COMPANY INITIATION

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Samsung Epis Holdings (0126Z0)

To eventually secure a platform valuation

- We initiate coverage of Samsung Epis Holdings with a BUY rating and a target price of KRW600,000.
- Solid biosimilar sales growth at subsidiary Samsung Bioepis underpins stable cash flows at Samsung Epis Holdings. Via the expansion of next-generation biosimilars and the rolling out of novel drug platforms, the firm should eventually re-rate.

WHAT'S THE STORY?

Biosimilar market outlook: The European biosimilar market has entered a mature phase. In its early stages, following the launch of first-generation blockbuster biosimilars, the market was characterized by intense price competition among numerous entrants. The market has since consolidated around a few players that have a competitive edge, shifting the key determinant of market share from price to product-specific sales strategy. The US market, while lagging behind Europe in terms of biosimilar adoption, is now experiencing rapid growth. Initially, penetration was hindered by PBM preference for originator products and rebate-driven pricing structures. However, structural reforms in the US PBM system coupled with increasingly biosimilar-friendly regulatory and reimbursement policies are creating a favorable long-term environment for increased biosimilar prescription penetration. Subsidiary Samsung Bioepis is moving beyond a low-price strategy, leveraging product differentiation through high-concentration formulations, user-friendly auto-injector delivery systems, and comprehensive patient support programs to expand its market share in both Europe and the US.

(Continued on the next page)

SUMMARY FINANCIAL DATA

	2025	2026E	2027E	2028E
Revenue (KRWb)	252	1,867	1,999	2,192
Operating profit (KRWb)	-64	255	267	278
Net profit (adj) (KRWb)	85	210	197	222
EPS (adj) (KRW)	21,211	8,429	7,924	8,919
EPS (adj) growth (% y-y)	n/a	-60.3	-6.0	12.5
EBITDA margin (%)	1.8	36.5	38.4	37.9
ROE (%)	1.4	3.5	3.2	3.5
P/E (adj) (x)	35.0	48.9	52.1	46.3
P/B (x)	3.1	1.7	1.6	1.6
EV/EBITDA (x)	4,190.9	15.6	13.2	11.5
Dividend yield (%)	0.0	n/a	n/a	n/a

Source: Company data, Samsung Securities estimates

▶ AT A GLANCE

BUY

Target price	KRW600,000	45.5%
Current price	KRW412,500	
Market cap	KRW10.3t / USD6.7b	
Shares (float)	24,883,049 (25.4%)	
52-week high/low	KRW743,000/KRW335,500	
Avg daily trading value (60-day)	KRW27.7b/ USD18.1m	

▶ ONE-YEAR PERFORMANCE

	1M	6M	12M
Samsung Epis Holdings (%)	-17.5	-37.8	n/a
Vs Kospi (%pts)	-29.0	-72.0	n/a

▶ KEY CHANGES

(KRW)	New	Old	Diff
Recommend.	BUY		
Target price	600,000		
2026E EPS	8,429		
2027E EPS	7,924		

▶ SAMSUNG vs THE STREET

No of estimates	2
Target price	620,000
Recommendation	3.5

※ Rating: 4 < → BUY, 3 = HOLD, 2 > → SELL

Initiating coverage at BUY with a 12-month target price of KRW600,000: We initiate coverage of Samsung Epis Holdings with a BUY rating and a target price of KRW600,000. Our valuation employs a dual approach—discounted cash flow (DCF) and EV/EBITDA—both of which yield similar intrinsic values. Subsidiary Samsung Bioepis' EBITDA is set to grow at a CAGR of 13% over 2026-2032, driven by new biosimilar launches and a rising US market penetration. While a discount-to-NAV is unavoidable (given its holding company structure), Samsung Epis Holdings looks undervalued versus its peers. For instance, Celltrion—operates a vertically integrated biosimilar business spanning development, manufacturing, and commercialization—commands a higher valuation multiple. Samsung Epis Holdings appears undervalued due to its holding company nature and short-term supply-demand uncertainty. This discount may narrow though if Samsung Bioepis expands its portfolio and its novel drug assets start being recognized in valuation models.

Resolving the discount is critical

Biosimilars represent sustained high growth; novel drugs remain an option

Despite sustained high-growth momentum for biosimilars, Samsung Epis Holdings' stock has underperformed due to structural factors: A holding company discount, amortization of purchase price allocation (PPA) expenses, and the lack of market recognition for its early-stage novel drug pipeline. Key to closing this discount should be revenue from new products and the public disclosure of clinical data related to novel drug candidates.

Investment points

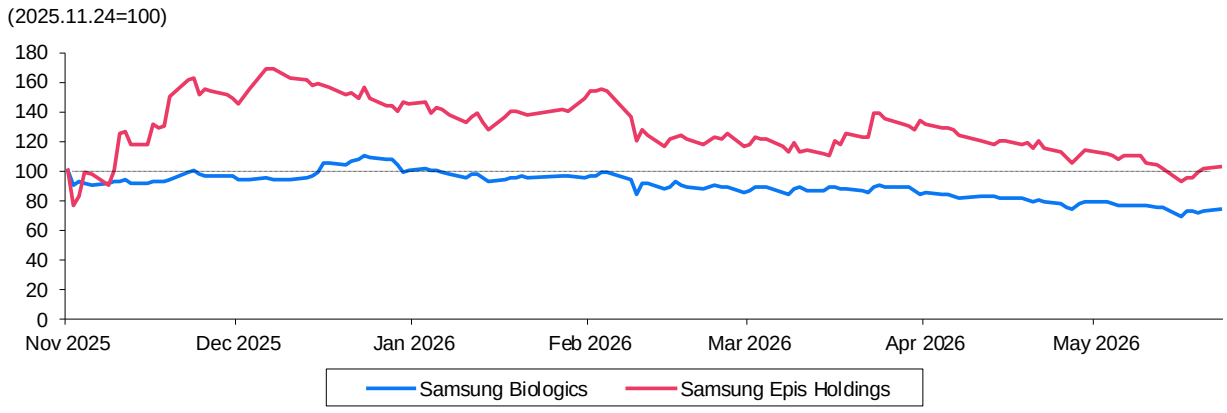
Samsung Epis Holdings' shares have been pressured by structural headwinds and a lack of pipeline visibility. Its spin-off from Samsung Biologics was initially priced based on the book value of its net assets, creating a disconnect between the theoretical price and the actual market price upon its relisting—*ie*, Samsung Biologics' market cap stood at KRW86.9t just before trading was suspended, while the combined market cap of both companies (Samsung Epis Holdings and Samsung Biologics) upon their relisting was KRW93.7t. Additionally, the amortization burden stemming from the purchase price allocation (PPA) related to the acquisition of Biogen's biosimilar assets distorts Samsung Epis Holdings' earnings quality, rendering P/E-based valuation metrics misleading. Meanwhile, its novel drug pipeline remains in early-stage development, making it difficult for the market to price in the firm's potential transition into a biopharma innovator.

However, the conditions necessary to overcome this underperformance are gradually being met. Samsung Epis Holdings is increasingly likely to be valued not simply as a biosimilar company, but also as a global bio-platform holding company anchored by Samsung Bioepis. Its core subsidiary, Samsung Bioepis, is steadily expanding its market share in the US and Europe, supported by a stable portfolio of biosimilars, and the subsidiary is poised to enter a high-growth phase over the next three to five years through the launch of new products. In particular, the US market is undergoing pharmacy benefit manager (PBM) structural reforms driven by policy pressure to reduce healthcare costs—shifting away from opaque, rebate-driven distribution models towards greater drug price transparency. This evolution is making it easier for biosimilars—which offer superior price competitiveness compared to originator drugs (which are burdened by high rebates)—to gain market access and secure formulary inclusion. As the burden of PPA amortization begins to ease, the gap between adjusted operating profit and actual cash generation is narrowing, enhancing earnings visibility. In the medium to long term,

Samsung Bioepis also holds strategic potential through its likely expansion into novel therapeutics, ADCs, and immunology—further elevating its value as a platform company.

The valuation gap between Samsung Epis Holdings and Celltrion reflects structural differences, but we believe the discount applied to Samsung Epis Holdings is excessive: Celltrion benefits from a vertically integrated model covering biosimilar development, manufacturing, and sales, commanding a higher EV/EBITDA multiple as a result. In contrast, Samsung Epis Holdings continues to trade at a discount due to its holding company status and PPA amortization. However, we expect its multiple to re-rate as key catalysts materialize: The shift towards direct sales, new private-label agreements with US private labels, revenue contributions from new products, and sustained momentum from its novel drug pipeline. A tangible novel drug catalyst could emerge in 2027 with the interim Phase-I results of SB303. If safety and early efficacy are confirmed, it could: 1) validate Samsung Bioepis' competitive positioning in the novel biologics space; and 2) begin to embed a 'transition into a biopharma innovator' narrative into the stock price.

Share prices of Samsung Biologics and Samsung Epis Holdings after they were relisted



Source: QuantiWise, Samsung Securities

Valuation

We initiate coverage of Samsung Epis Holdings with a 12-month target price of KRW600,000 and a BUY rating. Our valuation employs a dual approach—discounted cash flow (DCF) and EV/EBITDA—both of which yield similar intrinsic values.

Under a DCF model, we applied a WACC of 9.5% and a perpetual growth rate of 4.8%, resulting in an enterprise value of KRW17.7t for Samsung Bioepis. After adjusting for net debt and applying a 15% holding company discount (a 15% NAV discount), we derived the implied equity value for Samsung Epis Holdings. The holding company discount reflects structural factors such as illiquidity. Should the company enhance its asset liquidity or announce a concrete shareholder return policy, this discount may narrow.

With Samsung Epis Holdings' earnings growth expected to accelerate over 2026-2028 (driven by growing sales of new products), we believe its valuation will expand. For the EV/EBITDA approach, we

benchmarked its global pharmaceutical peers (which are expected to achieve 10-20% revenue growth *pa* over 2026-2028), applying a multiple of 27x (consistent with Celltrion's EV/EBITDA). Based on a 12-month forward EBITDA, this yields an implied enterprise value of KRW18.1t. After applying the same 15% holding company discount, we arrive at a target price of KRW600,000, implying that some upside exists from current levels. An additional valuation re-rating is also expected if its new pipeline advances and if revenue from new products emerges.

Samsung Bioepis' operating profit is poised to grow at a 2026-2030 CAGR in the double digits, driven not only by steady biosimilar sales but also by the full-scale commercialization of new biosimilar products. Given the high operating leverage inherent in the biosimilar industry—once initial upfront R&D costs are incurred—the company is well-positioned to generate strong free cash flow (FCF) over the longer term. Our DCF assumptions incorporate rising biosimilar penetration in the US, the successful launch of new pipeline candidates, and improved global SG&A efficiency. The WACC was conservatively set, reflecting both the biopharma industry's average cost of capital and Samsung Epis Holdings' holding company structure. While short-term share-price volatility may persist due to difficult listing-related supply-demand dynamics, the company is well-positioned to re-rate over the medium- to longer term as it should increasingly be seen as a platform business with stable cash generation ability.

Samsung Epis Holdings' valuation: EV/EBITDA

(KRWb, KRW)	Estimated value	12M fwd EBITDA	EV/EBITDA (x)
Samsung Epis Holdings (A=B+C)	18,098		
Operating value (B)	18,461	684	27
Net Debt (C)	363		
Outstanding shares ('000)	24,883		
Fair price per share (KRW)	727,311		
Discount applied price	618,214		15% holding company discount
Target Price (KRW)	600,000		

Note: Target EV/EBITDA applies the 2026E average EV/EBITDA of Novo Nordisk, Eli Lilly, and Merck, global pharmaceutical companies expected to deliver revenue growth of 10-20%. Source: Samsung Securities estimates

Source: Samsung Securities estimates

Samsung Epis Holdings' valuation: DCF

(KRWb)	2026E	
Samsung Epis Holdings (A=B+C+D)	17,304	
Present value of FCF	4,409	
PV of terminal value	13,258	
Net debt	363	
Outstanding shares ('000)	24,883	
Fair price per share (KRW)	695,393	
Discount applied price	591,084	15% holding company discount
Target Price (KRW)	600,000	

Source: Samsung Securities estimates

Samsung Epis Holdings' DCF valuation

(KRWb)	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Revenue	1,867	1,999	2,192	2,342	2,495	2,626	2,759
Chg (% y-y)	*641.9*	*7.1*	*9.7*	*6.8*	*6.5*	*5.3*	*5.1*
EBIT	255	267	278	340	392	427	460
TAX	9	49	55	80	97	95	89
NOPLAT	246	218	222	260	295	332	371
Depreciation	426	500	552	557	592	621	656
Capex	4	0	0	0	0	0	0
Chg in working capital	0	0	0	0	0	0	0
FCFF	668	718	774	817	886	953	1,027
WACC (%)	9.5						
Terminal growth (%)	4.8						
Terminal value							22,861
Discount rate (%)	0.0	8.7	16.6	23.8	30.5	36.5	42.0
Present value of FCF	668	655	646	622	616	605	595
PV of terminal value							13,258
Target value	17,666						

Note: Assumes COE of 7.7%, risk-free rate of return of 3% (3-year KTB yield) + market risk premium of 9% × beta of 0.7;
COD is 7.7% and terminal growth is 4.8%;
Source: Samsung Securities estimates

Risk factors

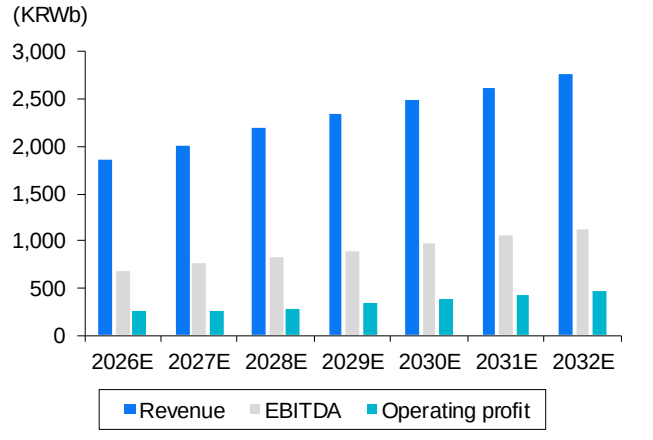
The most significant risk remains the valuation discount associated with Samsung Epis Holdings' status as a holding company. The Korean market typically applies a discount to pure holding companies relative to their net asset value (NAV), and Samsung Epis Holdings is likely to continue trading at a discount to the intrinsic value of its core subsidiary Samsung Bioepis. Earnings volatility may arise given the irregular timing milestone fees are recognized, while profitability could underperform expectations due to intensifying price competition in the biosimilar industry and structural shifts in PBM negotiation frameworks. New biosimilar launches by its competitors may also bring about greater pricing pressure over the longer term. While production delays for biosimilar products cannot be entirely ruled out, Samsung Bioepis maintains conventional inventory levels of finished goods, limiting near-term supply-disruption risk. Other key monitoring items include potential changes in US regulatory policy, patent litigation risks, forex volatility, and cash flow implications of future capital investments or strategic expansions.

Earnings outlook

2026 outlook: We forecast Samsung Epis Holdings will post 2026 consolidated sales of KRW1.867t, an EBITDA of KRW681.3b, and an operating profit of KRW255b. Its 2026 consolidated results should reflect the full-year contribution from subsidiary Samsung Bioepis, with the impact of expanded biosimilar product launches and the transition to a direct sales model likely to expand greatly. Samsung Bioepis is expected to drive structural revenue and profit growth through rolling out new products: Ospomyv (biosimilar to Prolia, launched in 2Q26 in the US), Epysqli (biosimilar to Soliris, launched in Apr 2025 in the US), and Byooviz prefilled syringe (PFS; to be launched in 2Q26 in Europe).

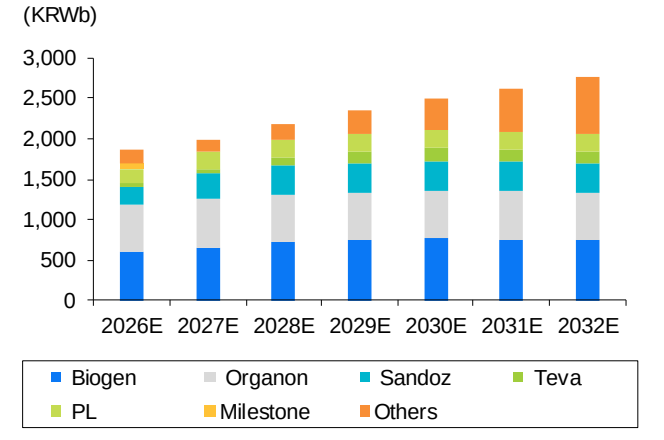
However, on a consolidated basis, Samsung Epis Holdings' earnings are likely to be burdened by an estimated KRW327.2b in PPA amortization expenses related to the acquisition of Biogen's biosimilar assets. This has created a structural disconnect between Samsung Bioepis' actual cash generation and Samsung Epis Holdings' consolidated net profit. Meanwhile, the holding company should post KRW93.2b in unrealized inventory gains in 2026 (as of end-1Q, Samsung Bioepis had unrealized gains of KRW290b), which represent profits from inventory acquired from Samsung Biologics (the profits can be partially recovered in consolidated results under accounting adjustments). This should partially offset the PPA amortization drag. We believe that Samsung Epis Holdings' 2026 consolidated net profit will come in lower than Samsung Bioepis' standalone operating profit due to the net impact of PPA amortization and inventory gain reclassification. However, EBITDA remains a more accurate indicator of underlying business performance, and should clearly reflect the core biosimilar business's operational growth trajectory.

Samsung Epis Holdings: Earnings outlook



Source: Samsung Securities estimates

Samsung Bioepis: Sales outlook, by classification



Source: Samsung Securities estimates

Samsung Epis Holdings: Quarterly earnings outlook

(KRWb)	1Q26	2Q26E	3Q26E	4Q26E	1Q27E	2Q27E	3Q27E	4Q27E	1Q28E	2Q28E	3Q28E	4Q28E	2026E	2027E	2028E
Revenue	454	448	467	498	470	490	510	530	504	526	570	592	1,867	1,999	2,192
Chg (% y-y)					*3.5*	*9.2*	*9.1*	*6.4*	*7.3*	*7.4*	*11.8*	*11.7*		*7.1*	*9.7*
Samsung Bioepis	455	448	467	498	470	490	510	530	504	526	570	592	1,868	1,999	2,192
EBITDA	191	162	172	156	193	192	207	175	206	202	229	193	681	767	830
Chg (% y-y)					*1.3*	*18.5*	*20.1*	*12.0*	*6.5*	*5.3*	*10.5*	*10.5*		*12.6*	*8.2*
EBITDA margin (%)	42.1	36.2	36.8	31.4	41.2	39.2	40.6	33.0	40.8	38.5	40.1	32.6	36.5	38.4	37.9
Samsung Bioepis	166	139	152	128	169	167	180	147	194	193	222	190	586	662	800
Others	25	23	20	28	25	25	26	28	12	9	6	3	96	105	30
Operating profit	91	60	67	38	75	70	80	43	68	64	91	55	255	267	278
Chg (% y-y)					*(17.0)*	*16.8*	*19.1*	*13.0*	*(9.9)*	*(7.9)*	*13.5*	*29.5*		*4.8*	*3.9*
OPM (%)	19.9	13.3	14.3	7.6	16.0	14.2	15.6	8.1	13.4	12.2	15.9	9.3	13.7	13.4	12.7
Samsung Bioepis	144	116	127	102	141	138	150	115	161	158	186	152	489	545	657
Others	(53)	(56)	(60)	(64)	(66)	(68)	(71)	(73)	(93)	(94)	(95)	(96)	(234)	(278)	(379)
Net profit	99	40	47	24	54	51	60	31	52	51	73	46	210	197	222
Chg (% y-y)					*(45.2)*	*27.8*	*29.3*	*32.1*	*(3.7)*	*(0.7)*	*21.2*	*45.8*		*(6.0)*	*12.5*
NPM (%)	21.9	8.9	10.0	4.8	11.6	10.4	11.8	5.9	10.4	9.6	12.8	7.7	11.2	9.9	10.1

Note: Completion of the SB27 clinical trial and potential partnership milestones represent upside, but are not reflected in estimates because the contract terms have not been disclosed. Following the spin-off, PPA amortization was transferred to Samsung Epis Holdings and is recognized in cost of goods sold as the value of intangible assets is expensed. Operating profit in 2026-2027 reflects both the PPA burden and the reversal of unrealized inventory profit. From 2028, the reversal benefit disappears, potentially resulting in a temporary y-y decline in operating profit. Source: Samsung Epis Holdings, Samsung Securities estimates

Source: Samsung Epis Holdings, Samsung Securities estimates

Company overview

Samsung Epis Holdings was established in Nov 2025 after being spun off from Samsung Biologics, serving as a bio-focused investment holding company. The separation was driven by structural conflicts of interest (COI) between Samsung Biologics' contract development and manufacturing organization (CDMO) business and its biosimilar product development unit. As a CDMO, Samsung Biologics produced drugs for global pharmaceutical clients, while simultaneously developing biosimilars that competed directly with those same clients' originator products—a structural COI that raised concerns among its customers. The spin-off resolved this issue—Samsung Biologics became a pure-play CDMO, while Samsung Epis Holdings assumed full ownership of biosimilar and novel drug investment activities, establishing clear strategic identities for both entities.

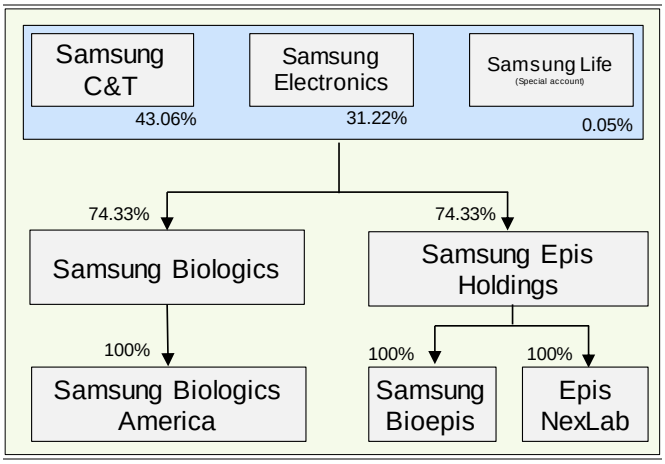
The separation was executed as a spin-off (stock dividend-based split; existing shareholders received shares in both companies in proportion to their original holdings) rather than as a split-off (used by firms like LGES and SK On). Market participants viewed this choice as a signal of structural reform.

Based on net asset value (as of end-1Q25), the split ratio was set at 65:35 in favor of Samsung Biologics. The 35% allocated to Samsung Epis Holdings primarily reflected the book value of its 100% stake in Samsung Bioepis, a subsidiary that Samsung Biologics acquired full ownership of in Apr 2022 for KRW2.765t (when it purchased the remaining 49.9% stake from Biogen). This book value significantly influenced the 65:35 allocation ratio.

However, book value does not equal market value. Prior to the split, Samsung Biologics had a market cap of KRW87t. Applying the 35% split mechanically would have implied a KRW30t market cap for Samsung Epis Holdings. Yet, upon its relisting, the opening price—determined within the simultaneous bidding range of 50-200% of the reference price—resulted in Samsung Epis Holdings having an initial market cap of KRW15t, closing the day at KRW11t. Contributing factors included its exclusion from the MSCI Korea Index, which triggered mandatory selling (at the price it traded at the end of the day it was relisted) by passive funds tracking the index. Estimated selling pressure from these funds amounted to KRW254.8b on the day it was relisted.

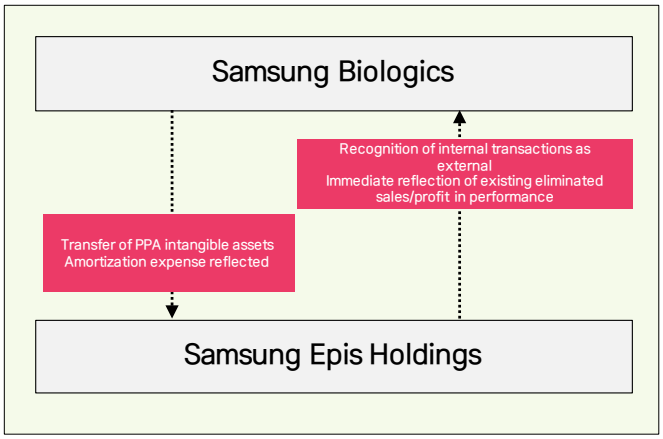
Its current valuation reflects three structural discounts. 1) Holding companies are typically discounted by 15% relative to the sum of their subsidiaries' intrinsic value, and Samsung Epis Holdings owns a 100% stake in Samsung Bioepis. 2) Quarterly earnings volatility inherent in biosimilars: Samsung Bioepis' revenue recognition model—mixing direct sales and royalty income—creates significant q-q fluctuations in earnings, making a consistent valuation difficult. 3) Unvalidated novel drug pipeline value: While its long-acting technology and Samsung Bioepis' ADC and bispecific antibodies technology show promising technical direction, the drugs in its pipelines remain in the early stage of development and lack clinical data, thus the market has not yet assigned a value to these assets. Its current share price reflects the intrinsic value of its biosimilar business, adjusted for the holding company discount, while excluding the potential value of its novel drug pipeline. For a re-rating to occur, three sequential milestones are critical: 1) reducing earnings volatility; 2) increasing direct sales (to stabilize profitability); and 3) the release of clinical data from its pipeline. Samsung Epis Holdings' transition from a passive holding company to a globally recognized bio-platform should mark the inflection point for a re-rating.

Governance structure of Samsung Biologics and Samsung Epis Holdings after the spin-off



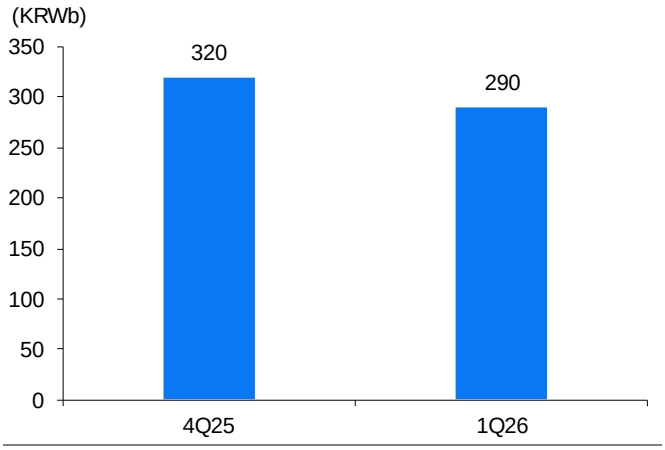
Source: Samsung Biologics, Samsung Epis Holdings

Impact of consolidation adjustments for Samsung Biologics and Samsung Epis Holdings



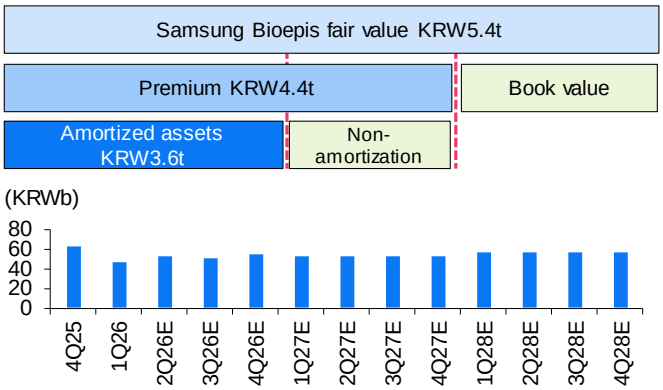
Source: Samsung Securities

Samsung Bioepis: Unrealized profit/losses



Note: Based on the balance at the end of each quarter
Source: Samsung Epis Holdings

Trend and outlook for Samsung Bioepis-related PPA amortization

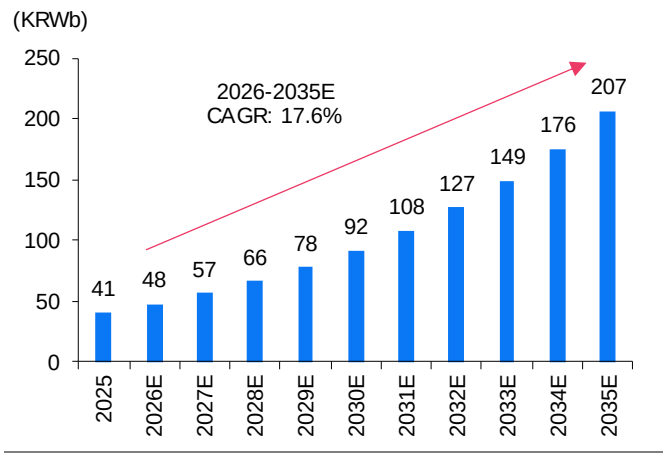


Note: No fair value revaluation of assets was conducted, and the carrying amounts were transferred unchanged. Additional PPA recognition for newly launched products is assumed. Although amortization of existing PPA declines, new PPA is added, resulting in total amortization remaining stable or increasing.
Source: Samsung Securities estimates

Biosimilar industry environment

The global biosimilar market (the first generation of biosimilars appeared over 2005-2009) began with the replication of simple protein therapeutics such as EPO and growth hormones. The second generation (2010-2019) expanded into more complex monoclonal antibodies, including TNF-α and oncology antibodies. Today, the third generation (2020-present) is pushing into high-complexity therapeutic domains: Ophthalmology, rare diseases, and endocrinology—marking a qualitative leap in sophistication. Projected to grow from USD40b in 2025 to USD207b by 2035, the sector is on track to record a sales CAGR of 17-18% over 2026-2035. The engine behind this anticipated surge is the impending expiration of patents on blockbuster biologics. Over 2025-2030, an estimated USD400b in annual global biopharma sales will lose exclusivity—the largest patent cliff in history. Key products are set to lose exclusivity (Prolia and Soliris in 2025, Perjeta and Cyramza in 2026, and Keytruda in 2028), and each expiration should unlock a new wave of market opportunities.

Biosimilar market size and outlook



Source: TowardHealthcare, Samsung Securities

Originator drug patent expiry schedule, from 2025

Original	Originator developer/rights holder	US LOE	EU LOE
Keytruda	Merck & Co.	Dec 2028	2031
Darzalex	Johnson & Johnson/Genmab	2029	2031-2032
Ocrevus	Roche/Genentech	2028-2029	2028-2029
Opdivo	Bristol Myers Squibb/Ono Pharmaceutical	2028	2030
Cosentyx	Novartis	2029	2030
Taltz	Eli Lilly	2030	2031
Dupixent	Sanofi/Regeneron	Mar 2031	2032-2033
Tremfya	Johnson & Johnson/Janssen	2031	2031
Entyvio	Takeda	2032	Expired
Enhertu	Daiichi Sankyo/AstraZeneca	2033, 2035	2033-2035

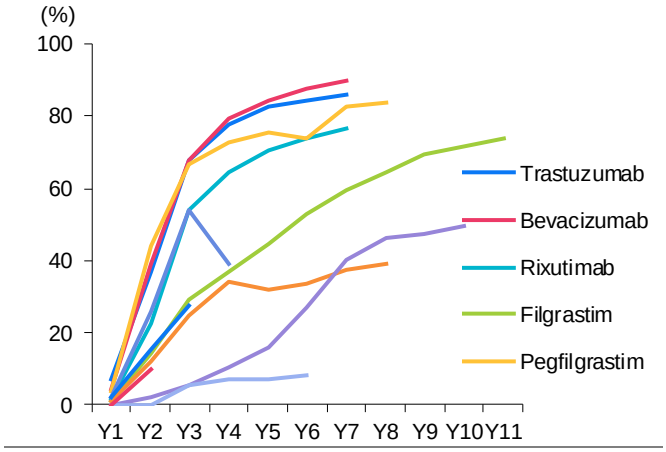
Note: Timing may vary by individual patent and regulatory exclusivity period
Source: Each company, Samsung Securities

Comparison of competitors' biosimilar product counts

Company	Biosimilars under development	Currently marketed/ commercialized products*	Key marketed products	Major targets under development
Sandoz	27	12	Humira, Neupogen, Stelara	Keytruda, Opdivo, Enhertu
Celltrion	5 or more	10	Remicade, Rituxan/MabThera, Herceptin	Keytruda, Darzalex, Ocrevus
Biocon Biologics	10	10	Herceptin, Humira, Lantus	Undisclosed, primarily insulin and mAbs
Fresenius Kabi/mAbxience	15	9	Humira, Neulasta, Actemra	Eylea, Entyvio, Rituxan/MabThera
Alvotech	9	5	Humira, Stelara, Prolia/Xgeva	Keytruda, Dupixent, Entyvio
Amgen	3	8	Humira, Avastin, Herceptin	Keytruda, Opdivo, Ocrevus
Formycon	5	5	Lucentis, Stelara, Eylea	Keytruda, Dupixent, undisclosed
Bio-Thera	4 or more	3	Actemra, Avastin, Stelara	Keytruda, Cosentyx, Simponi
Henlius	8 or more	6	Rituxan/MabThera, Herceptin, Humira	Keytruda, Opdivo, Darzalex

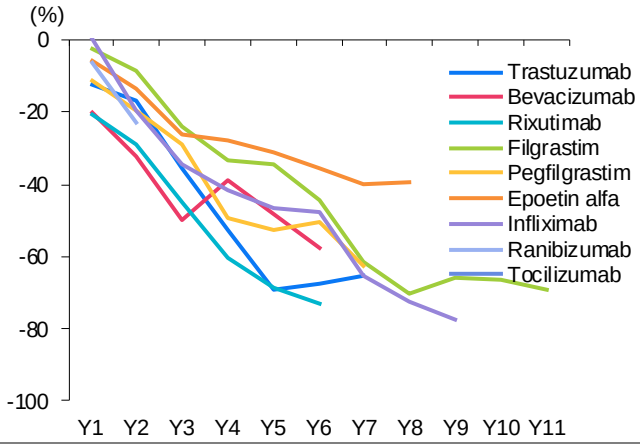
Note: *If official disclosures are inconsistent, the number is based on active ingredient groups
Source: Each company, Samsung Securities

Biosimilar market share, by originator drug



Source: Samsung Bioepis biosimilar market report (4Q25), Samsung Securities

Drug price reductions following release of biosimilars



Source: Samsung Bioepis biosimilar market report (4Q25), Samsung Securities

Strategy for securing competitive advantage: How to survive a saturated market

In the biosimilar market, late entrants can differentiate themselves in three ways. First, niche targeting. By entering markets that large pharmaceutical companies tend to avoid firms can achieve market exclusivity with minimal competition—*ie*, Xolair recorded 2025 sales of USD5.4b. Second, formulation differentiation. Shifting from intravenous (IV) to subcutaneous (SC) administration, or leveraging AI-driven formulation improvements to enhance dosing convenience should enable companies to move beyond price competition and create compelling rationale for doctors to switch drugs. Third, building direct sales infrastructure. Transitioning from a royalty-based partnership model to a direct sales model should significantly improve margins.

SC formulations, auto-injectors, and prefilled syringes (PFS) have evolved beyond mere convenience enhancements—they are now critical determinants of market share. SC formulations reduce administration time from tens of minutes (IV) to just a few minutes, cutting chair time and enabling self-administration (by patients). Auto-injectors reduce dosing errors and alleviate psychological burdens for patients, while PFS simplifies drug preparation and ensures precise dose delivery. For biosimilar developers, adoption of SC delivery, auto-injectors, and PFS have become *de facto* requirements for market entry. Moreover, a reverse differentiation strategy is emerging: Launching an SC biosimilar before the originator has transitioned its own product to SC, pre-empting the SC market.

The shift to SC formulations by the three leading immuno-oncology blockbusters presents a complex strategic dilemma for biosimilar developers. Following the FDA's approval of Tecentriq SC in Sep 2024, Opdivo SC received US approval in 2024, and Keytruda SC (Keytruda Qlex) gained FDA approval in Sep 2025 for 38 indications, effectively establishing SC formulations as the standard in immuno-oncology. This represents a classic 'patent hopping' strategy: Even though the original Keytruda IV patent expires in the US in 2028, if prescriptions become overwhelmingly SC, the market for IV biosimilars will have shrunk dramatically before the 2028 expiry arrives. BMS aims to convert at least 30% of Opdivo IV users to SC, and in early-launch markets, conversion rates have already reached 50%,

underscoring the tangible threat of a hopping strategy. For biosimilar developers, developing only an IV biosimilar means chasing a shrinking market. Yet pursuing an SC biosimilar introduces another hurdle: The patent barrier surrounding Halozyme's hyaluronidase (rHuPH20), a key enabler of SC delivery. Currently, Samsung Bioepis, Amgen, Sandoz, Celltrion, and BioNTech are advancing IV-based Keytruda biosimilars through clinical development. Whether these firms will extend their programs to include SC formulations will be a decisive factor in determining their future market position.

Biosimilar differentiation strategies

Category	Details
Capture market blank space	Celltrion obtained the first Xolair biosimilar approval and an interchangeability designation simultaneously, becoming the first to secure a competitor-free market (*ie*, the only firm to sell biosimilars in that market)
Formulation	Subcutaneous formulation: Improves patient convenience through technologies such as hyaluronidase
	High-concentration, additive-free formulation: Reduces injection pain and halves injection volume through a higher concentration
	Autoinjector formulation: Improves self-injection convenience and reduces the burden of hospital visits
	PFS (prefilled syringe) formulation: Reduces medication errors versus conventional vials and improves convenience for ophthalmologists

Source: Samsung Securities

Europe: Structural deepening of a mature market

Europe pioneered the global biosimilar market in 2006 with the EMA's approval framework, and has since evolved into the world's most mature market. In Sep 2022, the EMA took a landmark step, declaring all EU-approved biosimilars interchangeable with their originator products. Yet approval is only the gateway: Real market penetration hinges on national procurement strategies. Germany drives biosimilar adoption through physician prescription quotas and gain-sharing agreements between physicians and social insurers. In France, biosimilar prices are set 40% below the originator's, and biosimilar procurement utilizes a three-tier bidding system (at national, regional, and hospital levels). Italy combines mandatory 20% discounts (vs the originator) with national and regional bidding.

A defining structural trait across Europe's tender markets is that most of the 27 EU nations still adhere to single-winner bidding. While this appears on the surface as a systemic risk limiting supply diversity, it functions as an entry barrier that favors established suppliers with proven track records and trusted reputations. With 24 major biologics set to lose patent protection over 2025-2032, the structural advantage should continue to favor early entrants (such as Samsung Bioepis) who have already built strong relationships and supply histories within the European bidding ecosystem, enabling them to capture new molecular markets ahead of their rivals.

US: Regulatory transformation by FDA, HHS, and CMS

On Oct 29, 2025, the FDA, HHS, and CMS announced an initiative to streamline biosimilar development. They unveiled draft guidance, proposing to waive comparative efficacy studies (CES) for biosimilars if analytical equivalence data alone can demonstrate biosimilarity. This move is expected to reduce development costs by up to 90% and shorten approval timelines from 5-8 years to 2-4 years. The FDA also signaled its intent to no longer require switching studies for interchangeability designation, while CMS implemented final rules in 2025 allowing Medicare Part D plans to conduct mid-year immediate substitutions of branded biologics with biosimilars. Yet, this regulatory relaxation is a dual-edged sword for Samsung Bioepis: While the regulation should enhance its pipeline

development efficiency, it will simultaneously lower the market entry barrier, accelerating rivals' market entry and heightening competitive pressure on Samsung Bioepis' established products.

The inclusion of Ospomyv (SB16) as a preferred biosimilar alternative to Prolia under CVS Caremark's formulary redesign symbolizes the rising prominence of the PBM direct-supply (private label) model as a new market channel paradigm. The Consolidated Appropriations Act, signed in Feb 2026, prohibits PBMs from earning compensation tied to drug prices, rebates, or volume-based incentives when contracting with Medicare Part D plans, and mandates public disclosure of formulary inclusion criteria. These reforms will take full effect around 2028-2029. As rebates disappear, originator brands and high-WAC biosimilars will lose their formulary advantage that was once sustained by generous rebates. Instead, products with true price competitiveness and robust clinical evidence will gain preference. Yet, automatic substitution at the pharmacy level remains governed by state law—and as of 2026, 34 states require prior authorization for biosimilar substitution. This disconnect between federal policy momentum and fragmented state implementation continues to serve as a structural bottleneck to Samsung Bioepis' broader US market penetration.

The regulatory transformation in the US and the structural dynamics in Europe affect Samsung Bioepis differently. In the US, FDA guidance relaxation directly reduces development costs and timelines, while the dismantling of PBM rebate barriers should create longer-term tailwinds for Samsung Bioepis' formulary access (given its price competitiveness). In Europe, the dominant single-winner bidding system acts as a structural moat: 1) favoring companies like Samsung Bioepis that have long-standing supply histories and direct sales channels; and 2) deterring late entrants. With Ospomyv (Prolia biosimilar) and Epysqli (Soliris biosimilar), Samsung Bioepis should be among the first to enter the market as key patents expire over 2025-2032. This head start lays the critical foundation for accelerated growth in Europe.

US biosimilar policy

Timing	Policy/event	Details
2022.10	IRA enacted	Biosimilar reimbursement at ASP +8%
2026.01	First IRA negotiated prices take effect	Conflict between the IRA and biosimilar policy
2026.02	Consolidated Appropriations Act	Prohibits rebate-linked compensation
2026.03	Expanded use of overseas clinical data by the FDA	Regulatory filing without a three-way PK study
2026.04	CVS Caremark formulary reform	Biosimilars listed as preferred drugs
2H26	Biosimilar interchangeability guidance	Pursuing automatic interchangeability designation for all products
2028-2029	Full implementation of PBM reform	Drug price transparency and mandatory formulary disclosure

Source: Samsung Securities

European biosimilar policy

Country	Tender method	Details
Germany	Mandatory discount to the originator	National-level tenders
France	Fixed 40% discount to the originator	National, regional, and hospital tenders; high regulatory stability
Italy	Mandatory 20% discount to the originator	National and regional tenders; high price stability
UK	Free competition	Multiple winners
Norway	Lowest-price tender	Single winner; supply diversity risk

Source: Samsung Securities

Samsung Bioepis: Current status

Samsung Bioepis was established in Feb 2012 as a joint venture between Samsung Biologics and Biogen. In 2013, Samsung Bioepis laid the foundations for its global commercialization through partnerships with MSD and Biogen. The company received its first domestic approval in 2015 for biosimilars of Remicade and Enbrel, followed in Jan 2016 by European approval for Benepali, its Enbrel biosimilar—marking its first overseas market authorization (just four years after its inception). That same year, in May, Flixabi, the Remicade biosimilar, also received EU approval. Subsequent approvals for Imraldi and Ontruzant in Europe (2017), followed by US approval (2019), rapidly expanded its global portfolio. In Apr 2022, Samsung Biologics acquired Biogen's entire stake in Samsung Bioepis, making it a wholly owned subsidiary.

Over its 13-year history, Samsung Bioepis has developed and launched biosimilars of 11 blockbuster biologics. Following its entry into Europe in 2016, the company expanded its commercial portfolio to 10 products within a decade—evolving from first-generation immunology-focused biosimilars to third-generation, high-complexity biosimilars in ophthalmology (Byooviz, Opuviz), rare hematologic disorders (Epysqli), and osteoporosis (Ospomyv). Today, Samsung Bioepis is enhancing its margin structure through direct-to-PBM (private label) distribution in the US and reclaiming direct sales previously held by Biogen. Simultaneously, it is investing in a pipeline of innovative biologics, including SBE303 (Nectin-4 ADC), to transition from a pure-play biosimilar company to a global biopharmaceutical player.

Sales strategy, by region

Samsung Bioepis' commercialization strategy in the US is built on two pillars: Partnerships and PBM distribution. Through traditional partnership channels, the company enhances market penetration by aligning with specialized partners in each therapeutic area. In immunology and osteoporosis, it partners with Organon (Hadlima, Renflexis, Eticovo, Ontruzant (oncology)) and Sandoz (Pyzchiva); in rare diseases, with Teva (Epysqli); and in ophthalmology, with Harrow (Byooviz, Opuviz). This diversified partner portfolio reduces dependency on any single entity. In parallel, Samsung Bioepis directly supplies biosimilars to the big three US PBMs under private-label arrangements. It simultaneously signed supply agreements with two of the three major US PBMs—Quallent, a subsidiary of Express Scripts, and Cordavis, a subsidiary of CVS Caremark—for its biosimilar Pyzchiva (SB17). Under this model, the PBMs prioritize listing Samsung Bioepis' biosimilar under their own private-label brands in their formularies, driving tangible shifts in physician prescribing behavior.

Notably, Hadlima gained full interchangeability status in May 2025, enabling automatic pharmacy substitution, while Opuviz also holds interchangeable designation—giving Samsung Bioepis a structural advantage in market penetration speed over competing biosimilars. In formulation, Hadlima offers the same convenience as the original Humira high-concentration version with its 100 mg/mL formulation and citrate-free composition. It remains the only adalimumab biosimilar on the market to combine interchangeability, high concentration, and citrate-free formulation.

In Europe, Samsung Bioepis has shifted towards direct sales to reduce reliance on partners and improve profitability. It now directly distributes five products in the region: The ophthalmology agents Byoo viz and Opuviz, the endocrine products Obodence and Xbryk, and the rare disease therapy

Epysqli (after Biogen returned the distribution rights). Benepali, Imraldi, and Flixabi—still its core revenue drivers—continue to be marketed by Biogen under extended distribution agreements.

In the US, Samsung Bioepis is pursuing a two-track strategy, partnering with Organon while also supplying PBM channels directly. The Prolia biosimilar was added to CVS Caremark's preferred list following its private-label contract in Jan 2026, helping it increase market share. Agreement has been finalized for the Eylea biosimilar (to be launched in the US in Jan 2027), paving the way for Samsung Bioepis' entry into the American ophthalmology market. With the Humira and Remicade biosimilars, the company is responding to intensified price competition through volume growth.

Samsung Bioepis biosimilar product portfolio

Originator	Indication	Code	Region	Product name	Approval	Launch	Partner/sales	Competitiveness and notes
Remicade (infliximab)	Autoimmune disease	SB2	US	Renflexis	Apr 2017	Jul 2017	Organon	Early entrant in the European infliximab biosimilar market
			Europe	Flixabi	May 2016	May 2016	Biogen	
Herceptin (trastuzumab)	Oncology	SB3	US	Ontruzant	Jan 2019	Apr 2020	Organon	First biosimilar to receive WHO prequalification
			Europe	Ontruzant	Nov 2017	Mar 2018	Organon	Expanded access in emerging markets
Enbrel (etanercept)	Autoimmune disease	SB4	US	Eticovo	Apr 2019	-	Organon	Launch delayed due to US patent issues
			Europe	Benepali	Jan 2016	Jan 2016	Biogen	No. 1 in Europe under the Benepali brand
Humira (adalimumab)	Autoimmune disease	SB5	US	Hadlima	Jul 2019 (low)/Aug 2022 (high)	Jul 2023	Organon	High-concentration (100mg/mL), citrate-free formulation
			Europe	Imraldi	Aug 2017	Jan 2018	Biogen	Both low- and high-concentration formulations
Avastin (bevacizumab)	Oncology	SB8	US		-	-	Organon	Focused on the European market; Mvasi (Amgen) was the first mover in the US
			Europe	Aybintio	Aug 2020	Sep 2020	Organon	
Lucentis (ranibizumab)	Ophthalmology	SB11	US	Byooviz	Sep 2021	Jun 2022	Harrow (from 2025)	World's first ophthalmology biosimilar
			Europe	Byooviz	Aug 2021	Mar 2023	Direct sales (from Jan 2026)	
Eylea 2mg (aflibercept)	Ophthalmology	SB15	US	Opuviz	May 2024	Jan 2027E	Harrow	PFS; Regeneron patent settlement in Feb 2026
			Europe	Opuviz	Nov 2024	May 2026	Direct sales	PFS launched in Europe; US launch scheduled
Stelara (ustekinumab)	Autoimmune disease	SB17	US	Pyzchiva	Jul 2024	Feb 2025	Sandoz	Rapid market penetration with Sandoz as the global partner
			Europe	Pyzchiva	Jul 2024	Jul 2024	Sandoz/PL (2)	Early entry at the time of Stelara patent expiry
Soliris (eculizumab)	Rare disease Autoimmune disease	SB12	US	Epysqli	Jul 2024	Apr 2025	Teva	Entry into the premium rare disease market
			Europe	Epysqli	May 2023	Jul 2023	Direct sales	Sandoz is the partner in the Middle East and Africa
Prolia (denosumab)	Osteoporosis	SB16 (SC)	US	Ospomyv	Feb 2025	Apr 2026	PL	Impact of Prolia IRA price negotiations
			Europe	Obodence	Feb 2025	Dec 2025	Direct sales	Provisional interchangeability designation
Xgeva (denosumab)	Myeloma	SB16 (IV)	US	Xbryk	Feb 2025	Not launched	TBD	
			Europe	Xbryk	Feb 2025	Jan 2026	Direct sales	

Note: PL, Private Label

Source: Samsung Bioepis, Samsung Securities

Pipeline roadmap: 20 products by 2030

The most notable development in Samsung Bioepis' pipeline is the regulatory submission for SB27 (pembrolizumab biosimilar). Positive results from a Phase-I pharmacokinetic (PK) study were reported in May 2026, and Phase-III trials should be concluded this year. This means that SB27 should be among the first biosimilars to enter the global market for Keytruda. However, since the originator has launched a subcutaneous (SC) formulation, Samsung Bioepis must either develop an SC version in parallel or pursue supplemental approval for SC after its initial launch. This strategic decision must be addressed early on in partner selection.

For preclinical candidates—SB33 (dupilumab biosimilar), SB36 (vedolizumab biosimilar), and SB34 (guselkumab biosimilar)—clinical development timelines must be strategically aligned with the patent expiry dates of their reference products: Dupixent (2030+), Entyvio (US; 2028), and Tremfya (around 2028). In particular, SB36 faces a competitive landscape where Alvotech has already completed PK studies; to differentiate itself, Samsung Bioepis must prioritize concurrent development of an SC formulation.

SB38 (trastuzumab deruxtecan biosimilar) represents an unprecedented challenge as the first biosimilar of an antibody-drug conjugate (ADC), with no established regulatory pathway yet defined. However, the technical barrier—requiring precise replication of all three components (antibody, linker, and payload)—severely limits the number of potential competitors. Should it succeed, it offers the most significant potential for exclusive market leadership.

SB37 (ocrelizumab biosimilar) and SB35 (ixekizumab biosimilar) are still in preclinical stages, with patent expiries for Ocrevus (US; 2029) and Taltz (2028) providing some breathing room. However, as Amgen and Celltrion are already in Phase-III trials for Ocrevab biosimilars, Samsung Bioepis' late entry requires a focused strategy—either through differentiated SC formulation or by targeting EMs.

At the center of Samsung Bioepis' pipeline strategy is Samsung Biologics' cost competitiveness, which it possesses through its vertically-integrated manufacturing capability and thanks to its global partnership network (comprising Sandoz, Organon, Teva, and Harrow). To achieve a portfolio spanning 20 biosimilars by 2030, accelerating the transition of current preclinical candidates into clinical development over the next three years should be the single most critical priority.

Samsung Bioepis biosimilar development pipeline

Code	Originator	Indication	Development stage	Expected approval	Partner	Competitive landscape	Notes
SB27	Keytruda (pembrolizumab)	Immuno-oncology	P1/3	2027-2028	TBD	Numerous competitors	Considering SC formulation development; first among competitors to complete P3 patient enrollment
SB33	Dupixent (dupilumab)	Atopic dermatitis and others	Preparing for clinical development	2029-2030	TBD	Numerous competitors	High technical barrier for IL-4/13 bispecific antibodies
SB34	Tremfya (guselkumab)	Autoimmune disease	Preparing for clinical development	2028-2029	TBD	Early stage	Monitor competition from J&J's oral ICOTYDE (icotrokinra)
SB35	Taltz (ixekizumab)	Autoimmune disease	Preparing for clinical development	Around 2028	TBD	Numerous competitors	Competition from multiple mechanisms in the psoriasis market
SB36	Entyvio (vedolizumab)	Autoimmune disease	Preparing for clinical development	2030+	Sandoz	Numerous competitors	Takeda has key patents valid through 2032, creating litigation risk; expanding Entyvio SC prescriptions make SC formulation development essential
SB37	Ocrevus (ocrelizumab)	Neurologic disease	Preparing for clinical development	2031+	TBD	Numerous competitors	The originator SC formulation is not yet approved, but SC development remains possible
SB38	Enhertu (T-DXd)	Oncology	Preparing for clinical development	2030+	TBD	Very limited	The ADC structure requires simultaneous reproduction of the antibody, linker, and payload; regulatory guidelines for ADC biosimilars must be clarified

Source: Samsung Bioepis, Samsung Securities

Updates on novel drug pipeline

Samsung Bioepis' strategic shift towards ADCs—rather than conventional antibody-based therapeutics—leverages Samsung Bioepis' core strengths. ADCs consist of an antibody linked to a cytotoxic payload via a chemical linker. The design, manufacture, and quality control of the antibody component are precisely the areas where Samsung Bioepis has built deep expertise over a decade of biosimilar development. In contrast, developing a novel monoclonal antibody requires starting from scratch—identifying new targets, designing the molecule, and building clinical programs entirely anew. With ADCs, Samsung Bioepis can focus on its proven capabilities in antibody development while sourcing external payload and linker technologies. This strategy is clearly reflected in its partnerships: SBE303, developed with IntoCell, and TJ108/SBE313, co-developed with Phrontline Biopharma.

Novel drug development status

Code	Mechanism	Indication	Development stage	Notes
SBE303	Nectin-ADC	Bladder cancer	P1	Collaboration with IntoCell; P1 FIH trial initiated in Mar 2026, with safety and efficacy to be evaluated in 149 patients in the US, Korea, and other countries
SBE313	EGFR-HER3 ADC	Lung cancer	Preclinical	Collaboration with Phrontline
Semaglutide LAI	GLP-1 RA	Obesity	Preclinical	Collaboration with G2GBio; in-licensed long-acting microsphere formulation

Source: Samsung Bioepis, Samsung Securities

SBE303, an ADC targeting Nectin-4 for bladder cancer, entered global Phase I clinical trials in Mar 2026 and presented preclinical data at the AACR 2026. Developed in partnership with IntoCell, it aims to be positioned as a next-generation option following Padcev. Meanwhile, SBE313 is currently in preclinical development through a joint effort with Phrontline Biopharma in China. Epis NexLab (a dedicated R&D subsidiary) has been established to focus on next-generation platforms, including

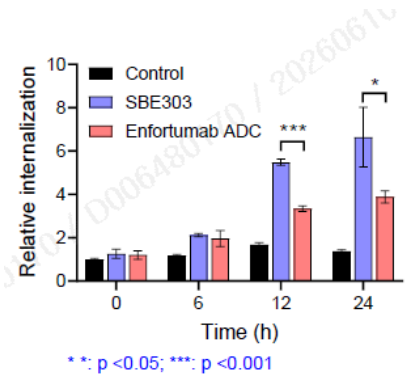
bispecific antibodies and dual-payload ADCs (*eg*, EGFR×HER3). Samsung Bioepis plans to advance at least one new clinical-stage candidate per year from 2027.

Nectin-ADC development landscape

Product	Developer	Payload	Linker	DAR	Development stage	Major indications	Approval/data status	Notes
Padcev	Pfizer/Astellas	MMAE	Cleavable	3.8	Approved (FDA 2019)	Urothelial carcinoma (1L and 2L)	EV plus pembrolizumab established as first-line standard of care (EV-302, OS HR 0.47)	First approved Nectin-4 ADC; demonstrated synergy with PD-1 combination; MMAE-specific toxicity
LY4052031	Eli Lilly	Topo-I inhibitor	Cleavable	8	P1 (NEXUS-01, presented at ASCO 2026)	Urothelial carcinoma and advanced solid tumors	ORR 67% in EV-naive patients; ORR 33% in EV-pretreated patients; DCR 79%	Covers EV-resistant patients; low-toxicity profile
SHR-A2102	Hengrui	Topo-I inhibitor	Cleavable	N/A	P1 (presented at ASCO 2026)	Urothelial carcinoma and advanced solid tumors	Early clinical data presented at ASCO 2026; detailed figures undisclosed	Chinese platform; lower scale-up costs; access to the Asian market
IPH4502	Innate	Topo-I inhibitor	Proprietary linker	N/A	P1 (PACIFIC-9 expected in 2H26)	Urothelial carcinoma, including EV-resistant disease, and low-expression solid tumors	Initial antitumor activity observed in EV-resistant patients	Insufficient early-stage data; intensifying competition in EV-resistant indications
SBE303	Samsung Bioepis	Novel Topo-I inhibitor	Proprietary linker	N/A	P1 (FIH initiated in Mar 2026)	Advanced solid tumors, including urothelial, lung, and breast cancer	FIH trial underway in 149 patients	No ILD observed; optimized internalization efficiency; development is 3-4 years behind Lilly; no clinical data

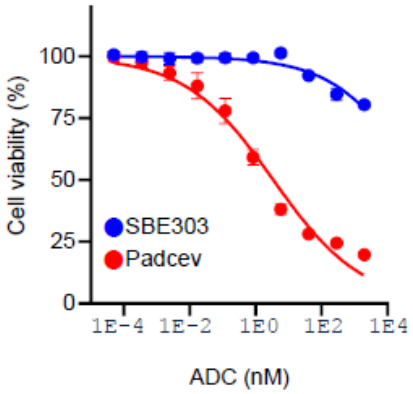
Source: Samsung Securities

SBE303 ADC internalization



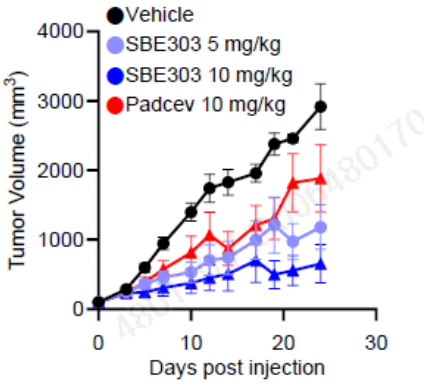
Source: Samsung Epis Holdings

SBE303 safety assessments



Source: Samsung Epis Holdings

SBE303 anti-tumor efficacy



Source: Samsung Epis Holdings

In Mar 2026, Samsung Bioepis and Epis NexLab entered a three-party strategic collaboration with G2GBio to co-develop a long-acting obesity therapeutic based on semaglutide. Leveraging G2GBio's proprietary microsphere-based drug delivery platform, the partners aim to create a sustained-release formulation of semaglutide—the same active ingredient as Wegovy. Samsung Bioepis has secured exclusive development rights to two candidate molecules, while Epis NexLab is leading joint R&D to build a robust drug delivery platform. The goal is to significantly reduce dosing frequency—from the current weekly injection of Wegovy to once-monthly or even longer intervals. Preclinical data have demonstrated improved PK stability, with a peak-to-trough concentration ratio of 1.3x compared to Wegovy's 1.8x. Samsung Epis Holdings has established a financial partnership with G2GBio, investing KRW20b in convertible bonds, and also secured first negotiation rights for three future drug candidates.

Samsung Bioepis' decision to partner with G2GBio stems from a growing recognition that the biosimilar monoclonal antibody market is hitting structural limits. First-generation blockbusters like Humira, Remicade, and Herceptin now face competition from over ten biosimilars each, driving severe price pressure. Even next-generation targets like Keytruda are being actively pursued by global giants preparing their own biosimilars. At the same time, the GLP-1 obesity market—led by Wegovy (semaglutide) and Mounjaro (tirzepatide)—is set to top USD100b by 2030. Yet, semaglutide and tirzepatide are peptide-based molecules, not antibodies. This represents a fundamental strategic gap: Samsung Bioepis' core expertise in antibody development cannot directly address this high-growth opportunity.

Choosing to license rather than build internally was a deliberate and pragmatic decision. Monoclonal antibodies are produced via cell culture (CHO cells), whereas peptides require entirely different chemical synthesis methods (SPPS). Building in-house peptide manufacturing and sustained-release capabilities from scratch would require years and massive capital investments. G2GBio's microsphere platform fills this gap immediately—making this a classic 'buy vs build' choice.

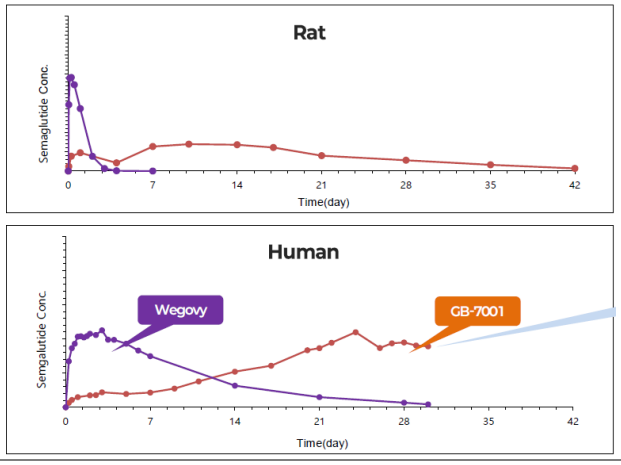
Samsung Bioepis has spent the past ten years building robust regulatory, development, and manufacturing infrastructure through its global biosimilar pipeline—gaining FDA and EMA approval track records, GMP-compliant production systems, and deep clinical design expertise. These capabilities are directly transferable to the development of modified new drugs. The commercial infrastructure is equally mature: In Europe, the company has established a direct sales network for four products; in the US, it already has supply agreements in place with major PBMs like CVS Caremark. This means that when the obesity drug receives approval, Samsung Bioepis will be able to immediately leverage these existing channels without needing to build them from scratch. In other words, the once-monthly semaglutide product is not simply G2GBio's technology paired with Samsung Bioepis' capital. It represents the full integration of Samsung Bioepis' accumulated capabilities in development, manufacturing, regulatory approval, and distribution—applied simultaneously to a new indication. This integrated advantage is precisely what pure-play biotech startups or peptide-focused companies cannot easily replicate.

That said, the once-monthly formulation carries significant technical and clinical challenges as well as substantial commercial risk. Extending semaglutide's half-life to a monthly duration would require either structural modification of the molecule itself or a controlled-release platform—such as hydrogels or microspheres. These approaches carry inherent risks, including immunogenicity, initial burst release, and PK variability. Pfizer, for example, had to conduct a separate Phase-IIb trial to confirm

sustained weight loss after transitioning from weekly to monthly dosing—highlighting the high bar for demonstrating PK and pharmacodynamic equivalence across dosing regimens.

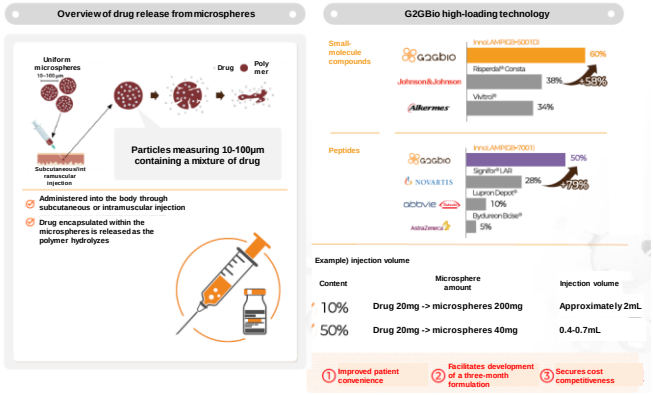
Amgen's MariTide (maridebart cafraglutide) is a dual-mechanism antibody targeting GLP-1R agonism and GIPR antagonism, designed for once-monthly dosing. In Phase II, it achieved a maximum weight loss of 16.2% at 52 weeks and is now advancing through six global Phase-III trials simultaneously. Pfizer, having acquired Metsera (including berobenatide (PF-08653944)) for USD10b in Nov 2025, is targeting the once-monthly market with this candidate (berobenatide). At ADA 2026, Pfizer presented Phase-IIb data showing a maximum weight loss of 15.9%—a result viewed by the market as inferior to Wegovy HD (20.7%) and Zepbound (22%). The US firm is now conducting ten Phase-III trials with a target approval date of 2028. Among biotech firms, Adocia presented preclinical results in 2024 at ADA using its biodegradable hydrogel platform, AdoGel, to convert semaglutide into a once-monthly formulation. ProLynx also disclosed preclinical data, demonstrating a 30-day half-life in mice and around 20% weight loss, using a hydrogel microsphere-based approach. However, neither firm has yet announced a timeline for clinical entry. Overall, the once-monthly landscape is increasingly dominated by Amgen and Pfizer, with no pure semaglutide once-monthly formulation yet approved by a major player.

G2GBio once-monthly semaglutide PK data



Source: G2G Bio

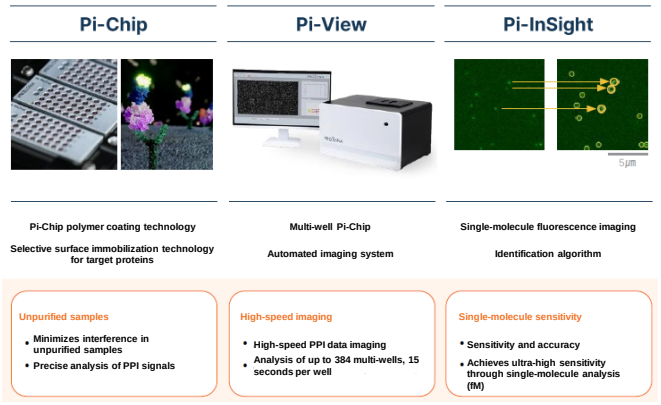
G2GBio once-monthly formulation platform technology



Source: G2G Bio

Samsung Bioepis has partnered with Proteina to build a seamless antibody development pipeline that combines AI-driven design, experimental validation, and clinical development. Proteina, a KAIST spinout, has developed SPID (Single-Molecule Protein Interaction Detection Platform), a proprietary system that uses AI to analyze large-scale protein-protein interaction data and accelerate antibody discovery. Proteina is responsible for platform development and data feedback, while Samsung Bioepis applies the findings to its novel drug and biosimilar programs. The system allows three researchers to evaluate 3,000-5,000 antibody candidates per week, shortening the full discovery cycle to approximately three months—a significant speed advantage. By combining its established antibody manufacturing capabilities with an AI-powered discovery platform, Samsung Bioepis aims to move beyond biosimilar replication and upgrade its R&D capacity to deliver first-in-class or next-generation biosimilar candidates.

Proteina SPID platform



Source: Proteina

Summary of the Samsung Bioepis-Proteina government-funded project

Category	Details
Project name	Development and demonstration project for antibody biobetters using AI models
Lead ministry	Ministry of Health and Welfare
Total budget	KRW 46.965bn
Project period	Oct 1, 2025-Dec 31, 2027, 27 months
Participating institutions	Proteina as the lead institution, jointly participating with Samsung Bioepis and Prof. Baek Min-kyung's team at Seoul National University
Key objective	Development of 10 AI-based antibody candidates
Milestones	Three candidates entering preclinical development and one candidate filing an IND
Core technology	AI antibody design, large-scale experimental data feedback, and the Proteina SPID platform
Proteina	Lead institution focused on the antibody design and validation platform
Samsung Bioepis	Leads candidate evaluation, clinical development, and commercialization

Source: Proteina, Samsung Epis Holdings, press releases

Income statement

Year-end Dec 31 (KRWb)	2024	2025	2026E	2027E	2028E
Sales	**n/a**	**252**	**1,867**	**1,999**	**2,192**
Cost of goods sold	n/a	159	924	1,005	1,165
Gross profit	**n/a**	**92**	**944**	**994**	**1,027**
Gross margin (%)	n/a	36.6	50.5	49.7	46.9
SG&A expenses	n/a	156	689	726	749
Operating profit	**n/a**	**-64**	**255**	**267**	**278**
Operating margin (%)	n/a	-25.3	13.7	13.4	12.7
Non-operating gains (losses)	**n/a**	**15**	**-36**	**-21**	**-0**
Financial profit	0	49	191	223	262
Financial costs	0	28	231	249	267
Equity-method gains (losses)	0	0	0	0	0
Other	n/a	-6	3	5	5
Pre-tax profit	**n/a**	**-49**	**219**	**246**	**277**
Taxes	n/a	-134	9	49	55
Effective tax rate (%)	n/a	275.7	4.0	20.0	20.0
Profit from continuing operations	0	85	210	197	222
Profit from discontinued operations	0	0	0	0	0
Net profit	**n/a**	**85**	**210**	**197**	**222**
Net margin (%)	n/a	33.9	11.2	9.9	10.1
Net profit (controlling interests)	n/a	85	210	197	222
Net profit (non-controlling interests)	n/a	0	0	0	0
EBITDA	n/a	4	681	767	830
EBITDA margin (%)	n/a	1.8	36.5	38.4	37.9
EPS (parent-based) (KRW)	n/a	21,211	8,429	7,924	8,919
EPS (consolidated) (KRW)	n/a	21,211	8,429	7,924	8,919
Adjusted EPS (KRW)*	n/a	21,211	8,429	7,924	8,919

Balance sheet

Year-end Dec 31 (KRWb)	2024	2025	2026E	2027E	2028E
Current assets	**n/a**	**1,900**	**2,757**	**3,451**	**4,233**
Cash & equivalents	n/a	131	380	879	1,449
Accounts receivable	n/a	320	454	491	531
Inventories	n/a	1,037	1,468	1,589	1,720
Other current assets	n/a	411	455	492	533
Fixed assets	**n/a**	**5,816**	**5,530**	**5,150**	**4,718**
Investment assets	n/a	35	51	51	51
Tangible assets	n/a	326	314	297	281
Intangible assets	n/a	5,323	5,068	4,706	4,289
Other long-term assets	n/a	133	96	96	96
Total assets	**n/a**	**7,716**	**8,286**	**8,601**	**8,950**
Current liabilities	**n/a**	**1,401**	**1,799**	**1,890**	**1,989**
Accounts payable	n/a	31	29	31	34
Short-term debt	n/a	237	602	602	602
Other current liabilities	n/a	1,133	1,168	1,257	1,353
Long-term liabilities	**n/a**	**409**	**370**	**397**	**425**
Bonds & long-term debt	0	95	50	50	50
Other long-term liabilities	n/a	314	320	347	375
Total liabilities	**n/a**	**1,810**	**2,170**	**2,287**	**2,415**
Owners of parent equity	**n/a**	**5,906**	**6,117**	**6,314**	**6,536**
Capital stock	n/a	62	62	62	62
Capital surplus	n/a	5,776	5,776	5,776	5,776
Retained earnings	n/a	85	295	492	714
Other	n/a	-18	-17	-17	-17
Non-controlling interests' equity	**n/a**	**0**	**0**	**0**	**0**
Total equity	**n/a**	**5,906**	**6,117**	**6,314**	**6,536**
Net debt	n/a	247	363	-136	-705

Cash flow statement

Year-end Dec 31 (KRWb)	2024	2025	2026E	2027E	2028E
Cash flow from operations	**0**	**-104**	**47**	**628**	**699**
Net profit	0	85	210	197	222
Non-cash profit and expenses	0	-65	464	552	588
Depreciation	0	3	19	17	15
Amortization	0	65	407	483	537
Other	0	-133	38	52	36
Changes in A/L from operating activities	0	-122	-586	-78	-85
Cash flow from investments	**0**	**-83**	**-153**	**-113**	**-113**
Change in tangible assets	0	-6	-4	0	0
Change in financial assets	0	-0	-0	-0	-0
Other	0	-77	-149	-113	-113
Cash flow from financing	**0**	**100**	**365**	**0**	**0**
Change in debt	0	378	365	0	0
Change in equity	0	5,838	0	0	0
Dividends	n/a	0	0	0	0
Other	n/a	-6,117	-0	0	0
Change in cash	0	-85	249	499	569
Cash at beginning of year	0	216	131	380	879
Cash at end of year	0	131	380	879	1,449
Gross cash flow	**0**	**20**	**674**	**749**	**810**
Free cash flow	**0**	**-110**	**43**	**628**	**699**

Financial ratios

Year-end Dec 31	2024	2025	2026E	2027E	2028E
Growth (%)					
Sales	nm	nm	641.9	7.1	9.7
Operating profit	nm	nm	nm	4.8	3.9
Net profit	nm	nm	145.9	-6.0	12.5
Adjusted EPS**	nm	nm	-60.3	-6.0	12.5
Per-share data (KRW)					
EPS (parent-based)	n/a	21,211	8,429	7,924	8,919
EPS (consolidated)	n/a	21,211	8,429	7,924	8,919
Adjusted EPS**	n/a	21,211	8,429	7,924	8,919
BVPS	n/a	237,782	246,269	254,208	263,143
DPS (common)	0	0	0	0	0
Valuations (x)					
P/E***	n/a	35.0	48.9	52.1	46.3
P/B***	n/a	3.1	1.7	1.6	1.6
EV/EBITDA	n/a	4,190.9	15.6	13.2	11.5
Ratios (%)					
ROE	n/a	1.4	3.5	3.2	3.5
ROA	n/a	1.1	2.6	2.3	2.5
ROIC	n/a	1.7	3.7	3.2	3.5
Payout ratio	n/a	0.0	0.0	0.0	0.0
Dividend yield (common)	n/a	0.0	n/a	n/a	n/a
Net debt to equity	n/a	4.2	5.9	-2.2	-10.8
Interest coverage (x)	n/a	-56.9	13.8	13.6	14.1

Note: *Excluding one-off items
**Fully diluted, excluding one-off items
***From companies subject to equity-method valuation

Source: Company data, Samsung Securities estimates

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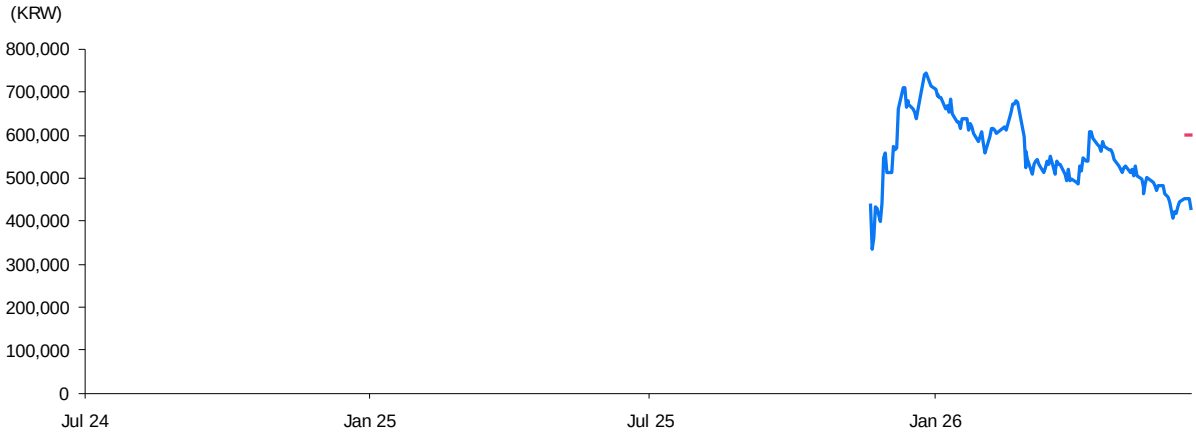

Rating changes over past two years (adjusted share prices)

Date	2026/6/16
Recommendation	BUY
Target price (KRW)	600000
Gap* (average)	
(max or min)**	

Note: * [(average, maximum, or minimum share price over duration of target price minus target price) / target price] x 100%
** Maximum/minimum share price if new target is higher/lower than market close on the business day prior to target price change

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Industry

OVERWEIGHT	Expected to outperform market by 5% or more within 12 months
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UNDERWEIGHT	Expected to underperform market by 5% or more within 12 months

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Percentage of ratings in 12 months prior to 2026.03.31

BUY(85.2%)·HOLD(14.8%)·SELL(0%)

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