients who have failed TKIs, platinum-based doublet chemotherapy with or without bevacizumab, single-agent chemotherapy, or PD-(L)1 inhibitor is usually considered. In China and the US, for driver mutation-negative advanced NSCLC, the 1L+ treatment options include chemoimmunotherapy with or without anti-angiogenic mAb bevacizumab, immunotherapies such as PD-1 and CTLA-4 inhibitors with or without chemotherapy.

Targeting indications under-explored by peers (such as OC) with combination potential

Well-positioned to address underserved needs in OC treatment. DualityBio is actively investigating DB-1305 for the treatment of advanced OC. Despite the encouraging therapeutic benefits shown by TROP2 ADCs, the global clinical development of TROP2 ADCs is currently heavily focused on TNBC, HR+/HER2- BC, UC and NSCLC. Because TROP2 is a significant prognostic biomarker and therapeutic target across other prevalent or hard-to-treat cancers, this leaves unmet needs among patients. OC, for example, is one of the leading causes of cancer death in women globally with over 300,000 diagnosed each year. Frequently diagnosed at an advanced stage, OC is associated with a higher mortality rate and poor prognosis, and many OC patients develop resistance to platinum-based chemotherapies and other standard treatments. The global OC drug market is expected to increase from US\$4.8bn in 2023 to US\$8.1bn by 2028, representing a CAGR of 11.1%, according to Frost & Sullivan.

Traditionally, ADC development has focused on FR α -positive OC patients, who constitute a limited subset of the OC population. Compared to FR α -directed ADCs, DB-1305



demonstrates broader treatment potential among a wide range of OC patients, due to TROP2's high overexpression rate (~83%) in this cancer type. In its ongoing phase 1/2a global trial, DB-1305 has shown preliminary efficacy in an all-comer cohort of advanced PROC patients. In January 2024, DB-1305 was granted Fast Track Designation by the FDA for patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, acknowledging its potential to address unmet medical needs.

Combination potential as backbone therapy in multiple solid tumors. DualityBio and BioNTech are actively exploring DB-1305's combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to evaluate the combination of DB-1305 and BNT327 (PD-L1/VEGF bsAb), aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. Early preclinical and clinical evidence released at the AACR 2025 (link) support BNT327 + ADC combinations. In October 2024, in China, DualityBio received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with late-stage/metastatic solid tumors.

Encouraging efficacy and manageable safety profile from phase 1/2a trial. Based on preliminary data from DB-1305's ongoing phase 1/2a global trial, which were published at the 2023 ESMO, DB-1305's uORR was 30.4% among heavily pre-treated patients with advanced solid tumors as of April 7, 2023. Among the 23 patients with post-baseline tumor scans, encouraging preliminary efficacy signals were observed in NSCLC patients: uORR was 46.2%. Encouraging preliminary efficacy signals of DB-1305 have also been observed in multiple other solid tumors. Based on preliminary data from its phase 1/2a global trial, DB-1305 was well-tolerated with grade 3 or above TRAEs reported at 34.1% (15/44) in all patients and low incidences of blood-related TRAEs.

Second wave of innovative assets

DualityBio's second wave of assets, leveraging its DIBAC and DIMAC, the bispecific and immune-modulating ADC platforms, is represented by next-generation ADCs with novel formats and components that open ADCs to front-line or difficult-to-treat settings and new therapeutic areas, such as BsADCs, including DB-1419 (B7-H3xPD-L1 BsADC), DB-1418 (EGFRxHER3 BsADC) and DB-1421, and immunemodulating ADCs for autoimmune diseases, including DB-2304 (BDCA2 ADC), and others.

DB-1419 (B7-H3xPD-L1 BsADC), potential FIC asset with data readout in 2026

DB-1419 is a potential first-in-class B7-H3xPD-L1 BsADC candidate with a DNA topoisomerase I inhibitor, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. The simultaneous action of delivering the toxin to tumor cell and modulate T cell activation provides potential synergistic anti-tumor effect. Combining payload mediated cytotoxicity with antibody mediated immunotherapy activity, DB-1419 provides an innovative approach for cancer treatment.

DualityBio believes B7-H3's pan-cancer expression coupled with PD-L1's immunemodulating function may offer enhanced anti-tumor effects across broad indications. Preclinical studies showed that DB-1419 exhibits both direct cancer cell killing and immune-modulation, with more potent tumor growth inhibition activity than the monospecific B7-H3 ADC and the monospecific B7-H3 ADC in combination with a PD-L1 mAb in immune reconstituted models. Moreover, it was well tolerated with repeat dose administration up to 120 mg/kg in monkeys.

DualityBio has obtained IND approval from the FDA for DB-1419 and initiated DB-1419's phase 1/2a global trial in September 2024.

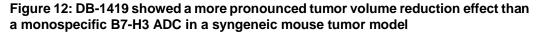
First-mover advantage. DB-1419 is a potential first-in-class B7-H3xPD-L1 BsADC candidate, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. As of Jun 2025, there were no approved drugs

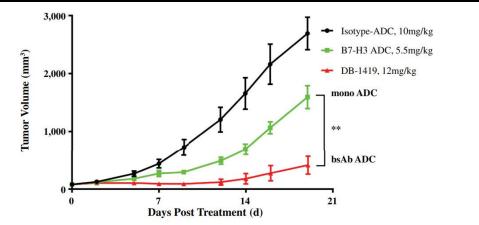


targeting both B7-H3 and PD-L1 globally and no B7-H3xPD-L1 BsADC candidates under clinical development worldwide. We believe B7-H3's pan-cancer expression coupled with PD-L1's immune-modulating function may offer enhanced anti-tumor effects across broad indications.

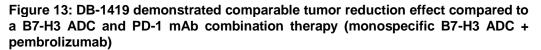
Synergistic immune modulation. By targeting PD-L1, DB-1419 blocks the interaction between PD-L1 and PD-1. This blockade reverses PD-L1-mediated immune suppression, enhancing T cell activation and promoting a robust anti-tumor immune response. The dual action of direct cytotoxicity and immune modulation can potentially improve overall therapeutic efficacy.

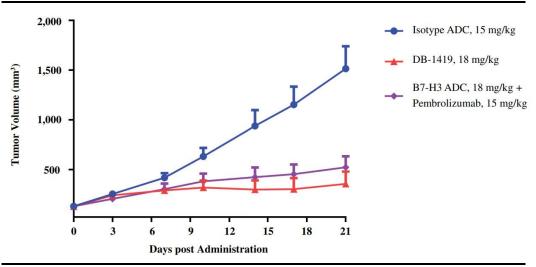
Potentially better efficacy than B7-H3 ADC. DB-1419 demonstrated superior efficacy over a monospecific B7-H3 ADC in syngeneic model and immune reconstitute model in preclinical studies. The results indicated that DB-1419 exhibit tumor growth inhibition effect through the simultaneous action of immune check point inhibitor activity and payload toxicity activity.





Source: Company data, CMBIGM





Source: Company data, CMBIGM



DualityBio has obtained IND approval from the FDA for DB-1419 and initiated DB-1419's phase 1/2a global trial in September 2024. DualityBio submitted an IND application to the NMPA in December 2024 to initiate DB-1419's phase 1/2a trial in China. DualityBio plans to explore the potential of DB-1419 across various solid tumors, including SCLC, HCC, NSCLC, melanoma, ESCC, and TNBC. DualityBio plans to publish the study design for DB-1419's phase 1/2a global trial at the 2025 AACR Annual Meeting, with data readout anticipated in 2026, and to complete this trial by 2027. As the first-in-human study for DB-1419, this phase 1/2a clinical trial provides foundational data that informs DualityBio's regulatory discussions with the competent authorities and shapes its late-stage clinical development strategy.

DB-1418/AVZO-1418 (EGFRxHER3 BsADC), differentiated drug design to potentially overcome drug resistance

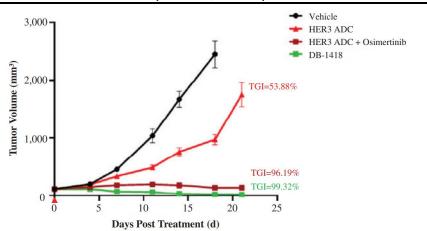
DB-1418 is an in-house discovered EGFRxHER3 BsADC. Due to target synergies, EGFRxHER3 BsADCs have demonstrated enhanced efficacy and ability to overcome resistance to EGFR- or HER3-directed treatments in clinical studies. DualityBio's DB-1418 is differentiated by a "1+1" format molecule design (two binding sites, one for each target) that translates to higher binding affinity to tumor cells as opposed to healthy cells. DB-1418 has also shown better efficacy in EGFR-resistant, EGFR-low or HER3-resistant models, potentially offering broader patient coverage. DualityBio is conducting IND-enabling studies for DB-1418 and expects to advance this molecule into clinical stage.

DualityBio entered into a collaboration and license agreement with Avenzo in December 2024, pursuant to which DualityBio granted Avenzo an exclusive license to develop, manufacture and commercialize DB-1418 globally excluding Greater China. DualityBio has also granted to Avenzo a non-exclusive license to develop and manufacture DB-1418 in Greater China solely for the development of DB-1418, for purposes of obtaining regulatory approval for DB-1418 and for the other exploitation of DB-1418 outside Greater China. DualityBio retains all other rights to develop, manufacture, commercialize and otherwise exploit DB-1418 in Greater China.

Differentiated "1+1" format molecule design. Leveraging the "1+1" format molecule design, DB-1418 exhibited higher binding affinity to tumor cells (which express both EGFR and HER3) compared to other BsADCs with a "2+2" design. Due to the "1+1" design, DB-1418 also demonstrates better internalization than other "2+2" format HER3xEGFR BsADCs.

Synergistic efficacy. Simultaneously binding to EGFR and HER3 by DB-1418 potentially translates to synergistic anti-tumor effects, significantly enhancing its therapeutic impact compared to traditional monospecific ADCs. In preclinical studies, DB-1418 achieved tumor growth inhibition of 99.32% in the NCI-H1975 model (EGFR++, HER3+) at 6mg/kg, significantly higher than the TGI of 53.88% for a HER3-targeting ADC.

Figure 14: DB-1418 in NCI-H1975 (EGFR++, HER3+) model



Source: Company data, CMBIGM



Overcoming resistance. A major advantage of DB-1418 is its ability to overcome resistance to conventional EGFR-targeted therapies. EGFR can bind to multiple ligands and, once internalized, the ligand-receptor complex can be recycled to cell surface. The recycling of ADCs may lead to inefficient payload processing in lysosome and potentially contribute to resistance mechanism of anti-EGFR monospecific ADCs. BsADCs like DB-1418 can better modulate intracellular trafficking by targeting two receptors and hence enhance intracellular release of payload.

DualityBio is conducting IND-enabling studies for DB-1418 and expects to advance this molecule into clinical stage in the first half of 2025. DualityBio plans to explore the potential of DB-1418 across various solid tumors, including ESCC, HNSCC, CRC, non-melanoma skin cancer, NSCLC, GC, pancreatic adenocarcinoma, nasopharyngeal cancer, bladder cancer, and BC.

DB-2304 (BDCA2 ADC), one of the most advanced ADCs targeting SLE and CLE

DB-2304 is a potential first-in-class BDCA2 ADC candidate for systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE), being one of the most advanced BDCA2 ADCs in terms of development progress, according to Frost & Sullivan. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system. DB-2304 holds promise to substantially improve upon the standard of care for SLE and CLE, such as glucocorticoids and immunosuppressants, and represents a major step in the innovation of autoimmune ADCs.

DualityBio designed DB-2304 with a novel BDCA2 mAb conjugated with a proprietary glucocorticoid receptor (GR) agonist as a payload. BDCA2 is a validated target that is specifically expressed on plasmacytoid dendritic cells (pDCs), whose over-production of type I interferon (IFN-I) is crucial in SLE and CLE pathogenesis. Although BDCA2-targeted mAbs have demonstrated reduced disease activity in SLE patients, their clinical efficacy is generally limited. By selectively targeting BDCA2, DB-2304 can deliver the immunemodulating payload directly to pDCs, which has demonstrated greater potency with synergistic effects in suppressing production of IFN-I as well as other pro-inflammatory cytokines in preclinical studies. Moreover, by delivering the GR agonist in a site-specific manner, DB-2304 showed good drug stability and serum stability, as well as a promising safety profile with a no observed adverse effect level (NOAEL) of 85 mg/kg in monkeys.

Novel targeted treatment to address unmet needs for SLE and CLE. SLE and CLE are autoimmune diseases that together affect over eight million patients globally, according to Frost & Sullivan. A major shortcoming of mainstay treatments, such as glucocorticoids and immunosuppressants, is their inability to address the high heterogeneity of pathogenesis in these complex diseases, which often result in limited efficacy and serious side effects, especially when used long term for chronic disease management. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system.

Good stability and safety profile. In preclinical studies, DB-2304 showed strong stability in plasma with little change in concentration or DAR value up to 21 days. Good stability and low level of systemic exposure of free payload indicates a good safety profile. DB-2304 also showed promising safety profile with a NOAEL of 85 mg/kg.

Strong efficacy with synergistic functions. Preclinical studies also show that DB-2304 demonstrates greater potency with synergistic effects in suppressing production of both IFN-I and pro-inflammatory cytokines. DB-2304 is designed to combine the efficacy of mechanisms mediated by BDCA2-targeting mAb (demonstrated by INF α suppression) and the GR agonist payload (demonstrated by IL-6 and IP-10 suppression).

DualityBio initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024, and has submitted IND applications to both the FDA and NMPA for DB-2304 and,



subject to regulatory approval, expects to complete DB-2304's phase 1 global trial in 2026 through separate protocols assessing single ascending doses in healthy volunteers and multiple ascending doses in SLE/CLE patients. Subject to clinical progress and communications with the competent authorities, DualityBio plans to achieve proof-of-concept in SLE patients in 2025 and enroll the first patient in DB-2304's phase 2 clinical trial in 2026.



Third wave of innovative assets

The Company's third wave of assets, enabled by DUPAC, its novel MOA payload ADC platform, is the driving force behind its novel ADC payload and linker technologies that potentially disrupt the ADC modality, opening the possibility to reach hard-to-treat tumors and staying ahead of the growing need to overcome acquired resistance to existing ADCs. DualityBio aims to receive the first IND approval for an ADC candidate derived from its DUPAC platform as early as 2026.

Duality Unique Payload Antibody Conjugate (DUPAC) reflects DualityBio's foresight into the future landscape of ADC innovation. DUPAC is one of the few ADC platforms globally dedicated to the development of linker-payload complexes with novel mechanisms of action, beyond traditional cytotoxic agents, to combat growing drug resistance and hard-to-treat tumors. Notably, the anti-proliferation activity of its unique payload, P5142, was examined on various cancer type cells and compared with Dxd, a DNA topoisomerase I inhibitor. Cell viability was evaluated after five days' treatment using the CellTiter-Glo® Luminescent Cell Viability kit. Significantly superior potency of P5142 was observed in Dxd-insensitive (low-response) cancer cells BT-474, JIMT-1 and NCI-H660. Overall, the different susceptibility of cells to Dxd and P5142 is due to the distinct mechanism of action of these two payloads.

DualityBio has made promising progress in a number of unique payload mechanisms and have obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies. In particular, its in-house discovered lead prototype has a unique mechanism of action with demonstrated broadspectrum anti-tumor activity across multiple solid tumors and remains potent in tumors resistant to deruxtecan. ADCs designed with its lead prototype have also shown potent direct and bystander killing effects and induce strong immunogenic cell death. DB-1316, for example, is a novel ADC asset derived from the DUPAC platform currently in preclinical stage positioned to target deruxtecan-resistant solid tumors. DualityBio aims to receive the first IND approval for an ADC candidate derived from its DUPAC platform as early as 2026.



Financial Analysis

We expect DualityBio's total revenue to reach RMB2.0bn/ 1.5bn/ 1.5bn in FY25E/ 26E/ 27E, mainly from license and collaborations revenue with its extensive partners. We expect the Company to book product sales revenue in 2027E.

Figure 15: Revenue forecasts

Revenue (RMB mn)	2023A	2024A	2025E	2026E	2027E	2028E	2029E	2030E
Sales of goods in China	0	0	0	0	551	1,007	2,159	3,612
DB-1311 (B7-H3 ADC) - China	0	0	0	0	0	28	130	350
DB-1310 (HER3 ADC) - China	0	0	0	0	0	95	541	1,209
DB-1305 (TROP2 ADC) - China	0	0	0	0	0	89	237	458
DB-1303 (HER2 ADC) - China	0	0	0	0	551	795	1,201	1,530
Licensing revenue & service income	1,787	1,941	1,992	1,487	996	1,724	2,000	2,658
DB-1311 (B7-H3 ADC), BioNTech - overseas	728	462	507	507	435	246	262	318
DB-1310 (HER3 ADC), Potential Partner - overseas	0	0	0	0	0	28	127	254
DB-1305 (TROP2 ADC), BioNTech - overseas	339	287	290	290	290	231	282	376
DB-1303 (HER2 ADC), BioNTech - overseas	700	817	580	442	241	320	430	513
DB-1303 (HER2 ADC), 3SBio - China	0	0	254	30	30	30	30	30
Other products	20	375	362	217	0	869	869	1,166
DB-1312 (B7H4 ADC) - upfront & milestone from BeiGene		332				291	291	291
DB-1312 (B7H4 ADC) - royalties from BeiGene								87
DB-1418 (HER3xEGFR BsADC) - upfront & milestone from Avenzo			362			312	312	312
DB-1418 (HER3xEGFR BsADC) - royalties from Avenzo								94
DB-1324 (unknown ADC) - upfront & milestone from GSK				217		265	265	265
DB-1324 (unknown ADC) - royalties from GSK								
Others (BDCA2 ADC, B7H3-/PD-L1 ADC, etc.)	20	43						117
Total	1,787	1,941	1,992	1,487	1,547	2,731	4,159	6,270

Source: Company data, CMBIGM estimates

DualityBio recorded net losses of RMB1,050mn in FY24A. We expect the Company to book attributable net loss of RMB675mn/ 592mn/ 618mn in FY25E /26E/ 27E.

Figure 16: P&L forecasts

YE Dec 31 (RMB mn)	2023A	2024 A	2025 E	2026 E	2027 E	2028 E	2029 E	2030 E
Revenue	1,787	1,94 1	1,99 2	1,48 7	1,54 7	2,73 1	4,15 9	6,27 0
ҮоҮ	111559 %	9%	3%	- 25%	4%	77%	52%	51%
Cost of sales	(428)	(1,15 7)	(1,12 7)	(797)	(705)	(1,02 6)	(648)	(1,01 1)
% of revenue	24%	60%	57%	54%	46%	38%	16%	16%
Gross profit	1,359	785	865	690	842	1,70 5	3,51 1	5,25 9
GPM	76%	40%	43%	46%	54%	62%	84%	84%
Selling and distribution expenses % of revenue	0	0	0	(100) 7%	(441) 29%	(604) 22 <i>%</i>	(864) 21%	(1,26 4) 20%
Administrative expenses % of revenue	(63) 4%	(159) <i>8%</i>	(200) 10%	(268) 18%	(232) 15%	(355) 13%	(499) 12%	(690) 11%
R&D expenses	(559)	(837	(920	(1,01 2)	(851	(1,09 2)	(1,45 6)	(1,88 1)
% of revenue	31%	43%	4 6%	68%	55%	40%	35%	30%
Profit/(loss) before tax	(202)	(1,01 5)	(675)	(592)	(618)	(321)	709	1,45 6
Income tax benefit (expense)	(155)	(36)	0	0	0	0	(106)	(218)
Profit/(loss) for the year	(358)	(1,05 0)	(675)	(592)	(618)	(321)	603	1,23 7
Non-controlling interests	0	0	0	0	0	0	0	0
Attributable net profit/(loss)	(358)	(1,05 0)	(675)	(592)	(618)	(321)	603	1,23 7

Source: Company data, CMBIGM estimates



Valuation

Initiate at BUY with TP of HK\$270.34

We derive our target price of HK\$270.34 based on a DCF valuation (WACC: 11.04%, terminal growth rate: 2.5%).

Figure 17: Base-case risk-adjusted DCF valuation

0	,											
DCF Valuation (RMB mn)		2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT		-675	-592	-617	-321	710	1,456	2,215	3,141	4,195	4,465	4,651
Tax rate		0%	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)		-675	-592	-617	-321	603	1,238	1,883	2,670	3,566	3,795	3,953
+ D&A		23	59	87	80	74	69	65	62	60	58	56
 Change in working capital 		134	-136	-811	-240	-27	-453	-237	-208	-90	22	77
- Capex		-100	-200	-200	-50	-50	-50	-50	-50	-50	-50	-50
FCFF		-618	-869	-1,541	-531	600	803	1,661	2,474	3,485	3,825	4,037
Terminal value												48,437
Present value (RMB mn)	19,196											
Net debt (RMB mn)	-2,938											
Equity value (RMB mn)	22,134											
Equity value (HK\$ mn)	23,800											
No. of shares (mn)	88											
DCF per shares (HK\$)	270.34											
Terminal growth rate	2.5%											
WACC	11. 0 4%											
Cost of equity	14.5%											
Cost of debt	3.5%											
Equity beta	1.1											
Risk free rate	3.5%											
Market risk premium	10.0%											
Target debt to asset ratio	30.0%											
Effective corporate tax rate	15.0%											
Source: CMBIGM estimates												

Source: CMBIGM estimates

Figure 18: Sensitivity analysis (HK\$)

				WACC		
		10.04%	10.54%	11.04%	11.54%	12.04%
	3.5%	361.59	326.92	297.19	271.47	249.05
	3.0%	341.04	309.88	282.93	259.44	238.82
Terminal growth rate	2.5%	323.22	294.97	270.34	248.73	229.65
	2.0%	307.61	281.80	259.15	239.15	221.40
	1.5%	293.83	270.08	249.12	230.52	213.93

Source: Company data, CMBIGM estimates



1) Risks related to research and development of drug candidates

DualityBio depends substantially on the success of its drug candidates. If it is unable to successfully complete clinical development, obtain regulatory approvals, or achieve commercialization for its drug candidates, or if it experiences significant delays or cost overruns in doing any of the foregoing, its business and prospects could be materially and adversely affected.

DualityBio faces intense competition and rapid technological change, and there is a possibility that its competitors may develop therapies that are similar, more advanced, or more effective than its own, which may adversely affect its financial condition and ability to successfully commercialize drug candidates.

2) Risks related to dependence on third parties

DualityBio has entered into license and collaboration agreements with third parties in the development, manufacturing and commercialization of its drug candidates, and may seek and enter into additional partnerships in the future. DualityBio may fail to identify suitable business partners or may not realize the benefits of such partnerships as expected. DualityBio's rights to develop and commercialize its drug candidates are subject, in part, to the terms and conditions of licenses granted to it by others.

DualityBio relies on third parties to monitor, support and/or conduct clinical trials and preclinical studies of its drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected timelines, DualityBio may not be able to obtain regulatory approval for, or commercialize, its drug candidates, and its business could be materially affected.

3) Risks related to operations

DualityBio is a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate its current business and predict its future performance. The Company has incurred net losses since its inception and anticipates that it will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.





Appendix: Company Profile

Figure 19: Major shareholders

Shareholder	% of stake
LAV Fund	18.95
King Star Med Lp	7.49
Zhongyuan Zhu	7.39
Shanghai Yinjia Ent	7.26
Wuxi Biologics Healthcare Venture	4.74
Our District (as of the 2005) OMDION	

Source: Bloomberg (as of Jun 2025), CMBIGM

Figure 20: Directors and management profile

Name	Positions	Date of joining our Group
Dr. ZHU Zhongyuan(朱忠远)	Chairman of the Board, Executive Director and CEO	1 January 2020
Mr. ZHANG Shaoren (张韶壬)	Executive Director and Vice President of Finance	1 May 2020
Ms. SI Wen (司文)	Executive Director and Executive Director of Human Resources	16 October 2020
Dr. QIU Yang (邱杨)	Chief Scientific Officer	19 July 2021
Ms. GU Wei (顾薇)	Chief Medical Officer	18 July 2022
Mr. WANG Xin (王昕)	Senior Vice President of Strategy and Business Development	27 June 2022
Dr. HUA Haiqing (花海 清)	Senior Vice President and Head of Drug Discovery	1 July 2021
Mr. YU Xin (于鑫)	Vice President and Head of Regulatory Affairs	1 August 2021
Dr. SHI Rong (施榕)	Vice President of Development Science	24 February 2022
Dr. CHU Ruiyin (储瑞 银)	Vice President of Translational Medicine	24 July 2023
Ms. ZHOU Lan (周岚)	Vice President of Commercial Strategy	1 May 2024

Source: Company data

Figure 21: Employee structure

Function	# of staff	% of total staff
Research and development	131	77.1%
Administrative	17	10.0%
Management	12	7.1%
Manufacturing and quality control	4	2.4%
Business development	6	3.5%
Total	170	100%

Source: Company data (as of 31 Dec 2024)

Figure 22: Employee location

Location	Number of Employees	% of total
China	147	86.5%
US	23	13.5%
Total	170	100%



Financial Summary

	20224	20224	20244	20255	20205	20275
INCOME STATEMENT	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Revenue	2	1,787	1,941	1,992	1,487	1,547
Cost of goods sold	0	(428)	(1,157)	(1,127)	(797)	(705)
Gross profit	2	1,359	785	865	690	842
Operating expenses	(372)	(622)	(995)	(1,120)	(1,380)	(1,524)
Selling expense	0	0	0	0	(100)	(441)
Admin expense	(32)	(63)	(159)	(200)	(268)	(232)
R&D expense	(340)	(559)	(837)	(920)	(1,012)	(851)
Operating profit	(369)	781	(189)	(255)	(690)	(682)
Other income	0	3	7	0	0	0
Gain/loss on financial assets at FVTPL	(22)	(1,018)	(873)	(500)	0	0
Other gains/(losses)	1	41	14	0	0	0
Interest income	3	34	48	81	98	65
Interest expense	(0)	(0)	(0)	(0)	(0)	(1)
Pre-tax profit	(387)	(202)	(1,015)	(675)	(592)	(618)
Income tax	0	(155)	(36)	0	0	0
Minority interest	0	0	0	0	0	0
Net profit	(387)	(358)	(1,050)	(675)	(592)	(618)
BALANCE SHEET	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Current assets	405	1,334	1,910	3,039	2,469	2,005
Cash & equivalents	376	1,131	1,209	2,717	2,147	906
Restricted cash	0	43	227	227	227	227
Receivables	1	101	379	0	0	121
Inventories	0	0	0	0	0	657
Prepayment	5	27	25	25	25	25
Other current assets	23	33	70	70	70	70
Non-current assets	59	166	180	257	399	511
PP&E	3	12	13	90	231	344
Right-of-use assets	5	5	6	6	6	6
Intangibles	51	54	46	46	46	46
Other non-current assets	1	94	116	116	116	116
Total assets	464	1,500	2,090	3,296	2,868	2,517
		1,000	_,	0,200	_,	_,
Current liabilities	1,231	2,561	3,872	580	444	411
Payables	129	235	671	426	290	257
Other current liabilities	1,099	2,263	2,959	(87)	(87)	(87)
Lease liabilities	3	3	3	3	3	3
Contract liabilities	0	60	238	238	238	238
Non-current liabilities	2	63	241	241	541	841
Long-term borrowings	0	0	0	0	300	600
Other non-current liabilities	2	63	241	241	241	241
Total liabilities	1,233	2,624	4,112	820	985	1,251
	~	0	•	^	^	~
Share capital	0	0	0	0	0	0
Retained earnings	(753)	(1,156)	(2,245)	(2,920)	(3,512)	(4,130)
Other reserves	(16)	32	223	5,396	5,396	5,396
Total shareholders equity	(769)	(1,124)	(2,022)	2,476	1,883	1,266
Minority interest	0	0	0	0	0	0
Total equity and liabilities	464	1,500	2,090	3,296	2,868	2,517

			00044	00055	00005	00075
CASH FLOW	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	(387)	(202)	(1,015)	(675)	(592)	(618)
Depreciation & amortization	0	1	3	23	59	87
Tax paid	0	(249)	(55)	0	0	0
Change in working capital	58	240	261	134	(136)	(811)
Others	29	1,026	1,091	500	0	1
Net cash from operations	(299)	816	286	(18)	(669)	(1,341)
Investing						
Capital expenditure	(2)	(11)	(4)	(100)	(200)	(200)
Others	(209)	(89)	(196)	(100)	150	150
Net cash from investing	(211)	(100)	(200)	(200)	(50)	(50)
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	0	0	0	0	300	300
Proceeds from share issues	0	0	0	1,626	0	0
Others	451	11	(8)	(0)	(0)	(1)
Net cash from financing	451	11	(8)	1,625	300	299
Net change in cash						
Cash at the beginning of the year	228	376	1,131	1,209	2,717	2,147
Exchange difference	18	6	1,131	0	2,717	2,147
Cash at the end of the year	376	1,131	1,209	2,717	2,147	906
GROWTH	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Revenue	na	111,558.8%	8.7%	2.6%	(25.4%)	4.0%
Gross profit	na	84,830.3%	(42.3%)	10.2%	(20.2%)	22.0%
PROFITABILITY	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec	LULLIN	2020/1	202-171	LOLOL	20202	
Gross profit margin	100.0%	76.1%	40.4%	43.4%	46.4%	54.4%
Operating margin	(23,036.4%)	43.7%	(9.7%)	(12.8%)	(46.4%)	(44.1%)
Return on equity (ROE)	na	na	na	(297.5%)	(27.2%)	(39.2%)
GEARING/LIQUIDITY/ACT		2023A	2024A	2025E	2026E	2027E
IVITIES						
YE 31 Dec	0.0	0.5	0.5	5.0	5.0	4.0
Current ratio (x)	0.3	0.5	0.5	5.2	5.6	4.9
Receivable turnover days	0.0	na	na	100.0	90.0	80.0
Inventory turnover days	0.0	0.0	0.0	0.0	0.0	340.0
Payable turnover days	0.0	155.5	142.9	137.9	132.9	132.9
VALUATION	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
P/E	ns	ns	ns	ns	ns	ns
P/E (diluted)	ns	ns	ns	ns	ns	ns
P/B	ns	ns	na	7.1	9.3	13.9

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.





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