中信建投证券 CHINA SECURITIES

Securities Research Report · H-share Quick Take | Biological Products

# Commercial value realized, innovation pipeline continues to progress

# KEYMED BIO-B (2162.HK)

## Key takeaway

Keymed Biosciences released its 2025 earnings report. During the reporting period, the company generated revenue of RMB 720 million, representing a 67% year-on-year increase, with product sales reaching RMB 315 million, in line with estimates. The core product CM310 (IL-4Rα) was successfully included in the NRDL for multiple indications, significantly accelerating commercialization; NewCo's secondary BD is expected to drive pipeline revaluation, while innovative technology platforms like small nucleic acids strengthen the company's long-term competitiveness. Going forward, attention can be focused on: 1) CMG901 (CLDN18.2 ADC), with Phase III second-line gastric cancer data expected to be released in the first half of 2026; 2) CM512 (TSLP/IL-1 bispecific antibody), with CRSwNP data expected in the first half of 2026; 3) IND submissions for multiple pipelines including siRNA, bispecific ADC, and PROTAC.

## Event

On March 26, 2026, Keymed released its 2025 annual results. In 2025, the company's operating revenue reached RMB 720 million, representing a 67% year-on-year increase.

## Quick Take

**I. Performance met expectations, with ample cash reserves**

On March 26, 2026, Keymed released its 2025 annual results. In 2025, the company achieved operating revenue of RMB 720 million, a 67% year-on-year increase, primarily driven by commercial sales of its core product Stapokibart and lisencing revenue. This included product sales of RMB 310 million and lisencing revenue of RMB 410 million, with R&D investment reaching approximately RMB 720 million. Cash on hand was RMB 1.96 billion.

## Maintain Buy


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Current price: HKD71.35

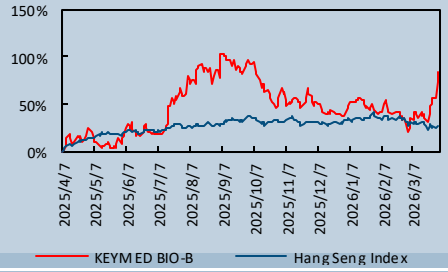
**Key Data**

**Absolute/Relative Share Performance (%)**

| 1 month | 3 months | 12 months |
|---|---|---|
| 37.61/43.29 | 33.49/35.49 | 52.95/44.72 |

| | |
|---|---|
| 12-month high/low price (HKD) | 78.50/38.65 |
| Total share capital (10,000 shares) | 29,873.56 |
| Tradable H Shares (10,000 shares) | 29,873.56 |
| Total market cap (HKD'00mn) | 213.15 |
| Tradable market cap (HKD'00mn) | 213.15 |
| 3-month average daily trading volume (10,000 shares) | 195.87 |
| Major shareholders | |
| Moonshot Holdings Limited | 25.16% |

**Share Performance**




**Related research reports**

**Key financial indicators**

| | 2024 | 2025 | 2026E | 2027E | 2028E |
|---|---|---|---|---|---|
| Revenue (million RMB) | 428.12 | 716.31 | 2,861.64 | 2,096.99 | 3,210.63 |
| YoY (%) | 20.91 | 67.31 | 299.50 | -26.72 | 53.11 |
| Net profit (in million RMB) | -515.24 | -522.64 | 781.30 | -195.29 | 545.67 |
| YoY (%) | -43.38 | -1.44 | 249.49 | -125.00 | 379.41 |
| Gross margin (%) | 97.15 | 87.71 | 84.07 | 94.03 | 94.11 |
| Net margin (%) | -120.27 | -72.96 | 27.26 | -9.30 | 16.97 |
| ROE(%) | -20.82 | -18.84 | 1.04 | -0.13 | 0.25 |
| EPS (Diluted/RMB) | -1.72 | -1.75 | 2.62 | -0.65 | 1.83 |
| P/E (multiple) | -41.37 | -40.78 | 27.28 | -109.14 | 39.06 |
| P/B (multiple) | 8.61 | 7.68 | 0.28 | 0.15 | 0.10 |

*Source: iFinD, China Securities*

## II. Stapokibart CM310 (IL-4Rα): The inaugural year of commercialization, accelerating Stapokibart's rapid sales volume expansion through multiple dimensions

Stapokibart (CM310) is the first biologic approved in China for chronic rhinosinusitis with nasal polyps (CRSwNP) and the first globally approved for seasonal allergic rhinitis (SAR). It covers three core indications: moderate-to-severe atopic dermatitis (AD), CRSwNP, and SAR. Subsequent indications are expanding into areas such as adolescent moderate-to-severe AD and prurigo nodularis, with ongoing realization of its commercial and clinical value.

**On the commercialization front, by the end of 2025, Stapokibart's three major indications and two packaging formats (vials and pre-filled injection pens) will be officially included in China's National Reimbursement Drug List (NRDL), with implementation beginning in January 2026, leading to rapid expansion in terminal coverage**. As of March 2026, the company's commercialization team had grown to nearly 500 members, with its products now available in over 1,500 hospitals—including more than 600 hospitals for in-hospital medication—and distributed through over 650 pharmacies. Since the NRDL inclusion, coverage has expanded to 30 provinces and more than 260 cities. The annual target of securing access to 1,000 hospitals by 2026 has already been exceeded by over 40%. In 2025, the product recorded annual sales of RMB 315 million, and in the first quarter of 2026, sales exceeded expectations, making significant progress toward the annual target.

At the clinical value level, Stapokibart demonstrated good efficacy in moderate-to-severe AD patients who previously showed no response or poor response to IL-4Rα inhibitor treatment. Meanwhile, leveraging its differentiated advantages as the first biologic for CRSwNP in China and the first SAR biologic globally, it has emerged as a core biologic product in China's rhinology field by 2025, with significant competitive differentiation barriers.

In terms of expanding indications, the company plans to submit a marketing application for the new indication of prurigo nodularis in the first half of 2026, further broadening the product's applicable population and commercial potential.

### III. CMG901/AZD0901: International clinical trials progress steadily, key registration milestones approach

AZD0901 (formerly CMG901) is the world's first Claudin 18.2 ADC drug approved for clinical use, independently developed by Keymed Biosciences. It has received FDA Orphan Drug Designation, Fast Track Designation, and CDE Breakthrough Therapy Designation. The company has entered into a global exclusive license agreement with AstraZeneca AB. In February 2026, the first patient was dosed in the global multicenter Phase III clinical trial for first-line gastric cancer combination therapy, triggering a $45 million milestone payment. The agreement stipulates cumulative milestone payments totaling over $1.1 billion.

**Global multicenter clinical trials are now fully underway, with significant progress in core registration clinical trials**. The global multicenter Phase III clinical trial of the product as a monotherapy for second-line and above advanced gastric cancer is expected to report core data in the first half of 2026, with a BLA submission planned for the second half of the year. Concurrently, the global multicenter Phase III clinical trial for first-line gastric cancer combination therapy is being advanced. Phase II clinical studies are also underway in multiple indications, including biliary tract cancer, pancreatic cancer, and perioperative gastric cancer, to further expand the product's therapeutic applications.

### IV. CM336: World's first expansion into autoimmune indications, a breakthrough in autoimmune disease treatment

CM336 is a bispecific antibody targeting BCMA/CD3 and a core investigational product for the treatment of multiple myeloma and various autoimmune diseases.

**Outstanding core clinical efficacy:** Clinical studies of the product for multiple myeloma demonstrated an objective response rate (ORR) exceeding 90% and a complete response (CR) rate of 75%, with favorable overall safety. Only less than 5% of subjects experienced Grade 2 cytokine release syndrome (CRS). In the field of autoimmune diseases, the product has also shown promising therapeutic effects for indications including primary immune thrombocytopenia (ITP) and atopic dermatitis.

**The expansion of indications continues to progress**. The company will further advance clinical research for CM336 in autoimmune indications such as ITP and systemic lupus erythematosus (SLE). By 2026, Phase II clinical data on the product for multiple myeloma will be published, while subsequent clinical research in the autoimmune field will also progress.

**Global collaboration secures long-term value**: Keymed Biosciences' NewCo partner Ouro Medicines has entered into an acquisition agreement with Gilead Sciences to accelerate worldwide development of the potential best-in-class TCE CM336/OM336. Upon deal completion, Keymed Biosciences will receive an upfront payment of approximately $250 million, plus potential milestone payments of up to $70 million, bringing the

total potential value to approximately $320 million. The company retains long-term benefits such as sales royalties and franchise rights. In addition to the upfront payment and existing milestone payments already received, there are additional milestone payments of up to $610 million.

**V. CM512: The world's second and potentially best-in-class TSLP x IL-13 bispecific antibody**

CM512 is a bispecific antibody targeting thymic stromal lymphopoietin (TSLP) and interleukin-13 (IL-13). It simultaneously targets both molecules, synergistically blocking downstream signaling pathways and effector cell activation associated with allergic inflammation, thereby effectively inhibiting allergic inflammatory responses. The product offers distinct advantages in dosing and efficacy, requiring only 2-4 annual injections. It provides prolonged drug maintenance with excellent overall safety. Its efficacy outside peak periods matches existing monoclonal antibodies, and some patients experienced no acute asthma attacks during pollen season. Additionally, the product's low immunogenicity and long half-life are expected to enhance clinical outcomes and patient adherence.

**The company has advanced clinical research on CM512 across multiple indications, with overall progress exceeding expectations**. For the Phase II clinical study on chronic rhinosinusitis with nasal polyps (CRSwNP), top-line data is expected to be released in June-July 2026, with plans to advance to Phase III clinical trials ahead of schedule. For the U.S. Phase I/II clinical study in asthma, patient enrollment is projected to be completed in Q2 2026. At the same time, clinical research for the product in indications such as moderate-to-severe atopic dermatitis and chronic obstructive pulmonary disease (COPD) is also progressing in parallel, positioning it as a core R&D milestone for the company in the first half of 2026.

**VI. CM518: A globally leading CDH17 ADC molecule with potential best-in-class properties**

CM518 is an antibody-drug conjugate (ADC) targeting CDH17 independently developed by Keymed Biosciences. As the company's core innovative pipeline for solid tumors, its R&D progress ranks among the top three globally. CM518D1 employs a cleavable linker combined with a topoisomerase I inhibitor, achieving a DAR of 8. Compared to competing products, it demonstrates superior cell binding and in vitro cytotoxicity, along with a potent bystander effect. In in vivo efficacy models for gastric and pancreatic cancer, CM518D shows an effective dose below 1 mg/kg and an HNSTD of 30 mg/kg, offering a safety window exceeding 30-fold. These characteristics position CM518D as a promising best-in-class candidate.

The key R&D milestones are clearly defined. In June 2025, a multicenter, open-label Phase I/II clinical study evaluating CM518D1 in patients with advanced solid tumors will be initiated (planned enrollment: 434 patients), with FDA IND clearance expected in July 2025. The Phase I clinical data from China will be presented at the ESMO GI Congress in the second half of 2026, potentially addressing the unmet clinical need in the global CDH17 ADC field and further expanding the commercial potential of the company's solid tumor pipeline.

**VII. Financial Analysis: Strong performance growth and solid financials, supported by refined R&D management and cash reserves for long-term development**

**Keymed Biosciences maintained a robust financial position in 2025, achieving strong revenue growth**

**driven by both product sales and business development (BD) collaborations**: full-year operating revenue reached RMB 720 million, representing a 67% year-on-year increase. The core product Stapokibart (CM310) generated commercial sales of RMB 310 million, while licensing revenue contributed RMB 410 million, demonstrating continued optimization of the revenue structure. R&D investment and pipeline advancement progressed efficiently in parallel. Full-year R&D expenses totaled RMB 720 million, remaining stable year-on-year. While comprehensively advancing clinical development of core pipelines and pursuing multiple indications simultaneously, the company implemented precise control over R&D expenditures, directing resources toward global development of clinical-stage pipelines, early innovation platforms, and candidate drug development. The company has ample cash reserves. As of the end of December 2025, cash and cash equivalents totaled nearly RMB 2 billion. These substantial financial reserves provide strong support for subsequent pipeline clinical development, commercial expansion, and production system construction.

**VIII. Future Outlook: Balancing R&D and commercialization, accelerating global business expansion**

Keymed Biosciences will leverage the expanded coverage of its core products under medical insurance and the global development of its innovative pipeline as dual engines to propel the company into a new phase of accelerated growth.

**Full-scale commercialization efforts:** Stapokibart (CM310) has achieved comprehensive coverage across all three major indications in the National Reimbursement Drug List (NRDL). In 2026, the company will further accelerate terminal coverage and market expansion, with hospital access targets already exceeding expectations—demonstrating significant long-term sales potential. The New Drug Application (NDA) for the prurigo nodularis indication is expected to be submitted in the first half of 2026, continuously expanding the product's commercialization potential.

**Global advancement of clinical pipelines**: The global clinical development of core pipelines continues to accelerate. The global Phase III clinical trial of AZD0901 (formerly CMG901) for second-line gastric cancer is expected to report core data in the first half of 2026 and submit an NDA in the second half of the year. The global multicenter Phase III clinical trial for first-line gastric cancer combination therapy has completed its first patient dosing. The Phase II clinical trial of CM512 for CRSwNP is expected to report top-line data in June-July 2026, with plans to advance to Phase III ahead of schedule. Phase I clinical data for CM518 will be presented at the upcoming ESMO GI academic conference. Subsequent clinical studies for autoimmune pipelines including CM336 and CM31 are progressing in parallel, further expanding the scope of potential indications.

**Production capacity and global collaboration ensure long-term growth**: The company has proactively established commercial production systems and sales teams for its core products to meet the commercialization demands of multiple pipelines. By leveraging global licensing partnerships, it accelerates the overseas value realization of early-stage pipelines, further strengthening its dual-engine strategy of "in-house development + global licensing." Keymed Biosciences will continue to focus on addressing unmet clinical needs, driving advancements in the biopharmaceutical sector through innovative therapies

and highly efficient execution.

**IX. Company Profit Forecast and Valuation:**

We project the company's operating revenue for 2026, 2027, and 2028 to be RMB 2.862 billion, RMB 2.097 billion, and RMB 3.211 billion, respectively, with corresponding growth rates of 299.5%, -26.72%, and 53.11%. Net profits are projected at RMB 781 million, -RMB 195 million, and RMB 546 million, respectively. Given the ongoing advancements in the company's self-developed new drugs, the efficient progress of clinical trials, and the increasingly robust commercialization team, we maintain "Buy" rating.

## Risks:

Industry policy risks: Changes in research design requirements, prices, volume-based procurement policies, and in the scope and proportion of medical insurance reimbursement brought about by industry policy adjustments.

The risk of R&D falling short of expectations: During the R&D process of new drugs, there are risks such as uncertain clinical enrollment progress, uncertain curative effect results and safety result data.

Slower-than-expected approval: Extension of the approval period due to factors such as the need for supplementary materials and changes in the approval process.

Risk of lower-than-expected sales: After a drug's launch, its sales may be affected by risks such as sporadic pandemic impacts, increased competition, insufficient logistics capacity, and inadequate production capacity. Additionally, industry anti-corruption measures may lead to slower-than-expected sales growth and market access for new products. Due to the phased implementation of policies, sales performance may vary across different market segments and regions.

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|---|---|---|---|
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| | | Overweight | Increase by 5%-15% relative to the benchmark index |
| | | Neutral | Increase by -5% to -5% relative to the benchmark index |
| | | Underweight | Decrease by 5%-15% relative to the benchmark index |
| | | Sell | Decrease by more than 15% relative to the benchmark index |
| | Industry ratings | Outperform | Increase by more than 10% compared to the benchmark index |
| | | Neutral | Increase by -10% to -10% relative to the benchmark index |
| | | Underperform | Decrease by more than 10% compared to the benchmark index |

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