Formycon. The Biosimilar Experts.
Half-Year Report 2025.

Formycon Group

key financial figures of the Formycon Group in the first half of 2025

	H1 2025	H1 2024
Revenue in € Million	**9.0**	26.9
EBITDA in € Million	**-17.9**	-16.9
Adjusted EBITDA in € Million	**-19.2**	-2.1
Working Capital in € Million	**17.0**	63.0

Highlights in the first half of 2025

FYB201
approved in
BRASIL

In Latin America, FYB201 is also approved in Peru, El Salvador, Honduras, and the Dominican Republic.

FYB202
approved in
CANADA and
the **UK**

FYB203
approved in the
EU and the
UK

Teva becomes commercialization partner for **FYB203** in **major parts of Europe**

Commercial launch of **FYB202/ OTULFI®** in the **US,** the **EU** and **CANADA**

Teva becomes commercialization partner for **FYB202/ FYMSKINA** in Germany

Valorum becomes commercialization partner for **FYB203** in the **US** and **CANADA** and ***Lotus*** in the **APAC REGION**

Formycon places **corporate bond** worth €70 million

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To our shareholders

An interview with our **Executive Board**

From left to right: *Dr. Andreas Seidl (CSO), Dr. Stefan Glombitza (CEO), Nicola Mikulcik (CBO), Enno Spillner (CFO)*

With several approvals, product launches, new partnerships as well as the entry first into the SDAX and then into the TecDAX, 2024 was a very successful year for Formycon. Was this development continued in the first half of 2025 and if so, were there any specific events that you would like to highlight?

Dr. Stefan Glombitza, CEO: "From an operational point of view, we are particularly pleased about the further approvals for our product pipeline: The Stelara®[1] biosimilar FYB202 (ustekinumab) was additionally approved in Canada and the UK. FYB203 (aflibercept), our Eylea®[2] biosimilar, received approvals for the European Union and the UK. Last, but not least, the Brazilian regulatory authority

[1] Stelara® is a registered trademark of Johnson & Johnson

[2] Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.

granted marketing authorization for our Lucentis®[3] biosimilar FYB201 (ranibizumab), an important entry point into the Latin American market.

Also, as you have already hinted at in your question, we were able to conclude further important strategic partnerships for the marketing of our products. In addition to some familiar names, I would like to highlight the partnership with Valorum for FYB203. This US biosimilar specialist has a unique network of experienced industry experts in the North American pharmaceutical market. That is an important enabling factor for the successful commercialization of our Eylea® biosimilar in the USA and Canada.

A milestone of particular importance in the first six months of 2025 was undoubtedly the scheduled launch of our second biosimilar FYB202/Otulfi®[4] by our commercialization partner Fresenius Kabi."

FYB202/Otulfi® was launched in the USA and Europe at the beginning of March; Canada followed suit at the end of May. However, the USA is proving to be a challenging market. How does Formycon deal with this?

Dr. Stefan Glombitza: "The market penetration for biosimilars in the USA is happening more slowly than originally expected, especially in the "Pharmacy Benefit Segment". This is the predominant **marketing channel** for our Stelara® biosimilar. A slow start does not mean that the US market is not sustainable – it simply takes longer for the market share for biosimilars to increase noticeably compared to the reference drug. This was also the case, for example, with the rheumatism drug Humira®[5] (adalimumab). What is surprising for many experts is the fact that this phenomenon is now repeating itself almost unchanged, and that ustekinumab biosimilars have only experienced very limited market penetration in the first year after introduction. In the short term, the focus of our commercialization partner Fresenius Kabi is therefore to gradually gain more market access through a large number of supply contracts. For Formycon, this also means the adoption of medium- and long-term strategic approaches that can be summarized under one motto: **stability through diversification."**

What does this mean in practice?

Dr. Stefan Glombitza: "The diversification mentioned above comprises several key elements: A central component is the broad geographical orientation of our marketing strategy. The core markets of the USA and the EU will remain important in the coming years, but the so-called "*emerging markets*" are becoming increasingly important as they combine growing economic strength with high unmet demand for biopharmaceutical treatment options. This is exactly where our biosimilars offer a solution.

Wide-ranging commercialization partnerships with local specialists enable us to position our products in important regions in an extremely targeted and market-oriented manner. We are currently expanding our marketing activities into further regions – Southeast Asia, Africa and Latin America, for example, markets that are growing in importance.

Semi-exclusive agreements in certain countries also provide us with the opportunity to maximize market penetration with our product in the same region through partners with complementary commercialization strategies."

3 Lucentis® is a registered trademark of Genentech Inc.

4 Otulfi® is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries

5 Humira is a registered trademark of AbbVie Biotechnology Ltd.

Does this strategy also have an impact on future development projects?

Dr. Stefan Glombitza: "The right portfolio selection is a key success factor. In this context diversification means covering a suitable range of indications, finding the right mix of blockbusters and less competitive "niche molecules", as well as taking the different marketing channels into account.

However, the advantages and opportunities resulting from the aforementioned diversifications can only be fully exploited if you are at the forefront of the competition. Ensuring this through excellence, agility and cost efficiency is our top priority.

Over the past few years, we have created a renowned development platform that has successfully brought three pipeline projects to international approval. The waiver of the phase III clinical trial for FYB206 enables us to shorten development cycles and bring products to market faster and at lower costs. The extensive biosimilar know-how of our teams, which we have gained over the years, helps us optimize processes and achieve efficiency gains. Optimizations facilitated through AI will also make a greater contribution in the future."

What exactly is the strategy in terms of expansion into the emerging markets mentioned above?

Nicola Mikulcik, CBO: "In addition to our activities in key markets such as the USA, Canada and Europe, markets in the so-called emerging economies are coming into focus. In these countries, we choose to rely on regional marketing champions. The markets for biosimilars work very differently locally. Therefore, we select partners who have a thorough understanding of their markets and have strong regional networks.

Thus, we have intensified our cooperation with MS Pharma on the basis of the successful market launch of our Lucentis® biosimilar in the MENA region. Our products FYB202 and FYB203 will also be commercialized in the MENA region by MS Pharma. For the Southeast Asian region, we concluded an exclusive license agreement with the regional player Lotus Pharmaceutical in February of this year. Lotus will market FYB203/AHZANTIVE®[6] in Indonesia, Malaysia, the Philippines, Singapore, Taiwan, Thailand, Vietnam and the Hong Kong Special Administrative Region."

The principal idea of Formycon's business model has always been to improve access to high-quality biologic drug therapies, especially in countries where the use of high-priced biologics has so far been severely constrained. Does the current marketing strategy fit this claim?

Nicola Mikulcik, CBO: "Yes, absolutely! The regions mentioned are very good examples of this and other markets will follow. The product launch of FYB201/Ranivisio®[7] in Brazil is planned for the fourth quarter of 2025. This marks the starting point for further market launches in Latin America until the beginning of 2027. Approvals have also been granted in Peru, El Salvador, Honduras and the Dominican Republic.

Just recently, a license agreement with the African biotechnology company Bio Usawa Biotechnology Ltd for FYB201 was concluded through our joint venture Bioeq AG. This will give Bio Usawa the exclusive rights to approval and commercialization of FYB201/BioUcenta™[8] in the Sub-Saharan Africa region, where an active ingredient such as ranibizumab is not yet available to the majority of patients. This initiative has laid the foundation for making a drug developed by Formycon for the treatment of severe retinal diseases available on the African continent."

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6 AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH

7 Ranivisio is a registered trademark of Bioeq AG

8 BioUcenta™ is a trademark of Bio Usawa Biotechnology Ltd.

Speaking of urgently needed drugs – what about the Keytruda® [9]biosimilar candidate FYB206?

Dr. Andreas Seidl, CSO: "In recent years, Keytruda® has revolutionized the treatment of a large number of tumor diseases through cancer immunotherapy and significantly improved the chances of recovery. Because of its great therapeutic, but also economic potential, FYB206 is of particular importance to us. That is why we have taken various steps to accelerate development – not least in the area of clinical trials. Based on the stringent study design of our Dahlia pharmacokinetics study, our sound scientific reasoning and the comprehensive analytical data, we have agreed with the US Food and Drug Administration (FDA) on an optimized clinical development program in which we can dispense with a Phase III study. This makes Formycon a pioneer for an innovative and lean clinical design of a pembrolizumab biosimilar. In the meantime, we were also able to successfully complete the patient recruitment for clinical development on schedule. This strengthens our position in the group of leading developers of a Keytruda® biosimilar."

Why is it so important to be at the forefront of development when market exclusivity does not expire until 2029 in the USA and in the EU after 2030?

Dr. Andreas Seidl: "There are several reasons for this. On the one hand, it enables an early start of the dialogue with the manufacturer of the reference drug in order to reach an agreement for the marketing launch. Ideally, this will give us a place in the first launch group. On the other hand, if a partnership has been concluded, each completed development step can lead to a success payment or, if no partnership has yet taken place, to a better negotiating position with potential marketing partners. Incidentally, we are registering a further sharp increase in interest here after the completion of recruitment for the ongoing PK study."

Formycon is not only breaking new ground in development, but also in the use of financial instruments. The company has just issued a bond – why?

Enno Spillner, CFO: "The Nordic Bond is a deliberate step for us to further support our growth strategy without diluting the existing shareholder structure. As a company in the Prime Standard and a member of the SDAX and TecDAX, we meet the highest transparency and governance standards. This creates trust and enables us to offer institutional and private investors a professional, capital market-ready investment product with an attractive risk-return profile in addition to traditional equity. Especially in the phase of transition to a profitable, even more commercially oriented company, the bond is a suitable financing component that brings a supplementary group of investors to Formycon."

How did the placement go?

Enno Spillner: "Beyond all expectation! Due to the high demand the bond was significantly oversubscribed, and as a result the originally targeted issue volume of € 50 million was increased to € 70 million. The significant oversubscription and the full placement confirm the attractiveness of this bond, but above all the confidence in our business model and the future of biosimilars. We have succeeded in effectively addressing a new investor base – internationally and in the domestic market, institutionally and in retail. The proceeds will give us the flexibility to optimize and expand our biosimilar platform and strengthen our overall position. We are very proud of the result."

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[9] Keytruda® is a registered trademark of Merck Sharp & Dohme LLC., a subsidiary of Merck & Co., Inc., Rahway, NJ/USA.

A good starting point for further development – what are the expectations for the coming months and years?

Dr. Stefan Glombitza: "As we have seen in recent months, there are unfortunately challenges arising now and again. This is to be expected given the dynamics and volatility of the emerging biosimilar market. For 2026 – or 2027 at the latest – we are aiming for positive EBITDA. By then, three of our products are expected to be available in key markets and generate corresponding sales.

FYB201/ranibizumab has already been established in 21 countries. The introduction of the FYB201 prefilled syringe is planned for the second half of the year – an important and technologically innovative application improvement with considerable benefits for doctors and patients, which is intended to open up further market potential, especially in Europe. The Stelara® biosimilar FYB202 is already being marketed in the USA, Canada and Europe. Furthermore, we are also entering additional marketing channels in Germany through secondary marketing by Teva/Ratiopharm under the Fymskina® brand[10]. Finally, FYB203/aflibercept is also in the starting blocks. The marketing authorizations have been granted and as soon as there is an agreement with the manufacturer of the reference drug, we are looking forward to the marketing launch of our third biosimilar.

In addition, our development pipeline is making very good progress – see FYB206. Here, we are aiming for the first commercial partnerships in 2025, which will contribute to the financial performance of Formycon AG through upfront and milestone payments. With FYB208, we are approaching the clinical development phase towards the end of 2025, also an important, value-generating step.

With our platform of excellence and our outstanding employees - for whose commitment I would like to take this opportunity to express my sincere thanks on behalf of the entire Executive Board - we are now entering the next phase of our company: from a developer to a commercial provider of biosimilars. We are supported by the great trust and appreciation of our shareholders. I would also like to thank you very much for that!"

Thank you for the interview!

[10] Fymskina® is a registered trademark of Formycon AG

Formycon on the stock market

Shares and the market environment

German and international stock market environment

Geopolitical tensions, particularly the ongoing armed conflicts in Ukraine and the Middle East, led to a mixed start to 2025 in the international equity markets with persistently high volatility in global capital flows. The U.S. government's announcement that it would impose tariffs on almost all imported goods also had a significant impact on stock prices. As a result, equity indexes suffered, especially in the U.S., where the market benchmarks abruptly lost up to 10% of their value at the start of April before regaining the losses beginning with the announcement of a temporary suspension of the tariffs starting April 9. The gains in technology and AI stocks were particularly pronounced. As of June 30, 2025, the NASDAQ closed at 5.5% for the six-month period,[11] while the MSCI World Index recovered after a weak start, gaining 4.2% in the month of May.[12] The S&P 500 ended the first half of the year at 6,205 points, likewise representing an increase of 5.5% since the start of the year.[13]

The Dow Jones Industrial Average index of U.S. blue chips closed the second quarter of the year at 44,094 points, up by 3.6%.[14]

While the U.S. market indexes posted gains again in the middle of the year, European equity markets have, on the whole, been performing more robustly, in some cases quite significantly, due largely to the shift in global capital flows away from the US and toward Europe.[15] With a gain of 22% since the beginning of the year,[16] Germany's DAX index has been one of the top performers in Europe.[17] The German equity market has thus so far proved to be largely immune not only to the geopolitical turbulence and tariff threats from the U.S. but also to anemic domestic growth.

So far this year, European equities as a whole have performed better than the U.S. benchmarks,[18] with the Euro STOXX 50 gaining 6.9% since the beginning of the year.[19] [20]

11 Stock Market Forecast: What Will The Last Half Of 2025 Bring? Here Are A FewClues.| Investor's Business Daily

12 Msci World Index Monthly Returns In 2025 | StatMuse Money

13 Stock Market Forecast: What Will The Last Half Of 2025 Bring? Here Are A Few Clues.| Investor's Business Daily

14 Stock Market Forecast: What Will The Last Half Of 2025 Bring? Here Are A Few Clues.| Investor's Business Daily

15 https://www.lbbw.de/artikel/news-und-einschaetzungen/halbjahresausblick-2025-aktien_akcbg4i31r_d.html

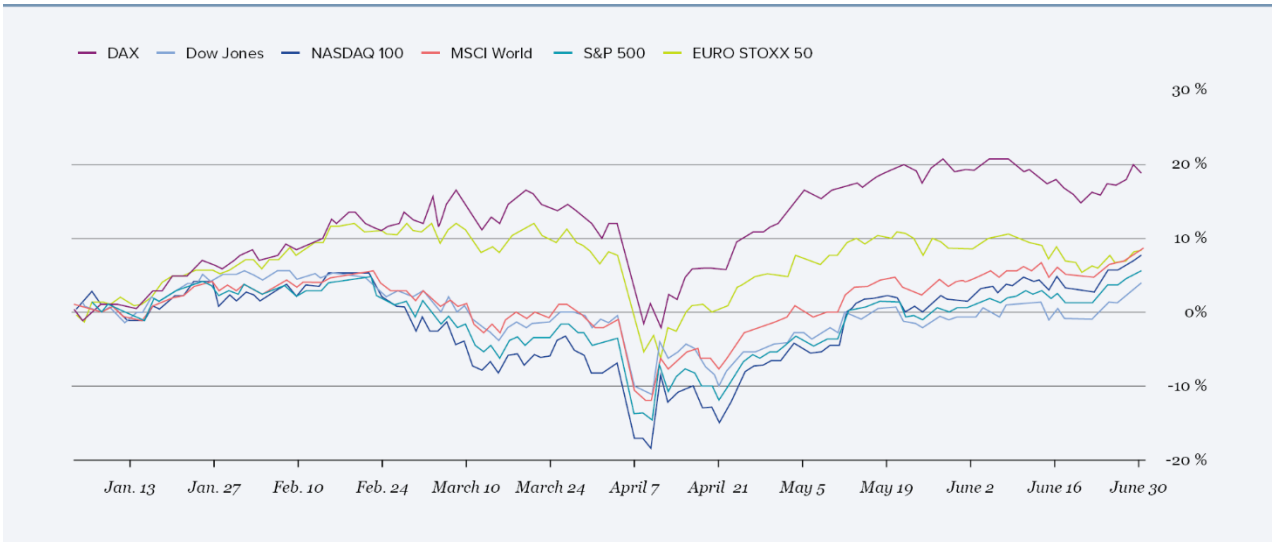
16 Marktausblick - June 2025 | DWS

17 Deutsche Aktien: Was Anleger im 2. Halbjahr 2025 erwartet

18 Marktausblick - June 2025 | DWS

19 Märkte und Trends 2025/06

20 From a U.S. investor's perspective, the outperformance is less pronounced on a currency-adjusted basis



Performance of the biotechnology sector

Following several years of a challenging market environment which made the financing of biotechnology R&D more difficult, the equity markets began to open up again slightly in the first half of 2025, with the primary drivers being pent-up investment demand and the expected easing of monetary policy. The environment for financing biotech companies in the development phase is becoming more favorable,[21] and specifically in Germany, the positive trend that tentatively emerged last year has continued.[22] Nevertheless, research-intensive start-ups and medium-sized companies continued to face investor reluctance during the first six months of 2025,[23] especially in the private financing sector.

Looking at the biotech equity indices, the first six months of the year were volatile. Following an initial high of 4,666 points, the NASDAQ Biotechnology Index plummeted to 3,732 points at the beginning of April, before subsequently recovering in part. By the end of June, it had once again exceeded the 4,200 mark.[24]Other indices, specifically including the DAXsubsector Biotechnology, a specialized equity index which tracks the performance of companies in Germany's biotech sector, have been showing this same trend.[25]

During the first half of 2025, the SPDR S&P Biotech ETF (XBI) recorded a period decline of approx. 8%, with the sector particularly impacted by the challenging macroeconomic environment and regulatory uncertainty. In the second quarter, the XBI showed a modest recovery with a gain of approx. 2.3%, tentatively suggesting stabilization and improved market sentiment. Overall, the biotechnology sector remains volatile but continues to benefit from long-term growth driven by innovation and healthcare research. As with other sectors, short-term uncertainties relating to interest rate policy and trade conflicts continue to impact equity market performance.

It remains to be seen whether the European Commission's recently announced Life Sciences Strategy will have a significant impact. This new program aims to raise the European biotechnology sector from third to first place worldwide by 2030, supported by € 10 billion in investments. The funding is intended to strengthen the food, agriculture, pharmaceutical and industrial biotechnology sectors, targeting key R&D areas such as cell therapies, gene therapies, and AI-guided drug development.[26]

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21 https://www.jefferies.com/insights/boardroom-intelligence/is-ai-ready-to-transform-healthcare-leaders-in-biotech-and-provider-services-weigh-in/

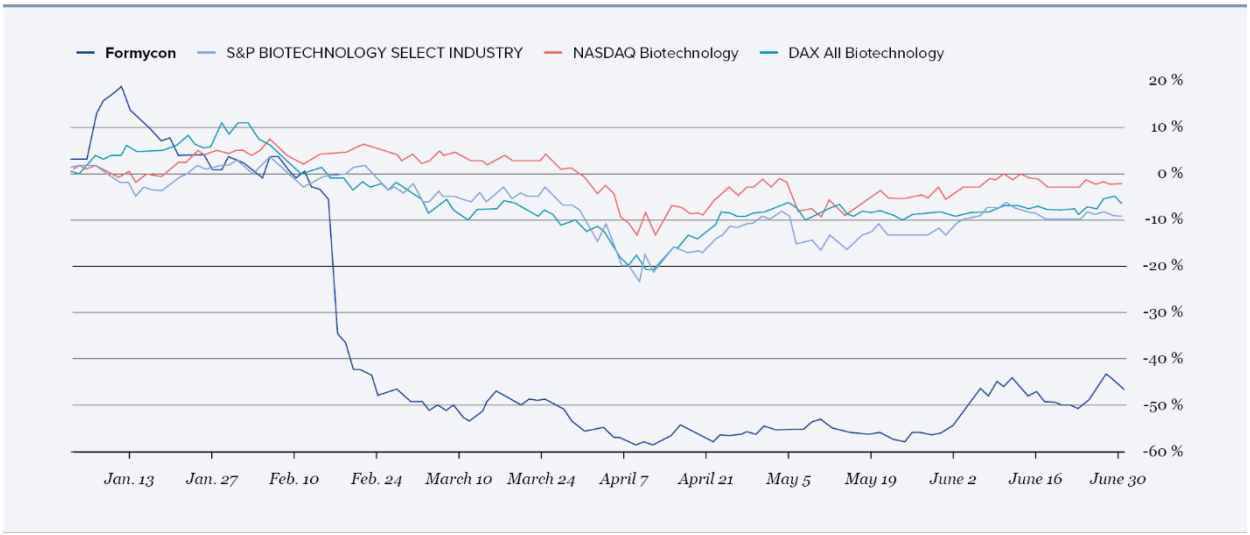
22 Statistiken zur Biotechnologie | Statista

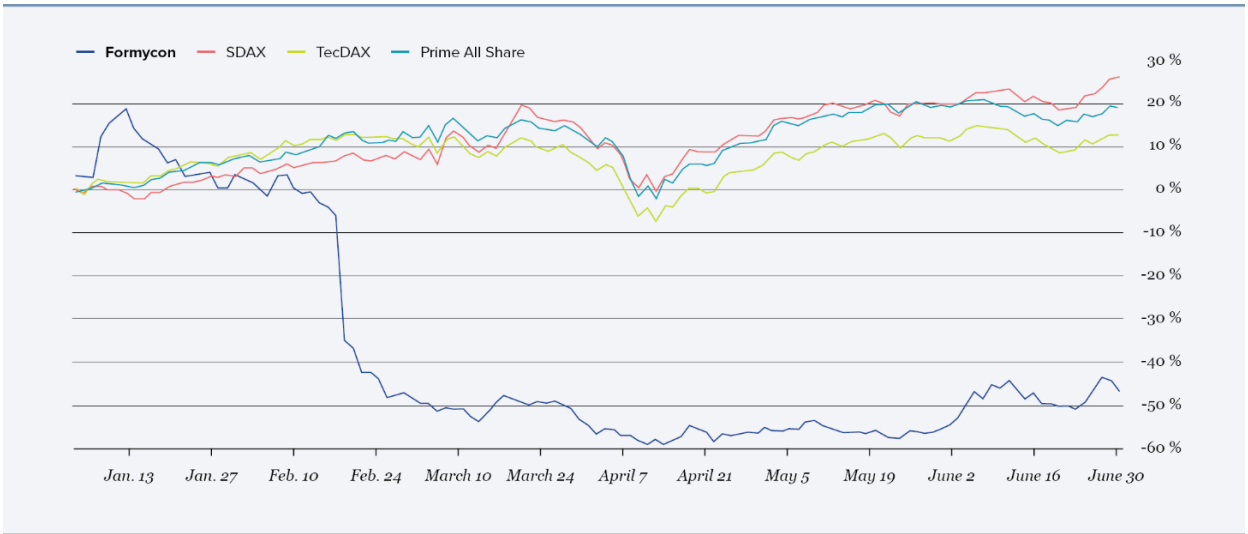
23 2025_07_Aristo-Half-Year-Report-25_DE.pdf

24 NASDAQ Biotechnology Index (NBI) Chart inkl. Chartanalyse • onvista

25 NASDAQ Biotechnology Index (NBI) Chart inkl. Chartanalyse • onvista

26 Europäische Kommission finanziert Life-Sciences-Strategie aus Mitteln des Kohäsionsfonds - European Biotechnology Magazine





Performance of Formycon shares

Since the end of 2024, Formycon shares have been included in the SDAX, Germany's benchmark index for the next 70 largest companies following the 90 DAX and MDAX members. Since January 13, 2025, Formycon has also been included in Germany's TecDAX index of technology companies. Both of these indexes posted gains during the first half of 2025, with the TecDAX rising 12.9% to 3,879 points[27] and the SDAX an even more impressive 26.7%.[28] The Prime All Share Index, to which Formycon was promoted through its uplisting in November 2024, posted a similar gain of approx. 22% over the first six months of the year.[29]

Formycon shares opened the trading year at € 54.10 and shortly thereafter reached a year-to-date high of € 63.70. Starting from mid-February, the price declined significantly due to a partially difficult news situation, reaching its low of € 20.00 in early April. The decline in share price was accompanied by the announcement of impairment charges based on negative commercial dynamics in the US biosimilars market environment: Specifically, Sandoz, the U.S. commercialization partner for Formycon's Lucentis® biosimilar FYB201/Cimerli®, announced in reaction to deepening price discounts that it would temporarily pause U.S. marketing in order to reposition the product.

27 https://www.finanzen.net/nachricht/aktien/optimismus-in-frankfurt-tecdax-verbucht-zum-handelsende-zuschlaege-14595664

28 https://www.finanzen.net/nachricht/aktien/starker-wochentag-in-frankfurt-sdax-schlussendlich-mit-gewinnen-14595666

29 https://stoxx.com/index/pxap/

Furthermore, in the run-up to the U.S. market launch of Stelara® biosimilar FYB202/Otulfi® by Formycon's commercialization partner Fresenius Kabi, it became increasingly apparent that price discounts would be deeper and market penetration slower than expected. Both of these developments necessitated corresponding adjustments to Formycon's valuation model and accounting practices. Even the very positive announcment regarding the optimized clinical development of the biosimilar candidate FYB206, resulting in significant time savings and reduced development costs, could only partially counteract this trend.

Due in large part to the multiple operational milestones achieved in the first half of 2025, the share price subsequently recovered somewhat, closing at € 28.18 as of June 30, 2025. Among these milestones was the successful launch of Formycon's public corporate bond issue. In response to high investor interest and oversubscription, the total issuance amount was increased from the originally planned € 50 million to € 70 million, and the offering period for the bond was shortened.

Formycon shares: Trading information

Ticker symbol	FYB
German securities identifier (WKN)	A1EWVY
ISIN	DE000A1EWVY8
Listed exchange, Market segment	Frankfurt Stock Exchange, Prime Standard, SDAX TecDAX since 13.01.2025
Trading venues	Xetra, Berlin, Düsseldorf, Frankfurt, Hamburg, Munich, Stuttgart, Tradegate
Designated Sponsors	Oddo BHF Corporates & Markets AG M.M. Warburg & Co.

Formycon shares: Performance information

in Euro	**2025**	**2024**
Opening price (Xetra) on Jan. 3, 2024 / Jan. 2, 2025	54.10	56.40
Closing price (Xetra) on June 30, 2024 / June 30, 2025	28.00	51.80
Average price (Xetra closing price)	32.90	47.15
Market capitalization as of June 30	494,603,956	914,627,524
in shares		
Total shares traded (on all trading venues)	7,997,856	1,721,660
Daily average shares traded (on all trading venues)	63,982	14,964
Total shares issued as of June 30	17,664,427	17,656,902

Formycon 2025/2029 bond issue

In the first half of 2025, Formycon AG successfully launched a public corporate bond issue totaling € 70 million. The Formycon 2025/2029 bond (ISIN: NO0013586024 / WKN: A4DFJH) was originally planned with a target volume of € 50 million but was increased in response to strong investor demand.

The senior unsecured four-year bond was issued with a final maturity date of July 9, 2029, and bearing a variable interest rate of 7.00% p.a. over three-month EURIBOR.

The bond has been listed for trading on the Open Market of the Frankfurt Stock Exchange since June 30, 2025. An additional listing on Euronext ABM (Oslo) is in preparation.

Through this bond market transaction, Formycon has strengthened its liquidity base. The issuance proceeds will be used to finance the ongoing development and commercialization of Formycon's biosimilar portfolio and will provide Formycon with additional flexibility to implement its medium- to long-term growth strategy. The broad investor base and strong demand reflect confidence in the Company's position in the growing global market for biosimilars.

Formycon 2025/2029 bond issue: Trading information

Issuer	Formycon AG, Planegg-Martinsried, Germany
Total issuance amount	€ 70,000,000
ISIN / German securities identifier (WKN)	NO0013586024 / A4DFJH
Interest rate (coupon)	3-Monats EURIBOR plus 7.0 % p.a.
Issuance price	100%
Nominal amount (face value) per bond	€ 1,000
Interest payment	Quarterly, starting October 9, 2025
Term	Four years, from July 9, 2025 until July 9, 2029
Scheduled repayment	Due on July 9, 2029
Status	Senior unsecured
Covenants	Customary covenants including restriction of distributions, maintenance of liquidity, and quarterly financial reporting.
Trading venue and market segment	Listed for trading on the Quotation Board, part of the Open Market segment of the Frankfurt Stock Exchange. Additional listing on the Euronext ABM of the Oslo Stock Exchange expected within six months.
Issuance and value date	July 9, 2025
Joint Lead Manager	IKB Deutsche Industriebank AG, Pareto Securities AS, Frankfurt Branch

Shareholder structure

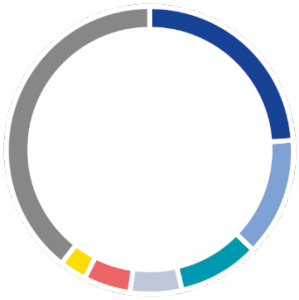
If certain voting rights thresholds are exceeded, the relevant shareholders are required, under German law, to file a notification thereof with the respective issuing company as well as with the German Federal Financial Supervisory Authority (BaFin). Since its uplisting on November 12, 2024 to the Regulated Market and to Frankfurt Stock Exchange's Prime Standard segment, Formycon AG has been subject to the provisions of sec. 33 ff. of the German Securities Trading Act (Wertpapierhandelsgesetz), including the resulting notification obligations in case of changes in significant shareholdings. The relevant thresholds under this law are 3%, 5%, 10%, 15%, 20%, 25%, 30%, 50% and 75%.

As of June 30, 2025, and based on the Voting Rights Notifications provided to Formycon in accordance with the Securities Trading Act, a combined total of approx. 60.79% of Formycon's share capital was held by anchor investors. The remaining 39.21% of shares were in free float.

Copies of such notifications received may be found on the Formycon website at

https://www.formycon.com/en/investor-relations/votingrights/

Shareholder structure as of Dec. 31, 2025



24.04 %
Santo Holding (Deutschland) GmbH

13.25 %
Wpart GmbH, Wen.Co Invest GmbH, Peter Wendeln

9.08 %
Richter Gedeon Vegyészeti Gyár Nyilvánosan Müködö Rt. (Gedeon Richter)

6.04 %
Active Ownership Fund SICAV SIF SCS

5.10 %
Detlef und Ursula Spruth

3.28 %
Stefan R.

39.21 %
Free Float

Structure as of June 30, 2025
This overview reflects the voting rights notifications pursuant to §§ 33ff of the German Securities Trading Act (Wertpapierhandelsgesetz – WpHG)

Directors' Dealings in the first half of 2025

Executive or Supervisory Board Member	Position	Transaction date	Type of transaction	Price	Transaction value
Dr. Andreas Seidl	CSO	February 21, 2025	Purchase	€ 30.00	€ 4,800

Reportable securities transactions by company executives (directors' dealings)

During fiscal year 2025, members of the Executive Board or Supervisory Board have conducted securities transactions subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR) as listed in the accompanying table. Further information regarding such transactions may be found on the Formycon website under *https://www.formycon.com/en/investor-relations/directors-dealings/*

Subscribed capital

As of January 1, 2025 and the period close on June 30, 2025, the registered capital (*Grundkapital*) of Formycon AG was € 17,664,427.00, divided into 17,664,427 bearer shares without par value but with an imputed nominal value of € 1.00 per share.

Investor relations

Professional dialog with investors and with the international capital markets forms an important component of Formycon's investor relations program. During the first half of 2025, Formycon's senior management and investor relations department presented the Company at a number of investor conferences within Germany and abroad, including the following:

- J.P. Morgan Healthcare Conference, San Francisco
- UniCredit & Kepler Cheuvreux German Corporate Conference, Frankfurt
- Oddo BHF Small & Mid Cap Conference (virtual event)
- Metzler Small Cap Days 2025, Frankfurt
- mwb Research German Select Conference, virtual
- Equity Forum Spring Conference, Frankfurt
- Berenberg European Conference 2025, New York
- mwb Research Roundtable (virtual event)
- Warburg Highlights, Hamburg

Beyond these organized conferences and roadshows, Formycon has strived to maintain active contact with existing and potential investors and to increase its visibility on the capital markets, such as through virtual roundtable and fireside chat events.

As of June 30, 2025, 11 national and international analysts were regularly providing equity research coverage with investment recommendations on Formycon AG.

During fiscal year 2025, the following banks or other research providers published studies on Formycon:

Bank or research provider	Analyst
Berenberg	Benjamin Thielmann
B. Metzler seel. Sohn & Co. KGaA	Alexander Neuberger
First Berlin Equity Research GmbH	Simon Scholes
Hauck Aufhäuser Lampe Privatbank AG	Alexander Galitsa
H.C. Wainwright	Yi Chen
Jefferies	Brian Balchin
Kepler Cheuvreux	Nicolas Pauillac
mwb Research	Alexander Zienkowicz
M.M. Warburg	Dr. Christian Ehmann
Oddo BHF	Damien Choplain
Royal Bank of Canada	Alistair Campbell

Further information about Formycon and its investor relations activities may be found in the "Investor relations" section of the Company's website at

https://www.formycon.com/en/investor-relations/formycon-shares/

Formycon believes in open dialogue with its investors and with the capital markets, as an integral part of its corporate philosophy. In this spirit, the investor relations department of Formycon AG stands ready to respond to any questions or suggestions:

Formycon AG
Sabrina Müller
Director Investor Relations & Corporate Communications
phone +49 89 864 667 149
ir@formycon.com

Interim Management Report of Formycon Group for the First Half of 2025

Basic Information about Formycon Group

Business activities

Formycon is a globally operating, independent biosimilars specialist with a comprehensive product pipeline and a scalable platform for biosimilar drug development for indications across various areas, including ophthalmology, immunology and immuno-oncology. Formycon is able to cover all technical stages of the biopharmaceutical development chain starting with the selection of highly promising biosimilar candidates, through cell line development, comparative analysis and process development, into preclinical studies and clinical trials, and all the way through to the preparation of regulatory approval application documents and management of the approval process. Formycon's core expertise also includes the management and coordinated oversight of the entire supply chain and product logistics. For the commercialization of its biosimilar products, Formycon relies upon strong, trustworthy and long-term partnerships around the world.

With FYB201/ranibizumab, Formycon already has an approved biosimilar product on the market in the United States and Canada, Europe, the Middle East and North Africa (MENA), and other geographical regions. Market launches and approvals in further markets such as Latin America and the sub-Saharan African region are planned for 2025/2026. After the current marketing pause, a reintroduction in the US is planned for 2026.

Since March 2025, a second biosimilar, FYB202/ustekinumab, is available on key markets, namely in the United States, Canada and Europe. Further market launches in additional regions are in preparation.

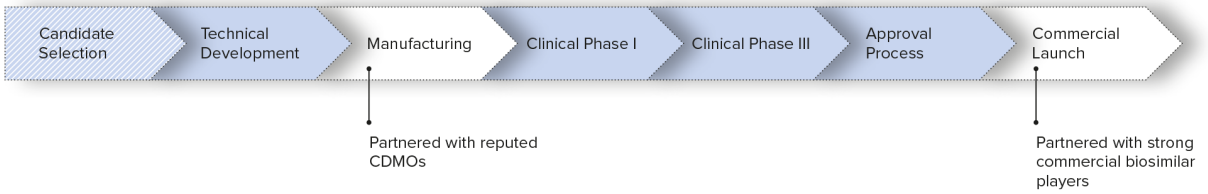
FYB203/aflibercept has been approved in the US, the EU and the UK. Formycon currently expects a market launch in the course of 2026, as no agreement has yet been reached with the manufacturer of the reference drug regarding a potential market launch date.

Four biosimilar candidates are currently in development, including FYB206/pembrolizumab, for which patient recruitment for clinical development has already been successfully completed.

Three other previously unpublished candidates (FYB208, FYB209 and FYB210) are currently in the preclinical phase. Of these, FYB208 is the most advanced and is expected to reach "Technical Proof of Similarity" (TPoS) in the course of 2025.

The continuous expansion of the portfolio through targeted selection, development and – fully or in partnership – commercialization of new biosimilar candidates forms the foundation of Formycon's long-term and sustainable growth strategy.

The biosimilar value chain



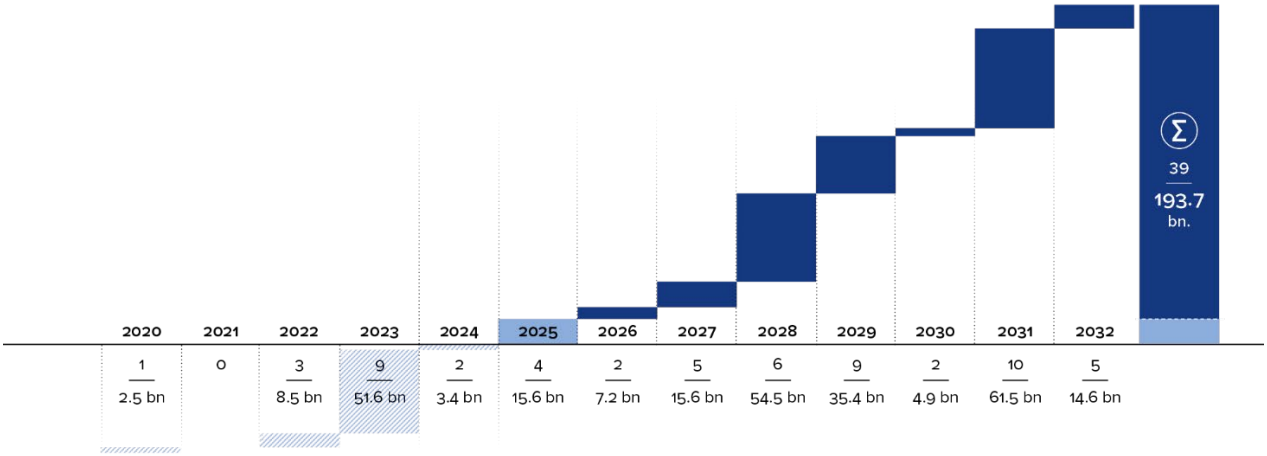
What are biosimilars?

Biosimilars are follow-on products to biopharmaceutical drugs whose market exclusivity has expired. They possess comparable quality, efficacy and safety, and they are subject to stringent regulatory approval processes in highly regulated markets such as the European Union, the United Kingdom, the United States, Japan, Canada and Australia based upon the biosimilar's proven comparability to the reference product.

Since the 1980s, biopharmaceuticals have revolutionized the treatment of serious diseases such as cancer, diabetes, rheumatism, multiple sclerosis and acquired blindness. Over the next seven years (2026-2032), many of these biotech drugs will lose their patent protection, including 39 blockbuster drugs[30] with total combined annual sales estimated at more than US$ 190 billion.

30 Blockbuster is defined here as a drug with annual sales of more than US$ 1 billion in the peak year. Analysis based on timing of U.S. patent expiry. Source: EvaluatePharma database, April 2022; press reports; McKinsey analysis

**Biosimilar potential -
by 2032, 39 blockbusters will
lose their market exclusivity (in US$ bn)[31]**

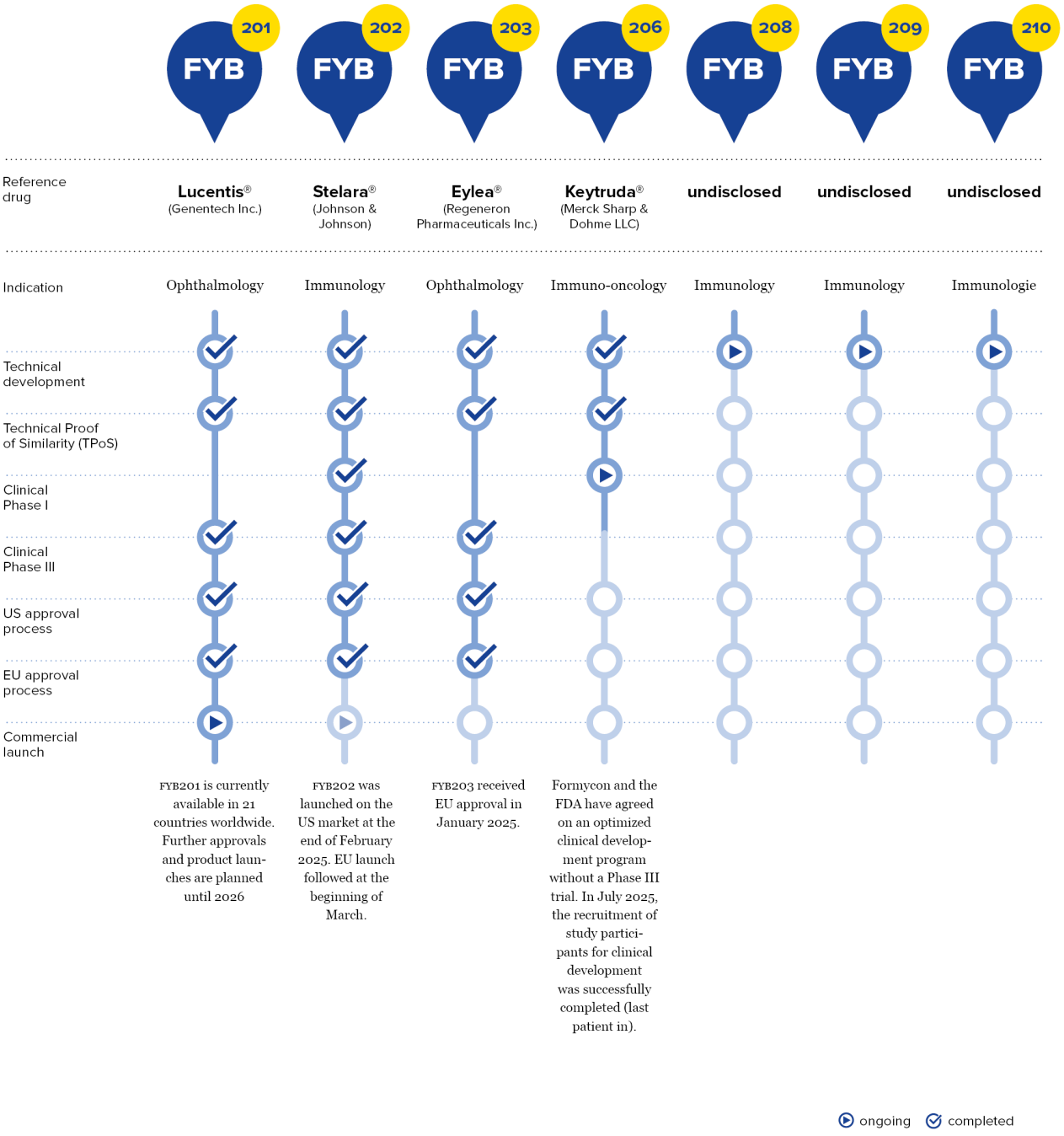


Product pipeline

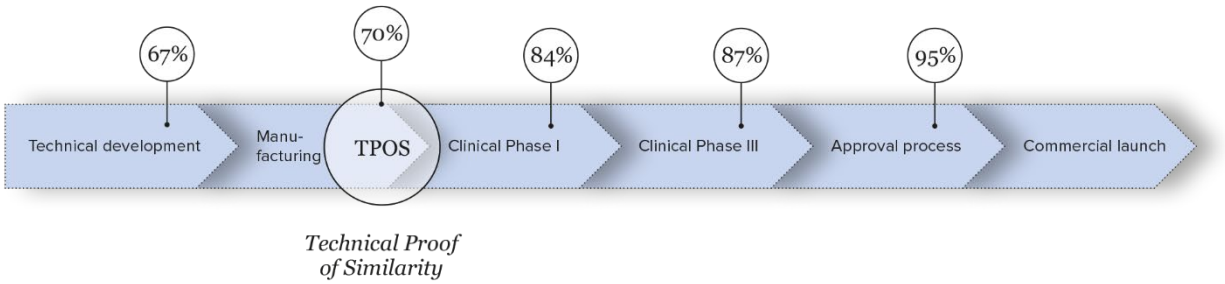
The development of new biosimilar drugs is the foundation for sustainable long-term growth. Within the area of biosimilars development, Formycon has the following projects in various stages of development:

[31] Fig. **Fehler! Nur Hauptdokument**: EvaluatePharma database, April 2022; press reports; McKinsey analysis

Formycon`s Biosimilar-Product-Pipeline



Biosimilar development
Probability of success



Even in the starting phase, the probability of a biosimilar being successfully approved is almost 70%

In terms of the risks and challenges involved, the biosimilar drug development approach differs fundamentally from the development of an innovative originator biopharmaceutical. While biosimilar drug development takes a confirmatory approach, whereby the biosimilar candidate is designed from the start to be demonstrably comparable to the reference drug and is accordingly managed over the entire development period of typically seven to ten years, the research and development process for an entirely new biological entails an exploratory approach and thus a significantly higher level of development risk along with significantly longer development times and vastly higher development costs.

With a comparable level of expertise and experience in the development of a biosimilar drug, the probability of success, i.e. that a biosimilar will be approved, is high from the start of the development process, as illustrated above. [32] In the case of the development of an innovative drug, the success rate is dramatically different, with only one in twenty projects in preclinical development, on average, reaching final approval.[33]

Business objective and strategy

Formycon's long-term goal is to become one of the leading independent specialists and partner of choice in the dynamically growing biosimilars market. By acting as a driving force in the development of biosimilars, the Group strives to facilitate the democratization of patient access to highly effective drugs, while at the same time easing the financial burden on the world's healthcare systems.

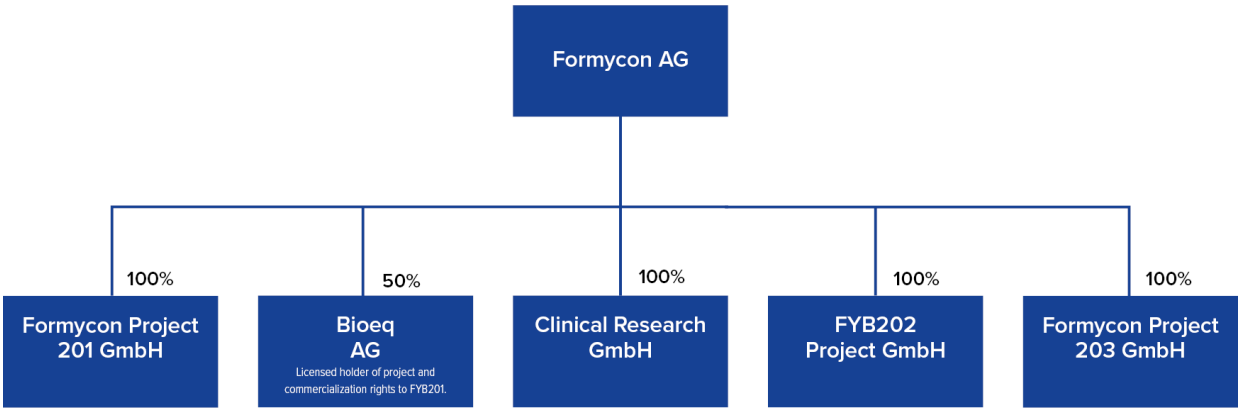
Group structure

Formycon Group consists of the parent entity, Formycon AG, along with its 100%-owned subsidiaries Formycon Project 201 GmbH, FYB202 Project GmbH, Formycon Project 203 GmbH and Clinical Research GmbH (formerly Bioeq GmbH), as illustrated in the accompanying figure. In addition, Formycon holds a 50% share of Bioeq AG, a joint venture between Formycon and Polpharma Biologics BV.

[32] The path towards a tailored clinical biosimilar development, Schiestl et. al 2020

[33] https://klinischeforschung.novartis.de/patienten/allgemeines-zu-klinischen-studien/entwicklung-von-medikamenten/, Development of medicines

Group structure



The corporate structure of Formycon Group reflects the establishment of dedicated legal entities for individual biosimilar projects, currently in advanced stages of development. Formycon AG performs research and development activities for its own projects, on behalf of its affiliated companies (subsidiaries) and for development partners.

The Formycon AG parent entity is a German stock corporation which is listed on the Frankfurt Stock Exchange and trades in the Exchange's "Prime Standard" segment (ISIN DE000A1EWVY8), which has the highest transparency requirements of all segments. Formycon AG serves, both legally and operationally, as the holding company for Formycon Group. As the Group's parent entity, Formycon AG determines corporate strategy and group-level strategic management as well as communications with Formycon's key target audiences and stakeholders.

In its current phase of corporate and organizational growth, the focus of Formycon Group is on research and development activities for both its own and out-licensed biosimilar projects. To the extent that it engages in other business activities, these are primarily in support of these research and development efforts and within existing partnership arrangements as well as for the management and coordination of the supply and production chains necessary to bring advanced-stage biosimilar candidates to market.

As a 100% subsidiary of Formycon AG, Clinical Research GmbH (formerly Bioeq GmbH) has acted as the sponsor of clinical trials. Specifically, it conducted the clinical trials for the FYB201, FYB202 and FYB203 development projects, which have since been successfully completed. Therefore, the two companies have jointly decided to merge Clinical Research GmbH into Formycon AG. As of June 30, 2025, the merger was not yet completed, and thus Clinical Research GmbH continues to appear in the group structure.

Executive Board members and allocation of resposibilities

Dr. Stefan Glombitza
Chair of the Executive Board
CEO (Chief Executive Officer) / COO (Chief Operations Officer)

Since July 1, 2022 (current term of office ends Dec. 31, 2027), previously served as COO (starting 2016)

Areas of responsibility:
Corporate Strategy and Corporate Development

- Program Management incl. Project Management Office
- Protein(analytics) – and Process Sciences
- Drug Product Development
- Regulatory Affairs
- Quality Management

Nicola Mikulcik
Member of the Executive Board
CBO (Chief Business Officer)

Since June 1, 2022 (current term of office ends May 31, 2027)

Areas of responsibility:
Business Operations

- Business Development and Licensing
- Launch Management and Supply Chain
- Intellectual Property Litigation
- Procurement

Dr. Andreas Seidl
Member of the Executive Board
CSO (Chief Scientific Officer)

Since July 1, 2022 (current term of office ends June 30, 2027)

Areas of responsibility:
Scientific and Pre-/Clinical Affairs

- Preclinics, Bioanalytics and Scientific Affairs
- Clinical Development and Operations
- Intellectual Property
- Innovation and Technology Management
- Occupational Safety

Enno Spillner
Member of the Executive Board
CFO (Chief Financial Officer)

Since April 1, 2023 (current term of office ends March 31, 2026)

Areas of responsibility:
General Administration / Enabling Functions

- Finance and Controlling
- Legal, Governance and Compliance
- Human Resources
- Corporate Communications, Investor Relations and Corporate Social Responsibility / ESG
- Information and Business Technology
- Facility/Environment/ Health and Safety

Management and oversight

As required under the German Stock Corporation Act (*Aktiengesetz*) for all German stock corporations, the Formycon AG parent entity is governed by a dual board system consisting of an Executive Board (*Vorstand*) and a separate Supervisory Board (*Aufsichtsrat*). The Executive Board currently consists of four members who are appointed and monitored by the Supervisory Board.

The Supervisory Board of Formycon AG consists of five members. At the Annual General Meeting on June 18, 2025, it was decided to expand the Board by another member to a total of six members. As of June 30, 2025, the amendment to the Company's Articles of Incorporation with regard to the expansion of the Supervisory Board had not yet been entered in the Commercial Register, and thus the Supervisory Board still legallyconsisted of five membersas of the period closing date.

Important processes, partners and sales markets

The development of biosimilar drugs for the world's most stringently regulated markets is subject to very strict standards for their safety, quality; comparability and efficacy. Within the EU, the requirements for quality assurance of the production processes and production environment for the manufacture of medicinal products and active ingredients are established through a European Commission directive laying down the principles and guidelines of Good Manufacturing Practice (GMP) for all medicinal products for human use. Formycon's laboratories are subject to these various guidelines and are periodically examined and audited by regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the regional government of Upper Bavaria.

Contract development and manufacturing organizations (CDMO) or "contract manufacturers" are important partners within the value chain for biosimilars development and play a critical role for Formycon, including in the production of active ingredients. In addition, Formycon is in the position to manage the product specific supply chain for the commercial market supply of a product, thereby providing the finished product to the commercialization partner.

For the global marketing of biosimilar products, Formycon relies upon commercialization partnerships for the different regions with internationally renowned pharmaceutical players such as Fresenius Kabi AG, Teva Pharmaceutical Industries Ltd., Ratiopharm GmbH (subsidiary of Teva-Group), Sandoz AG, MS Pharma, Blomm SA and Bio Usawa Biotechnology Ltd.

The target market for Formycon's biosimilar products is the global pharmaceutical market, specifically in the United States, Europe (including also the UK), Japan and Canada, as well as Australia, the Middle East and North Africa (MENA) region, sub-Saharan Africa and Latin America.

While originator biopharmaceuticals are already available for the effective treatment of many serious diseases, these powerful drugs are very expensive due to the complexity of their development and manufacture, and they can often be prohibitively expensive as a first-line therapy for all patients, even in highly developed countries. However, once the legal protection period for an originator biopharmaceutical expires, thereby ending its exclusivity, biosimilar drugs may be introduced to the market. The reduced costs of effective treatment through new competition from biosimilars not only helps to relieve the burden on the world's health providers such as statutory health insurers: They also make it possible to bring these powerful treatments to more patients and at an earlier stage of treatment progression, thereby potentially opening entire new markets.

Competitive situation

Internationally published studies predict annual growth rates (CAGR) for the global market for biosimilars over the next decade (2025 through 2034) of 16.5% on average.[34] Despite substantial barriers to market entry due to high development costs (approx. US$ 150 to 300 million per biosimilar development project), long development cycles (seven

34 Three imperatives for R&D in biosimilars | McKinsey

to ten years), and the specialized expertise required to develop a biosimilar, there are a number of international competitors in this attractive market segment. In addition to major pharmaceutical corporations such as *Amgen, Biocon, Biogen, Fresenius Kabi, Pfizer, Samsung Bioepis*, *Sandoz* and *Teva* but also smaller companies specializing in biosimilars such as *Alvotech, Celltrion and XBrane*. (These are just examples and are listed in alphabetical order.)

Because of Formycon's positioning as an independent developer, situations may arise in which such a company, particularly a major pharmaceutical name, is a competitor for one or more products while at the same time it is a commercialization partner for one or more biosimilar development projects. For each of its biosimilar development projects, Formycon seeks out the most suitable commercialization partner, not only for the area of indication but also for the relevant region, Formycon aims distinguishing itself from its competitors through innovative development concepts, the reliability of the scientific processes which it uses, a rigorous selection of reliable partners, and the highest standards of quality and scientific expertise in the selection of its service providers and consultants. Further discussion of competitive risks can be found within the "Report on risks and opportunities".

Corporate strategy and management

Formycon's strategic goal is to sustainably expand the scope of its business activities with the aim of becoming one of the leading independent development specialists and partner of choice in the rapidly growing biosimilars market. In order to achieve this goal, Formycon will continue to invest heavily in the advancement and expansion of its project pipeline so that it is able to bring new biosimilars to market at regular intervals. In parallel, Formycon is pursuing an organizational growth strategy so that it has the resources to grow sustainably and profitably as a biosimilars specialist. In order to achieve this goal, the Executive Board is open to considering medium- to long-term cooperation arrangements and integration in selected areas of the manufacturing process as well as building its own commercialization capabilities in certain geographies. In pursuing this vision, Formycon's strategic focus is on long-term profitability and sustainable cash flows.

Formycon may, as necessary, adapt its strategy and operational approach to specific market conditions. There was no need to make any significant changes in strategic orientation compared to the same period of the previous year.

The drivers of Formycon's success are its agility and its drug development expertise

Above all, Formycon stands out from competitors, particularly large pharmaceutical companies with biosimilar ambitions, through the high level of agility and flexibility of its operational activities, while at the same time maintaining the highest quality standards. In biopharmaceutical development, it is important to align structures, processes and behaviors along the value chain in such a way as to foster an integrated platform which is able to learn and thus constantly improve, and which is intensely focused on the excellent execution of the many activities needed for successful drug development. This kind of operational excellence strives for the holistic and continuous improvement of all direct and indirect functions throughout the value creation process, thereby enabling ever higher levels of organizational performance and sustained improvements in operational and financial metrics. With its operating efficiency, lean management and organizational structures, and staff of 245 committed employees, Formycon currently has the capacity and resources to develop multiple biopharmaceutical projects in parallel.

Financial performance indicators

In managing Formycon Group, the Executive Board relies to a significant extent upon the following set of financial performance indicators: revenue, EBITDA, Adjusted EBITDA, and working capital. Adjusted EBITDA additionally includes Formycon's participation in earnings from FYB201, which due to the current contractual structure is accounted for at equity, thereby providing a broader and more complete measure of Formycon's Group operating performance. This change is intended to improve measurability and transparency, for the Group's management as well as readers of this report.

Key financial performance indicators in accordance with IFRS
in € million

	H1 2025	H1 2024	H1 2023
Revenue	**9.0**	26.9	43.8
EBITDA	**-17.9**	-16.9	7.3
Adjusted EBITDA	**-19.2**	-2.1	1.1
Working capital	**17.0**	63.0	55.0

At the present time, Formycon AG limits itself to announcing specific guidance forecasts with regard to the above key performance indicators for the current fiscal year only. Formycon holds a portfolio of partnered biosimilar candidates which, even after successful transfer to licensed or cooperation partnerships, generate revenue for Formycon from development work performed, advance payments, milestone payments and license payments. As the pipeline of development projects matures, Formycon expects the proportion of revenue from milestone payments and license payments from product sales to further increase.

EBITDA – Earnings before Interest (meaning specifically finance income/expenses), Tax, Depreciation and Amortization – is a common measure of operating profitability which excludes non-cash depreciation of property, plant and equipment and amortization of intangible assets. Because EBITDA excludes certain expense items that are not directly related to current business operations, the Executive Board believes that the indicator is suitable for measuring the Group's operating performance.

As already noted, Adjusted EBITDA additionally includes Formycon's participation in earnings from Bioeq AG, which is under joint control. Bioeq AG's earnings, in turn, result solely from its operating profit generated by our FYB201 product. Because this holding is under joint control and therefore necessarily accounted for at equity, earnings from this Formycon product are not included in operating income and therefore also excluded from EBITDA. Adjusted EBITDA, in contrast, includes these earnings from FYB201.

Through close attention to the Group's working capital, the Executive Board is able to monitor liquidity needs and changes and to ensure that Formycon's financial soundness is maintained in the future. Working capital measures the extent to which current assets (trade and other receivables, contract assets, and cash and cash equivalents) exceed current liabilities excluding shareholder loans and the current portion of conditional purchase price payment obligations. All else being equal, a higher level of working capital means a lower risk of liquidity shortfalls. Formycon's goal is to maintain positive working capital on a consistent, long-term basis.

These financial performance indicators are planned and continuously monitored on a Group-wide basis. Formycon measures deviations between planned and actual financial performance monthly, not only for Formycon Group as a whole but also for the Formycon AG parent entity. These key indicators are analyzed monthly as well as quarterly. The Executive Board also regularly reviews the detailed business plan against these actual monthly and quarterly figures. Moreover, the development plan for each of Formycon's product candidates is intensively examined and reviewed in considerable detail three times per year, including any impact on the financial plan. In managing the Group, the key financial performance indicators described above are supplemented by various non-financial management indicators (see "*Other non-financial aspects*" below).

Report on business performance

Macroeconomic framework conditions

In the first half of 2025, the global economy experienced a moderate but fragile recovery—despite ongoing geopolitical tensions, supply chain disruptions, and restrictive monetary policies. According to the latest OECD Economic Outlook[35], global GDP growth is projected to decline from 3.3% in 2024 to an average of 2.9% in 2025 and 2026.[36]

The decline in global GDP growth is expected primarily in the US, Canada, Mexico, and China, while other economies will likely see only minor downward revisions. Although total US growth is expected to slow to 1.8% (from 2.8% in 2024) due to trade uncertainties, the US economy remains a key driver of global growth, supported in particular by rising real wages and a still-strong labor market.

China is forecasted to grow by 4.0% in 2025, aided by government stimulus programs, although trade policy uncertainties and tariffs are expected to dampen the outlook. Additionally, the new US tariffs on Chinese and European products are causing significant tensions in global trade. The OECD sees this as a potential inflationary factor, and as especially burdensome for export-oriented sectors in Europe and Asia.[37]

The OECD also notes that inflationary pressures may be more persistent than previously anticipated. For 2025, OECD-wide inflation is projected at 4.2%, an upward revision from the 3.7% forecast in December 2024. A decline to 3.2% is expected for 2026, still above the earlier estimate of 2.9%. This is attributed in part to high service prices and rising food prices across several OECD economies[38].

Global pharmaceutical industry developments

According to a report by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the pharmaceutical industry continues to play a vital role in global economic development. Investments in pharmaceutical research and development (R&D) have reached record levels, with the 50 largest pharmaceutical companies spending a combined total of US$ 167 billion in 2022, and global R&D spending expected to exceed US$ 200 billion by 2025. Key growth drivers include innovations in biotechnology, a growing portfolio of biosimilars, and expanded vaccine development. The report also emphasizes that regulatory adjustments in the US and Europe—such as accelerated approval procedures and reliance mechanisms—are helping to bring biopharmaceutical products to patients more quickly[39].

However, the newly imposed US tariffs[40] pose an additional challenge for the global pharmaceutical industry. European manufacturers are particularly affected, as their exports to the US may become up to 25% more expensive. As a result, companies are increasingly considering relocating production capacities to other regions or exploring new supply routes. Analysts foresee not only short-term price adjustments but also potential delays in the market launch of innovative medicines due to the need to restructure global supply chains. These trade

35 Global economic outlook shifts as trade policy uncertainty weakens growth

36 On the basis of the tariff levels of 30 June 2025 and subject to changes in trade policy

37 Status: 17.06.2025 – It cannot be ruled out that the framework conditions have already changed after this date

38 Economic outlook | OECD

39 #AlwaysInnovating: Pharmaceutical Industry Facts & Figures | IFPMA

40 Status: 17.06.2025 – It cannot be ruled out that the framework conditions have already changed after this date

barriers could also have long-term effects on R&D planning, particularly for export-oriented products[41].

Economic situation in Germany

The German economy recorded growth of 0.7% in the first half of 2025 (Q1: +0.4%, Q2: +0.3%)[42] supported by a recovery in construction and industrial production. According to the OECD Germany Report 2025, investments in green technologies and the healthcare sector, along with stable export demand in high-end industrial segments, contributed positively to economic performance.

Despite ongoing consumer reluctance due to uncertainty and high energy prices, inflation is expected to fall to 2.4% in 2025. The unemployment rate is projected to remain low at 3.6%, indicating a robust labor market.

The formation of a new government following the February 2025 elections improved business sentiment. The new governing coalition announced investment programs focused on digitalization, renewable energy, and the expansion of healthcare infrastructure[43].

However, export-oriented industries are coming under additional pressure due to the new US tariffs.[44] Key German sectors which are highly dependent on the US market, such as mechanical engineering, automotive suppliers, and parts of the chemical and pharmaceutical industries—will be particularly affected. Industry associations such as the Federation of German Industries (BDI) warn of a "domino effect" on supply chains and production costs. Some companies are already considering alternatives such as expanding production in the US to avoid tariff burdens[45].

Additionally, the EU Commission postponed its decision on possible counter-tariffs against the US to early August 2025, in an effort to avoid further escalation. This delay is causing uncertainty in Germany's export sector, as no short-term relief is expected and companies must continue to navigate existing trade barriers.[46] [47]

Developments in the biosimilar market –

Global perspective

The global biosimilar market experienced strong growth in the first half of 2025. According to IQVIA, the market is expected to grow from US$ 25.1 billion in 2022 to approximately US$ 74 billion by 2030[48]. North America and Europe continue to lead the global market, with Europe holding around a 37% market share.

However, regions such as Latin America, Africa, and Southeast Asia – particularly Brazil, South Africa, and India – are gaining increasing importance. For Latin America, a CAGR of nearly 29.6% is projected for 2024 to 2033, driven by rising demand and supportive regulatory frameworks. These regions are promoting the adoption of biosimilars by expanding local production capacities and implementing simplified approval procedures aligned with international standards[49].

A significant advance in the regulatory environmentis the ability to waive Phase-III clinical trials for biosimilars which meet certain criteria. Leading regulatory authorities – including the European Medicines Agency (EMA), FDA, and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) – are increasingly approving biosimilars based on robust analytical, functional, and PK/PD[50]- comparative data, eliminating the need for large-scale Phase-III efficacy trials for qualifying drug candidates. This emerging trend, enabled by advanced analytical technologies and validated by real-world

41 Trump droht mit 200 Prozent: Pharmabranche zittert vor toxischen US-Zöllen - n-tv.de; Trumps Zollankündigung versetzt Europa in Aufruhr | tagesschau.de

42 BMWE - BIP Nowcast für das erste und zweite Quartal 2025

43 OECD Economic Surveys: Germany 2025 | OECD

44 Status: 17.06.2025 – It cannot be ruled out that the framework conditions have already changed after this date

45 Trump droht mit 200 Prozent: Pharmabranche zittert vor toxischen US-Zöllen - n-tv.de; Trumps Zollankündigung versetzt Europa in Aufruhr | tagesschau.de

46 Handelsblatt: US-Zölle: EU verschiebt Gegenzölle gegen USA bis Anfang August

47 Status: 17.06.2025 – It cannot be ruled out that the framework conditions have already changed after this date

48 fokus-biosmilars/newsletter-fokus-biosimilars-ausgabe-10

49 Biopharmaceutical Market Growth, Size, Forecast, 2033
Biosimilars Market Size, Trends, Growth & Share Analysis 2025 - 2030

50 PK: Pharmacokinetics; PD: Pharmacodynamics

approvals, promises to shorten development timelines and significantly reduce costs for biosimilars[51].

Formycon has successfully played a part in this regulatory streamlining: In consultation with the FDA, the company has become the first developer of a pembrolizumab biosimilar to decide against conducting a Phase-III clinical trial for its candidate FYB206. As a result, Formycon can significantly shorten development time and is expected to realize savings in the high tens of millions of euros.

Biosimilars in Germany

The German biosimilar market continued its dynamic growth. In 2024, Germany generated € 1.7 billion in revenue from biosimilars.[52] Based on *Biosimilars in Numbers 2024* by the Pro Biosimilars working group, almost 90% of administered daily doses in Germany were distributed under rebate contracts. These figures highlight the strong integration of biosimilars into clinical practice and the high level of acceptance among both physicians and patients[53].

The market development of biosimilars in Germany has been supported by a generally supportive regulatory and political environment. The system of early benefit assessment and reimbursement eligibility, combined with established rebate agreements, has enabled rapid market access and high usage rates. IQVIA analyses indicate particularly high penetration rates in the therapeutic areas of rheumatology and gastroenterology[54].

The financial benefit to the German healthcare system is considerable. In 2024, biosimilars generated savings of nearly € 2 billion for the statutory health insurance system (GKV), driven by price competition and rebate agreements[55]. These savings not only affect biosimilar revenues themselves but also generate savings through price adjustments for reference products and substitution effects across the entire market.

Further growth is projected for the future. IQVIA expects an expansion of the biosimilar-eligible segment in Germany, supported by the introduction of new molecules and an increasingly competitive market environment.

European Union

The EU's *Pharmaceutical Strategy for Europe* is driving the growth of the biosimilar market by simplifying regulatory processes and promoting competition. As reported by IQVIA[56], simplified approval procedures and harmonized comparability standards have lowered entry barriers for manufacturers and enabled faster market access.

Since 2006, competition from biosimilars has generated cumulative savings of around € 56 billion for European healthcare systems. These savings enable broader access to biologics and reinvestment in healthcare innovation. IQVIA emphasizes that the continuation of these measures is essential for the long-term success and sustainability of the European biosimilar ecosystem.

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51 Rethinking Biosimilar Approval: A Future Without Phase 3 Trials?

52 Biosimilars-in-Zahlen_Kalenderjahr-2024.pdf

53 Biosimilars-in-Zahlen_Kalenderjahr-2024.pdf

54 Fokus Biosimilar: Trends und Entwicklungen im deutschen Biopharmazeutika Markt, Q4 2024 - IQVIA

55 Country Scorecards for Biosimilar Sustainability - IQVIA

56 The Impact of Biosimilar Competition in Europe 2024 - IQVIA

Summary statement of Executive Board on business performance and economic environment

In the first half of 2025, Formycon AG was able to maintain its position in a market environment that remained challenging. The operational progress achieved confirms the consistent pursuit of the company's strategic goals.

Several key milestones were achieved at the regulatory level and in pipeline development: The Stelara® biosimilar FYB202 received further approvals in Canada and the UK and FYB203 (reference product: Eylea®) was approved in both the EU and the UK. For FYB206, a biosimilar candidate to Keytruda®, a strategically significant change in the development approach was implemented following positive feedback from the FDA: Continuing development without a Phase III trial not only reduces the required investment, but also significantly shortens the development time. In addition, early-stage-projects—particularly FYB208 and FYB210—were further advanced, which strengthened the pipeline with a focus on the most promising product candidates.

In the area of commercialization and partnerships, regional marketing partnerships were concluded for FYB203 between Klinge Biopharma and other renowned partners such as Teva (Europe), Valorum Biologics (US) and Lotus Pharmaceuticals (Asia Pacific). Of particular note is that Formycon will, for the first time, assume responsibility for the entire FYB203 supply chain and market supply on behalf of its license partner Klinge Biopharma.

A key focus was on the market launch of the FYB202/ustekinumab biosimilar in the US and Europe in early March 2025 by our partner Fresenius Kabi. In the run-up to the market launch, commercial negotiations between the Fresenius Kabi US team and the relevant US contract partners indicated a higher-than-expected price discount for biosimilars and slower market penetration in the US. As a result, royalties from FYB202 from the sales during the first four months were in the low single-digit million range. Nevertheless, we remain confident in the product's medium to long-term international potential.It is expected that sales in the latter part of the year will grow sufficiently to achieve the annual forecast.

In February 2025, Sandoz AG announced a temporary pause in the US commercialization of FYB201/Cimerli® starting in the second quarter of 2025, during which the product will be commercially repositioned. As a result, US sales and the associated license revenue showed a significant year-on-year decrease. The same applies to Bioeq AG's share of earnings, reported as an at-equity result below EBITDA which wasnegative for the first half of the year. For the full year, FYB201 is expected to see a significant decline in sales and finacial performance in the US. In the other 21 markets, including Europe and the MENA region, FYB201 continues to be successfully marketed. With the planned launch of the technologically innovative prefilled syringe in the course of 2025, further market penetration is expected in several European countries.

The strategic focus on high-quality biosimilars with global marketing potential has proven to be sustainable despite current obstacles in the US market. In particular the progress in clinical development and the achievement of regulatory milestones for several pipeline products highlight the company's innovation, quality, and operational excellence.

The global market for biosimilars continued to grow dynamically but remains difficult to predict in certain regions. The signs point to further expansion in the future. The global biosimilar market is expected to grow to US$ 74 billion by 2030[57], which allows us to look ahead to the coming years with confidence.

In the first half of 2025, we generated consolidated revenue of € 8,997K, which represents a significant decline compared to the previous year (H1/2024: € 26,893K). This change is due in large part to the fact that deferred revenue from success-based payments for FYB202 was no longer recognized compared to the first half of 2024. However, reimbursements from development services for FYB201

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and FYB203 also declined further as expected due to the successful progress of development.

Consolidated earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to €-17,927K and, in addition to sales and the associated cost of sales, primarily reflect expensed (non-capitalized) research and development expensed investments in the early stage pipeline projects FYB208 and FYB210.

The adjusted EBITDA reflects the total revenue from our FYB201 ranibizumab biosimilar, which is largely recognized as at-equity income below EBITDA through the existing 50% stake in Bioeq AG. The temporary issues in the US have had a significant Impact here, resulting in a negative equity income and adjusted EBITDA of €-19,160K. A more detailed presentation can be found in the segment reporting in the Notes to the Consolidated Financial Statements.

Formycon Group's cash and cash equivalents amounted to € 27,279K as of June 30, 2025. This does not include the proceeds from the bond issue in the amount of €70 million (gross issuance proceeds), which were settled at the beginning of July 2025 and therefore not included in cash and cash equivalents for the first half of the year.

Comparison of actual and forecast business performance

Amounts in € million

	2024 actual	2025 forecast per Annual Report 2024	Financial forecast in the Half-Year Report 2025	Change	1H 2025 actual
Revenue	**69.7**	55.0 to 65.0	55.0 to 65.0	→	**9.0**
EBITDA	**-13.7**	-20.0 to -10.0	-20.0 to -10.0	→	**-17.9**
Adjusted EBITDA	**-1.6**	-20.0 to -10.0	-20.0 to -10.0	→	**-19.2**
Working Capital	**55.1**	25.0 to 35.0	55.0 to 65.0	↗	**17.0**

Financial condition and financial performance

In the first six months of 2025, Formycon Group generated consolidated revenue of € 8,997K compared to € 26,983K in the prior-year period. The change is mainly due to the discontinuation of accruals of the success fee of € 11,347K received in the previous year, for the realization of the FYB202 project in partnership with Fresenius Kabi. The market launch of FYB202 in Europe and the US in March of this year generated license revenue of € 1,688K during the reporting period. At the same time, revenue from the development partnerships for FYB201 and FYB203 decreased due to the advanced stage of maturity of these projects.

Consolidated EBITDA was € -17,927K (1H 2024: € -16,904K). The declining revenue was likewise reflected in a lower cost of sales (before depreciation and amortization), so that EBITDA remained stable. Adjusted EBITDA additionally includes the contribution from Formycon's investment participation in Bioeq AG in the amount of € -1,233K (1H 2024: € 14,757K), resulting in adjusted EBITDA of € -19,160K compared to € -2,147K in the prior-year period.

Consolidated net income amounted to € -54,192K (1H 2024: € -10,095K). In addition to the effects of EBITDA less depreciation and amortization, the net result was impacted by an increase in the provision for conditional purchase price payments in the amount of € 22,186K, which resulted, among other factors, from a decrease in the prevailing discount rate.

In line with its business model, Formycon Group continued during 2025 to vigorously drive forward with the development of its biosimilar projects. As a result of the out-licensing of FYB201 at the end of 2013 and FYB203 in 2015, Formycon generated significant revenue, as in previous years, through ongoing contractual payments received for development services that Formycon has provided on behalf of the licensees. For both of these projects, Formycon passes on costs incurred for development work and clinical studies to the respective licensees. In addition, a commercialization agreement was concluded with Fresenius Kabi on February 1, 2023, covering the FYB202 product, which was an unfinished development project at the time of this deal. The agreement encompasses transfer of the product license, certain success-related payments until regulatory approval by the FDA and EMA is achieved, and finally license payments from subsequent product sales. Since the approval of the product at the end of the previous year, the relevant assets on the balance sheet have been depreciated and amortized as scheduled, resulting in cost of sales of € 12,468K (1H 2024: € 0K).

The start of the development work on Formycon's new biosimilar candidate FYB210 in the previous year led to an increase in research and development expenses. Costs for the FYB209 project were, however, significantly less than in the preceding year, leading to stable research and development expenses.

As of June 30, 2025, the Group equity ratio was 55.0% (Dec. 31, 2024: 56.5%). The Group's non-current assets are largely covered by equity and non-current liabilities for conditional purchase price payment obligations, which is suggestive of a healthy balance sheet structure. More than one third of current assets are in the form of cash and cash equivalents and current financial assets.

Current liabilities include the current portion of the conditional purchase price payment obligations in the amount of€ 8,706K resulting from the acquisition of shares in 2022. As in the past, key liquidity indicators (cash and cash equivalents, working

capital) remained adequate. Current assets of € 63,050K were offset by current liabilities (excluding current portion of conditional purchase price) of € 32,220K. The Group did not have any bank loans during the period. As of the reporting date, € 0K was drawn from the shareholder loan facility out of the € 48,000K credit. As explained in the ”Subsequent events”, section of the consolidated financial statements, the shareholder loan facility was terminated on July 9, 2025.

As of June. 30, 2025, the Group held cash and cash equivalents in the amount of € 27,279K (Dec. 31, 2024: € 41,834K) and working capital (including cash and cash equivalents) in the amount of € 17,015K (Dec. 31, 2024: € 55,106K). The decrease compared to the prior-year period reflects the course of business for the year. Consolidated cash outflows for operating activities increased from € -31,185K to € 6,798K, mainly resulting from the reduction in trade receivables and the increase in current liabilities. Cash outflows for investing activities included, in addition to investments in FYB206 amounting to € 24,590K (1H 2024: € 16.567K), repayments of the loan to Bioeq AG in the amount of € 7,500 (1H 2024: € 5,000K), resulting in an increasein cash outflows from € -11,862K to € -17,024K. During the reporting period, current contingent purchase price obligations were satisfied, resulting in net cash inflows from financing activities of € -4,329K (previous year: € 56,632K). Reference is made to the Condensed Consolidated Statement of Cash Flows.

The performance of the FYB201 segment during the fiscal year was largely in line with Formycon’s expectations. Revenue within this segment consists primarily of license revenue determined on the basis of global product sales. In the reporting period the segment generated revenue of € 823K, compared to € 3,760K in the prior year, leading to total segment revenue of € 2,395K compared to € 8,173K in the prior year period. This change, is mainly expected due to the marketing pause in the US as of April 1,2025. While the segment continues to generate revenue from the recharging of development costs incurred, these amounts are declining as planned. Investment income from Bioeq AG, is also allocated to this segment. Due to the strategic realignment of Formycon`s marketing partner in the US, net income from investments fell from € 14,757K to € -1,233K. This decline was likewise expected.

The FYB202 segment similary performed in line with expectations. Upon the successful regulatory approval of FYB202 at the end of September of the previous year, scheduled amortization of the previously capitalized intangible asset was initiated and included within cost of sales. Following the product launch, Formycon was able to recognize the first revenue from license payments in the amount of € 1,688K.

In the FYB203 segment, revenue of € 3,986K was realized during the reporting period (1H 2024: € 7,373K), primarily from the recharging of development costs incurred. In addition, revenue was also realized from the newly concluded agreement with Klinge Pharma for the organization and management of the supply chain, including product production.

The remaining three segments FYB206, FYB208, and FYB 210 performed during the reporting period in line with expectations.

Financial management

Principles and objectives

The guiding principle and central objective of Formycon Group's financial management is to ensure that sufficient liquidity is available in order for its development projects to be carried out according to plan.

Liquidity management

Toward this end, expected cash flows from the Group's individual projects are regularly analyzed and updated so that Formycon is at all times able to maintain an overview of expected future project spending needs. With its five-year planning horizon, the Group is well able to anticipate changing needs and to take measures as necessary, thereby proactively managing its liquidity. Liquidity is centrally monitored at the Group's headquarters in the Munich suburb of Martinsried/Planegg.

Overview of financial position

The Group's cash and cash equivalents (working capital as described above) – together with the bond issued after the reporting date – secure the company's long-term financing.

Limiting of financial risks

Formycon Group is not currently exposed to any significant financial risks. Payment obligations in foreign currencies (USD, GBP, CHF and JPY) are not material to the Group. Interest rate risks are not significant.

Investment analysis

Significant investments in long-term assets currently consist primarily of capitalized development costs for the FYB206 project, which is also allocated to the FYB206 segment. Significant investments in the completion of the development are also expected in subsequent years. Substantial and necessary items of property, plant and equipment, primarily laboratory equipment, are typically financed through lease agreements.

Other non-financial aspects

Staff

The development of biosimilars is a research-intensive field of activity requiring the expertise of highly qualified and capable employees. For this reason, financial performance indicators alone cannot provide a comprehensive picture of Formycon's value creation potential, and therefore the Executive Board, in managing the Group, also considers such other non-financial aspects. Above all, these include the critically important activities of the Group's workforce, who contribute their knowledge, their skill and their passion for biosimilars development each and every day, thereby forming the basis for Formycon's success.

As of June. 30, 2025, Formycon Group employed a total headcount of 245 persons (June. 30, 2024: 239).

In the interest of increasing the informative value of the number of employees by function and taking into account the proportion of part-time employees, Formycon Group also reports the average number of full-time equivalents (FTEs) as of June 30, 2025, and the percentage change compared to June 30, 2024:

Unaudited information

Average Formycon Group staffing during the period by function (in FTE, rounded, including Executive Board members)

	2025	2024	Change
Research and development	168.7	170.0	**-0.8%**
Business operations	13.0	12.5	**+4.0%**
General and administrative	38.0	29.9	**+27%**
Total	219.7	212.4	**+3.4%**

Unaudited information

Educational level of Formycon staff – more than 80% with university degree

36.3 %	Doctorate
22.5 %	Master's
14.7 %	Master's equiv. (Diplom)
6.9 %	Bachelor's
8.6 %	Vocational training (technical)
9.4 %	Vocational training (administrative)
1.6 %	Not (yet) completed or none

Unaudited information

Diversity of Formycon staff

59.2 %	Female
40.8 %	Male

Formycon *employs* **staff** from a total of **31** different **countries**

58 Unaudited information

Unaudited information

Division of second-level management by gender

40.5 % Female
59.5 % Male

Unaudited information

Division of all management positions by gender

31.6 % Female
68.4 % Male

As of June 30, 2025, Formycon AG's personnel expenses totaled € 11,763K (1H 2024: € 12,178K). The decrease in total personnel expenses despite a slight increase in the number of employees compared to the previous year is mainly due to lower provisions for vacation and lower expenses for bonus payments and stock option programs.[59]

Formycon Group's workforce is highly qualified, particularly in terms of educational level, and training is also a company priority. As of June. 30, 2025, over 80% of the Group's employees have completed a university degree, which in the case of 36.3% is a doctoral degree.[60] Since 2022 Formycon has been cooperating with the regional chamber of commerce (IHK) in offering technical vocational training positions for young people, under which it currently employs three trainees as IT specialists for systems integration.[61] In addition, a qualified vocational training program in office management will be offered for the first time starting from September 2025.

As to gender diversity, some 60% of the Group's workforce is female. The employee average age as of June 30, 2025 was 42 years.[62] Formycon is proud of the diverse organization that it has developed over the years. The international diversity of Formycon's staff, from 31 different countries, reinforces its self-image as a truly global organization and biopharmaceutical company.[63]

Research and development

Because Formycon has been, over the past fiscal year as well as in the preceding years, and remains today focused primarily on the development of its own biosimilar projects, out-licensed projects, and those under development through partnerships, the Group's activities are essentially limited to research and development activities. A large part of the Group's reported sales revenue results from the provision of staff services under so-called "FTE agreements" for development work on biosimilar candidates that have been previously licensed out or are under development through partnerships.

As of June 30, 2025, a total of 162.2 group employees were, on a full-time equivalent (FTE) basis, working in research and development (June 30, 2024: 170.0).[64] During the reporting period, research and development costs of € 24,590K were capitalized. These were costs for the FYB206 project, which attained a development milestone during fiscal year 2022 such that the capitalization of costs incurred from this milestone onwards was mandatory. Product development activities are proceeding on schedule, and thus prospects for the success of these development activities remain strong. Including capitalized development costs from prior years, the total book value of these capitalized development costs as of June 30, 2025 was € 75,371K. The costs for the FYB202 project, which had been recorded in the prior fiscal year as unfinished development work, were reclassified as completed following the successful attainment of regulatory approval in the US and Europe, and scheduled depreciation was accordingly initiated.

The productivity of Formycon's research and development staff, measured in terms of hours directly allocable to development projects, remained at the similarly high level of previous years. During the reporting period, 79.9% (1H 2024: 85.1%) of all hours worked were project-related. Over this same period, 17.5% (1H 2024: 16.6%) of hours worked were performed by employees who are not assigned to the research and development area.[65]

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Report on risks and opportunities

Risk strategy and policies

The effective management of risks and opportunities is an essential part of Formycon's corporate management, serving to ensure that the company is able not only to realize its currently existing potential as successfully as possible but also to maximize its future business and financial potential. Formycon understands risks as both internal and external events that could potentially have a negative impact on the achievement of its business objectives and forecasts. Working within the overall risk level which we consider justifiable and appropriate, the Executive Board then decides which specific risks Formycon should accept in order to take best advantage of the available opportunities. Formycon's goal is to identify risks as early and proactively as possible, to assess them appropriately, and to mitigate or completely avoid them by taking suitable actions. The risk strategy, which encompasses Formycon's entire scope of activities, is regularly reviewed by the Executive Board and further developed as necessary. A risk policy has been developed and established as a framework within Formycon for all relevant risk management activities and actions.

Risk management system

Formycon, one of the few independent developers of biosimilars, operates in a dynamic global market with many different participants and influencers. Business success is determined by the identification of profit opportunities, along with an effective system for the best possible assessment of the many and varied risks associated with these. Regular reviews of this system further ensure that it is constantly improved and that, as circumstances change, changes are likewise made to the system promptly and in accordance with evolving needs.

Risk management is a cornerstone of Formycon Group's governance, ensuring compliance not only with legal and regulatory requirements but also with general principles of sound corporate governance. Regular bottom-up reporting from all departmental areas is utilized to identify and analyze risks to the company wherever these may exist along the value chain, and wherever possible to mitigate them, with the aim of preventing these risks from occurring in the first place or, if this is not possible, to proactively manage the consequences in the event that the risk nonetheless materializes. The focus is first and foremost upon those risks that could have a significant adverse impact on business activities or even jeopardize the Group's continued existence.

In 2024, Formycon established a new bottom-up risk reporting process to broaden and strengthen its system for the early detection of risks so that the company is able to gather risk-related information more rapidly and in a more structured manner.

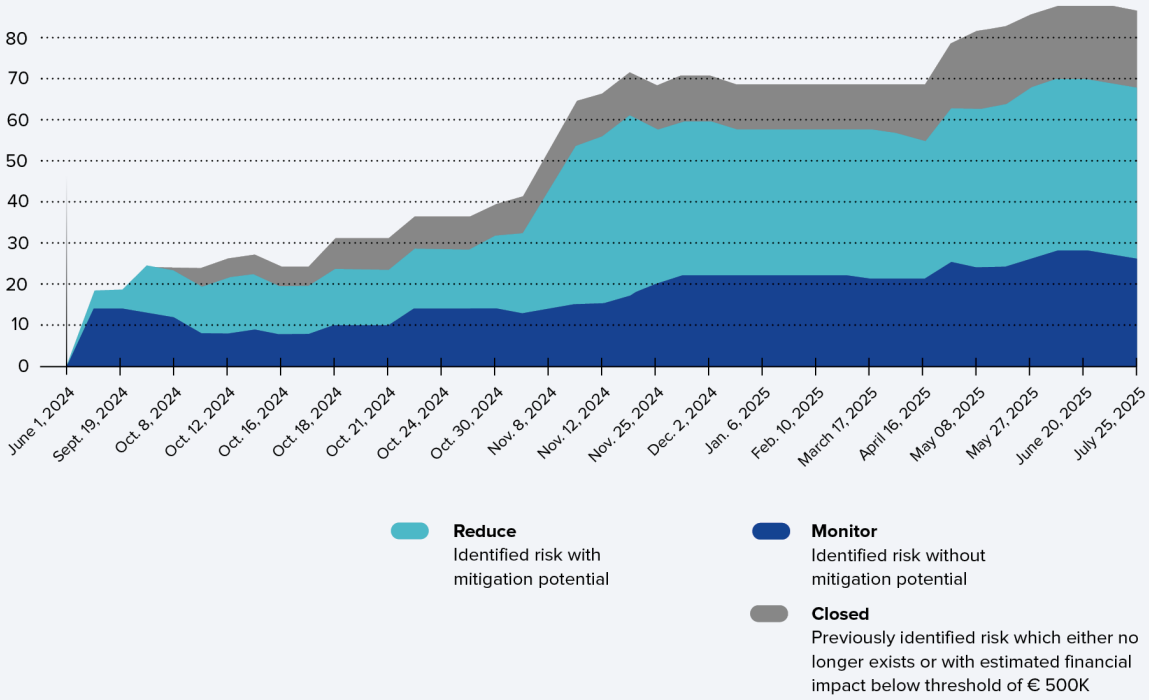
On this basis, risk reports are prepared and presented twice each year to the Executive Board, which examines identified risks and available routes of action to mitigate them. The Executive Board, in turn, reports its findings to the Supervisory Board.

In parallel with these ongoing risk monitoring processes, the Group may also identify and report special short-term risks that could require prompt action so that effective and timely countermeasures may be put in place as necessary.

The risk management system specifically encompasses the following risk areas, which are further described in the following sections: strategic risks, operational risks, IP risks, regulatory and political

risks, financial risks, industry, market and competitive risks, risks relating to environmental protection, health, and workplace safety, IT risks, staff and process risks, and legal and compliance risks.

Risik count
based on Risk status



Reduce
Identified risk with mitigation potential

Monitor
Identified risk without mitigation potential

Closed
Previously identified risk which either no longer exists or with estimated financial impact below threshold of € 500K

Risks

The following overview reflects Formycon's assessment of the primary risks that could have a negative impact on its business performance, financial condition and corporate reputation. The statements made are within the context of a multi-year planning horizon. The risk assessments within the overview are based on the "net principle", i.e. taking into account the offsetting effects of risk management, risk mitigation and risk hedging measures.

Strategic risks

Compared to the development of an entirely new biopharmaceutical, the financial investment required for the development of a biosimilar drug is considerably less but nevertheless significant. The development of a biosimilar may cost in the range of US$ 150 to 300 million per product, requiring cost-intensive analytical, preclinical and clinical studies to demonstrate its comparability to the reference product in terms of quality, safety and efficacy. Because of these complex requirements, the development of a biosimilar also requires a relatively long development timeframe of seven to ten years until application for regulatory approval in the world's highly regulated markets.

The prospects for the future commercial success of a biosimilar development project are largely determined by the selection of product candidates at the start of the process. With its FYB201 and FYB203 projects, Formycon is focusing on ophthalmic preparations, while its FYB202 project is targeted at immunological disorders and FYB206 at immuno-oncological disorders.

The future size and growth trajectory of these markets may be derived from existing sales statistics for the respective reference products. Declining sales of a reference product could result in a potential future market size for a biosimilar under development by Formycon which is significantly smaller than originally assumed. This could, in the worst case, lead to future product sales inadequate to make the biosimilar development effort profitable and thus termination of the project. In such case, the anticipated future income would not be realized. With its biosimilar candidates, Formycon is targeting established high-revenue biopharmaceutical products. Provided that their development reaches successful completion, the profitability of these projects, as they stand right now, can be reasonably assumed.

Nevertheless, the possibility of a competitive situation cannot be ruled out in which the rate of market penetration, targeted volume of products sold and/or realizable product unit prices might be lower than anticipated, with correspondingly negative effects on revenue and earnings contributions.

Operational and project risks associated with the development of biosimilars

The quality, comparability, efficacy and safety of a biosimilar medicine must be comprehensively demonstrated to the regulatory authorities through analytical and preclinical studies along with clinical trials. Both the planning and implementation of any individual stage of product development could potentially entail delays which are generally not predictable and which, in turn, would result in higher costs. There is, moreover, the risk that final regulatory approval of a biosimilar candidate might take longer than planned, or that the drug might not be approved at all.

In its biosimilar development work, Formycon relies in part upon external partners. Should an external partner fail to provide the required resources, or fail to provide them within the required timeframe, or should the timeframe in which such resources are made available be shifted for other reasons, this could lead to delays in the Group's development projects.

With this in mind, Formycon plans all steps of product development with the greatest possible care and, to the extent feasible, with reasonable time allowance – derived from our own experience for delays that might arise. Preclinical and clinical studies as well as the extensive program of analytical characterization take place in close consultation with the respective authorities and with assistance and expert advice from outside specialists. Notwithstanding this, the results or outcome of any such study cannot be completely predicted in advance.

It cannot be ruled out that particular stages of a product development program might need to be repeated, that one or more such studies might not reach successful conclusion, or that a development program might fail in its entirety. Within the scope of the Group's development activities, the production of active ingredients and finished products by third-party producers represents a substantial cost component. It should be specifically noted here, in the context of risks that might arise, that such production capacities must typically be planned and arranged with lead times of one to two years and that, for this reason, short-term changes to the project cycle could result in additional waiting periods along with substantial cancellation fees.

Another risk is that such outside partners might not be able to comply with the stringent regulatory requirements which apply to gaining regulatory approval of a biosimilar drug, such as inspections and audits. Should such an event arise, regulatory approval could be delayed or completely denied. In addition, difficulties arising in the recruitment of patients for clinical trials, or in the availability of production capacity, production components or precursors, and/or other necessary inputs could have an impact on development works or clinical trials, thereby also adversely affecting the timeline and/or profitability of a drug development project or even jeopardizing a project in its entirety.

Operational and project risks relating to clinical trials conducted by Clinical Research GmbH in its function as clinical trial sponsor and its merger with Formycon AG

Clinical Research GmbH acted as a 100% subsidiary of Formycon AG as the designated sponsor for clinical trials, specifically for the FYB201, FYB202 and FYB203 development projects. These have since been successfully completed and the products have been approved accordingly. Clinical Research GmbH therefore no longer has any relevant function. For this reason, both companies have decided to merge Clinical Research GmbH into Formycon AG. The merger had not yet been finalized as of June 30, 2025, and thus Clinical Research GmbH still appears in this risk and opportunity report.

With the merger, the risks of Clinical Research GmbH will be transferred to Formycon AG.

Formycon manages risks in clinical development and the conduct of clinical trials through an appropriate industry-standard monitoring and quality management system, using a risk-based approach in order to assess and ensure quality and safety through all phases of the clinical trial process. This includes but is not limited to ensuring the protection of clinical trial participants and the accuracy and reliability of the clinical trial results. Toward this end, predefined checks are regularly carried out along the entire clinical investigation process as part of the risk control system, with particular attention to relevant aspects of proper medical care, patient protection and data integrity. Any liability risks which may nonetheless arise are further managed through the insurance of participating patients within the framework of legal requirements. In the case of clinical trials involving biosimilars, however, it should be noted that the risk of harm to participating patients or other test subjects can generally be assessed as low because the proteins employed have been in regular clinical use by the originator for a number of years and have already become an established therapy for the respective indication.

As clinical trial sponsor, Formycon AG is, moreover, obligated to comply with detailed and rigorous regulatory requirements for good clinical practice

(GCP) when conducting clinical trials of medicinal products for human use under the EU Clinical Trials Regulation, which apply to clinical trials worldwide and which serve to protect patients and ensure the integrity and correctness of the data and findings generated through the trials. The clinical trial sponsor, participating study centers and other parties involved in the clinical trials process are regularly subject to GCP inspections by local health authorities to ensure compliance with these GCP regulatory requirements.

Patent and other intellectual property (IP) risks

Formycon Group's success, competitive position and future revenues depend upon its ability to navigate the complex intellectual property landscape as it develops its biosimilar candidates with the aim of approval and market launch, generally as promptly as possible upon patent expiry of the originator drug. This means that Formycon must not only establish legal protections for its own intellectual property and know-how but also ensure that it does not encroach upon the legitimate intellectual property rights of third parties, such as patents, trademarks and design rights. This may, under certain circumstances, also mean challenging the validity or scope of intellectual property rights claimed by third parties.

The possibility of patent infringements, even if only alleged, is an inherent risk in biosimilar development because of the large number of potentially relevant patents which must be considered. Disputes with competitors or other patent owners, or defense against lawsuits claiming patent infringement, may pose a considerable financial burden. Particularly in the US, such legal actions can be very expensive. Such disputes may extend over a long period of time and thus lead to a delayed market launch. In the worst case, such proceedings canresult in restrictions on, or even the prohibition of, the marketing of one or more products within relevant markets, and/or the imposition of sizable fines. Such legal action could also make it necessary to cease the development, launch or marketing of one or more products.

In order to avoid infringements upon the intellectual property rights of others, Formycon conducts exhaustive patent searches already at the time that project candidates are selected, then continues to closely monitor the relevant patent environment over the course of the development of its biosimilar candidates. Nevertheless, the possibility cannot be excluded that Formycon could be the subject of patent litigation, even if such litigation is unjustified. In the US in particular, patent litigation between the suppliers of reference products and biosimilar manufacturers is standard procedure.

Regulatory and political risks

The requirements and conditions for the regulatory approval of drugs by the relevant authorities are subject to constant change. The risk cannot be excluded that these authorities might change the regulatory requirements in such a way as to impede, or even entirely preclude, the regulatory approval required for a biosimilar to reach market. Moreover, the political and public policy environment, particularly in the European Union and the United States, may have a significant influence on market opportunities for biosimilars as a whole or within specific areas of indication. For example, politically influenced changes to regulations governing biosimilars and their interchangeability with the original patent drugs may have an impact on competition or pricing and thus have a significant impact on sales revenue for the biosimilar market as a whole and on future Formycon-developed products in particular. Furthermore, the possibility cannot be ruled out, particularly in the U.S., that a partial or complete government shutdown could lead to delays in the regulatory approval process.

Specifically in the US, there is a risk that tariffs on biosimilars or on materials used to manufacture them could affect their economic viability in strategically important target markets. Such import tariffs could significantly reduce the price advantage over reference drugs or domestically produced biosimilars, thereby jeopardizing the company's international competitive position. If customs duties are passed on in full to consumers, this could lead to a decline in sales volumes, which could reduce the profitability of individual products. As a result, it could become necessary to postpone or cancel

planned market launches which could lead to declines in sales. Even if market launches proceed as planned, there is the related risk that the strategic investment in the development and approval of individual biosimilars might not pay off.

A final assessment of the economic and strategic consequences of any customs and import risks is not possible at this point in time, as both regulatory developments and market reactions are not yet foreseeable. In particular, it is currently unclear whether and when import tariffs will be established, at what level they will be set, and what exactly they will apply to. With regard to this issue, the various license agreements with Formycon's distribution partners are structured in different ways. For these reasons, it remains unclear to what extent potential tariffs will affect planned market launches, sales trajectories, and the long-term profitability of individual development projects.

The military conflict between Russia and Ukraine have resulted in price increases over the past years, especially in the energy markets. Until now, Formycon’s operating processes have been only marginally affected. Nevertheless, the risk continues to exist that raw materials, preliminary products and/or services which are important to Formycon could become more expensive or potentially even scarce. Formycon strives to mitigate these risks through a long-term sourcing strategy based upon strategic partners and transparent pricing. However, the possibility cannot be ruled out that delays or interruptions in development projects could occur as a result of a potential scarcity of resources or rationing of energy, or that the development costs thereof could become significantly greater. The recruitment of patients for clinical studies or the conduct of such studies could also be significantly impacted by the conflict in Eastern Europe, which could have the effects of increasing competition for participating study patients, of delaying clinical studies, or of otherwise increasing costs.

The ongoing war between Hamas and Israel currently represents one of the greatest geopolitical risks which could potentially impact Formycon’s current and future markets. A further continuation of the military conflict could affect the surrounding region and, in particular through rising oil prices, adversely influence the global economic situation and thus potentially also all of Formycon’s sales markets.

There is significant uncertainty about the extent and duration of disruptions which could directly or indirectly arise as a result of these conflicts, as well as their ultimate impact on the global economy. There can therefore be no guarantee that the Group's projects will not experience delays or interruptions due, for example, to potential resource shortages, energy rationing, or other adverse impacts to Formycon’s development projects and the costs thereof.

Overall, it must be recognized that cross-border business activities around the globe are facing increased risks due to an increasing number of armed conflicts, threats (e.g. Taiwan), and spreading nationalism in multiple regions, all of which pose risks to Formycon, not only in terms of the markets for its products but also its procurement needs.

Industry, market and competitive risks

From the standpoint of Formycon, conditions in the healthcare sector remain favorable. As populations continue to age and people around the globe live longer, the need for intensive and costly medical treatments is growing relentlessly, regardless of economic cycles and consumer purchasing power.

Moreover, advances in medical technology are enabling the treatment of diseases which a few decades or even years ago were regarded as untreatable or only poorly treatable. Biopharmaceuticals, in particular, are a significant driver of these treatment advances. Of the world’s best-selling drugs, most are biopharmaceuticals. Within Germany, biopharmaceuticals comprised 36% of the total drug market in 2024, corresponding to some € 23 billion in

sales revenue – and the trend is continuing upward.[66,67]

At the same time, however, the high cost of these powerful treatments, which in some cases may exceed € 100,000 per patient per year[68], is a major burden on healthcare system costs. The political will to act as a result of these cost pressures could also, by increasing the pressure on biopharmaceutical prices, impact Formycon's business environment.

The prevailing overall economic situation is characterized by additional uncertainties (see "Regulatory and political risks") which could have a negative impact on the market situation.

The current aim of Formycon is to launch its products, through its respective partners either entirely or in part, upon expiry of patent protection on the reference product in the respective market. Due to Formycon's positioning as an independent player within the biosimilars market space, situations may arise in which a commercialization partner for one product, such as a partner company named in this report, is also a competitor for another product. In each market, Formycon must compete not only with the manufacturer of the reference drug, who might attempt to defend its market position and establish barriers to market entry (e.g. through life-cycle management), but also with other biosimilar producers. These include not only major pharmaceutical corporations such as Amgen, Biocon, Biogen, Fresenius Kabi, Pfizer, Samsung Bioepis, Sandoz and Teva but also smaller and highly specialized biosimilars companies such as Alvotech, Celltrion and Xbrane. The competition situation in each specific case is influenced by the pricing of the reference product, the number of competitors, their pricing strategy, and the market potential.. It is, in addition, entirely possible that the manufacturer of the originator product might reduce its pricing upon the market entry of new and competing biosimilars, or seek to enter into discount agreements with health insurers or other major buyers over extended contractually binding periods, in order to retain market share. This would improve its defensive competitive position against a new biosimilar entry and make it more difficult for the biosimilar to gain share.

Through the experience and expertise of its staff and its strategic partners, the strategic positioning of its product development portfolio, and its strong financial footing, Formycon strives to face these competitive challenges. Nevertheless, it cannot be excluded that competitors might, in an unexpected or unpredictable way, find themselves in an advantageous competitive position relative to, and to the detriment of, Formycon's products, thereby adversely impacting financial performance.

Financing, credit and liquidity risks

Formycon's liquidity situation and equity capitalization are stable, and the Group's liquidity position is particularly satisfactory for a company which has not yet attained profitability and whose products are largely still in the development stage. Irrespective of this, conditions within the Group's operating business may change, giving rise to financial risks – for example, through slower market penetration, lower product sales volumes or lower product unit prices than expected, as well as delayed or lower proceeds from out-licensing. As some of the Group's early-stage products are drug candidates which have not yet obtained regulatory approval, it cannot be ruled out that one or more such approvals could come later than anticipated, or that the scope of approval could be different than planned, or that approval could be denied. Moreover, the required financial outlays for product development, regulatory approval and market launch could substantially exceed planned budgets. There is also the possibility that future license income, even subsequent to regulatory approval, could be less than anticipated. An increased number of change orders and uncertainties within ongoing projects have the effect of increasing not only costs but also risks.

66 Unaudited information

67 Source: IQVIA – https://www.iqvia.com/de-de/locations/germany/library/publications/trends-und-entwicklungen-im-deutschen-biopharmazeutika-markt-q4-2024

68 Unaudited information

In order to mitigate such financial risks in its ongoing operating business, Formycon undertakes highly detailed and long-term planning, drawing also on outside expertise. The financial risks of project development, which Formycon bears entirely by itself during the initial development phase, have been significantly reduced for projects FYB201 and FYB203 through partial or total out-licensing deals at an early stage.

The possibility cannot be entirely excluded, however, that one or more of such development partnerships could be terminated for reasons not under Formycon's control. Such an event could have a material adverse impact on the Group's profit and loss accounts as well as on its financial planning. At the present time, Formycon assesses this risk as very low.

Formycon intends to add further biosimilar candidates to its development pipeline in the future with a view to transferring them, either in whole or in part, to promising partnerships.

At the end of June 2025, Formycon placed a four-year unsecured floating-rate bond in the amount of €70 million with an interest rate of EURIBOR plus 7.0% p.a. Under the terms of the bond issue, Formycon is required to comply with certain financial figures (Maintenance Covenants). Specifically, Formycon is required to maintain a cash balance of €7.5 million for each reporting period ending on or before September 30, 2026. In addition, the EBITDA debt ratio as of December 31, 2026, and as of December 31 of each subsequent year may not exceed 4:1. A breach of these covenants could result in the acceleration of bond repaymentor in a deterioration of the financing terms. Although the risk of non-compliance is currently considered low given Formycon`s current liquidity situation and financial planning, there is an inherent risk in the event of any unexpected adverse developments (e.g., project delays, market disruptions, or regulatory changes).

With its strong financial footing, Formycon is well positioned to overcome future financial risks as these may arise. The Group's existing financial resources should be sufficient to largely cover its short- to medium-term capital needs. This, however, cannot be used to infer any sort of assurance as to the availability of medium- to long-term financial resources. There are, at present, no identifiable fundamental risks which would jeopardize the Group's near-term continued existence. The failure of current or future development projects to attain regulatory approval or failure of approved products to generate the expected level of sales revenue could, however, result in fundamental risks, depending on the relevance of the respective project to Formycon Group as a whole.

Environmental protection, health, and workplace safety

Workplace safety and health, as well as the protection of employees and the environment, is a top priority for Formycon. Formycon therefore places great importance not only on the fulfillment of statutory and regulatory requirements but also on the regular training and further qualification of all of its staff in the relevant aspects of workplace safety. Comprehensive procedures have been established for this purpose. Significant fines may be imposed for violations of environmental protection laws. In addition to compliance with laws, measures to ensure the health and safety of staff also serve to mitigate the risks and consequences of employee absences, which may affect not only production or business functions but also employee perception and thus the potential to impact employee satisfaction or turnover. In addition to the company's biological safety officer, designated project manager as required under the German Genetic Engineering Act (Gentechnikgesetz) and trained safety specialist, Formycon has designated several other experienced employees with specific responsibilities in the area of workplace safety and protection. A company doctor regularly conducts preventive examinations and advises employees as well as the Executive Board on medical matters. Formycon holds all permits and approvals required for its operations. Compliance with all regulatory requirements regarding safety and the protection of employees and the environment is monitored internally on an ongoing basis. Moreover, the Group constantly seeks new opportunities to further protect the health and safety of its staff. As an

example, Formycon recently obtained certification of its company health management system.

Information and technology risks

Formycon's operating activities depend upon the proper functioning of its laboratories and IT infrastructure. Various risks can be identified which might impair or interrupt the availability of these critical resources, temporarily or even over an extended period. To the extent possible, the financial risks which might result from such events are insured. In addition, Formycon employs modern technologies and established processes to eliminate or mitigate the risks cyberattacks or other potential data loss. The Group also regularly conducts maintenance and inspections of its critical equipment by trained personnel or specialized service providers, making changes to equipment as necessary to ensure that it remains at the state of the art.

Rigorous compliance with laws and regulations relating to information security and data protection serves not only to protect operational activities but also to preclude legal penalties. These risks are closely monitored by Formycon.

Staff and process continuity risks

The expertise and many years of experience of its employees are key pillars of Formycon's success. In particular, the development of a biosimilar drug, from early-stage analysis through to regulatory approval, requires highly qualified specialists. Over recent years, Formycon has been able to recruit numerous highly qualified scientists and managers. This demonstrates that the Group is a highly attractive employer, able to successfully fill these critical positions, even in a fiercely competitive labor market. For a growing organization, staff turnover is relatively low. The loss of key staff, particularly with critical knowledge and expertise, would constitute a significant risk. To keep this risk as low as possible, the Group has implemented a number of staff motivation and retention initiatives, along with talent planning to ensure that future succession is in place. It is also impossible to rule out the risk of staff absences due to illness. Formycon has, for this reason, established a health management system to mitigate the impact of staff absences resulting from illness.

Legal and compliance risks

Formycon does business in a competitive international environment and in highly regulated markets. There is thus the possibility that Formycon could be drawn into legal disputes which might even be unjustified or frivolous, which could, for example, be based upon patent law, competitive or antitrust law, tax law or environmental law, or arising from agreements or other contractual claims. Moreover, the possibility cannot be excluded that such legal actions might, whether through court judgements, binding arbitration or regulatory or other official decisions, result in financial burdens which are, for example, not covered by insurance or only partially insured.

The uplisting of Formycon AG in November 2024 and its inclusion in the SDAX and TecDAX stock market index have the effect of increasing regulatory obligations, along with the potential for penalties or other legal consequences in the event of failure to comply with these obligations.

Additional risks arise from the Group's other compliance obligations. Actions or inactions by the Group could, for example, be legally contested, inadequate, misleading or untimely financial communications could result in fines, or improperly conducted shareholder meetings or shareholder resolutions could be disputed. With these risks in mind, Formycon assesses and monitors all of its relevant processes, procedures and decisions from a legal standpoint, using in-house and/or outside expertise as necessary. The Group has, in addition, introduced a compliance management system that takes into account applicable legal and regulatory requirements, which are also incorporated into the Group's Code of Conduct as well as other Group policies and standard operating procedures. The legal and regulatory requirements specifications are regularly reviewed and adjusted as necessary. The Group's internal training system, random validation checks and case-by-case review of specific individual situations that may arise further serve to ensure proper compliance with all applicable requirements.

Opportunities

Formycon's core business is the development of high-quality biosimilar medicines for the world's most stringently regulated markets. In this global market, Formycon seeks growth through the expansion of its product portfolio, not only in terms of the number of biosimilar candidates under development but also, and at least as importantly, through their quality and the market opportunity which they represent. Possible strategic collaborations may significantly contribute toward maximizing these opportunities.

Biosimilar medicines have the advantage over their reference products of more cost-effective development because of procedures which are already scientifically proven and development processes which are largely well established. Because the similarity and comparability of a biosimilar to its reference product must already be demonstrated analytically, the likelihood that the development of the biosimilar will fail in one of the subsequent clinical phases is generally far lower than in the case of innovative biopharmaceuticals.

The agreement with the FDA to waive a Phase III clinical trial for FYB206 not only represents significant financial and time savings for the biosimilar candidate but also opens up the opportunity to implement an optimized clinical strategy without Phase III trials for other Formycon biosimilar candidates. This would significantly reduce development times and project costs. More broadly, there are indications that the regulatory authorities are fundamentally reevaluating the need for Phase III efficacy trials for the approval of biosimilars. Shorter development timelines and lower development costs could result in more biosimilar candidates being brought to market in less time.

Due to the comparatively high barriers to market entry, in particular the complexity of producing biopharmaceuticals and the specialized expertise required, the level of competition in the area of biosimilar development is, with few exceptions, generally modest compared to the market for generic drugs. Formycon is able to overcome these considerable barriers through the long and proven experience of its staff, the innovative concepts and the reliability of the scientific processes which Formycon applies for its biosimilar development projects, the stringent selection of strong and reliable partners, the Group's high degree of integration along with its agility, and finally the quality and scientific expertise of the service providers and advisors on which Formycon additionally relies.

Within this core business area and market, Formycon sees no change in its favorable future outlook.

Demographic trends, particularly in Western countries, point to a continued increase in the proportion of the population over 55 years of age.[69] This demographic segment has a higher incidence of requiring intensive medical treatment. In addition, life expectancy is increasing around the world, meaning that long-term treatments, in particular recurring drug administrations, are often possible or even medically necessary over longer remaining lifespans.

Formycon established its position in the highly promising market for biosimilars development at an early stage and, with its comprehensive expertise, is able to exploit the potential of this fast-growing market. Formycon's business model is scalable. The continued promising development of both the market environment and Formycon`s own business

[69] Unaudited information

and organization shows that Formycon Group is on the right path with its corporate strategy.

Overall risk assessment by Executive Board

Compared to the prior-year period, the risks described above remain stable. With regard to the various risks broadly associated with the development and commercialization of biosimilars as described in the various sections above, the Executive Board has reviewed its risk assessment. Geopolitical turmoil and potential adverse changes in the US economic and business environment (tariff and pricing policy), as well as product sales volumes and product unit prices below expectations, could have a significant negative impact on Formycon's financial performance.

In view of the fact that certain regulatory authorities have, in the past, expressed reservations arising from audits of production facilities of individual contract development and manufacturing organizations (CDMOs), as well as of certain competitors of Formycon, the Executive Board has determined that the risk should, in accordance with the criteria of the risk matrix, be assessed as “relatively high”.

Summary risk matrix

Risk	Risk type	Assessed risk level	Change
Operational and project risks associated with the development of biosimilars	Strategic	High	→
Operational and project risks relating to clinical trials and to the role of Clinical Research GmbH as clinical trial sponsor	Strategic	Low	→
Patent and other intellectual property (IP) risks	Strategic / Commercial	Relatively low	→
Regulatory and political risks	Strategic / Commercial	Relatively high	→
Industry, market and competitive risks	Commercial	Relatively high	→
Financing, credit and liquidity risks	Financing	Relatively high	→
Environmental protection, health and workplace safety	Operating	Relatively high	→
Information and technology risks	Operating	High	→
Staff and process risks	Operating	Relatively high	→
Legal and compliance risks	Operating	Relatively high	→

Determination of risk level based upon estimated probability of occurrence and estimated financial impact in the event of occurrence

	Probability of occurrence (PoO)			
Estimated financial impact	< 20 % Low	20 – 50 % (relatively low)	50 – 80 % (relatively high)	> 80 % High
> € 8.000K	Relatively high	High	High	High
€ 4.000K - € 8.000K	Relatively low	Relatively high	High	High
€ 500K - € 4.000K	Low	Relatively low	Relatively high	High
< € 500K	Low	Low	Relatively low	Relatively high

Report on risks relating to the use of financial instruments

The financial instruments currently used by Formycon to any significant extent are trade receivables, trade liabilities, shareholder loans, conditional purchase price payment obligations, and bank balances. Liabilities are settled within the stipulated period. Potential currency risks, which could have a negative effect on the Group's asset situation, financial position and profitability, are mitigated by avoiding the accumulation of significant foreign-currency positions.

The Group's most significant foreign-currency exposure arises from purchases of third-party services in Swiss francs (CHF) and U.S. dollars (US$), which are paid promptly in order to minimize currency risks.

Formycon's risk management policy is fundamentally to protect against financial risks of all kinds.

In managing its financial position, the Group follows a conservative risk policy. To the extent that payment default or other credit risks are identifiable with regard to financial assets, these risks are reflected through value adjustments.

Report on outlook for Formycon Group

The information provided within this section includes forward-looking statements based upon our current expectations and certain assumptions. Identified and unidentified risks, inherent uncertainties and other factors may lead to significant deviations between the expectations outlined herein and actual future results. Such future deviations from these expectations could involve the Group's future financial situation and overall development as well as the future sales of its current or potential products. With regard to its pipeline projects, Formycon AG makes no representations, warranties or other guarantees of any kind that these will receive the necessary regulatory approvals or that these will be commercially available and/or successful.

Business and financial outlook for Formycon Group for fiscal year 2025 Confirmed for the Formycon Group – Working capital increased thanks to successful bond placement

The development of biosimilars remains the strategic focus of Formycon Group and forms the basis for the company's long-term and sustainable growth.

In terms of product development, Formycon expects to achieve further operational milestones in the financial year 2025, which will form the basis for its transformation in the medium term from a successful development company into a profitable commercial biopharmaceutical company. In every phase of a company's development, it is important to invest in pipeline projects. Based on its development expertise and associated international reputation, the company is receiving an increasing number of inquiries regarding the development or partial development of biosimilars on behalf of third parties. These opportunities are examined on a case-by-case basis and evaluated in economic terms. It is thus possible that Formycon might, in addition to developing its own biosimilar candidates, develop products on behalf of third parties in the future to a limited extent .

The global market for biosimilars is expected to continue its dynamic growth and, according to IQVIA, grow to US$ 74 billion by 2030.[70] However, prevailing conditions, particularly in the United States, may have a near-term impact on Formycon's business activities. These could include, for example, a slower opening of certain market segments and higher price discounts than previously assumed. Added to this is the current risk that tariffs on imported biosimilars will reduce their price advantage over reference drugs or domestically produced biosimilars. On the other hand, it is advantageous that Phase III clinical studies are, going forward, expected to be necessary for fewer development projects in the future.

Formycon therefore plans to further optimize its R&D strategy for biosimilars in terms of efficiency, agility and costs in order to secure its competitiveness in the global biosimilars sector. In particular, this includes optimization of manufacturing costs across the entire value chain and the use of AI-supported processes. Additionally, further diversification of commercial partnerships will serve to position our products more broadly, flexibly and even closer to markets around the globe.

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[70] https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/fokus-biosmilars/newsletter-fokus-biosimilars-ausgabe-10.pdf

Development of the biosimilar pipeline

The developments published at the beginning of the year underscore the volatility in certain areas of marketing but also highlight the opportunities in this market environment.

In the case of FYB201, our US partner Sandoz AG responded to increasing price pressure by adjusting its marketing strategy for FYB201/Cimerli®. Accordingly, following a temporary pause in US marketing, the product will be commercially repositioned in order to tap new customer segments following its market reintroduction with an adapted pricing strategy.

The temporary pause of marketing means that Formycon must expect significant declines in sales and earnings for this product in 2025, which cannot be offset by revenues from Europe and other territories. However, the product is expected to be relaunched in the US in 2026 with improved market opportunities. Marketing in Europe and other markets outside the US is not affected by this tactical marketing measure. The launch of the FYB201 prefilled syringe is planned for the second half of the year, and is expected to open up further market potential, particularly in Europe.

The product launch of FYB201/Ranvisio® in Brazil is scheduled for the fourth quarter of 2025 and marks the starting point for further market launches in Latin America through the beginning of 2027. In addition, a license agreement was concluded with the African biotechnology company Bio Usawa Biotechnology Ltd for FYB201, which granted exclusive rights to register and market FYB201/BioUcenta™[71] in the sub-Saharan Africa region.

During the first half of 2025 FYB202, Formycon's second biosimilar, entered the phase of commercial marketing. In the US pharmacy benefit market segment, it became apparent that the market opening for biosimilars is developing more slowly and requires greater price reductions than previously assumed. Towards the end of 2025 our commercialization partner expects to sign further agreements with US contract partners, which will generate momentum downstream.

In Europe, FYB202/Otulfi® was launched in various countries at the beginning of March 2025. Furthermore, starting from the third quarter of 2025, Teva subsidiary Ratiopharm will now be marketing FYB202/Fymskina®, another Formycon ustekinumab biosimilar, on a semi-exclusive basis in Germany. Marketing in Europe is developing positively, and the product is gradually being launched in other European countries.

Due to this step-by-step market introduction for FYB202, Formycon expects that the majority of sales contributions will be generated in the last quarter of 2025.

Regulatory developments in the US for our immuno-oncology biosimilar candidate FYB206 can be assessed as positive. They show that the framework conditions for the development of biosimilars in the US continue to improve. Similar efforts in Europe are likewise expected to steamline the approval process with the European Medicines Agency (EMA).[72]

During a scientific advice meeting, the FDA confirmed that extensive analytical data, together with the ongoing Phase I study in the agreed design, will be sufficient to demonstrate the therapeutic comparability of our biosimilar candidate FYB206 to Keytruda®. This eliminates the need for a Phase III study for FYB206. This is an important step that will not only significantly shorten the development time but also massively reduce the required investment. This result underscores the importance of the quality of our analytical and preclinical data and confirms Formycon's pioneering and leading role among Keytruda® biosimilar developers. Patient recruitment for the optimized Phase I clinical development program has now also been successfully completed.

Following the successful approvals of the Eylea® biosimilar FYB203 in the US and Europe, Formycon is engaged in various patent activities aimed at

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71 BioUcenta™ is a trademark of Bio Usawa Biotechnology Ltd.

72 Reflection paper on a tailored clinical approach in biosimilar development

establishing a potential market launch date. No decision has yet been reached, thus Formycon is not planning on any marketing revenues for FYB203 in 2025. Teva Pharmaceuticals International GmbH is the semi-exclusive marketing partner for large parts of Europe and Israel, while Lotus Pharmaceutical is the marketing partner for the Asia Pacific region.

An exclusive license agreement for the marketing of FYB203 in the US and Canada has been concluded with the US biosimilar specialist Valorum Biologics LLC ("Valorum").

The biosimilar candidates FYB208, FYB209 and the FYB210 project launched in 2024 are in earlier stages of development. Upon reaching the Technical Proof of Similarity (TPoS) milestone, FYB208 is expected to enter clinical development in the second half of 2025.

Biosimilars have already demonstrated through the experience of numerous existing commercial products that they can achieve a sustainable longterm market position and that the business modelis profiable. Our strategy remains focused on achieving a leading position in this dynamic growth area together with our partners.

Revenue

Despite the establishment of FYB201 in numerous countries and planned market launches in additional territories, Formycon expects FYB201 to make significantly lower contributions to revenue and earnings in fiscal year 2025 due to the temporary tactical measure in the United States. The reintroduction at a more stable price level is expected in the first half of 2026.

As a result of the market launches of FYB202/Otulfi® in the first quarter of 2025 in the US and parts of Europe, the first revenue contributions from the product are expected in 2025. The company anticipates that a significant part of the sales that will contribute to achieving the forecast revenue volume for 2025 will be generated in the last quarter of 2025.

Following the successful completion of the development of the prefilled syringe for the ophthalmic biosimilars FYB201 and FYB203, revenue from the reimbursement of development services rendered for these two projects will continue to decline as expected.

Given the advanced stage of clinical development of FYB206 and the FDA's approval to waive Phase III clinical trials, the Group plans to conclude an initial licensing partnership for FYB206 before the end of 2025. This could lead to significant revenue, particularly in the fourth quarter, upon conclusion of the agreement. This planning is further supported by the advanced stage of studies for the biosimilar candidate. Patient recruitment for the Phase I clinical program has already been completed, and results for the primary study endpoint are expected in the first quarter of 2026. Overall, Formycon continues to expect consolidated fullyear revenue for 2025 to be between €55.0 million and €65.0 million.

EBITDA

The basis for value creation is Formycon's development pipeline. The company will therefore continue to invest in its maturing product pipeline. Development costs for FYB206 are capitalized rather than expensed and thus do not directly flow through the income statement. EBITDA for 2025 is expected to remain negative and in a corridor between €–20.0 million and €–10.0 million, which reflects the stable revenue forecast for 2025 and the continuing significant non-capitalized R&D investments in addition to other ongoing costs.

Adjusted EBITDA

Adjusted EBITDA additionally includes Formycon’s at-equity participation in earnings from the Bioeq AG joint venture. Bioeq AG's results are derived exclusively from the operating success of the FYB201 product. Due to the strategic realignment and the associated suspension of marketing in the US, this amount is expected to be €0 in 2025. Bioeq AG is classified as a jointly controlled entity and is therefore not included as an operating segment. In order to provide a broader and more meaningful measure of operating performance, Formycon reports

adjusted EBITDA, which includes this at-equity participation in earnings. Thus, Formycon continues to expect adjusted EBITDA for the year 2025 to fall

within the same range as EBITDA: between €-10.0 million and €-20.0 million.

Working capital

A reduction in working capital is expected due to investments in the FYB206 project. This outflow is to be offset by part of the proceeds from the senior unsecured floating rate bond in total of € 70.0 million issued in July 2025, which replaces the previous shareholder loan facility. Based on this bond totaling €70.0 million, which was successfully closed in the second half of 2025, the forecasted working capital will be increased from original €25.0 million to €35.0 million to €55.0 million to €65.0 million

Medium-term outlook

Formycon is aiming for sustainable and EBITDA-profitable growth in the medium term. Management currently expects that positive EBITDA can ideally be achieved as early as 2026 but no later than in fiscal year 2027.

Four factors in particular are expected to contribute significantly to Formycon's success and the achievement of this goal over the short to medium term.

FYB201: Resumption of marketing following the temporary pause in the US and increasing establishment in already developed markets through the launch of the pre-filled syringe and the development of further markets such as Latin America.

FYB202: Solid establishment in key markets, such as the United States, Europe, Canada and other territories.

FYB203: Agreement or resolution of the patent situation with the reference drug manufacturer and medium-term market launch.

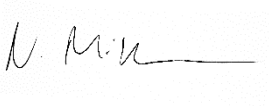
FYB206: Signing of regional or global partnerships deal, including upfront or milestone payments to Formycon.

Key financial performance indicators in accordance with IFRS in € million

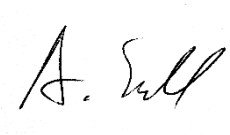
	2024 actual	1H 2025	Guidance for 2025	
Revenue	77.7	9.0	55,0 to 65,0	unchanged
EBITDA	1.5	-17.9	-20,0 to -10,0	unchanged
Adjusted EBITDA	13.3	-19.2	-20,0 to -10,0	unchanged
Working capital	38.9	17.0	55,0 to 65,0	raised (previously 25,0 to 35,0)

Martinsried/Planegg, Germany,
August 6, 2025

Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

Enno Spillner

Condensed Consolidated Financial Statements of Formycon Group for the period from January 1, 2025 to June 30, 2025

Condensed Interim Statement of Financial Position in € thousand	explanatory note	June 30, 2025	Dec. 31, 2024
Assets			
Non-current assets			
Goodwill		-	-
Other intangible assets	14	456,145	444,116
Right-of-use (ROU) assets	14	10,466	10,749
Property, plant and equipment		3,620	3,821
Investment accounted for using the equity method	10	150,637	151,870
Financial assets	16	58,644	66,134
Deferred tax assets	12	-	-
Total non-current assets		**679,512**	**676,691**
Current assets			
Inventories		1,173	262
Trade and other receivables	16	10,784	23,693
Contract assets	6, 16	4,106	7,016
Other financial assets		6	6
Prepayments and other assets	16	19,491	22,123
Income tax receivables	12	210	91
Cash and cash equivalents	16	27,279	41,834
Total current assets		**63,049**	**95,024**
Total assets		**742,562**	**771,715**
Equity and liabilities			
Equity			
Subscribed capital	15	17,664	17,664
Capital reserve	11.15	496,704	496,021
Accumulated profit/loss carryforward		-51,843	73,829
Period income (loss)		-54,192	-125,672
Total equity capital		**408,334**	**461,843**
Non-current liabilities			
Non-current lease obligations		8,661	9,097
Other non-current liabilities	10.16	183,178	164,726
Deferred tax liabilities	12	101,463	102,156
Total non-current liabilities		**293,302**	**275,979**
Current liabilities			
Provisions		-	-
Current lease obligations		1,545	1,496
Other current liabilities	16	12,198	12,932
Trade payables	16	25,155	17,437
Current income tax liabilities	12	2,028	2,028
Total current liabilities		**40,926**	**33,893**
Total liabilities		**334,228**	**309,872**
Total equity and liabillities		742,562	**771,715**

Condensed Interim Statement of Comprehensive Income in € thousand			
	explenatory note	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Revenue	6	8,997	26,893
Cost of sales	7	-22,437	-24,985
Research and development expenses	8	-8,176	-9,692
Selling expenses		-738	-593
Administrative expenses	9	-8,775	-9,298
Other expenses		-363	-314
Other income		101	6
Operating profit/loss (EBIT)		**-31,391**	**-17,983**
Income from investments accounted for using the equity method	10	-1,233	14,757
Finance income	10	243	820
Finance expense	10	-22,544	-5,287
Change in Impairments based on the expected credit loss model	10	40	-6
Net finance income		-23,494	10,284
Profit before tax		**-54,886**	**-7,699**
Income tax expense	12	693	-2,395
Profit (loss) / Comprehensive income (loss) for the period		**-54,192**	**-10,094**
Basic (undiluted) earnings per share (in €)		-3.07 €	-0.58 €
Average number of shares outstanding (undiluted)		17,664,427	17,286,654
Diluted earnings per share (in €)		-3.07 €	-0.58 €
Average number of shares outstanding (diluted)		17,664,427	17,286,654

Condensed Interim Statement of Changes in Equity in € thousand						
	explanatory note	Subscribed capital	Capital reserve	Accumulated loss carry-forward	Period income (loss)	Total equity
as of Jan. 1, 2024		**16,053**	**412,871**	**73,827**	**-**	**502,751**
Capital increase against cash contributions	14	1,604	81,240	-	-	**82,844**
Costs of capital increase		-	-	-	-	**-**
Effect of stock options granted	10	-	801	-	-	**801**
Shares issued through exercise of stock options		-	-	-	-	**-**
Period income (loss)		-	-	-	-10,094	**-10,094**
as of June 30, 2024		**17,657**	**494,912**	**73,827**	**-10,094**	**576,302**
as of Jan. 1, 2025		**17,664**	**496,021**	**-51,843**	**-**	**461,843**
Effect of stock options granted		-	683	-	-	**683**
Period income (loss)		-	-	-	-54,192	**-54,192**
as of June 30, 2025		**17,664**	**496,704**	**-51,843**	**-54,192**	**408,334**

Condensed Interim Statement of Cash Flows for the period from January 1, to June 30, 2025 in € thousand			
	explanatory note	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Profit (loss) for the period		-54,192	-10,094
Adjustments for non-cash items:			
Depreciation and amortization		13,465	1,079
Net finance income	10	23,494	-10,285
Effect of stock options	11	683	802
Net loss (gain) arising from disposals of non-current assets		4	3
Other non-cash transactions		-341	256
Income tax expense	12	-693	2,395
Changes in operating assets and liabilities:			
Decrease (increase) in inventories		-911	-1,656
Decrease (increase) in trade and other receivables		12,908	864
Decrease (increase) in contract assets		2,910	-12,246
Decrease (increase) in prepayments and other assets		2,632	-2,265
Increase (decrease) in other liabilities		-759	-274
Increase (decrease) in trade payables		7,718	628
Increase (decrease) in current provisions		-	-387
Income taxes paid	12	-119	-5
Net cash used for operating activities		**6,798**	**-31,185**
Investments in intangible assets	14	-24,590	-16,647
Investments in property, plant and equipment		-165	-982
Repayments from loans granted		7,500	5,000
Interest received		231	767
Net cash used for investing activities		**-17,024**	**-11,862**
Proceeds from issuance of shares		-	82,843
Payment of lease liabilities		-834	-599
Outflows for the repayment of financial liabilities		-3,453	-25,388
Interest paid		-42	-224
Net cash from financing activities		**-4,329**	**56,632**
Net increase (decrease) in cash and cash equivalents		**-14,555**	**13,585**
Cash and cash equivalents as of Jan, 1		**41,834**	**27,035**
Cash and cash equivalents as of June, 30		**27,279**	**40,620**

Notes to the Condensed Consolidated Financial Statements of Formycon Group for the period from January 1, 2025 to June 30, 2025

1. Reporting entity

FORMYCON AG (hereinafter also the "Company"), together with the subsidiaries within its scope of consolidation (hereinafter "Group" or together "Formycon"), is a leading independent developer of high-quality biosimilar drugs, meaning follow-on products to biopharmaceuticals already on the market. Formycon has long specialized in the development of biosimilars and is able to cover all technical stages of the biopharmaceutical development chain from analysis and cell line development to preclinical studies and clinical trials, all the way through to the creation and submission of regulatory approval application documents. In addition to its decades of experience in protein chemistry, analysis and immunology, Formycon also has extensive expertise in the successful transfer of antibodies and antibody-based therapies into the clinical development stage.

FORMYCON AG has its registered offices in Martinsried/Planegg, Germany, and is entered into the commercial register (Handelsregister) of the District Court of Munich under number HRB 200801. The Company's shares are listed in the Frankfurt Stock Exchange's Prime Standard (Deutsche Börse: German securities identifier (WKN): A1EWVY, ticker symbol: FYB, ISIN: DE000A1EWVY8).

2. Significant accounting principles

These condensed consolidated interim financial statements (hereinafter also the "Financial Statements") presented here in translation from the German original have been prepared in accordance with IAS 34 ("Interim Financial Reporting"). As interim financial statements, these do not include all of the explanatory notes typically included in full-year financial statements.

The accounting policies applied by Formycon Group in the preparation of these Financial Statements correspond to those applied by Formycon Group in its consolidated financial statements for fiscal year 2024.

3. Use of judgements and estimates

The preparation of these Financial Statements in accordance with IFRS requires Formycon's management to make certain judgements, estimates and assumptions that affect the reported amounts of revenues, expenses and income, assets and liabilities, as well as related notes. Uncertainties regarding these estimates and underlying assumptions may lead to situations whereby a material adjustment is required in future periods to the carried amount of the relevant asset or liability.

These estimates and underlying assumptions are subject to regular review. Revisions to estimates are generally recognized prospectively. During the review of estimates for the current period, no grounds were identified for any such revisions.

The key discretionary decisions made by Formycon's management in the application of accounting principles and valuation methods in the preparation of these Financial Statements, along with the main sources of estimate uncertainties, were compared with those in the preparation of the consolidated financial statements for fiscal year 2024.

All judgements and assumptions applied in preparing this Interim Financial Statements are

comparable to those made in the financial statements for 2024.

Measurement of fair values

A number of the Group's accounting policies and disclosures require the measurement of fair values, for both financial and non-financial assets and liabilities.

When measuring the fair value of an asset or liability, the Group uses observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

— Level 1: Quoted prices (unadjusted) in active markets for identical assets and liabilities.

— Level 2: Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).

— Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability are categorized in different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

Assumptions have been made in measuring fair values in the following cases:

— Valuation of conditional purchase price payments in determining and allocating the purchase price (see Note 16),

— Valuation of obligations arising from share settled as well as cash-settled share-based compensation arrangements (see Note 11).

4. Changes in accounting and valuation methods

The accounting principles applied in the preparation of these Financial Statements correspond in full to those used in the preparation of the consolidated financial statements of Formycon Group for the fiscal year ending December 31, 2024.

The amendments to existing International Financial Reporting Standards regarding the determination of an exchange rate for a currency with a lack of interchangability which are to be applied for the first time for fiscal years beginning January 1, 2025, had no effect on the preparation of these Financial Statements.

Segments 2025 in € thousand				
	FYB201	**FYB202**	**FYB203**	**FYB206**
External revenue	2,395	2,559	3,986	-
Segment revenue	**2,395**	**2,559**	**3,986**	**-**
Segment profit (loss)	-18,507	-22,285	-1,501	-
Finance income	-	-	-	-
Finance expense	-16,995	-5,191	-	-
Income from investment participations at equity	-1,233	-	-	-
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-2,582	-6,910	-5,303	-
Other expenses (selling expenses, miscellaneous)	-	-	-	-
Depreciation and amortization	-91	-12,744	-184	-
Income taxes	-	-	-	-
Assets				
Investment accounted for using the equity method	150,637	-	-	-
Additions to non-current assets	-	-	-	24,590

Segments 2024 in € thousand				
	FYB201	**FYB202**	**FYB203**	**FYB206**
External revenue	8,173	11,347	7,373	-
Segment revenue	**8,173**	**11,347**	**7,373**	**-**
Segment profit (loss)	18,439	-5,320	-69	-
Finance income	-	-	-	-
Finance expense	-	-	-	-
Income from investment participations at equity	14,757	-	-	-
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-4,367	-16,207	-7,237	-
Other expenses (selling expenses, miscellaneous)	-	-	-	-
Depreciation and amortization	-124	-460	-206	-
Income taxes	-	-	-	-
Assets				
Investment accounted for using the equity method	181,802	-	-	-
Additions to non-current assets	-	-	-	16,567

	FYB208	FYB209	FYB210	Total for reportable operating segments	Remaining amount	Formycon Group
	-	-	-	8,940	57	8,997
-	**-**	**-**	**-**	**8,940**	**57**	**8,997**
-	-9,253	-955	-2,285	-54,786	594	-54,192
-	-	-	-	-	283	283
-	-	-	-	-22,186	-358	-22,544
-	-	-	-	-1,233	-	-1,233
-	-8,910	-909	-2,228	-26,842	919	-25,923
-	-	-	-	-	-1,000	-1,000
-	-343	-46	-57	-13,465	-	-13,465
-	-	-	-	-	693	693
-	-	-	-	150,637	-	150,637
-	-	-	-	24,590	424	25,014

	FYB208	FYB209	FYB210	Total for reportable operating segments	Remaining amount	Formycon Group
	-	-	-	26,893	-	26,893
	-	**-**	**-**	**26,892**	**-**	**26,892**
	-7,176	-3,305	-	2,569	-12,663	-10,094
	-	-	-	-	820	820
	-	-	-	-	-5,293	-5,293
	-	-	-	14,757	-	14,757
	-6,978	-3,214	-	-38,002	-4,894	-42,896
	-	-	-	-	-901	-901
	-198	-91	-	-1,079	-	-1,079
	-	-	-	-	-2,395	-2,395
	-	-	-	181,802	-	181,802
	-	-	-	16,568	3,420	19,987

5. Operating segments

For the reporting period reportable segments developed as shown in the table above.

6. Revenue

Revenue streams

During the period, Formycon generated revenue by providing development services to the respective development partners for its partnered development projects FYB201, FYB202 and FYB203. These costs include not only product development costs but also costs incurred for the management of clinical studies. In addition, with the market launch of FYB201 and FYB202 in the UK, the EU and the USA, Formycon began generating revenue through license income from the granting of partially exclusive marketing rights to the respective partners. Such license revenues are recognized only from the point at which they can be reliably determined. During the fiscal year, a total of € 2,511 thousand (2024: € 3,760 thousand) was recognized as license revenue.

Geographical breakdown of revenue in € thousand

Region	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Germany	4,489	7,373
Switzerland	4,508	19,520
Total	**8,997**	**26,893**

Geographical breakdown of revenue

During the period, and based upon customer domicile, the Group's revenues were generated entirely in Germany and Switzerland as shown above.

Contract receivables and contract assets

Assets arising from contracts with customers are included as both trade receivables and contract assets. As of the reporting date, such receivables from customers were € 6,752 thousand (Dec. 31, 2024: € 18,497 thousand), while receivables from services not yet invoiced and separately reported as contract assets were € 4,106 thousand (Dec. 31, 2024: € 7,016 thousand).

Cost of sales in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Cost of materials	-276	-297
Contract research expenses	-3,364	-18,274
Staff expenses	-5,160	-5,817
Amortization FYB202	-12,468	-
Depreciation, amortization and write-downs	-177	-186
Regulatory approval fees	-206	-224
Other expenses	-786	-186
Total	**-22,437**	**-24,985**

7. Cost of sales

Cost of sales include all costs directly related to generated revenue and thus all costs that can be allocated to the Group's partnered and launched projects. Starting from February 1, 2023, with the conclusion of the marketing agreement with Fresenius Kabi and the associated realization of revenue from performancerelated payments using the cost-to-cost method, all further development costs were recorded as cost of sales. With the approval of the FYB202 project end of September 2024, the scheduled amortization of the development costs capitalized up to this point began. Cost of sales during the fiscal year consisted primarily the above cost types.

The regulatory approval fees are fees for the applications to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for the approval of FYB201, FYB202 and FYB203.

8. Research and development expenses

Formycon Group has, in support of its FYB207 project, been awarded government grants from the Bavarian Research Foundation (Bayerische Forschungsstiftung), an agency of the Bavarian state government, as well as under the Bavarian state government's special "BayTherapie 2020" grant program. Grant awards in the amount of € 0 thousand (1H 2024: € 0 thousand) were offset against the corresponding research and development expenses. During the reporting period the final payment of € 2,637 thousand (1H 2024: € 0 thousand) was disbursed by the grantor.

Research and development expenses include all such costs attributable to the Group's non-partnered projects. Research and development expenses in the financial year were essentially made up as follows:

Research and development expenses in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Cost of materials	-547	-302
Contract research expenses	-4,714	-6,826
Staff expenses	-2,163	-1,960
Depreciation, amortization and write-downs	-125	-117
Other expenses	-628	-486
Total	**-8,176**	**-9,692**

9. Adminstrative expenses

During the reporting period Administrative expenses developed as shown in the table "Administrative Expense". The decrease compared to prior year mostly is a result of a decerase in legal and consulting fees for financial and strategic projects which happened in 2024 and did no reoccur in the reporting period. This is partially compensated by an increase in IT expense due to the ongoing implantation of a new ERP System.

Administrative Expense in €K

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Staff expenses	-4,437	-4,380
Legal and advisory expenses	-1,737	-3,022
IT expenses	-1,562	-527
Depreciation, amortization and write-downs	-599	-647
Other expenses	-439	-722
Total	**-8,775**	**-9,298**

10. Net finance income

The Group's net finance income during the reporting period was as shown below.

During the reporting period € 22,186 thousand have been recognized as finance expese (1H 2024: € 4,970 thousand). The expense is mainly due to a change in the interest rate used for discounting.

Net finance income in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Investment gain from Bioeq AG	-	14,757
Income from investments accounted for using the equity method	-	14,757
Realized and unrealized gains from foreign currency translation	13	53
Interest income per effective interest method	230	767
Finance income	**243**	**15,577**
	-	-
Bank fees	-10	-8
Realized and unrealized losses from foreign currency translation	-99	-18
Interest expense from lease liabilities	-188	-104
Interest expense per effective interest method	-61	-187
Share of loss from Bioeq AG	-1,233	-
Change in fair value of FYB202 conditional purchase price	-22,186	-4,970
Finance expense	-23,777	-5,287
Change in Impairments based on the expected credit loss model	40	-6
Net finance income	**-23,494**	**10,284**

11. Share-based compensation arrangements

During the reporting period there have been slight changes to the outstanding grants within the existing share-based compensation programs due to the departure of one receipient. During the reporting period, the total current expense for share-based compensation payments was € 429 thousand (1H 2024: € 802 thousand). As of June 30, 2025, the impact of these share-based payments on the capital reserve account was € 8,867 thousand (Dec. 31, 2023: € 8,184 thousand). At the same time a liability for cash settled programs was recognized under other non-current liabilities at the amount of € 223 thousand (Dec. 31, 2024: € 477 thousand).

12. Income tax expense

Taxes recognized in profit or loss

Current, deferred and total income tax expenses (income) during the reporting period were as shown below:

Income tax expense in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Current tax expense	-	-35
Deferred tax expense / income		
from valuation at equity	-	197
from differing asset valuations	20	5
from capitalization of certain leases as right-of-use (ROU) assets and corresponding liabilities from lease obligations	-13	-34
from accounting for cash-settled share-based compensation arrangements	68	-59
from capitalization of certain internally generated intangible assets	3,361	6,561
Other	398	-3
from deferred taxes on tax loss carry-forwards	-4,527	-4,236
Total tax expense / income	**-693**	**2,395**

Deferred tax assets on tax loss carryforwards are written down to the extent that the Group cannot demonstrate that future taxable profits will be sufficient to utilize the loss carryforwards.

Deferred tax assets and deferred tax liabilities in € thousand

	June 30, 2025		Dec. 31, 2024	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Valuation of participation in affiliate	-	-	-	-
Valuation of non-current assets	-	154	-	134
Right-of-use (ROU) assets and corresponding leasing obligations	136	-	123	-
Arising from capitalized assets in course of a business combination	-	96,517	-	96,517
Capitalization of internally generated intangible assets	-	20,901	-	17,539
Other	149	628	226	241
Tax loss carryforwards - Formycon AG corporate tax (Körperschaftssteuer)	8,249	-	6,062	-
Tax loss carryforwards - Formycon AG trade tax (Gewerbesteuer)	5,525	-	4,074	-
Tax loss carryforwards - FYB202 Project GmbH	2,678	-	1,790	-
Offset (netting) of deferred tax assets and liabilities	-16,737	-16,737	-12,275	-12,275
Total	-	**101,463**	**-**	**102,156**

Reconciliation of expected income tax expense in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
Profit before tax	-54,886	-7,699
Tax rate	26.68%	26.68%
Expected income tax expense	**-14,643**	**-2,054**
Tax-free income from the valuation of financial instruments	-	-2,414
Non-taxable expense from the valuation of financial instruments	5,919	-
Taxes for prior years	-	-
Other	280	1,459
Non-recognition of deferred tax assets on tax losses	7,751	5,405
Total tax expense	**-693**	**2,395**

EBITDA and adjusted EBITDA in € thousand

	Jan. 1 – June 30, 2025	Jan. 1 – June 30, 2024
EBIT	-31,391	-17,983
Depreciation of property, plant and equipment	361	346
Depreciation of right-of-use (ROU) assets	542	607
Amortization of intangible assets	12,562	126
EBITDA	**-17,927**	**-16,904**
At-Equity Result Bioeq AG	-1,233	14,757
adjusted EBITDA	**-19,160**	**-2,147**

13. EBITDA and Adjusted EBITDA

The Management Board additionally presents earnings before finance income/expenses, taxes, depreciation and amortization (EBITDA) in this section of the Financial Statements because it relies upon consolidated EBITDA as well as Adjusted EBITDA as key performance measures in managing the Group and believes that this measure is relevant to an understanding of the Group's financial performance. EBITDA is derived and calculated from reported operating income (EBIT).

Adjusted EBITDA additionally includes the contribution from Formycon's jointly controlled investment accounted for using the equity method Bioeq AG. While EBITDA is not a defined performance measure under cost of sales method, the Group's definition of EBITDA is consistent with usual definitions.

EBITDA and Adjusted EBITDA for the reporting period are derived and calculated as shown below

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14. Other intangible assets and Right-of-use Assets

Capitalized development expenditures

As part of a business combination, all rights to the FYB202 project, which was still under development, were reacquired by Formycon and recognized accordingly. From May 1, 2022 until January 31, 2023, all costs for the further development of the project, both external and internal, were also capitalized as eligible development expenditures. Starting from February 1, 2023, all subsequent development costs were expensed as incurred and included in cost of sales. With the receipt of the approvals for FYB202 in Europe and the US, the asset is amortized over its expected useful life.

Upon attainment of TPOS all costs for the development of the FYB206 project, both external and internal, have been capitalized as eligible development expenditures. As of June 30, 2025, the amount of capitalized development expenditures for this project was € 75,371 thousand (Dec. 31, 2024: € 50,781 thousand).

Right-of-use assets

Right-of-use asstes comprise rented properties at the companies headquarters and technical equipment and machinery.

15. Equity

Changes to Equity during the reporting period are presented in the Consolidated Statement of Changes in Equity.

Number of shares outstanding

At the end of the reporting period, the Company had registered capital (Grundkapital) of € € 17,664,427.00, divided into 17,664,427 bearer shares without par value. All shares have full voting and dividend rights.

16. Financial instruments

Valuation

The Group generally classifies all financial assets and liabilities as financial instruments measured at amortized cost. The sole exception to this is the conditional portion of the purchase price for the acquisition of the shareholdings in FYB202 Project GmbH and Bioeq AG (see preceding Notes 22 and 23), which is measured at fair value. For all financial assets and liabilities except for the shareholder loan to Bioeq AG, which is at a non-market interest rate, book value is an adequate approximation of fair value. The book values and fair values of the Group's financial assets and liabilities are summarized in the table below.

The contingent purchase price obligations are measured at fair value based on level 3 input factors under the fair value hierarchy (see Note 6). The contingent purchase price payments were valued at a fair value of € 191,662 thousand as of the reporting date (Dec. 31, 2024: € 172,929 thousand). During the fiscal year, € 3,453 thousand of the contingent purchase price payments were paid. The remaining difference in the amount of € 22,186 thousand was recognized as profit or loss in the finance income (finance costs). The valuation model is based upon the expected cash flows discounted at risk-adjusted rates depending upon the respective future payment dates. As of the reporting date, the rate used to discount the conditional purchase price payments was 8.7%.(31.12.2024: 10.0%)

Book values and fair values of the Group's financial assets and liabilities in € thousand

	Book value at June 30, 2025	**Fair value at June 30, 2025**	FV category
Financial assets not carried at fair value			
Financial assets	58,644	55,532	3
Trade and other receivables	10,784	10,784	3
Contract assets	4,106	4,106	3
Prepayments	19,491	19,491	3
Cash and cash equivalents	27,279	27,279	3
Financial liabilities carried at fair value			
Current portion of conditional purchase price	8,706	8,706	3
Non-current portion of conditional purchase price	182,955	182,955	3
Financial liabilities not carried at fair value			
Trade payables	25,155	25,155	3

	Book value at December 31, 2024	**Fair value at December 31, 2024**	FV category
Financial assets not carried at fair value	-	-	-
Financial assets	66,134	55,673	3
Trade and other receivables	23,963	23,963	3
Contract assets	7,016	7,016	3
Prepayments	22,123	22,123	3
Cash and cash equivalents	41,834	41,834	3
Financial liabilities carried at fair value	-	-	-
Current portion of conditional purchase price	8,680	8,680	3
Non-current portion of conditional purchase price	164,249	164,349	3
Financial liabilities not carried at fair value	-	-	-
Trade payables	17,437	17,437	3
	-	-	-

17. Transactions with related parties

Key management personnel and members of Supervisory Board

The Group's key management personnel are the members of the Management Board of Formycon AG.

Beyond regular remuneration, there were no transactions with any member of the Management Board or Supervisory Board during the reporting period or prior-year period.

Related companies

Since the acquisition by Athos in 2022 of a shareholding in Formycon AG along with representation on the Supervisory Board, Athos Group companies have been recognized as related companies. Bioeq AG, an entity jointly controlled by Formycon, is likewise recognized as a related company.

During the reporting period, sales revenue in the amount of € 4,769 thousand (2024: € 15,546 thousand) was recognized with related companies, of which € 2,753 thousand (2024: € 8,173 thousand) was with jointly controlled Bioeq AG. Out of the Group's total trade receivables on the closing balance sheet, receivables in the amount of € 2,048 thousand (Dec. 31, 2024: € 6,049 thousand) were due from related companies. The balance sheet also includes a loan receivable from Bioeq AG in the nominal amount of € 58,919 thousand (Dec. 31, 2024: € 64,9419 thousand) including accrued interest.

In addition to the sales revenue and trade receivables resulting from these development partnerships, the Group has also received a loan facility from key shareholders (see Note 22). In addition, Formycon has liabilities relating to conditional purchase price payments to Athos Group companies resulting from the business combination transaction. As of the reporting date, the amount of this recorded liability was € 191,662 thousand (Dec. 31, 2024: € 172,929 thousand), while finance expense during the reporting period included € 22,186 thousand (2024: € 4,970 thousand) arising from the fair value measurement of these obligations.

Some of these companies had transactions with the Group during the Financial Years. The terms and conditions of such transactions have been at armths length.

There were no other transactions with related persons or companies during the reporting period.

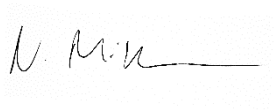
18. Subsequent events

With settlement on July 9, 2025 the company issued an unsecured bond with a volume of € 70,000 thousand to private and institutional investors. The bond carries interest at 3-month Euribor plus 700 basis points and has a maturity of 4 years. With the settlement of the bond the shareholder loan line was dissolved.

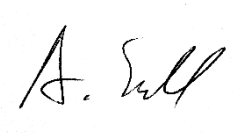
With entry in the commercial register on July 15, 2025 and August 4, 2025 Clinical Research GmbH, Holzkirchen was merged on Formycon AG, Martinsried/Planegg with tax effect as of January 1, 2025. Ther merger will have no impact on the consolidated financial statements.

Martinsried/Planegg, Germany,
August 6, 2025

Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

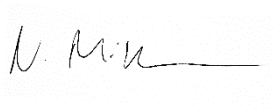
Enno Spillner

Responsibility statement

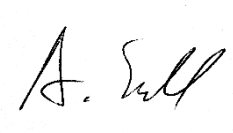
To the best of our knowledge, and in accordance with the applicable reporting principles, the interim financial statements give a true and fair view of the assets, finances, and operating results of the Formycon AG and the Group, and the combined management report includes a fair view of the development and performance of the business and the position of Formycon AG and the Group, together with a description of the principal opportunities and risks associated with the expected development of Formycon AG and the Group for the remaining fiscal year.

Martinsried/Planegg, Germany,
August 6, 2025

Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

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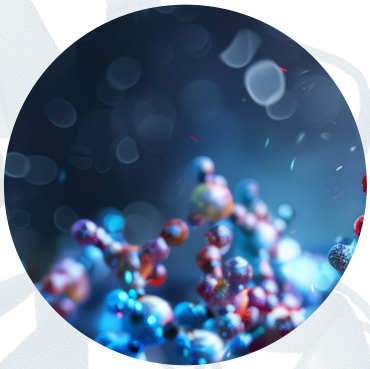

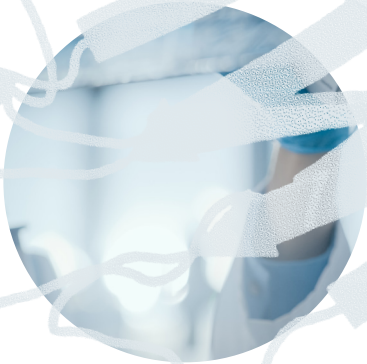

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