



트레이드 렌즈
TRADE LENS

Bringing investing into focus.

COMPANY RESEARCH / No.07

KOSDAQ 196170 · Commercialisation and cash conversion

Alteogen Keytruda SC's European Patent Dispute Conditions for ALT-B4 Royalty Realisation

Sales milestones, cash conversion and manufacturing investment

\$463m

Qlex Q2 2026 sales [6]

\$1.0bn

Sales-milestone ceiling [7]

2%

Net-sales royalty after conditions [7]

**Sales validate the platform.
Contracts and patents govern the timing of cash.**

Separate restrictions in specific European markets from platform-wide failure, and distinguish product sales, milestones, royalties and cash.

Analysis date 16 October 2026

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Business structure · contracts · patent risk · cash flow



01 / RESEARCH VIEW

Commercial validation holds. The sequence of income matters.

TradeLens view | European restrictions first affect the timing of monetisation, not the existence of the whole platform.

Core view

Qlex sales validate commercial use of ALT-B4. The European dispute remains material, and Alteogen's income is not simply 2% of current product sales. Near-term milestones and their collection precede the contractual conditions for ongoing royalties. [\[1\]](#) [\[6\]](#) [\[7\]](#)

01

What has changed?

Restrictions in some European markets intersect with a growing commercial launch.

02

Why does it matter?

A later sales trajectory can defer milestones and the start of subsequent royalties.

03

Who is exposed?

MSD product sales, Alteogen licence income and factory capital recovery are different exposures.

04

What is decisive?

Territorial access, cumulative sales, receipts, operating cash and capital deployment.

The positive evidence is actual selling activity. The uncertainty is how quickly that activity becomes recurring income and cash for Alteogen. Confusing the two can understate the dispute or overstate the damage to the platform.

Decision rule

Product approval is not unrestricted selling, recognised licence income or collected cash. Test each link separately.

02 / EUROPEAN DISPUTE

European injunction: scope and revenue risk

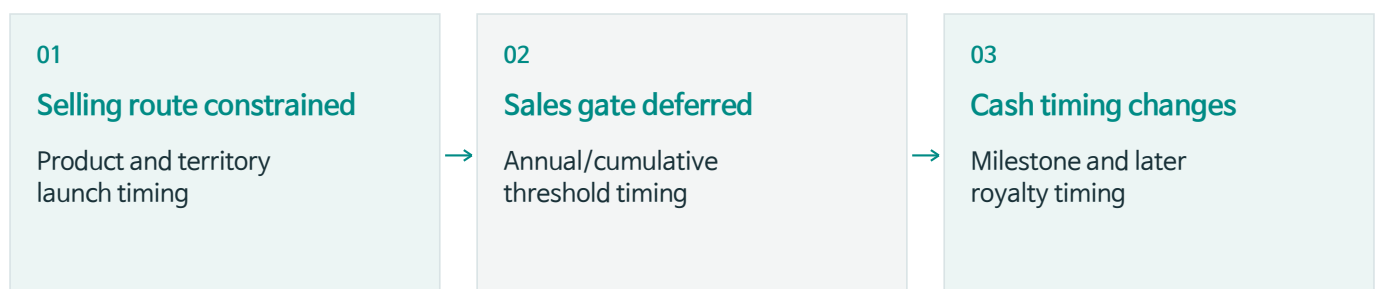
As announced on 7 October 2026. Separate the reported order from each litigant's position.

Halozyme announced that the Dutch court in The Hague restricted MSD BV's manufacture and commercial handling of Keytruda SC under EP 2,797,622. The territories are Belgium, Denmark, France, Ireland, Italy, Sweden, Switzerland and the Netherlands. IV Keytruda is excluded. [1]

Item	Published position	Interpretation limit
Dutch case	Restrictions on manufacture, sale, import, stock and facilitation by MSD BV [1]	Country count is not a sales-loss percentage
Merck response	Disagrees with the decision, disputes validity/infringement and evaluates next steps [2]	An objection is not a stay or appellate victory
Other proceedings	German preliminary injunction and U.S. litigation are separate [1]	No automatic global outcome

Business impact depends on duration, supply routes and conversion

Distribution, packaging and the marketing-authorisation holder matter as well as direct sales restrictions. Alternative supply routes and country launch delays require separate evidence. This report does not assume a worldwide halt in SC sales.



TradeLens transmission framework; no termination or permanent revenue loss is assumed.

TradeLens assessment

The relevant range lies between “no effect” and a total shutdown. The first test is whether European conversion delays move contractual sales gates into later periods.

03 / THREE DISTINCT RIGHTS

Approval, owned patents and freedom to operate are distinct

Commercial utility and the right to operate against third-party claims answer different questions.

01

Regulatory approval

Safety, efficacy and authorised use

02

Owned patent

Exclusion rights over an invention

03

Freedom to operate

Ability to operate around others' rights

Evidence	What it establishes	What it does not establish
FDA approval [3]	SC formulation approved on 19 Sep 2025	A non-infringement determination
Formulation patent [5]	European grant announced on 23 Sep 2026	Assurance of no overlap with Halozyme claims
Commercial restraint [1]	A constraint on specified products, conduct and territories	Clinical failure of ALT-B4 or invalidation of every licence

WIPO's freedom-to-operate framework asks whether a product or process encroaches on others' patent rights. Owning a patent does not replace that analysis. Equally, a third-party dispute does not erase the clinical evidence behind an authorised product. [4]

Implication for licence economics

Owned patents can support bargaining power while third-party rights constrain cost and timing. Any settlement, added licence fee or territorial change must be traced to its actual payer. No undisclosed obligation is assigned to Alteogen here.



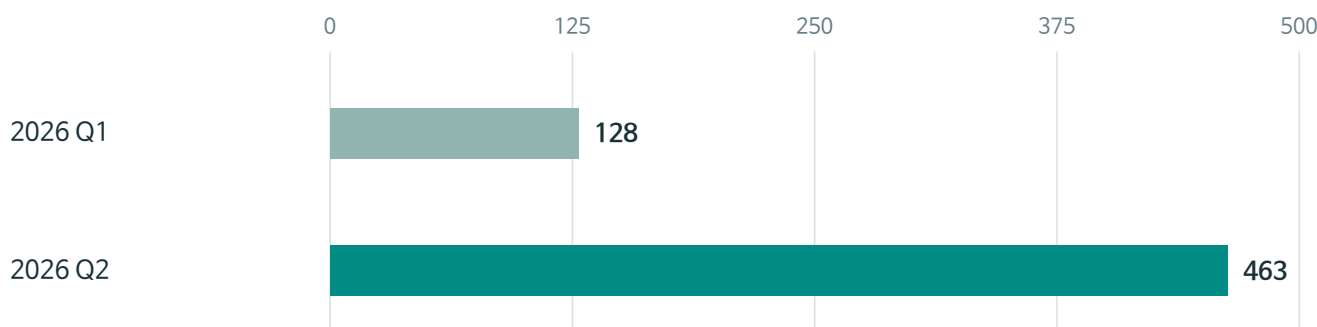
04 / COMMERCIAL EVIDENCE

Qlex sales have grown. Patient conversion is a separate measure.

Merck product sales and Alteogen licence income belong to different entities and accounts.

Keytruda Qlex quarterly sales

USD m · company reported



Q1: company-distributed release [8]. Q2 and H1: Merck supplement [6]. Rounded quarters total 591 (128+463), while reported H1 is 590; do not overwrite the reported half-year total.

Measure	Reported / calculated	Appropriate interpretation
H1 2026 Qlex	USD 590m [6]	Merck's realised product revenue
Q2 U.S. sales	USD 395m [6]	Centre of the current geographic mix
Q1-to-Q2 increase	Approx. 261.7%, from rounded sales	Not an annual growth rate or patient conversion rate

Do not extrapolate a launch quarter into a long-run growth rate

Reimbursement and prescribing-channel adoption can shift revenue timing during a launch. The company identifies the U.S. J-code as one facilitating factor. Price, dose and channel inventory differences prevent a revenue mix from being read as patient conversion. [8]

Next evidence to require

Track later Qlex sales, geographic mix and actual contract receipts together. One fast-growing quarter does not establish that recurring royalties have begun for Alteogen.

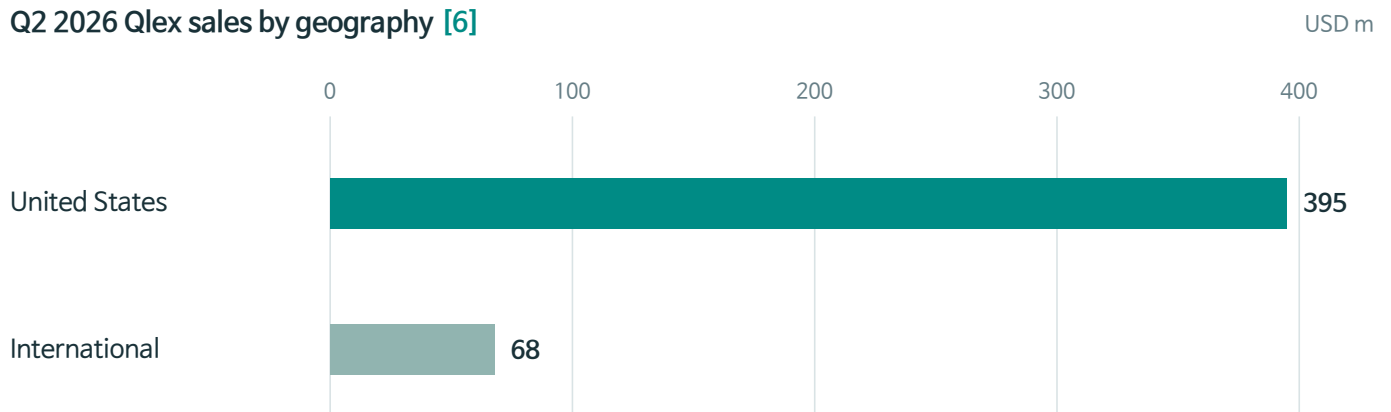


05 / TERRITORIAL EXPOSURE

International sales are not a proxy for European exposure

Use the right denominator; distinguish today's mix from future growth opportunity.

Q2 2026 Qlex sales by geography [6]



Scope	Revenue / share	Limitation
United States	395 / 463 = 85.3%	Outside the direct territory of the Dutch order
All international	68 / 463 = 14.7%	Not the sales of the eight European markets
Future SC sales in affected territories	Not separately disclosed	Current mix cannot cap lost future opportunity

Measure exposure through delayed sales, not a country count

The current U.S. concentration argues against treating European restrictions as a global shutdown. But a small early-stage revenue share need not imply an unimportant future market. Delays must be assessed separately against annual and cumulative contractual gates. [1] [6] [7]

Excluded shortcut

No loss is estimated as eight countries times an arbitrary revenue amount, or as all international revenue disappearing. Country SC sales, duration and alternative routes are required.



06 / CONTRACTUAL CASH WATERFALL

The 2% net-sales royalty follows the sales milestones

Separate income categories and their sequence using Merck's disclosed licence terms.

Income stage	Disclosed terms [7]	Economic character
Regulatory milestones	Up to USD 51m	Event-dependent payments
Sales milestones	Annual/cumulative targets; up to USD 1bn in total	Stepwise income at specified sales gates
Subsequent royalty	2% of net sales after all sales milestones are achieved	Recurring income only after the stated conditions



Alteogen announced the first USD 25m sales milestone on 31 August, and its 23 September release referred to receipt. That is 2.5% of the USD 1bn ceiling, not 2.5% progress towards the underlying sales targets or a measure of time remaining until royalties. [8] [5]

Annual and cumulative gates differ: later catch-up does not guarantee payment in the same period. The specific contractual conditions remain decisive. [7]

Preventing double counting

Do not book current Qlex sales times 2% as current Alteogen royalties and then add milestones. Distinguish contractual gates, revenue recognition and receipt, and do not impose MSD's 2% terms on other licences.



07 / TIMING SENSITIVITY

A partial sales delay can move a milestone into another period

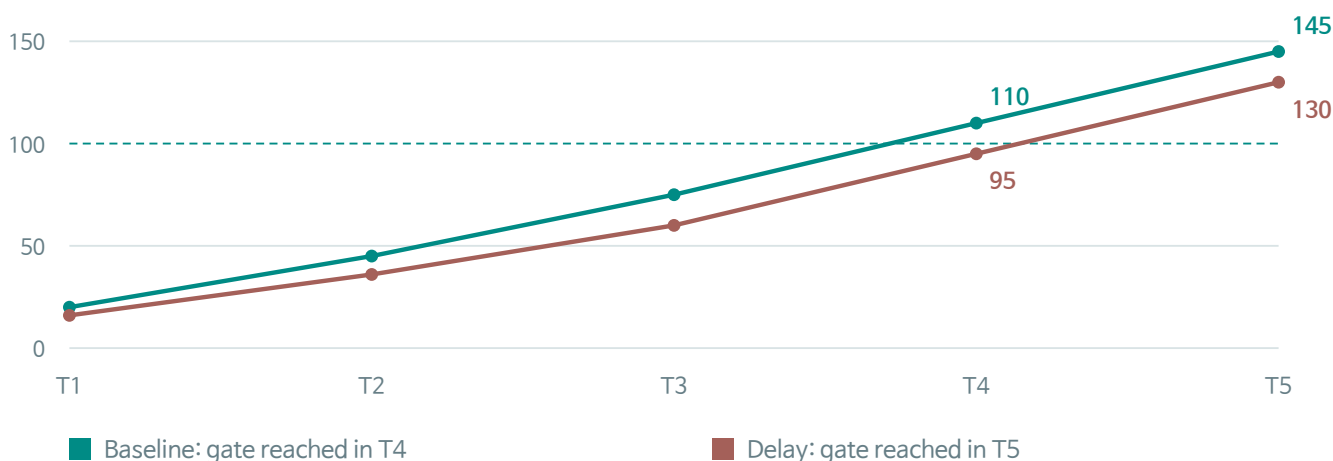
Illustrative model only: not actual sales, payment thresholds or country losses.

Model assumptions

Set an arbitrary cumulative gate at 100. Baseline period sales are 20, 25, 30, 35 and 35. The delay case has 20% lower sales for the first three periods, then returns to baseline. Lost volume is not subsequently recaptured.

Cumulative sales and an arbitrary gate

Index · illustration



T1 - T5 are fictional quarters, not calendar dates. One cumulative gate is modelled; actual annual gates, multiple thresholds, catch-up and settlement terms require separate assessment.

Distinguish delay from permanent loss, without ignoring time

Identical unit royalty terms can produce different receipt dates. For example, after all conditions are met, USD 1bn of qualifying net sales times 2% equals USD 20m. This is arithmetic, not a sales, start-year or company net-profit forecast. [7]

Variables that change the conclusion

Duration, actual U.S./other-market growth and the structure of annual/cumulative targets matter. A small current European share alone does not remove timing risk.



08 / EARNINGS QUALITY

H1 earnings growth is not recurring royalty growth

Consolidated H1 2026. Revenue, operating profit and net income measure different things.

Consolidated · KRW bn	H1 2025	H1 2026	Change
Revenue	102.34	140.49	+37.3%
Operating profit	60.59	73.48	+21.3%
Net income	48.72	101.33	+108.0%
Operating margin	59.2%	52.3%	-6.9pp

Source: consolidated half-year income statement [10]. Growth calculated before rounding. Net income includes non-controlling interests.

Separate the source of margin from its repeatability

The company attributes H1 contributions to upfronts and milestones from partners including Tesaro and Biogen. High margins are therefore not proof of a mature, stable sales-royalty stream. Later margins can vary with payment events, development work and operating expenditure. [9]

Question	Required distinction
Revenue quality	Upfront, development/regulatory and sales milestones, material supply and royalties
Earnings quality	Operating growth versus financing and valuation effects
Repeatability	Income sustainable without new licences versus deal-dependent income

TradeLens assessment

The business is transitioning towards sales-based income, not yet demonstrating a fully mature royalty stream. Revenue growth also coexisted with a lower operating margin.

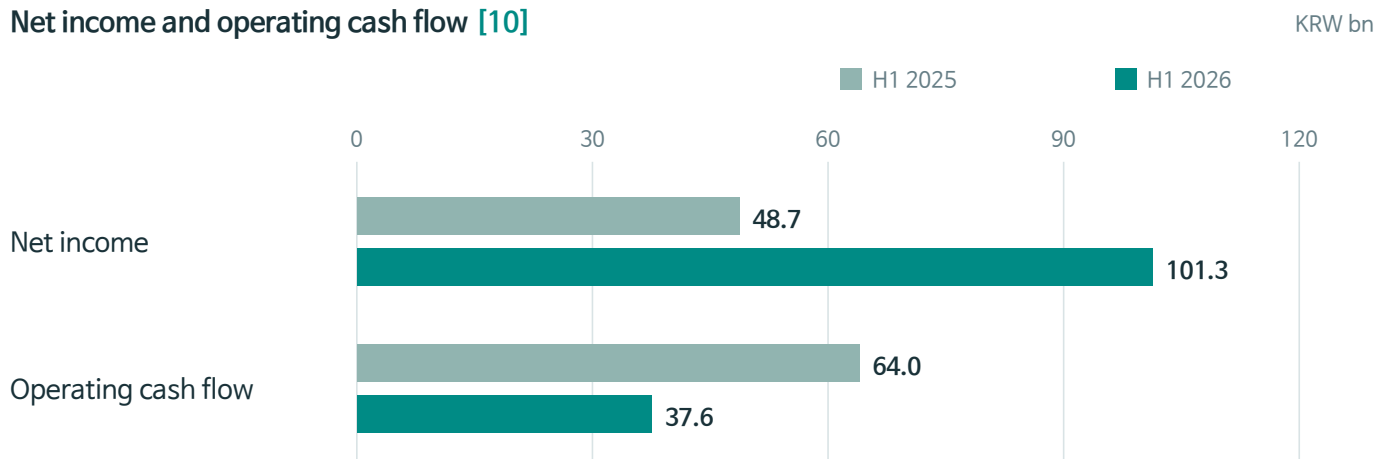


09 / CASH CONVERSION

Net-income growth did not translate into operating cash growth

Compare the same six months on a consolidated basis; keep future investment plans separate.

Net income and operating cash flow [10]



Operating cash flow fell 41.3% year on year. The measures are not a subtraction bridge; every bar begins at zero. [10]

H1 2026 cash calculation	KRW bn	Meaning
Operating cash flow	37.55	Reported cash-flow subtotal
Less: cash PP&E purchases	16.23	Not accounting asset additions
Less: cash intangible purchases	0.56	Cash outlay in the period
Difference of the three items	20.76	Reference before dividends, debt and leases

Closing cash and cash equivalents were KRW 80.37bn, not a measure of all freely available liquidity. Short-term investments, restrictions and funding terms also matter. Total investing cash flow includes financial-product purchases and disposals, so it is not factory capex. [10]

The cash test

Check whether licence revenue remains in receivables/contract assets or converts into receipts. Milestone recognition and financing inflows are not the same as operating cash generation.



10 / CAPITAL & CLAIMS

The KRW 200bn funding plan is not the same as completed funding

Read conversion/redemption rights alongside completed-payment disclosures.

On 6 October, the company announced a KRW 200bn financing plan for facilities and new products/technology. Separate 14 October filings report payment of approximately KRW 50bn of CPS and KRW 50bn of RCPS. The announced total is not treated as fully received cash. [\[11\]](#) [\[12\]](#) [\[13\]](#)

Disclosure unit	Amount	Status as of 16 October
Total financing announcement [11]	KRW 200bn	Total announced programme
Individual CPS completion [13]	191,473 shares / approx. KRW 50bn	Payment completed 14 October
Individual RCPS completion [12]	174,066 shares / approx. KRW 50bn	Payment completed 14 October
Additional RCPS decision [14]	Approx. KRW 50bn	Separate tranche scheduled for 30 October

The total programme contains the individual issues; rows are not additive. Each completed amount is slightly below KRW 50bn owing to share-count pricing and is rounded here.

The roughly KRW 100bn balance between the KRW 200bn plan and first completed payments is not added to cash at 16 October.

An issue premium alone does not measure the cost of capital

CPS creates a conversion/dilution channel; RCPS adds a conditional redemption channel. The cost depends on reset provisions, preferred distributions and redemption terms. New investment funds the company; it is not free incremental value for existing common shareholders.

Capital-allocation question

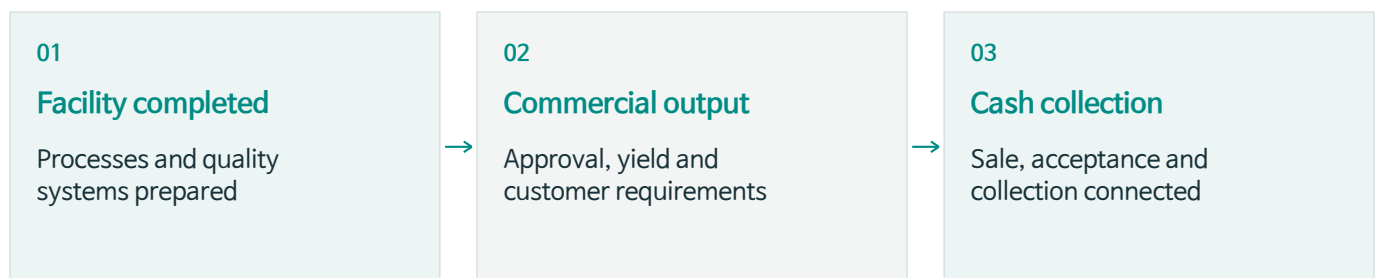
How flexible is spending while licence receipts remain uncertain? Test staged facility/technology commitments and cash generation ahead of potential redemption dates.

11 / MANUFACTURING & INTEGRATION

Manufacturing integration adds opportunity and fixed cost

Investment, completion, manufacturing authorisation and customer orders are separate stages.

Change	Published plan	Cash-recovery condition
Daejeon facility [15]	KRW 253.2bn investment; planned completion 30 Sep 2028	Authorisation, quality, utilisation and demand
Subsidiary absorption [16]	600,477 new shares; planned merger 29 Dec 2026	Integration benefits versus development/operating costs



Neither accelerate factory sales nor re-add subsidiary revenue

Owned production may reduce outsourcing cost and improve supply control, but depreciation, quality and maintenance weigh on low utilisation. The KRW 253.2bn plan is not near-term revenue or profit. Economics require validated yield, batch scale and unit costs.

The merger target is already a consolidated subsidiary. Its existing sales do not become newly consolidated solely through absorption. The changes concern organisation, funding, decision-making and shares issued to outside holders; synergies need subsequent cost and cash-flow evidence. [10] [16]

TradeLens assessment

Do not transfer licence margins unchanged onto a factory. Expanding a contract portfolio and expanding manufacturing capacity require separate return tests.



12 / OUTLOOK & MONITORING

Sales progression and capital recovery must advance together

Retain the commercialisation case, conditioned on European access and investment timing.

Monitor	Evidence strengthening the view	Evidence weakening the view
European restrictions	A stay/lifting or evidenced commercial resumption	Prolonged restraint or disruption in further territories
Qlex sales	Sustained U.S. growth and international progress	Persistent slowdown or conversion delays
Licence receipts	Further gates achieved and cash received	Delayed gates, changed terms or slow collection
Investment / capital	Funding completes, staged spend, quality validation	Fixed costs and spending outpace receipts

Three paths to assess against new evidence

Condition	Business and cash-flow interpretation
Sales hold; dispute persists	U.S. sales and milestones progress; European timing remains a separate risk
Access restored; gates reached	Broader access alongside receipts strengthens growth visibility
Restrictions last; spending leads	Delayed gates plus fixed-cost growth require renewed cash and spending discipline

Conclusion supported by the evidence

Alteogen is moving towards sales-based income, but neither recurring royalty commencement nor manufacturing capital recovery is a completed transition. Restored European selling routes and cash collection at the next sales gates would strengthen visibility.

No share-price direction, target or trading timing is provided. Legal discussion is a business-risk assessment based on published material, not an independent legal opinion.



13 / SOURCE REGISTER

Legal events, approval, product sales and licence terms

Select a teal citation, source title or “Open source” to open the cited material.

01. Halozyme European injunction announcement for Keytruda SC	Open source
2026.10.07 · Litigant press release · EP622, MSD BV, territories and IV exclusion	
02. Reuters / AOL European order and Merck's response	Open source
2026.10.07 · Original reporting, syndicated · Merck spokesperson and dispute status	
03. FDA Approval of subcutaneous pembrolizumab / berahyaluronidase	Open source
2025.09.19 · Regulatory release · Approval scope, PK comparison and efficacy limits	
04. WIPO Launching a New Product: Freedom to Operate	Open source
2005.09.30 · Official explanatory article · Own patents versus third-party rights	
05. Alteogen / Hankyung European grant of Keytruda SC formulation patent	Open source
2026.09.23 · Company-issued press release · Formulation patent; first sales milestone receipt	
06. Merck / SEC Q2 2026 sales supplement · Exhibit 99.2	Open source
2026.08.04 · Filed financial tables · Qlex quarterly, half-year, U.S. and international sales	
07. Merck / SEC Q3 2025 Form 10-Q · Alteogen licence terms	Open source
Period ended 30 Sep 2025 · SEC filing · Regulatory/sales milestones and subsequent 2% net-sales royalty	
08. Alteogen / Hankyung First USD 25m sales milestone achieved	Open source
2026.08.31 · Company-issued press release · Initial milestone and Qlex Q1/Q2 sales	

Source character: company-issued releases express that company's position. Reproduced filings and filing summaries identify their host. Litigant claims, realised sales, contract terms and illustrative calculations remain distinct.

14 / SOURCE REGISTER

Company earnings, financing and investment evidence

Select a teal citation, source title or “Open source” to open the cited material.

09. Alteogen Q2 and H1 2026 preliminary results	Open source
2026.08.07 · Official results release · Upfront and milestone contributions to H1 results	
10. Alteogen / FinancialFilings H1 2026 report · reproduced original filing	Open source
2026.08.14 · Reproduced company filing · Consolidated income, cash flows and subsidiary	
11. Alteogen / Hankyung KRW 200bn financing and use-of-proceeds plan	Open source
2026.10.06 · Company-issued press release · Total CPS/RCPS plan, facilities and new technology	
12. Alteogen filing / Bosoop RCPS issue result · filing 20261014900508	Open source
2026.10.14 · Reproduced filing · 174,066 shares; approximately KRW 50bn paid	
13. Alteogen filing / Bosoop CPS issue result · filing 20261014900506	Open source
2026.10.14 · Reproduced filing · 191,473 shares; approximately KRW 50bn paid	
14. Alteogen filing / EconomyReports Additional RCPS decision · payment scheduled for 30 October	Open source
2026.10.06 · Filing summary · Filing 20261006000323; KRW 50bn planned, not paid	
15. Alteogen filing / Dartbrief New facility investment · filing 20260821900238	Open source
2026.08.21 · Reproduced filing figures · KRW 253.2bn; planned end 30 September 2028; scope	
16. Alteogen / Hankyung Planned absorption merger of Alteogen Biologics	Open source
2026.10.06 · Company-issued press release · Subsidiary integration, 600,477 shares, planned 29 December	

Source character: company-issued releases express that company’s position. Reproduced filings and filing summaries identify their host. Litigant claims, realised sales, contract terms and illustrative calculations remain distinct.

Methodology, disclaimer and use of this report

Distinguish facts, company plans, TradeLens analysis and illustrative calculations.

Item	Basis
Analysis date	16 Oct 2026. Legal event: 7 Oct announcement and parties' positions. Earnings: Merck Q2 and Alteogen H1.
Entities / accounts	Separate Merck product sales from Alteogen licence income. Alteogen comparisons are consolidated; net income includes NCI.
Contract / legal limits	The 2% net-sales royalty follows all sales milestones. No country SC sales, actual gates or settlement cost is imputed.
Calculation / rounding	Page 8 uses an arbitrary index. Page 10 deducts cash PP&E/intangible purchases from OCF, before dividends, debt and leases.
Plans versus outcomes	Separate the KRW 200bn announcement from individual payments. Facility/merger dates are plans, not guarantees of sales or cash.

Currencies are not translated at an assumed FX rate. Ratios use underlying figures before rounding. No post-deal EPS, litigation win probability or fair share price is estimated.

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