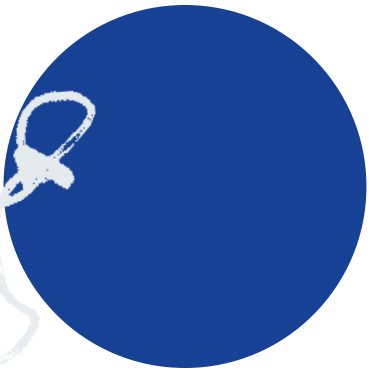
formycon®



Formycon. The Biosimilar Experts.

Half-Year Report 2024

Formycon Group
key financial figures

	1H 2024	1H 2023
Revenue in € Million	**26.9**	43.8
EBITDA in € Million	**-16.9**	7.3
Adjusted EBITDA in € Million	**-2.1**	1.1
Working Capital in € Million	**63.0**	55.0

This English version is a translation of the legally definitive German version

June 28, 2024

FDA approval of our
Eylea® Biosimilar **FYB203**
— AHZANTIVE®

Table of contents

About Formycon

Founded in 2012, Formycon is a Munich-based Pure-Play Biosimilar Company.

More than 230 employees from 32 different countries work at Formycon, of which 60% are women.

Some 80% of Formycon's workforce is engaged in R&D activities.

With its expertise and resources in biosimilar development, Formycon is currently able to develop multiple biosimilar projects in parallel.

Formycon's pipeline consists of an approved biosimilar drug, two late-stage and three pre-clinical biosimilar development projects

The combined global market size for the reference (originator) drugs to Formycon's FYB201, FYB202, FYB203 and FYB206 biosimilar projects is currently approx. USD 47 billion.

To our shareholders

An interview with our **Executive Board**

Formycon is regarded as a “pure play” biosimilars company. What exactly does this mean?

Dr. Stefan Glombitza, Chief Executive Officer: „Formycon is a globally operating, independent specialist in the development of biosimilar drugs. We aim to firmly establish our company as leader in the growing biosimilars segment and partner of choice for the major pharmaceutical names with their strength and reach in sales and marketing. For us, being a “pure play” specialist means complete and absolute focus on our capabilities and excellence spanning all phases of biosimilars development, from the process of selecting biosimilar candidates all the way through to regulatory approval.“

Dr. Stefan Glombitza, CEO

What makes you so confident that biosimilars are a growth market?

Stefan Glombitza: „Three reasons: firstly, the vast combined market size of the biologics which will lose their market exclusivity over the next few years; secondly, the large and ever increasing need for doctors to be able to effectively treat patients; and thirdly, the growing financial strains on the world’s healthcare systems. Because of the high cost of many biologics, it remains true even today that too few patients are being treated with these highly effective drugs at a sufficiently early disease stage. Biosimilars, with their comparable efficacy, represent a cost-effective solution to this global problem. Biosimilars can provide the financial relief so that as many patients as possible can receive the optimal therapy as early as possible. The “gold standard” for treating serious diseases should not be reserved for just the privileged few.“

Can you give us an example of a disease for which medical needs are not currently being fully met because there is, in fact, an undersupply of biologics?

Stefan Glombitza: „One of many examples is Crohn’s disease, a chronic inflammatory bowel disorder. Even in a rich country like Germany, only

→

about 15% of Crohn's patients are currently being treated with highly effective biologics.[1] In the acute phases of Crohn's disease, severe inflammatory symptoms often occur for periods of several weeks, severely impacting quality of life for those afflicted, including tremendous psychological stress. The treatment option is there, but it is being used too rarely. We want to change this - in this specific case with FYB202, our candidate biosimilar to Stelara®[2], for which we expect EU approval shortly following the CHMP's positive recommendation.[3] As biosimilars like our FYB202 enter the market, competition increases, costs fall, and patient care improves."

Formycon announced quite a number of development advances over the first six months of this year. Which of these were the highlights for you?

Stefan Glombitza: „At the start of the year, we said: In 2024 we will lay the foundation for the next phase of Formycon's growth, which will lead us to sustainable profitability over the medium term, through the approval of biosimilars and preparations for their market launch by early 2025. We're on track for this.

A particular highlight is certainly the FDA's[4] approval of FYB203, our biosimilar to Eylea®[5]. With this approval for the U.S. market of FYB203 – which, like our FYB201 product, can be used to treat serious retinal diseases such as "wet" age-related macular degeneration and various diabetes-related diseases – we are now even more strongly positioned in the ophthalmology sector."

What about Formycon's other biosimilar development projects?

Stefan Glombitza: „We're coming along very well and in some cases are making progress even faster than anticipated. With the launch of clinical trials in June, we hope to secure a strong market position for FYB206, our candidate biosimilar to Keytruda®[6]. As a biosimilar to the world's top-selling drug, the economic importance of this project can hardly be overstated. We see enormous future demand.

As to the FYB202 project which I mentioned before, we expect EU approval as early as the beginning of the fourth quarter of 2024, a few weeks ahead of our original plan, due in no small part to the superb work and quick response times of our development teams. In the United States, we likewise expect FDA approval for FYB202 around the end of September. In addition, we hope to begin work on FYB210, a new biosimilar candidate, in the second half of the year. In other words, you can look forward to more positive news from Formycon over the coming weeks and months."

Dr. Glombitza mentioned the economic importance of FYB206 to Formycon. What more can you tell us about this?

Dr. Andreas Seidl, Chief Scientific Officer: „With this entry into immuno-oncology, we are opening up an area of active ingredients with extraordinarily large market potential. The IARC[7] expects that worldwide cancer cases will continue to increase sharply in the future. The demand for these modern therapies is immense – so there's a good reason why so many biosimilars are being developed for cancer treatment."

How can FYB206 help cancer patients?

Andreas Seidl: „With FYB206, or pembrolizumab, we are developing a candidate biosimilar that works by activating the body's own immune response to fight the tumor. This is a highly promising approach for numerous cancer indications, notably

1 Baumgart, Misery, Naeyaert, Taylor: Biological Therapies in Immune-Mediated Inflammatory Diseases: Can Biosimilars Reduce Access Inequities?
2 Stelara® is a registered trademark of Johnson & Johnson
3 The opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA is the basis for the European Commission's marketing authorization decision

Dr. Andreas Seidl, CSO

including non-small cell lung cancer and melanoma, a particularly aggressive form of skin cancer. These are, in fact, the two specific indications for which we are currently conducting our clinical trials."

So both of these clinical trials are already in progress?

Andreas Seidl: „Yes, the two clinicals studies are being conducted in parallel across several centers in Eastern Europe and Southeast Asia. In mid-June, we launched the Dahlia phase I study, comparing the pharmacokinetics, safety and tolerability of FYB206 with the reference drug Keytruda®. Study participants are patients who have had a malignant melanoma surgically removed.

For the Lotus phase III study, we recruited patients with non-small cell lung cancer and began the actual clinical trials starting from the end of July. The Lotus study compares the safety and efficacy of FYB206 to its reference drug Keytruda®.

Top-selling reference drugs generally mean a lot of potential competitors in the biosimilars market space. Where do you see Formycon in this competition?

Andreas Seidl: „The start of clinical trials is a good indicator for comparing our own development progress to that of our competitors. All in all, we can be very satisfied by this metric because it means that we are in the leading tier of biosimilar developers, particularly within the target markets of the United States and Europe."

I know that a lot is also happening in the area of commercialization. What are Formycon's current priorities?

Nicola Mikulcik, Chief Business Officer: „Our FYB201 product, the biosimilar to Lucentis®[8], also known as ranibizumab, is already available in 19 countries worldwide. In the United States and various other markets, we are pleased with the very good market penetration we've already achieved, and we are clearly leading in ranibizumab biosimilars. And the market launches are continuing: Most recently, we were able to announce the launch in Saudi Arabia through our commercialization partner MS Pharma. Further approvals and product launches are planned through to 2026, with a particular regional focus on Middle Eastern and Latin American markets."

How have the European markets been developing?

Nicola Mikulcik: „We are working hard to further expand our market share within Europe. The introduction of pre-filled syringes to complement the currently available vials will play a key role in these

4 US regulatory authority – U.S. Food and Drug Administration
5 Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.
6 Keytruda® is a registered trademark of Merck Sharp & Dohme LLC.
7 IARC – International Agency for Research on Cancer
8 Lucentis® is aregistered trademark of Genentech Inc.

efforts. This more convenient dosage form should be available to doctors and eye clinics over the course of the coming year.“

FYB202 and FYB203 are both approaching the commercialization stage. What are the next steps as you prepare for market introduction?

Nicola Mikulcik: „In the case of FYB202, our candidate biosimilar to Stelara®, we’re focusing on the initial market launches together with our marketing partner Fresenius Kabi and working hard to ensure that the product is available in sufficient quantities starting with the United States and Europe.

For our second ophthalmology biosimilar, FYB203, our partner and license holder Klinge Biopharma has concluded an exclusive license and supply agreement with MS Pharma for marketing in the MENA region. MS Pharma is very well positioned throughout this region and has already been successfully introducing our FYB201 product in these markets.

As to the United States and Europe, we expect to conclude corresponding agreements with strong commercialization partners in the second half of the year.“

How is 2024 looking so far from a financial perspective?

Enno Spiller, Chief Financial Officer: „The entry of Gedeon Richter as a strategic investor at the start of the year was a major statement of confidence. For us, this was not only a big success as a transaction but also a validation of our growth path and remarkable achievements over the past few years. The cash inflow from this transaction of roughly € 83 million has made a significant contribution

Nicola Mikulcik, CBO

to our capacity to continue pushing forward with our biosimilar development projects, particularly FYB206, at a consistently rapid pace while also ensuring the highest quality standards.“

In the case of two biosimilar candidates, development is almost complete. What are your expectations for FYB202 and FYB203?

Enno Spillner: „As of now, we are fully on schedule with all of our development projects and are looking forward to the launch of FYB202, our candidate biosimilar to Stelara®, in 2025. Once the global market launch by our commercialization partner Fresenius Kabi is complete, FYB202 will significantly increase Formycon’s sales revenue and help us attain sustainable EBITDA profitability over the medium term. The settlement agreements with Johnson & Johnson have paved the way not only for the U.S. market but also, more recently, for the European and Canadian markets.

We cannot currently give a specific launch date for

Enno Spillner, CFO

FYB203, as no agreement has yet been reached with Regeneron, the manufacturer of the reference drug.“

You’ve just issuance an upward revision to your guidance for fiscal year 2024. This is certainly a very positive signal. What were the triggers?

Enno Spillner: „Our current 2024 operating figures are looking good, and everything is going according to plan. Sales and EBITDA are expected to remain within the forecast range. We were pleased to be able to announce a significant upward adjustment to our Adjusted EBITDA forecast due to better-than-expected results from sales of FYB201, which are reported through our investment participation in the Bioeq AG joint venture. These ongoing earnings will make a sustained contribution to our company’s success.“

In summary, it’s clear from everything you’ve said that the first half of 2024 was very successful. Would you say that the path to future success is also clear?

Dr. Stefan Glombitza: „Our path to becoming a globally leading, independent, pure-play biosimilars specialist is supported by a deep personal commitment from the entire #TeamFormycon. This extends to the members of the Supervisory Board with their extensive industry experience not only in Germany but internationally.

On this subject, I would like to once again extend our deepest gratitude to Dr. Olaf Stiller and Peter Wendeln, the two Supervisory Board members who stepped down in June after having done so much to help us to reach where we are today. With remaining members Wolfgang Essler and Klaus Röhrig as well as newly elected members Dr. Bodo Coldewey and Nick Haggar, along with Colin Bond starting from October 2024, we aim to continue Formycon’s successful path but with an increasingly international orientation.

On behalf of the Executive Board, I would like to specially thank our employees. Without the extraordinary efforts of the entire team, the many remarkable successes achieved during the first half of 2024 would not have been possible. We are also grateful to our shareholders for their continued confidence in Formycon and in the work that we do.“

Thank you for taking the time to speak with us!

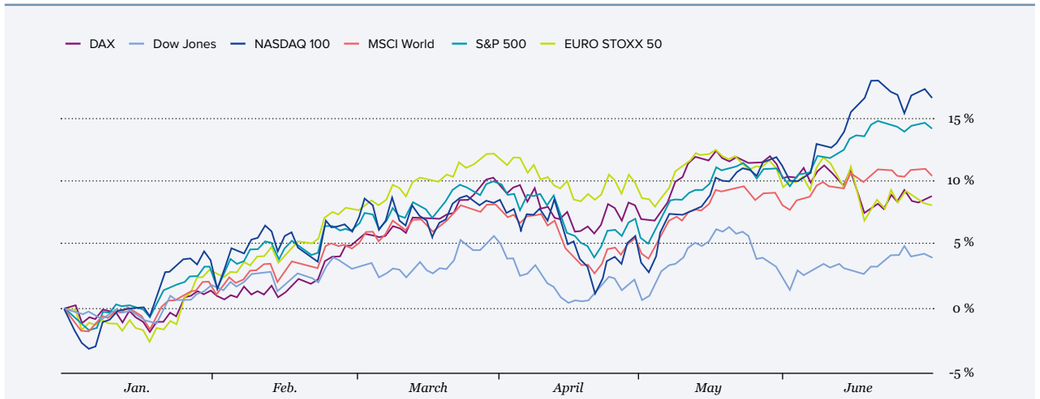
Formycon on the stock market

Shares and the capital markets

German and international stock market environment

The positive trend on global stock markets continued through the first half of 2024, albeit at a more modest pace than during the previous year. The MSCI World international equity index extended its strong performance from 2023, posting an increase of approx. 11% in the first six months of the year. Specifically within Germany, the DAX 40 benchmark index was able to achieve a gain of approx. 9%[1] in the first half, with solid gains during the first quarter following by a decline of 1.5% in the second quarter.[2] Despite this slight setback, the German benchmark was able to reach a new all-time high in the first half of 2024. In the United States, the three leading equity indexes – the Dow Jones 30, the S&P 500 and the technology-heavy Nasdaq 100 – each continued to post new gains, with the Dow rising by almost 4%, the S&P 500 by 14.5% and the NASDAQ by an even greater 17%.[3] This positive ongoing equity market performance was not dampened even by the weakened expectations of interest rate cuts by the U.S. Federal Reserve, which remain unlikely for now as inflation within the U.S. proves more persistent than expected. Despite this shift in expectations, equity markets have remained robust, driven by factors including the boom in technology stocks, particularly in the area of artificial intelligence, as well as the continuing economic resilience of various companies.[4]

The continuing positive equity market performance was seen more broadly in Europe as well, with the Euro Stoxx 50 index of Eurozone stocks extending its gains through a further rise of 8% during the first half of the year.[5] In view of the various challenges and uncertainties during the second quarter,



[1, 3, 5] https://www.onvista.de/index/chart/DAX-Index-20735
[2] https://www.morningstar.de/de/news/250633/b%C3%B6rsen-ausblick-wie-k%C3%B6nnte-es-im-q3-weitergehen-f%C3%BCr-deutsche-aktien.aspx
[4] https://www.tagesschau.de/wirtschaft/finanzen/marktberichte/marktbericht-geldanlage-finanzen-aktien-rendite-konjunktur-inflation-100.html

particularly surrounding the elections in France, this can be considered a relatively strong market performance. The positive trend has been supported by several factors, including expectations of an interest rate cut, economic resilience, and the technology sector boom.

Performance of the biotechnology sector

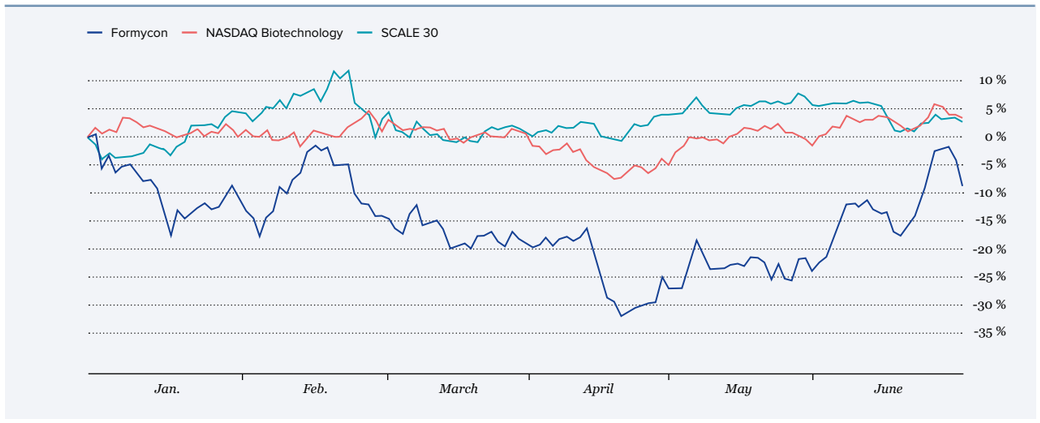
After three years of below-average performance, the biotech sector has been showing convincing signs of a revival. Since the start of the year, the Nasdaq Biotechnology Index has gained almost 4%[1] and was able to break through the key threshold of 4,350 points, which was seen as a significant technical breakthrough. The recovery of biotech stocks this year may be attributed to several factors: Firstly, valuations are now more attractive following the weak relative performance of recent years. Secondly, innovative forces in the industry appear to be on the rise, driven by new technologies including artificial intelligence. Finally, the slowing of inflation and expectations of potential interest rate cuts may also be having a positive impact on this capital-intensive sector. These three factors may have played an important role in the renewed investor interest in biotech companies seen during the first half.[2]

The Frankfurt Stock Exchange's Scale 30 Index, which includes the most liquid stocks among Germany small- to medium-sized companies such as Formycon, has gained approx. 3% since the beginning of the year.[3]

Overall, it remains a challenging environment for companies in the small and mid-cap sector and for companies without sustainable profitability, in which financing or IPOs are extremely difficult to realize.

Performance of Formycon shares

The Formycon share closed the 2023 trading year at a final price of € 56.40 and opened the new year on January 2, 2024, at € 57.00,[4] which also marked the first-half high. Following this strong start to 2024, Formycon's stock price performance was mixed through to the middle of April before slumping to a first-half low of € 38.20.[5] Following this first-half low, the stock was able to quickly recover most of the lost ground over the remainder of the second quarter, ending the period at a price of € 51.80[6], as of the close of trading on June 28, representing a price decline of approx. 8.1%[7] over the first half of the fiscal year.



1, 3 https://www.onvista.de/aktien/chart/FORMYCON-AG-Aktie-DE000A1EWVY8
2 https://www.ey.com/en_us/life-sciences/biotech-outlook#form
4 https://www.finanzen.net/historische-kurse/formycon
5, 6 https://www.finanzen.net/historische-kurse/formycon

The average share price over the 127 trading days during the first half of the year was € 47.15. Announcements of positive operational progress in Formycon's biosimilar projects, such as the launch of phase I clinical trials for Keytruda® biosimilar candidate FYB206 and U.S. FDA approval of Eylea® biosimilar FYB203, have generally been followed by price increases. The positive series of announcements towards at the end of the second quarter has had the apparent effect of stabilizing Formycon's share price and reestablishing the positive trend.

Formycon shares: Trading information

Ticker symbol	FYB
German securities identifier (WKN)	A1EWVY
ISIN	DE000A1EWVY8
Listed exchange Market segment	Frankfurter Wertpapierbörse, Scale (Open Market)
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 €	**1H 2024**	**1H 2023**
Opening price (Xetra) on Jan. 2, 2024 / Jan. 2, 2023	56.40	59.30
Closing price (Xetra) on June 30, 2024 / June 30, 2023	51.80	85.40
Average price (Xetra closing price)	47.15	69.10
Market capitalization as of June 30	914,627,524	1,291,997,385
in shares		
Total shares traded (on all trading venues)	3,815,854	3,620,234
Daily average shares traded (on all trading venues)	14,964	14,087
Total shares issued as of June 30	17,656,902	15,128,775

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). According to sec. 33 para. 4 of the German Securities Trading Act (Wertpapierhandelsgesetz), however, this provision regarding voting rights thresholds does not apply to all domestic issuers. The term "issuer" is restricted to those issuing companies whose shares are listed on an organized market within the meaning of sec. 2 para. 11 of the Act. Thus, these provisions of the Securities Trading Act do not extend to companies which, like Formycon, are listed in the unofficial regulated market (Freiverkehr), or "Open Market",[1] as these companies are not legally considered to be listed on an official exchange.

Under sec. 20 of the German Stock Corporation Act (Aktiengesetz), however, entities owning more than one fourth (25%) of the shares of a stock corporation with registered offices in Germany are subject to notification requirements. Through its entry as part of the 2022 capital increase transaction with a major capital contribution in kind, Athos KG had an indirect shareholding of more than 25% and continued to be Formycon's largest shareholder during the period. Through the capital increase transaction against cash in early 2024 and the entry of the Hungarian specialty pharmaceutical company Gedeon Richter as a new strategic investor, the total shareholding of ATHOS KG was accordingly diluted during the period and fell back below the 25% threshold. ATHOS KG and the relevant direct and indirect entities thereunder provided the corresponding notification to Formycon and published an announcement in the Federal Gazette in accordance with sec. 20 of the Stock Corporation Act.[2]

As of June 30, 2024, a combined total of approx. 58% of Formycon's share capital was held by anchor investors ATHOS KG (indirectly), Wendeln & Cie. KG, DSP Beteiligungsgesellschaft mbH & Co. KG., Active Ownership Capital, and Gedeon Richter Plc. The remaining 42% of total share capital was, in the Company's own assessment, held in free float (as defined by the Deutsche Börse).

Shareholder structureas oj June 30, 2024

58% ■ Anchor investors including Athos KG, Active Ownership Capital, Wendeln & Cie. KG, Gedeon Richter, DSP

42% ■ Free float per definition of Deutsche Börse (Company's own assessment)

[1] German Federal Financial Supervisory Authority (BaFin), "General principles for filing notifications under sections 33, 38 and 39 of the WpHG"
[2] Publication in the Federal Gazette (Bundesanzeiger) in accordance with sec. 20 para.1 of the Stock Corporation Act

Reporting of securities transactions by company executives (directors' dealings)

During the first half of 2024, members of the Executive Board or Supervisory Board conducted the following securities transactions subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR):

Directors' Dealings

Executive or Supervisory Board Member	Position	Transaction date	Type of transaction	Price	Transaction value
Dr. Stefan Glombitza	CEO	April 22, 2024	Purchase	€ 39.00	€ 91,260
Dr. Stefan Glombitza	CEO	April 22, 2024	Purchase	€ 38.65	€ 6,184
Nicola Mikulcik	CBO	April 25, 2024	Purchase	€ 40.00	€ 48,000

Scale (Open Market) market segment

The Company's shares have, since March 1, 2017, been listed in the Frankfurt Stock Exchange's "Scale" segment for small- to medium-sized companies. The initial listing requirements and ongoing obligations of this Open Market (unofficial regulated) segment are designed to facilitate capital raising for small- to medium-sized companies and to provide access to German and international investors. Formycon shares were added to the Deutsche Börse's "Scale 30 Index" of the 30 most liquid shares within the Exchange's Scale segment in February 2018, soon after the launch of this new market index of Germany's most actively traded small- to medium-sized companies at the start of 2018. The inclusion of Formycon within the Scale 30 Index was based primarily upon order book turnover on the Xetra and Frankfurt Stock Exchange trading venues as well as its market capitalization. The composition of the Scale 30 Index is regularly adjusted. The index is calculated in real time, is denominated in euros, and is available in both price and performance variants. Since the creation of this select index of the most traded stocks in the Scale segment, these stocks have been gaining greater visibility among investors.

Formycon is subject to the requirements of the Market Abuse Regulation and, as such, is obligated to publicly release ad hoc announcements of information relevant to its share price, to report securities transactions by its executives (directors' dealings), and to maintain a registry of Company insiders.

Subscribed capital

As of January 1, 2024, the registered capital (Grundkapital) of Formycon AG was € 16,053,025.00, divided into 16,053,025 bearer shares without par value but with an imputed nominal value of € 1.00 per share.

Acting under the authority granted by resolution of the Annual General Meeting of July 25, 2023 (the "Approved Capital 2023"), the Executive Board and

Supervisory Board of Formycon AG resolved in January 2024 to increase the Company's registered capital by € 1,603,877.00, from € 16,053,025.00 to € 17,656,902.00, through the issuance of 1,603,877 new shares. These new shares were subscribed by Gedeon Richter Plc. for cash consideration through a private placement transaction under exclusion of shareholder subscription rights at a price of € 51.65 per newly issued share, generating gross issuance proceeds of approx. € 82.84 million. These new shares corresponded to approx. 9.082% of the Company's shares already outstanding at the time of issuance.

The registered capital of Formycon AG thus amounted to a total of € 17,656,902.00 as of June 30, 2024.

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 2024, 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

— Oddo BHF Forum, virtual event

— UniCredit & Kepler Cheuvreux German Corporate Conference, Frankfurt

— Alster Research Pop-up Konferenz Health Care, virtual event

— Berenberg EU Opportunities Conference 2024, London

— Jefferies Pan-European Mid-Cap Conference, London

— Metzler Small Cap Days, Frankfurt

— Equity Forum Spring Conference, Frankfurt

— Hauck Aufhäuser Stockpicker Summit, Kitzbühel

— 10th Berenberg European Conference 2024, New York

— mwb Research Roundtable, virtual event

— Jefferies Global Healthcare Conference, New York

— Warburg Highlights, Hamburg

The following analysts published research studies on Formycon during the first half of 2024

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

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.

As of June 30, 2024, 11 analysts were regularly providing equity research coverage with investment recommendations on Formycon AG.

The number of analyst reports published during the first half of 2024 increased over the prior-year period by 83%, underscoring the strong investment-side interest in Formycon shares.

Further information about Formycon and its investor relations activities may be found in the "Investors" section of the Company's website: www.formycon.com/en/investor-relations/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

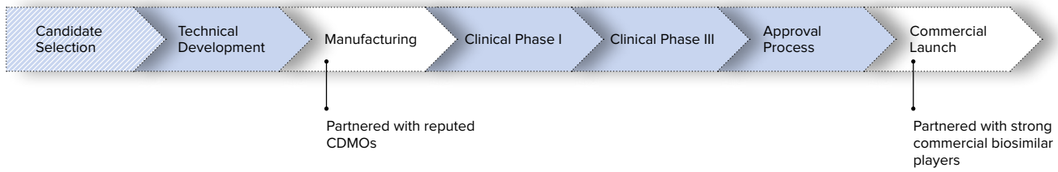
Interim Management Report of Formycon Group for the First Half of 2024

Basic information about Formycon Group

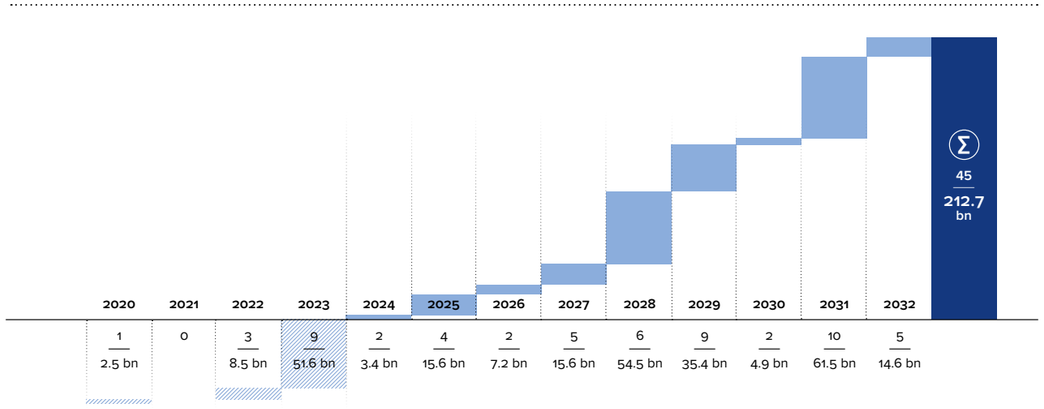
Business activities

Formycon is a globally operating, independent biosimilars specialist with a highly attractive product pipeline and a fully 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 beginning-to-end design and coordinated oversight of its supply chain and product logistics. For the manufacturing and commercialization of its products, Formycon relies upon strong and renowned partners around the world. With its FYB201 project, Formycon achieved successfully regulatory approval of a biosimilar product that is already being marketed in the United States and Canada, Europe, the Middle East and North Africa (MENA), and other geographical regions. A further five biosimilar drugs candidates are currently in the Group's development pipeline, of which one has recently been approved by the U.S. Food and Drug Administration and a second is at an advanced stage in the regulatory review process, with approval expected during 2024. Formycon's long-term and sustainable growth strategy is built upon steady expansion of its product portfolio through the targeted selection of new biosimilar candidates, the development of these projects, and their ultimate commercial success through commercialization partnerships, either partly or in their entirety.

The biosimilar value chain



Biosimilar potential – by 2032, 45 blockbusters* will lose their market exclusivity (in USD bn)



What are biosimilars?

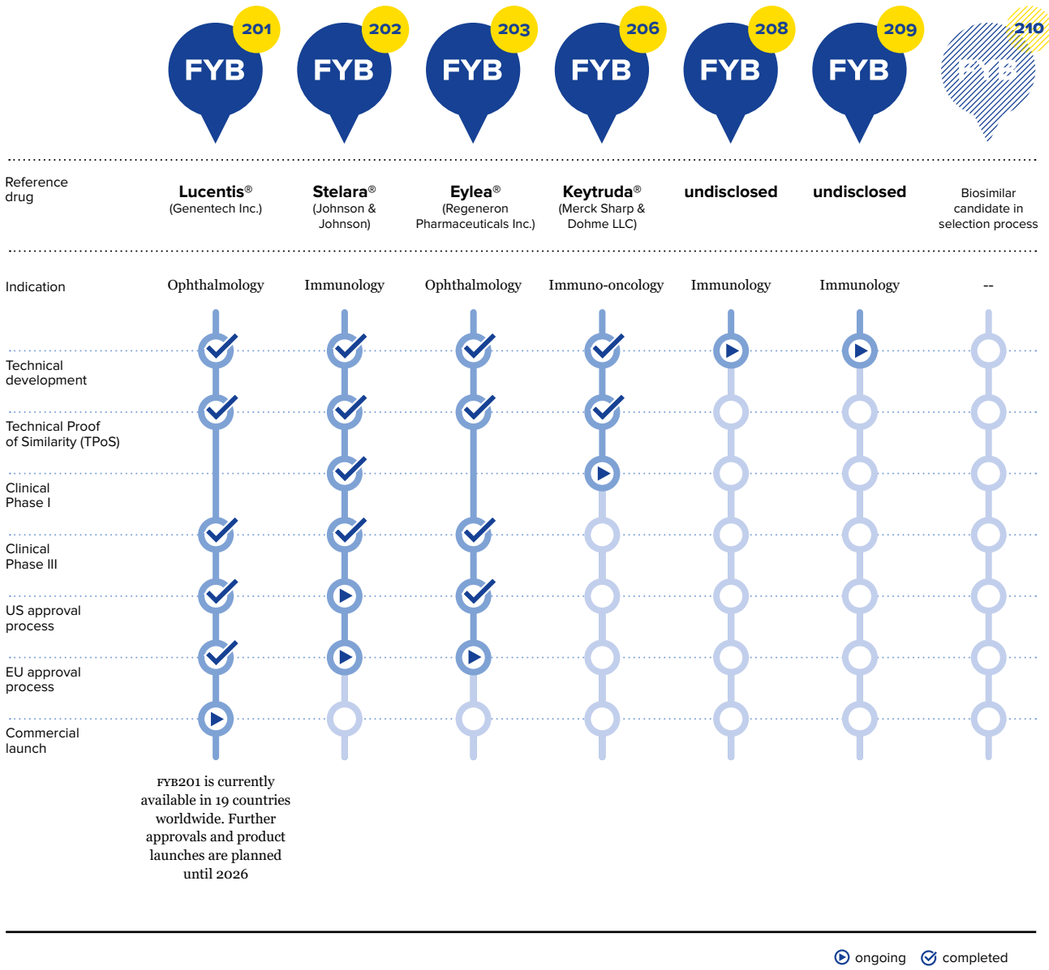
Since the 1980s, biopharmaceuticals have been revolutionizing the treatment of serious diseases such as cancer, diabetes, rheumatism, multiple sclerosis and acquired blindness. Starting from the mid 2020s, patents on many of these powerful biopharmaceuticals began expiring, and over the next nine years, many more of these biotech drugs will lose patent protection, including 45 blockbuster drugs with total combined annual sales estimated at more than USD 200 billion.

Biosimilars are follow-on products to biopharmaceutical drugs whose market exclusivity has expired. Their comparable quality, efficacy and safety is proved through studies, 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.

Product pipeline

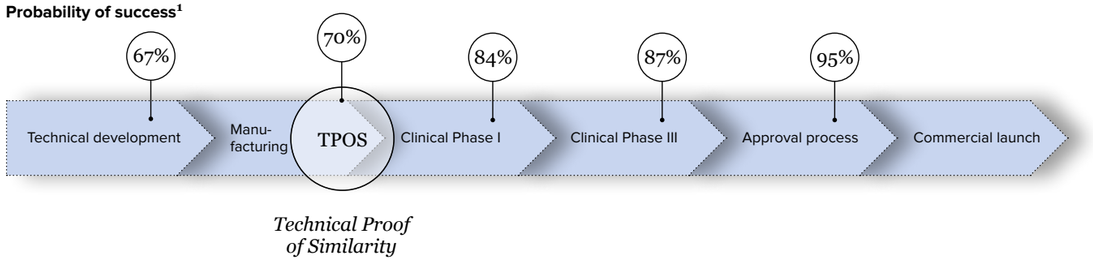
The development of new biosimilar drugs is the foundation for the Group's sustainable long-term growth. Within the area of biosimilars development, Formycon has the following projects in various stages of development:

[1] Blockbuster is defined here as a drug with annual sales of more than USD 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 development

Probability of success[1]



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, remains high throughout the course of its development, as illustrated below. In the case of the development of an innovative drug, the success rate is dramatically different, with only one in twelve projects in preclinical development, on average, reaching final approval.[2]

Business objective and strategy

Formycon's guiding aim is to become the leading independent specialist and partner of choice in the rapidly growing biosimilars market. The Group strives to help democratize patient access to highly effective drugs, while at the same time relieving the financial burden on the world's healthcare systems, by acting as a driving force in the development of biosimilars.

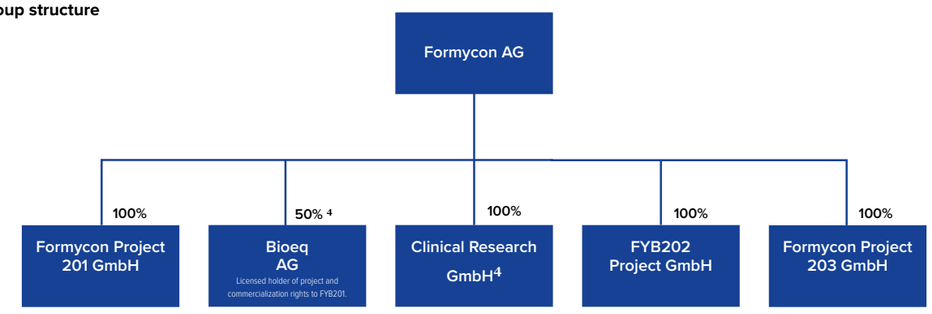
Group structure

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[3]), 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.

The corporate structure of Formycon Group reflects the establishment to date of dedicated legal entities for certain individual biosimilar projects, particularly in advanced stages of development. Formycon AG performs research and development activities not only for its own projects but also on behalf of its

1 The path towards a tailored clinical biosimilar development, Schiestl et. al 2020
2 Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)
3 Bioeq GmbH was legally renamed to "Clinical Research GmbH" with effect from Dec. 19, 2023.

Group structure



affiliated companies (subsidiaries) and 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 Open Market "Scale" segment for growth companies. 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.

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 as well as for the design and coordination of the supply and production chains necessary to bring advanced-stage biosimilar candidates to market.

Management and oversight

The Formycon AG parent entity is, as required under the German Stock Corporation Act (Aktiengesetz) for all German stock corporations, 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 is elected by the Annual General Meeting and, as of June 30, 2024, consisted of four members. In order to broaden the Board's international representation and expand its industry and financial expertise, the Annual General Meeting on June 12, 2024 voted to expand the Supervisory Board from four to five members and to elect three new and independent members: Dr. Bodo Coldewey, managing director of WEGA Invest GmbH, the family office of the Wendeln family, and Nicholas Haggar, a long-time pharmaceutical industry executive who is currently chief executive officer of Healthqube Ltd. were elected to replace Dr. Olaf Stiller, heretofore Chair of the Supervisory Board, and Peter Wendeln, heretofore Deputy Chair, who had previously announced their respective resignations with effect from the end of the Annual General Meeting. Colin Bond, former chief financial officer of Sandoz Group AG, was elected as the new fifth member of the enlarged Supervisory Board with effect from October 1, 2024.

4 The other 50% of Bioeq AG is held by Polpharma Biologics BV

Executive Board members and allocation of responsibilities

Dr. Stefan Glombitza
CEO (Chief Executive Officer)

Since July 1, 2022 (current term of office ends Dec. 31, 2024), previously served as COO (starting 2016)

Areas of responsibility:
Corporate Strategy and Product Development

- Protein and Process Sciences
- Drug Product
- Program Management
- Regulatory Affairs and Quality Management

Nicola Mikulcik
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
- Supply Chain and Logistics
- Intellectual Property Litigation
- Procurement

Dr. Andreas Seidl
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

Enno Spillner
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 and Compliance
- Human Resources
- Corporate Communications, Investor Relations and Corporate Social Responsibility / ESG
- Information and Business Technology
- Facility/Environment/ Health and Safety

Remuneration of Executive Board and Supervisory Board

The remuneration of Executive Board members includes both fixed and variable components. Formycon does not yet publish a separate remuneration report. The remuneration of Supervisory Board members, which was most recently determined at the 2024 Annual General Meeting and with effect from June 12, 2024, is € 80,000 per fiscal year for the Chair of the Supervisory Board, € 50,000 for the Deputy Chair, and € 30,000 for other members. Each Supervisory Board member receive additional fixed remuneration of € 5,000.00 per fiscal year for committee work, with the Chair of the Audit Committee receiving fixed committee remuneration of € 15,000 per fiscal year and the Chair of the Nomination and Remuneration Committee receiving € 10,000. In addition, each member of the Supervisory Board and each member of a committee receives an attendance fee of € 1,000 per Supervisory Board or committee meeting up to a maximum of eight meetings per fiscal year, with Chair of the Supervisory Board and each committee chair receiving an attendance fee of € 1,500 per chaired meeting, up to a maximum of eight meetings per fiscal year. For 2024, the new remuneration schedule will be applied *pro rata temporis*.

Important processes, partners and sales markets

The development of biosimilar drugs for the world's most stringently regulated markets demands exacting standards for their safety, quality 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).
With the acquisition of Bioeq GmbH in 2022, which as of Dec. 19, 2023 was renamed to "Clinical Research GmbH", Formycon expanded the spectrum of its in-house development resources to encompass clinical development and the management of clinical trials. As a sponsor of such clinical studies, Clinical Research GmbH is obliged to comply with detailed regulations on Good Clinical Practice (GCP) when conducting clinical trials of medicinal products for use in humans. Even where not statutory, these GCP guidelines are an international standard recognized throughout the world, serving to protect patients and to ensure the integrity and correctness of the data and findings generated through such clinical studies. Compliance with GCP guidelines on the part of the study sponsor, the participating study centers and other parties involved in the clinical study process is verified during GCP inspections conducted by local health authorities.

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. The entry of the Hungarian specialty pharmaceutical company Gedeon Richter Plc. in February 2024 as a strategic investor in Formycon, with Gedeon Richter's capabilities and scope as a multinational player with core competencies in manufacturing, has opened new opportunities to jointly exploit long-term strategic opportunities in the future in the areas of development, manufacturing and commercial value streams.

For the global marketing of biosimilar products, Formycon relies upon commercialization partnerships and cooperation agreements with internationally renowned pharmaceutical players such as Fresenius Kabi AG, Teva Pharmaceutical Industries Ltd. and Sandoz AG.[1]

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

In terms of areas of application for biosimilars globally, oncology currently dominates. According to the International Agency for Research on Cancer (IARC), some 20 million new cancer diagnoses were reported worldwide during 2022, and by the year 2050, the IARC forecasts that this number will increase by 77% to 35 million new cancer cases each year.[2] At the same time, the number of disease areas in which biosimilars are approved and in active use is, in the aggregate, steadily increasing. The growth in recent and expected biosimilar approvals is particularly striking for indications in immunology and ophthalmology. A study in the UK found that one in ten people suffer from some kind of autoimmune disease.[3] According to the Global Autoimmune Institute, the most common diagnoses are psoriasis, Crohn's disease, lupus, and type 1 diabetes.[4] The global market for autoimmune disease therapeutics is forecasted to grow from USD 137,557.2 million in 2023 to USD 205,584.6 million by the end of 2033, which is an average annual growth rate (CAGR) of 4.1% over these ten years.[5]

While originator biopharmaceuticals are already available for the effective treatment of many serious diseases, these powerful drugs are also 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 brought to 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, thereby also 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), on average, of 16.5%[6]. Despite substantial barriers to market entry due to high development costs (approx. USD 150 to 300 million per biosimilar development project), long development cycles (seven 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 and Sandoz 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 at the same time that 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, and to distinguish itself competitors through its innovative development concepts, the reliability of the scientific processes which it uses, 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" (page 35).

[1] Zu Beginn des Jahres 2024 wurden die FYB201 Kommerzialisierungsrechte von Coherus BioSciences, Inc. auf die Sandoz AG übertragen.
[2] https://www.tagesschau.de/wissen/gesundheit/krebs-who-zunahme-100.html
[3] Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: a population-based cohort study of 22 million individuals in the UK, The Lancet
[4] https://www.autoimmuneinstitute.org/understanding-autoimmune-disease/
[5] Autoimmune Disease Therapeutics Market: Global Industry Analysis 2017-2022 and Opportunity Assessment 2023-2033, Future Market Insights 2023

Corporate strategy and management

Formycon's strategic goal is to sustainably expand the scope of its business activities with the aim of becoming the leading independent specialist and partner of choice in the rapidly growing biosimilars market. In order to achieve this goal, Formycon will continue to invest heavily into the advancement and expansion of its project pipeline so that it is able to bring new biosimilars to market at regular intervals. In parallel with this strategic thrust, Formycon is pursuing an organizational growth strategy so that it has the resources to compete and be sustainably growing and profitable as a biosimilars specialist. In order to achieve this strategic vision, 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 to 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 particular market conditions. There has been no need for significant change in Formycon's strategic orientation compared to the prior-year period.

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

Formycon stands out from competitors, particularly large pharmaceutical companies with biosimilar ambitions, above all in the high level of agility and flexibility in its operational activities, combined with very high quality. In biopharmaceutical development, 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 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 239 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 upon a defined set of key financial performance indicators. As of the first half of fiscal year 2023, the comparison period for this report, these were revenue, EBITDA, net profit/loss, and working capital.

In deciding upon the most relevant and meaningful financial performance indicators for the full 2023 fiscal year, the Executive Board decided, subsequent to the closing date for the first half of 2023, to replace net profit/loss with Adjusted EBITDA, in particular because net profit/loss and certain other financial statement items have, starting in 2023, been significantly influenced by the fair value remeasurement of the conditional purchase price payment obligations under the Athos transaction, the valuation of which is impacted by changes in external factors, in particular the applicable market rates used to calculate the weighted average cost of capital (WACC). An increase (decrease) in the WACC would have a material positive (negative) impact on reported net profit/loss. Due to the high volatility and influence of these external valuation parameters, net profit/loss does not, in the opinion of the Executive Board, provide a suitable measure of the Group's overall after-tax operating performance, i.e. taking into account all income and expense items in the respective period.

Key financial performance indicators in accordance with IFRS
in € million

	1H 2022	1H 2023	**1H 2024**
Revenue	17.6	43.8	**26.9**
EBITDA	-7.6	7.3	**-16.9**
Adjusted EBITDA	-8.7	1.1	**-2.1**
Working capital	30.7	55.0	**63.0**

Accordingly, the Executive Board has since been managing, and will henceforth manage, the Group based on 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.

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 the operational success of 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 is therefore also excluded from EBITDA, which is derived and calculated from reported operating profit (EBIT). Adjusted EBITDA, in contrast, includes 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 into 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 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

General economic conditions

During the first half of 2024, the global economy once again proved to be remarkably resilient, despite the ongoing war in Ukraine, widespread inflationary concerns, and high interest rates. Global economic growth has been remaining stable and inflation slowly returning to normal.[1] The International Monetary Fund (IMF) forecasts global economic growth of 3.2% for 2024 and 3.3% for 2025.[2] The German economy, in contrast, is expected to grow just 0.2% in 2024, thus lagging significantly behind global growth.[3]

Although the German economy showed some modest signs of recovery at the start of 2024, indicators as of this writing, in the early summer, continued to paint a subdued picture of the German economy, with the noticeable brightening of business sentiment indicators bringing only incremental gains in real growth. While first-quarter GDP growth of 0.2% over the preceding quarter suggests a modest recovery dynamic, the figure was 0.9% lower than the prior-year quarter. The main drivers of growth were construction investment, which benefited from favorable weather conditions, and foreign trade. On the other hand, capital investment and private consumption were quite weak.

The latest sentiment indicators for private consumption, such as the GfK Consumer Climate index and the HDE Consumer Barometer, have recently deteriorated somewhat, dampening the previous upward trend. Nevertheless, domestic demand should increasingly pick up in view of the overall robust employment situation in Germany, moderating consumer price increases, and rising real incomes.[4] For June 2024, the German Federal Statistical Office (Destatis) calculated an annual inflation rate of 2.2% compared to the same month in 2023.[5]

Despite the overall weak economy, the labor market was robust. In May 2024, some 45.9 million people residing in Germany were employed. According to preliminary calculations by the Federal Statistical Office, the number of employed persons rose by 20,000 people compared to the previous month, adjusted for seasonal factors. In April 2024, the number of employed persons increased by 25,000 compared to the previous month, and thus by a similar increment.[6]

The economic situation in Germany in May 2024 points to a gradual economic recovery, supported by a stabilization of the labor market and the uplifting effects of foreign trade. However, uncertainty remains high due to geopolitical risks and challenges facing the global economy.

In recent past years, crises and war-related special effects created supply bottlenecks and led to significant price increases for energy and in upstream production stages. While Formycon's business operations are not directly affected by the weak economic situation, they may nevertheless be affected by reduced availability of materials as well as interest rate increases and higher prices for products and services.

[1, 2] https://www.imf.org/en/Publications/WEO/Issues/2024/04/16/world-economic-outlook-april-2024
[3] https://www.imf.org/en/Publications/WEO/Issues/2024/07/16/world-economic-outlook-update-july-2024
[4] https://www.bmwk.de/Redaktion/DE/Pressemitteilungen/Wirtschaftliche-Lage/2024/20240715-die-wirtschaftliche-lage-in-deutschland-im-juli-2024.html
[5] https://www.destatis.de/DE/Presse/Pressemitteilungen/2024/07/PD24_256_611.html
[6] https://www.dashboard-deutschland.de/indicator/tile_1667822587333?origin=dashboard&db=arbeitsmarkt&category=arbeitsmarkt

Developments in the global biosimilars market

The global biosimilars market has been growing for a number of years and is, under various expert forecasts, expected to continue this dynamic growth. According to IQVIA, a leading provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry, the global biosimilars market will grow to USD 74 billion by 2030. Biosimilars are the fastest-growing sub-segment within the pharmaceuticals sector. Over the next ten years, more than 45 biological blockbusters with sales of over USD 200 billion will lose their exclusivity.[7]

Biosimilars are clearly on the rise worldwide, but it should also be noted that there are regional differences in market penetration. IQVIA[8] expects the overall U.S. market for biosimilars – which is of utmost importance to Formycon and in which the company has been building share since the launch of its Lucentis® biosimilar in 2022 – to generate sales of up to USD 49 billion by 2027. With a compound annual growth rate (CAGR) of 26% in 2023 and 2024, the U.S. market remains among the world's most rapidly growing.

The European market for biosimilars has changed significantly since 2008 and has been shown showing strong momentum, particularly in recent years. In 2022, biosimilars accounted for 63% of total biological drug sales, compared to just 36% in 2019.[9] Since the first biosimilar received approval in 2006, a total of 105 biosimilars have been approved in the European Union.[10] The European biosimilars market generated sales of some € 9 billion in 2023.[11] Studies forecast an average annual growth rate of 8% through 2028.[12]

The Asia-Pacific market, while smaller, is forecast to experience the highest growth rate through 2028, driven by low government regulation and increasing collaborations between major leading players and regional providers.

Global competition in the biosimilars market continues to intensify. Asian manufacturers, particularly from China and India, are continuously expanding their know-how in biotechnology-based production as well as biopharmaceutical development. Nevertheless, Europe continues to hold a dominant role as a production location due to its high level of expertise in the manufacture of innovative and technically complex biopharmaceuticals. In addition to Germany, the UK and France are, in particular, among the most rapidly expanding national markets. For 2021 to 2031, IQVIA expects the UK market to grow by 213% and the French market by 260%.[13]

Within Europe, a further 110 biologicals are expected to lose their market exclusivity by the end of 2032. The potential available reference market for these products facing loss of exclusivity (LoE) is estimated

[7] Blockbuster is defined here as a drug with annual sales of more than $1 billion in the peak year. Analysis based on timing of US patent expiry. Source: Evaluate Pharma database, Apr 2022; press reports; McKinsey analysis
[8] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027
[9] https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/artikel-in-der-fachpresse/2023/know-how_iqvia_mahp_01-2023.pdf
[10] https://de.euronews.com/gesundheit/2023/10/19/eu-will-biosimilars-fur-patienten-verfugbarer-machen
[11] https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2023
[12] https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars
[13] https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/

at approx. € 30 billion in the years between 2030 and 2032. Over the next 10 years, the largest numbers of LoE opportunities for biosimilars are expected to be in the areas of oncology (24%), immunology (11%) and blood disorders (10%).[1]

Summary statement of Executive Board on business performance and economic environment

Formycon can look back upon a very successful first half of the fiscal year, with significant operational, commercially, regulatory and clinical progress in its various ongoing development projects. The development of Formycon's commercial partnerships, product sales and financing activities has likewise been highly satisfactory.

Consolidated first-half financial figures for Formycon Group were in line with expectations. In addition to significant sales revenue following the successful commercialization and market launch of FYB201 in the UK, the United States and individual EU countries, as well as revenue from the provision of development services for Formycon's out-licensed biosimilar candidates, period revenue of € 26,893K also includes pro rata realizations of milestone payments from the FYB202 commercialization partnership with Fresenius Kabi AG. Consolidated EBITDA for the period of negative € 16,904K was largely attributable to research and development expenses as well as general and administrative expenses. Formycon Group's liquidity position remained stable at € 40.7 million as of June 30, 2024, supported by the capital increase carried out in February, generating gross issuance proceeds of approx. € 82.8 million.

The global market for biosimilars continued its growth dynamic, with signs for the future pointing towards continued expansion. The global biosimilar market is expected to grow to more than USD 100 billion by 2032.[2]

Formycon is able to take satisfaction from the commercial performance of its first biosimilar product, FYB201. In the United States, Formycon's initial distribution partner Coherus BioSciences, Inc. was able to successfully launch this new Lucentis® biosimilar under the U.S. trade name CIMERLI® and secure significant market share, even against biosimilar competitors. According to information from Coherus BioSciences, Inc., U.S. sales of CIMERLI® totaled USD 32.4 million as of March 31, 2024.[3] Following the strategic realignment of Coherus BioSciences, Inc., the marketing rights for CIMERLI® along with the Coherus BioSciences ophthalmic sales team were transferred with effect from March 1, 2024 to Sandoz AG, which thereby took over the distribution of CIMERLI® within the United States. As of April 30, 2024, CIMERLI®'s market share of the U.S. ranibizumab market was 45.1%.[4]

Within the UK, Formycon's distribution partner Teva Pharmaceuticals Inc. has 79% of the ranibizumab market for the relevant indications under the trade name Ongavia® and has thus already established a very strong market position.[5]

FYB201 was introduced into additional markets during the first half of 2024, including Canada and Saudi Arabia. As of the reporting date, FYB201 is now being actively marketed in a total of 19 countries.

Formycon's participation in the overall commercial success of FYB201 is reflected in Adjusted EBITDA for the period, further details of which may be found in the segment reporting section of the Condensed Notes to the Interim Consolidated Financial Statements (p. 68/69).

In the case of FYB202, Formycon's candidate biosimilar to Stelara®, a settlement agreement was concluded with Johnson & Johnson during the first half of 2024 which will enable the commercial launch of the biosimilar in Europe and Canada. It was agreed that the terms of the agreement will remain confidential. U.S. market entry, under a separate agreement concluded last year covering the United States, is expected no later than April 15, 2025.

An important further milestone was achieved during the first half with the approval of FYB203, Formycon's biosimilar to Eylea®. On June 28, 2024, FYB203/AHZANTIVE®[6] received FDA approval for the treatment of patients with neovascular ("wet") age-related macular degeneration (nAMD) and other serious eye diseases such as diabetic macular edema (DME), diabetic retinopathy (DR) and macular edema due to retinal vein occlusion (RVO). The decision on approval in Europe is expected by the beginning of 2025 at the latest. MS Pharma will be responsible for marketing FYB203 in the Middle East and North Africa (MENA) region. Negotiations regarding commercialization partnerships for the U.S. and Europe are currently in an advanced stage. While no agreement has yet been reached with the manufacturer of the reference drug, Regeneron Pharmaceuticals, Inc., regarding a potential market launch date, intensive negotiations are in progress. The FYB206 project entered the clinical phase with the successful recruitment of the first patient into phase I trials to compare the pharmacokinetics (PK), safety and tolerability of FYB206 with the reference drug Keytruda® (pembrolizumab) in patients with malignant melanoma, a particularly aggressive form of skin cancer. A parallel phase III study will compare the safety and efficacy of FYB206 to Keytruda® in patients with non-small cell lung cancer. Recruitment is scheduled to commence in the second half of the year.

With the entry of Hungarian specialty pharmaceutical company Gedeon Richter as a strategic investor through its participation in the capital increase transaction in the early part of the year, Formycon was able to raise € 82.84 million against the issuance of new shares amounting to 9.08% of total capital. The two companies share not only a strong conviction in the enormous potential of biosimilars but also areas of strategic overlap. The investment transaction specifically opens up future, long-term strategic opportunities to jointly exploit synergies in the areas of drug development, manufacturing and commercial value streams.

The proceeds from the capital increase will primarily be used to push forward with development efforts in Formycon's existing biosimilar pipeline, in particular the FYB206, FYB208 and FYB209 projects. In addition, the launch of development work on FYB210, a new biosimilar candidate, is planned for the second half of the year.

[1] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/
[2] https://www.centerforbiosimilars.com/view/global-biosimilar-market-projected-to-reach-1-3-trillion-by-2032
[3] https://investors.coherus.com/news-releases/news-release-details/coherus-biosciences-reports-first-quarter-2024-financial-results
[4] IQVIA Weekly WSP Data
[5] IQVIA 04/2024 Monthly Data R3M = Rolling three Month
[6] AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH

Financial performance

The Group generated consolidated revenue of € 26,893K during the first six months of 2024, in line with expectations, compared to € 43,789K during the prior-year period. The difference was primarily the result of recognized significant additional non-recurring revenue from advance payments and milestone payments in the previous year as well as the accrual of expected success payments of € 23,664K as of June 30, 2023 realized from the FYB202 project under the partnership with Fresenius Kabi, which had been newly established. For comparison, € 11,347K was realized pro rata during the current reporting period. Revenue from Formycon's out-licensing of FYB201 during the first half of 2024 amounted to € 3,760K (1H 2023: € 1,149K). The remaining revenue share results from the charging of development costs for the FYB201 and FYB203 projects.

Consolidated EBITDA was negative € 16,904K (1H 2023: € 7,262K), reflecting the decline in revenue and increases in research and development as well as general and administration expenses. Adjusted EBITDA, which additionally includes the earnings contributions from Bioeq AG in the amount of € 14,757K (1H 2023: neg. € 6,162K), was negative € 2,147K for the six-month period, compared to € 1,100K in the prior-year period. This adjusted EBITDA performance underscore the increasingly and important contribution of FYB201 product sales. The period net loss for the first half of 2024 was negative € 10,094K (1H 2023: period net profit of € 1,804K). The prior-year period had benefitted from a non-cash gain from the decrease in the fair value of the contingent purchase price payment obligations resulting from an increase in the applicable discount rate. During the current period, in contrast, the change in the fair value of the contingent purchase price payment obligations resulted in additional interest expense of € 4,970K, which affected the period net loss accordingly.

During the first half of 2024, Formycon continued to vigorously push forward with the development of its biosimilar candidates and to generate significant revenue through the provision of development services for its out-licensed projects FYB201 and FYB203. Under this arrangement, Formycon generates revenue through ongoing contractual payments in the amount of € 11,786K (1H 2023: € 18,976K) received for development services which Formycon provides 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.

Under the marketing agreement concluded with Fresenius Kabi in 2023 for FYB202, Formycon anticipates success-based milestone payments through to approval by the FDA and EMA as well as subsequent license income from future product sales, which will likewise be reflected in revenue. Compared to the prior-year period, the progress of the development work on Formycon's early stage biosimilar candidates FYB208 and FYB209 has led to an increase in research and development expenses. Moreover, costs for the FYB207 project during the current period were significantly less than in the first half of 2023. Through the combination of these effects, research and development expenses were, in total, significantly lower than during the prior-year period.

The Group ended the first half of 2024 with a strong equity ratio of 60.9% (Dec. 31, 2023: 56.5%). The Group's non-current assets are covered by equity and non-current liabilities for conditional purchase price payment obligations, which is suggestive of a solid balance sheet structure. More than one third of current assets are in the form of liquid and near-liquid assets. The increase in customer contract assets is mainly due to the recognition of expected future revenue from success-based payments under the marketing agreement with Fresenius Kabi.

As in the past, cash and cash equivalents as well as working capital, the Group's key liquidity indicators, remained adequate, with current assets of € 95,881K offset by current liabilities (excluding current portion of conditional purchase price) of € 18,246K. The Group did not have any bank loans during the period. During the reporting period, the entire remaining € 20,485K under the shareholder loan was repaid, along with accrued interest, leaving zero outstanding as of the reporting date out of the total available credit line of € 48,000K.

To significantly further strengthen the Group's financial structure, 1,603,877 newly issued shares were privately placed with strategic investor Gedeon Richter, as a capital increase under exclusion of subscription rights, at a price of € 51.65 per share.

As of June 30, 2024, the Group held cash and cash equivalents in the amount of € 40,620K (Dec. 31, 2023: € 27,035K) and working capital (including cash and cash equivalents) in the amount of € 63,032K (Dec. 31, 2023: € 38,889K). The sizable respective increases over the prior year reflect the capital increase transaction along with positive business performance. Reference is made to the Consolidated Statement of Cash Flows.

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 for the whole group.

Overview of financial position

The Group's liquid and near-liquid assets, or more specifically working capital as described above, along with remaining availability under the shareholder loans as of the reporting date, are sufficient to ensure further financing of the development projects.

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. There are currently no significant interest rate risks on the liquidity side.

Investment analysis

Significant investments in long-term assets currently consist primarily of capitalized development costs for the FYB206 project. 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.

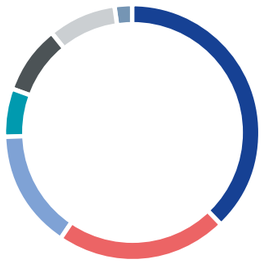
As of June 30, 2024, Formycon Group employed a total headcount of 239 persons (June 30, 2023: 224).

Formycon Group's staffing as of June 30, 2024, expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff, is shown below, divided by functional area and including a comparison to June 30, 2023:

Formycon Group staffing by function (in FTE, rounded, including Executive Board members)

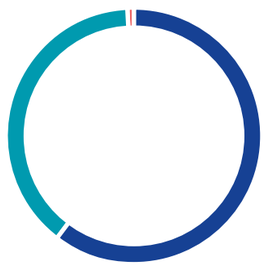
	1H 2024	1H 2023	Change
Research and development	**170.0**	157.1	**+8.2%**
Business operations	**12.5**	9.6	**+30.2%**
General and administrative	**29.9**	23.7	**+26.2%**
Total	**212.4**	190.5	**+11.5%**

Educational level of Formycon staff



37.8 % Doctorate
21.8 % Master's
15.1 % Master's equiv. (Diplom)
5.9 % Bachelor's
8.8 % Vocational training (technical)
8.5 % Vocational training (administrative)
2.1 % Not (yet) completed or none

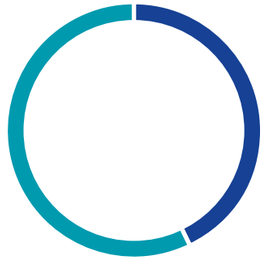
Diversity of Formycon staff



57.9 % Female
41.3 % Male
0.8 % Not specified

Formycon *employs* **staff** from a total of **32** different **countries**

Division of second-level management by gender



43.3 % Female
56.7 % Male

Division of all management positions by gender

35.3 % Female
64.7 % Male

Staff expenses for Formycon AG during the first half of 2024 were € 12,180K (1H 2023: € 10,650K), with the increase due primarily to the greater average number of employees.

Formycon Group's workforce is highly qualified, particularly in terms of educational level, and training is also a company priority. As of June 30, 2024, 80.6% of the Group's employees have completed a university degree, which in the case of 37.8% is a doctoral degree. 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 one trainee as an IT specialist for systems integration.

As to gender diversity, some 60% of the Group's workforce is female. The employee average age as of June 30, 2024 was 41 years. Formycon is proud of the diverse organization that it has developed over the years. The international diversity of Formycon's staff, from 32 different countries, reinforces its self-image as a truly global organization and biopharmaceutical company.

Research and development

Because Formycon has been, over the past fiscal year 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 and approval management 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, 2024, a total of 170.0 group employees were, on a full-time equivalent (FTE) basis, working in research and development (June 30, 2023: 157.1). During the reporting period, consolidated group research and development investments of € 16,567K were capitalized, which are costs for the continued development of FYB206 project. In the area of patent protection, Formycon continued to push forward with the internationalization of its pending patent applications and to manage and uphold patents already granted. Product development activities are proceeding on schedule, and thus prospects for the success of these development activities remain strong. Including capitalized development costs for the FYB202 project acquired as part of the acquisition transaction, the total book value of these capitalized development costs as of June 30, 2024 was € 529,745K.

The productivity of Formycon's research and development staff, measured in terms of hours directly allocable to development projects, remained at the high level of previous years. During the reporting period, 85.1%* (1H 2023: 85.1%*) of all hours worked were project related. Over this same period, 16.6%* (1H 2023: 14.6%*) of hours worked were performed by employees who are not assigned to the research and development area.

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 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.

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.

Twice each year, the risk report is presented to the Executive Board, which examines 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; industry and market risks; financial risks; workplace safety, organizational and patent risks; and operational risks.

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. Nevertheless, the development of a biosimilar may cost in the range of USD 150 to 300 million, 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 advanced-stage biosimilar candidates, Formycon is focused on three of the world's best-selling biopharmaceuticals with combined 2023 global sales revenue of more than € 22 billion, so that – provided that their development reaches successful completion – the profitability of these projects, as they stand right now, seems assured.

Industry and market 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 have been enabling the treatment of diseases which a few decades or even years ago were regarded as untreatable or only poorly treatable. Biopharmaceuticals, in particular, have been a significant driver of these treatment advances. Of the world's best-selling drugs, most are biopharmaceuticals. Specifically within Germany, biopharmaceuticals comprised 34.5% of the total drug market in 2023 (€55.7 billion), corresponding to some € 19.2 billion in sales revenue – and the trend is continuing upward. At the same time, however, the high cost of these powerful treatments, which in some cases may exceed € 100,000 per patient per year, 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.

Environmental protection, health protection, 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. 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 regarded safety and the protection of employees and the environment is monitored internally on an ongoing basis. Moreover, the Group constantly seeks out 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.

Financing and liquidity risks

Formycon's liquidity situation and equity capitalization remain 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. As most of the Group's 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.

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 in the case of the FYB201 and FYB203 projects through partial or total out-licensing deals. Moreover, Formycon has been granted an available line of credit in the amount of up to € 48 million by a consortium of two major company investors: Athos and the healthcare-focused investment group Active Ownership. Out of this total availability, € 40 million was drawn down, of which € 20 million was already repaid in the first half of 2023 and the remaining € 20 million outstanding in the first quarter of 2024. The line of credit is thus currently undrawn and flexibly available in its entirety until its scheduled expiry on May 31, 2025.

The possibility cannot be entirely excluded, however, that such one or more 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 will continue to fund its future development pipeline projects from its own financial resources, with the aim of moving these into attractive partnership arrangements, in whole or in part, starting from a certain product development stage.
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 long-term financial resources. There are, at present, no identifiable fundamental risks which would jeopardize the Group's near and long-term continued existence. The failure of current or future development projects could, however, result in fundamental risks, depending on the relevance of the respective project to Formycon Group as a whole.

Organizational 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.

Patentrisiken

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 U.S., such legal actions can be very expensive. In the worst case, such a dispute could result 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 a 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.

Staff 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.

General 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 allowances 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.

Risks relating to clinical trials and to the role of Clinical Research GmbH as clinical trial sponsor

With the takeover and integration of Bioeq GmbH in May of 2022, Formycon expanded the scope of its drug development capabilities to include clinical development and the direct management of clinical trials. Bioeq GmbH, a legally separate subsidiary of Formycon Group which has since been legally renamed to "Clinical Research GmbH", continues to serve, as it did before its acquisition by Formycon, in the role of "clinical trial sponsor" for Formycon-developed biosimilar candidates and thus as the official contracting entity for these clinical trials. In its role as clinical trial sponsor, Clinical Research GmbH bears not only financial risks but also the risk of liability towards participating patients or other test

subjects. With the acquisition of Clinical Research GmbH as a subsidiary company belonging to Formycon Group, these risks are effectively assumed by Formycon.

Formycon and Clinical Research GmbH manage these risks 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, Clinical Research GmbH 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.

Legal 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.

Additional risks arise from the Group's compliance obligations. Actions or inactions by the Group could, for example, be legally contested, inadequate 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 specific 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.

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.

Competitive risks

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, such as a partner company named in this report, is also a competitor. 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, and Sandoz but also smaller and highly specialized biosimilars companies such as Alvotech, Celltrion and Xbrane. The competition situation in each specific case will depend upon the pricing of the reference drug as well as the pricing of any new competitors in the market. 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 overextended 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 take 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.

Special risks relating to geopolitical events

The military conflict between Russia and Ukraine involves risks that cannot yet be assessed but which, in particular, have a bearing upon the cost and availability of energy in Germany and may make raw materials and preliminary products as well as services which are important to Formycon 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 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.

In addition, the Islamist militant group Hamas launched a surprise attack on Israel from the Gaza Strip on October 7, 2023. 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.

There is significant uncertainty about the extent and duration of disruptions which could directly or indi-

Opportunities

rectly 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.

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.

At the same time, the level of competition in the area of biosimilar development is generally, with few exceptions, modest compared to the market for conventional generic drugs due to the comparatively high barriers to market entry, in particular the complexity of producing biopharmaceuticals and the specialized expertise required. 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. This demographic segment has a higher incidence of requiring intensive medical treatment. In addition, the 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 growth of both the market environment and Formycon own business 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, there have been no fundamental changes in the risks described above. With regard to the general risks associated with the development of biosimilars described above, the Executive Board has reviewed its assessment of the risk level of this category, in particular 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 this risk should, in accordance with the criteria of the risk matrix, continue to be assessed as "medium".

Summary risk matrix

Risk	Risk type	Assessed risk level	Change
General risks associated with the development of biosimilars	Strategic	Medium	→
Risks relating to clinical trials and to the role of Clinical Research GmbH as clinical trial sponsor	Strategic	Low	→
Patent risks	Strategic / Commercial	Medium	→
Regulatory and political risks	Strategic / Commercial	Medium	→
Industry and market risks	Commercial	Medium	→
Competitive risks	Commercial	Medium	→
Financing and liquidity risks	Financing	Medium	→
Controlling	Operating	Low	→
Environmental protection, health protection,	Operativ	Niedrig	→
Organizational risks	Operating	Low	→
Staff risks	Operating	Medium	→
Legal risks	Operating	Medium	→
Special risks relating to geopolitical events	Operating	Low	→

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

	Probability of occurrence (PoO)		
	< 25 %	25 – 75 %	> 75 %
< € 10 million	Low	Low	Medium
€ 10 – 50 million	Low	Medium	High
> € 50 million	Medium	High	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, 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 viable and/or successful.

Future development of Formycon Group

The development of biosimilars is the strategic focus of Formycon Group and the fundamental basis for its sustainable long-term business growth.

With the launch of its first biosimilar product in 2022 and 2023, Formycon entered a new phase of its corporate development in which expected operating cash flows should open up new growth opportunities for the company. In addition, through the 2022 transaction with Athos KG and the associated acquisition of a 50% share of biosimilar FYB201 and a 100% share of biosimilar candidate FYB202, Formycon will now be able to enjoy a significantly higher share of future revenues and earnings from the marketing of these drugs.

It is planned to invest the expected cash inflows from these product sales primarily into the expansion of Formycon's development pipeline. In doing so, we will have achieved key conditions necessarily to further strengthen Formycon's position as a global and independent player in the biosimilars market segment and to further build the Formycon organization into a leading and sustainably profitable specialist within this rapidly growing segment.

On the capital markets side, Formycon is also considering the possibility of upgrading its share listing to a more highly regulated stock market segment such as the Frankfurt Stock Exchange "Prime Standard" segment, thereby raising the appeal of its shares, particularly among international and institutional investors, and ultimately broadening its shareholder base.

Product development

For the second half of fiscal year 2024, Formycon continues to expect meaningful contributions to its revenue and earnings from sales of its FYB201 product, the biosimilar to Lucentis® being marketed under the brand names Ranivisio®[1] , Ongavia®[2] , CIMERLI®[3] , Ravegza®[4] , Uptera®[5] and Ranopto™[6]. At the start of 2024, Formycon's U.S. commercialization partner Coherus BioSciences, Inc. sold the marketing rights for CIMERLI® to Sandoz AG, which became the new commercialization partner for FYB201 biosimilar CIMERLI® in the United States with effect from the transaction closing on March 1, 2024.

Following the recent approval by the U.S. Food and Drug Administration (FDA) of FYB203 (AHZANTIVE®), the biosimilar to Eylea®, Formycon likewise expects approval decisions in 2024 from both the European Medicines Agency (EMA) and FDA for FYB202, Formycon's candidate biosimilar to Stelara®. The EMA's decision on FYB203 is expected by the beginning of 2025 at the latest.

Assuming that approval of these two new biosimilars is successfully obtained, Formycon expects to generate future revenue, which may be deferred revenue, from contractual milestone payments as well as from sales of both new drugs.

As to FYB206, Formycon's candidate biosimilar to Keytruda®, the first patient has now been recruited into phase I clinical trials. This launch of clinical development puts Formycon among the leading biosimilar developers to have announced the entry into the clinical phase of a pembrolizumab biosimilar for the EU and U.S. markets. Recruitment for parallel phase III clinical trials was also commenced as planned (after the reporting period). Formycon's two newest biosimilar candidates FYB208 and FYB209 are both in the early development stage. In the second half of 2024, Formycon hopes to launch development of an additional biosimilar candidate (FYB210) as the next step towards a broad and sustainable project pipeline.

2024 financial outlook for Formycon Group

In terms of its product development activities and capabilities, Formycon expects to attain further key operational milestones during fiscal year 2024, which will in turn form the basis for the Group's transformation from a successful developer to a biosimilars leader which will, over the medium term, become sustainably profitable. With the market launch and successful establishment of its next two biosimilar candidates FYB202 and FYB203, Formycon specifically seeks to achieve EBITDA and cash flow profitability within the medium term. Until then and beyond, Formycon is committed to further increasing investment into pipeline projects. In addition, the company intends, where possible, to independently develop its biosimilar candidates through to a more advanced stage in the value chain, which on the one hand will require project investment and thus greater capital, but on the other hand will mean considerably higher participation in subsequent product revenues, thereby significantly and sustainably increasing value creation.

Revenue

Thanks to the continuing progress in establishing Ranivisio®, Ongavia®, CIMERLI® Ravegza®, Uptera® and RanoptoTM (region-specific trade names for FYB201, the biosimilar to Lucentis®) in key global markets, as well as further planned market launches in various other territories, Formycon expects further increases in contributions to the Group's 2024 revenue and earnings from its participation in product sales. In addition, assuming successful regulatory approval, further milestone payments are expected during 2024 for the FYB202 project. Because part of these milestone payments were already recognized and reported in fiscal year 2023 as accrued

1 Ranivisio® is a registered trademark of Bioeq AG
2 Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd.
3 CIMERLI® is a registered trademark ofCoherus BioSciences, Inc.
4 Ravegza® is a registered trademark of MS Pharma Saudi
5 Uptera® is a registered trademark of MS Pharma Jordan
6 Ranopto™ is a registered trademark of Teva Canada Ltd.

Key financial performance indicators in accordance with IFRS in € million

	2023 actual	Outlook for 2024 per Annual Report 2023	1H 2024 actual	Updated guidance for 2024	Significant assumptions and factors
Revenue	77.6	55.0 to 65.0	**26.9**	**55.0 to 65.0**	unchanged
EBITDA	1.5	-25.0 to -15.0	**-16.9**	**-25.0 to -15.0**	unchanged
Adjusted EBITDA	13.3	-15.0 to -5.0	**-2.1**	**-5.0 to 5.0**	Positive marketing development of FYB201 leads to significantly higher at-equity result
Working Capital	38.9	10.0 to 20.0	**63.0**	**35.0 to 45.0**	Early receipt of a profit payment from FYB202 that has already been deferred on the revenue side and is now affecting liquidity due to earlier EU approval

revenue for an expected success-based milestone payment, the full amount of the milestone payments received will not be reflected in 2024 reported revenue.

On an overall basis, we continue to expect reported consolidated revenue for full-year 2024 to be in the range of € 55 to 65 million, which is below the past year's level. This is primarily due to the effect of the milestone revenue accrual described above as well as to declining current revenue for development compensation payments for the largely completed projects FYB201 and FYB203, the realization of which will ultimately help to create greater long-term value for our shareholders.

EBITDA

Formycon's value creation is fundamentally based upon its development pipeline. The Group will therefore continue to invest significantly into its advancing product pipeline, including FYB208, FYB209 and the soon-to-be-launched FYB210 project. Because development expenditures for the FYB206 project are capitalized, these do not flow through EBITDA.

Overall, EBITDA for full-year 2024 is expected to in the range of € -25 million to € -15 million, unchanged from the last report, due to the significant non-capitalized development investments combined with the lower expected revenue for 2024.

Adjusted EBITDA

Adjusted EBITDA additionally includes Formycon's at-equity participation in earnings from Bioeq AG, which was originally expected to be approx. € 10 million in the current fiscal year.

Bioeq AG's result is due to the operational success of our product FYB201, which developed much more positively than previously anticipated over the course of the first half of the year. As a result,

Formycon expects a total at-equity result of € 20 million for 2024, which is why the forecast for adjusted EBITDA has been raised from the original € -15.0 to -5.0 million to € -5.0 to 5.0 million.

Working Capital

Compared to the previous forecast, working capital is expected to be higher in 2024 than originally expected. This is due to the receipt of a cash-effective profit payment already accrued on the revenue side but now anticipated for 2024 (instead of Q1 2025) due to an EU approval for FYB202 expected earlier than originally assumed.

We are therefore raising our forecast from € 10.0 to 20.0 million to a total of € 35.0 to 45.0 million.

Summary statement by Executive Board on expected future development

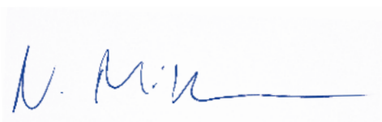
Formycon is not planning any significant changes to its corporate goals or strategy. We aim to continue expanding our position as a global biopharmaceutical company with an exclusive focus on biosimilars and their development while maintaining our high standards of performance and quality. To achieve this goal, Formycon will continue to invest heavily into the development and expansion of our own pipeline and in-house capacities so that we will be able to commercialize new biosimilar products on a regular basis.

In parallel with this strategic thrust, Formycon is pursuing an organizational growth strategy so that we have the resources to compete as a leading and sustainably profitable pharmaceuticals company, specifically within the biosimilars segment. In order to achieve this strategic vision, the Executive Board is open to considering cooperation arrangements and integration in selected areas of the manufacturing process as well as to building Formycon's own commercialization capabilities in certain geographies.

Over both the short and long term, our management focus will continue to be on operational excellence and on the generation of stable cash flows.

Planegg-Martinsried, Germany, August 08, 2024

Dr. Stefan Glombitza



Nicola Mikulcik

Dr. Andreas Seidl

Enno Spillner

Interim Financial Statements of Formycon Group January 1 to June 30, 2024

Condensed Interim Statement of Financial Position in €K

	explanatory note	June 30, 2024	Dec. 31, 2023
Assets			
Non-current assets			
Goodwill		44,534	44,534
Other intangible assets	13	524,921	508,403
Right-of-use (ROU) assets	13	11,051	9,300
Property, plant and equipment		3,663	3,027
Investment accounted for using the equity method	8	181,802	167,044
Financial assets		85,929	90,907
Deferred tax assets		-	-
Total non-current assets		**851,900**	**823,215**
Current assets			
Inventories		2,124	467
Trade and other receivables		10,554	11,612
Contract assets	6	28,806	16,561
Other financial assets		6	6
Prepayments and other assets		13,600	11,335
Income tax receivables		171	131
Cash and cash equivalents		40,620	27,035
Total current assets		**95,881**	**67,147**
Total assets		**947,781**	**890,362**
Equity and liabilities			
Equity			
Subscribed capital	14	17,657	16,053
Capital reserve	10, 14	494,912	412,871
Retained Earnings		73,827	-1,968
Period income (loss)		-10,094	75,795
Total equity capital		**576,302**	**502,751**
Non-current liabilities			
Non-current lease obligations		9,631	7,815
Other non-current liabilities	10, 15	191,020	187,690
Deferred tax liabilities	11	125,230	122,800
Total non-current liabilities		**325,881**	**318,305**
Current liabilities			
Provisions		-	387
Current lease obligations		1,233	1,186
Other current liabilities	15	27,352	51,349
Trade payables		16,948	16,319
Current income tax liabilities		65	65
Total current liabilities		**45,598**	**69,306**
Total liabilities		**371,479**	**387,611**
Total equity and liabillities		**947,781**	**890,362**

Condensed Interim Statement of Comprehensive Income in €K

	explanatory note	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Revenue	6	26,893	43,789
Cost of sales		-24,985	-26,153
Research and development expenses	7	-9,692	-5,170
Selling expenses		-593	-437
Administrative expenses	9, 10	-9,298	-5,543
Other expenses		-314	-142
Other income		6	14
Operating profit/loss (EBIT)		**-17,983**	**6,358**
Income from investments accounted for using the equity method	8	14,757	-6,162
Finance income	8	820	8,960
Finance expense	8	-5,287	-93
Change in Impairments based on the expected credit loss model		-6	-
Net finance income		10,284	2,705
Profit before tax		**-7,699**	**9,063**
Income tax expense	11	-2,395	-7,259
Profit (loss) / Comprehensive income (loss) for the period		**-10,094**	**1,804**
Basic (undiluted) earnings per share (in €)		-0.58 €	0.11 €
Average number of shares outstanding (without dilution)		17,286,654	15,826,442
Diluted earnings per share (in €)		-0.58 €	0.11 €
Average number of shares outstanding (with dilution)		17,286,654	15,955,167

Condensed Interim Statement of Changes in Equity in €K

	explanatory note	Subscribed capital	Capital reserve	Retained earnings	Period income (loss)	Total equity
as of Jan. 1, 2023		**15,129**	**343,419**	**-1,967**		**356,581**
Capital increase against cash contributions		**910**	**69,160**			**70,070**
Costs of capital increase			-1,736			**-1,736**
Effect of stock options granted			696			**696**
Period income (loss)					1,804	**1,804**
as of June 30, 2023		**16,039**	**411,539**	**-1,967**	**1,804**	**427,415**
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**
Effect of stock options granted	10		801			**801**
Period income (loss)					-10,094	**-10,094**
as of June 30, 2024		**17,657**	**494,912**	**73,827**	**-10,094**	**576,302**

Condensed Interim Statement of Cash Flows in €K

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Profit (loss) for the period	-10.094	1.805
Adjustments for non-cash items:		
Depreciation and amortization	1.079	904
Net finance income	-10.285	-2.705
Effect of stock options	802	695
Net loss (gain) arising from disposals of non-current assets	3	16
Other non-cash transactions	256	-
Income tax expense	2.395	7.259
Changes in operating assets and liabilities:		
Decrease (increase) in inventories	-1.656	-394
Decrease (increase) in trade and other receivables	864	-16.656
Decrease (increase) in contract assets	-12.246	-7.026
Decrease (increase) in prepayments and other assets	-2.265	-1.772
Increase (decrease) in provisions	-387	387
Increase (decrease) in contract liabilities	-	1.336
Increase (decrease) in other liabilities	-274	-403
Increase (decrease) in trade payables	628	8.402
Income taxes paid	-5	-179
Net cash used for operating activities	**-31.185**	**-8.331**
Investments in intangible assets	-16.647	-12.313
Investments in property, plant and equipment	-982	-253
Proceeds from loans granted	5.000	-
Interest received	767	236
Net cash used for investing activities	**-11.862**	**-12.330**
Proceeds from issuance of shares	82.843	70.070
Costs relating to issuance of shares	-	-1.736
Inflows from the assumption of financial liabilities	-	-20.165
Payment of lease liabilities	-599	-465
Outflows for the payment of financial liabilities	-25.388	-
Interest paid	-224	2
Net cash from financing activities	**56.632**	**47.706**
Net increase (decrease) in cash and cash equivalents	**13.585**	**27.045**
Cash and cash equivalents as of Jan. 1	**27.035**	**9.820**
Cash and cash equivalents as of June 30	**40.620**	**36.865**

Condensed Notes to the Interim Financial Statements

1. Reporting entity

Formycon AG (hereinafter also the “Company”), together with the subsidiary companies within its scope of consolidation (hereinafter “Formycon Group”, “Formycon” or the “Group”), 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 Open Market “Scale” segment for small- to medium-sized companies (Deutsche Börse: Open Market, Scale, 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 2023.

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 2023.

All judgements and assumptions applied in preparing this Interim Financial Statements are comparable tot those made in the financial statements for 2023.

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 15 "Financial instruments"),
— Valuation of obligations arising from share settled as well as cash-settled share-based compensation arrangements (see Note 10 "Share-based compensation arrangements")

4. Changes in accounting and valuation methods

Accounting 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, 2023.

The amendments to existing International Financial Reporting Standards regarding the classification of liabilities as non-current or current and lease Liabilties in a sale and leaseback transaction which are to be applied for the first time for fiscal years beginning January 1, 2024, had no effect on the preparation of these Financial Statements.

Geographical breakdown of revenue in €K

Region	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Germany	7,373	14,181
Switzerland	19,520	29,608
Total	**26,893**	**43,789**

5. Segment Information

For the reporting period reportable segments developed as shown on pages 68 – 69.

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 and FYB203, as well as FYB202. These costs include not only product development costs but also costs incurred for the management of clinical studies. In addition, Formycon generates revenue through license income from the granting of exclusive marketing rights to Bioeq AG for FYB201. Such license revenues are recognized only from the point at which they can be reliably determined. During the reporting period, a total of € 3,760 thousand (1H 2023: € 1,149 thousand) was recognized as license revenue from FYB201.

In addition, revenue from partial realization of development milestone from the marketing agreement for FYB202 was recognizes at € 11,347 thousand (1H 2023: € 23,664 thousand).

Geographical breakdown of revenue

During the period, and based upon customer domicile, the Group's revenues were generated entirely in Germany and Switzerland, the details of which may be found in the accompanying table "Geographical breakdown of revenue".

The revenue generated in Germany during fiscal year 2024 and 2023 corresponds to FYB203 segment revenue.

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 € 5,621 thousand (Dec. 31, 2023: € 6,757 thousand), while receivables from services not yet invoiced and separately reported as contract assets were € 28,806 thousand (Dec. 31, 2023: € 16,561 thousand).

Segments 2024 in €K

	FYB201	FYB202	FYB203	FYB206		FYB208	FYB209	Total for reportable operating segments	Remaining amount	Formycon Group
External revenue	8,173	11,347	7,373					26,893	0	26,893
Segment revenue	**8,173**	**11,347**	**7,373**	**-**		**-**	**-**	**26,893**	**0**	**26,893**
Segment profit (loss)	18,439	-5,320	-69	-		-7,176	-3,305	2,569	-12,663	-10,094
Finance income								-	820	820
Finance expense								-	-5,293	-5,293
Income from investment participations at equity	14,757							14,757	-	14,757
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-4,367	-16,207	-7,237	-		-6,978	-3,214	-38,002	-4,894	-42,896
Other expenses (selling expenses, miscellaneous)								-	-901	-901
Depreciation and amortization	-124	-460	-206	-		-198	-91	-1,079	-0	-1,079
Income taxes								-	-2,395	-2,395
Assets										
Investment accounted for using the equity method	181,802							181,802	-	181,802
Additions to non-current assets	-	-	-	16,567		-	-	16,567	3,420	19,987

Segments 2023 in €K

	FYB201	FYB202	FYB203	FYB206	FYB207	FYB208	FYB209	Total for reportable operating segments	Remaining amount	Formycon Group
External revenue	6,082	25,000	14,043					45,125	0	45,125
Segment revenue	**6,082**	**25,000**	**14,043**	**-**	**-**	**-**	**-**	**45,125**	**0**	**45,125**
Segment profit (loss)	-5,305	25,000	-1,055	-	-1,748	-3,000	-1,266	12,626	-2,644	9,982
Finance income								-	8,960	8,960
Finance expense								-	-93	-93
Income from investment participations at equity	-6,162							-6,162	0	-6,162
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-5,045	-	-14,580	-	-1,688	-2,897	-1,222	-25,432	-713	-26,145
Other expenses (selling expenses, miscellaneous)								-	-565	-565
Depreciation and amortization	-179	-	-518	-	-60	-103	-43	-904	-	-904
Income taxes								-	-10,234	-10,234
Assets										
Investment accounted for using the equity method	180,244							180,244	-0	180,244
Additions to non-current assets	150	12,971	-	8,993	-	-	-	22,114	1,139	23,253

Finanzergebnis in T€

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Realized and unrealized gains from foreign currency translation	53	59
Interest income per effective interest method	767	386
At-equity result Bioeq AG	14,757	-
Change in fair value of conditional purchase prices		8,515
Finance income	**15,577**	**8,960**
Bank fees	-8	-7
Realized and unrealized losses from foreign currency translation	-18	-47
Interest expense from lease liabilities	-104	-36
Interest expense per effective interest method	-187	-3
Share of loss from Bioeq AG	-	-6,162
Change in fair value of conditional purchase prices	-4,970	-
Change in Impairments based on the expected credit loss model	-6	-
Finance expense	**-5,293**	**-6,255**
Net finance income	**10,284**	**2,705**

Administrative Expense in €K

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Staff expenses	-4,380	-3,289
Legal and advisory expenses	-3,022	-1,031
IT expenses	-527	-405
Depreciation, amortization and write-downs	-647	-642
Other expenses	-722	-175
Total	**-9,298**	**-5,543**

7. 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 2023: € 2,826 thousand) were offset against the corresponding research and development expenses and thus recognized in profit or loss for the reporting period. Disbursements have not taken place in the reporting and in the comparison period. Acitve development of FYB207 has been suspended during the reporting period. However, the grant term ends July 31, 2024 and the company is currently preparing the final report for the grantor. Thereafter the payout of the remaining grant is expected.

8. Finance income/expense

The components of finance income and expense during the reporting period may be found in the accompanying table "Finance income and expense". Period finance expense include € 4,970 thousand (1H 2023: € 8,515 thousand finance income) resulting from the fair value remeasurement of the contingent purchase price payments, primarily due to the unwinding of the discount.

9. Administrative Expense

During the reporting period Administrative expenses developed as shown in the table "Administrative Expense". The increase versus the comparison period is mainly a result of an increase in staff expense to € 4,380 thousand (1H 2023: € 3,289 thousand) due to the continuously growing number of employees and legal and advisory expense related to projects for strategy and financing opportunities for the company of € 3,022 thousand (1H 2023: € 1,031 thousand).

10. Share-based compensation arrangements

During the reporting period there have been no changes to the outstanding grants within the two existing share-based compensation programs.

During the reporting period, the total current expense for share-based compensation payments was € 802 thousand (1H 2023: € 695 thousand). As of June 30, 2024, the impact of these share-based payments on the capital reserve account was € 7,310 thousand (Dec. 31, 2023: € 6,509 thousand). At the same time a liability for cash settled programs was recognized under other non-current liabilities at the amount of € 265 thousand (Dec. 31, 2023: € 44 thousand).

Components of income tax expense in €K

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Current tax expense / income	-35	80
Deferred tax expense		
from valuation at equity	197	-82
from differing asset valuations	5	-5
from capitalization of certain leases as right-of-use (ROU) assets and corresponding liabilities from lease obligations	-34	-26
from accounting for cash-settled share-based compensation arrangements	-59	-
from capitalization of certain internally generated intangible assets	6,561	7,065
Other	-3	-356
from deferred taxes on tax loss carryforwards	-4,236	584
Total tax expense	**2,395**	**7,259**

11. Income tax expense

Components of income tax expense

The components of current and deferred income tax expense during the reporting period (including offsetting gains) may be found in the accompanying table “Components of income tax expense”. 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 carryforward if they exceed deferred tax liabilities.

Further information on deferred tax liabilities as of the reporting date may be found in the accompanying table “Calculation of deferred taxes”.

Reconciliation of expected income tax expense / income to reported total tax expense / income:

Calculation of deferred taxes in €K

	June 30, 2024		Dec. 31, 2023	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Valuation of participation in affiliates	234		431	
Valuation of non-current assets		95		91
Right-of-use (ROU) assets and corresponding leasing obligations	108		74	
Arising from assets recongized during the purchase price allocation		119,116		119,116
Capitalization of internally generated intangible assets		22,362		15,801
Other	1,705	1,522	198	76
Tax loss carryforwards – Formycon AG corporate tax (Körperschaftssteuer)	15,499		15,499	
Tax loss carryforwards – Formycon AG trade tax (Gewerbesteuer)	9,573		9,573	
Tax loss carryforwards – FYB202 Project GmbH	7,749		5,980	
Offset (netting) of deferred tax assets and liabilities	-17,864	-17,864	-12,284	-12,284
Valuation adjustment to deferred tax assets	-17,002		-19,470	
Total	**-**	**125,230**	**-**	**122,800**

Reconciliation of expected income tax expense / income in €K

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
Profit / Loss before tax	-7,699	9,063
Tax rate	26.68%	26.68%
Expected income tax expense / income	**-2,054**	**2,418**
Tax-free income and non-taxable expenses from the valuation of financial instruments	-2,414	-710
Taxes for prior years		83
Other	1,459	186
Non-recognition of deferred tax assets on tax losses	5,405	5,282
Total tax expense	**2,395**	**7,259**

EBITDA and adjusted EBITDA in €K

	Jan. 1 – June 30, 2024	Jan. 1 – June 30, 2023
EBIT	-17,983	6,358
Depreciation of property, plant and equipment	346	265
Depreciation of right-of-use (ROU) assets	607	547
Amortization of intangible assets	126	92
EBITDA	**-16,904**	**7,262**
At-Equity Result Bioeq AG	14,757	-6,162
Adjusted EBITDA	**-2,147**	**1,100**

12. EBITDA and adjusted EBITDA

The Executive 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 the IFRS cost of sales method, the Group’s definition of EBITDA is consistent with usual definitions.

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

Capitalized development expenditures

All costs for the development of the FYB202 project, both external and internal, have been capitalized as eligible development expenditures up until Jan. 31, 2023. As of June 30, 2024, the capitalized book value of this pending development project was € 485,050 thousand (Dec. 31, 2023: € 485,050 thousand). Starting February 1, 2023 prospectively all expenditure on the project was recorded as Cost fo Sales. Amortization of the asset will start as soon as the asset is ready for use.

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, 2024, the amount of capitalized development expenditures for this project was € 44,696 thousand (Dec. 31, 2023: € 21,128 thousand).

During the reporting period, borrowing costs of € 300 thousand (1H 2023: € 860 thousand) under the shareholder loans were allocated to these two qualifying assets, FYB202 (in 2023 only) and FYB206, and capitalized as part of their acquisition costs.

Right-of-use assets

During the reporting period the existing rented area at the companies site in Martinsried have been extended and at the same time the term for all existing areas was extended until June 2034 (5 years fixed and 5 years optional). An exercise of the lease extension option is assumed in the lease term because the Company believes it likely that the option will be exercised.

14. Equity

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

Number of shares outstanding

The Company has registered capital (Grundkapital) of € 17,656,902.00, which is divided into 17,656,902 bearer shares without par value.

Through court entry into the commercial register on February 8, 2024, the Company’s registered capital was increased by € 1,603,877.00 through a partial utilization of the Authorized Capital 2023. The new shares were issued as part of a capital increase by a strategic investor at an issuance price of € 51.65 per share and thus a total cash contribution to the Company in the amount of € 82,843,475.00. Subsequent to the capital increase, the Company’s registered capital was € 17,656,902.00. The excess of the issuance price over the imputed nominal value of € 1.00 per share is included in the capital reserve account.

15. 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 under the ATHOS transaction during 2022 as partial consideration for the acquisition of the shareholdings in FYB202 Project GmbH and Bioeq AG, which are measured at fair value. For all financial assets and liabilities except for the shareholder loan to Bioeq AG 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 below. In the prior fiscal year, the book value for all financial assets and liabilities represented a reasonable approximation of their respective fair value, and thus the fair values were not specifically disclosed.

These contingent purchase price payments are measured at fair value based on level 3 input factors under the fair value hierarchy. As of Dec. 31, 2023, the contingent purchase price payments were valued at € 214,824 thousand as of the reporting date, these were valued at € 214,890 thousand. During the reporting period € 4,904 thousand (1H 2023: € 165 thousand) have been paid on the conditional purchase price. The remaining difference of € 4,970 thousand is in majority resulting from interest effects and therefore was recognized in finance expense. 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 discount rate was 11.7% (Dec. 31, 2023: 11.2% to 11.8%).

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

	Book value at June 30, 2024	Fair value at June 30, 2024	FV categorie
Financial assets not carried at fair value			
Financial assets	85,929	79,561	3
Trade and other receivables	10,554		3
Contract assets	28,806		3
Cash and cash equivalents	40,620		3
Financial aliabilities carried at fair value			
Current portion of conditional purchase price	24,136	24,136	3
Non-current portion of conditional purchase price	190,754	190,754	3
Financial liabilities not carried at fair value			
Trade payables	16,948		3

16. Transactions with related persons and companies

Key management personnel and members of Supervisory Board

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

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

Related companies

During the reporting period, sales revenue of € 15,546 thousand (1H 2023: € 20,126 thousand) with related companies was recognized, of which € 8,173 thousand (1H 2023: € 6,098 thousand) was with jointly controlled Bioeq AG. In terms of the closing balance sheet € 5,621 thousand (Dec. 31, 2023: € 6,471 thousand) is recognized under trade receivables. In addition, the loan receivable from Bioeq AG amounts to € 86,300 thousand (Dec. 31, 2023: € 91,300 thousand) including accrued interest.

In addition to the sales revenue and trade receivables resulting from these development partnerships, the Group has also received loans from key shareholders. During the reporting period € 20,485 thousand including accrued interest have been repaid to the shareholders. At the same time the credit line of € 48,000 thousand was prolonged for another year until May 31, 2025. As of the reporting date € 0 thousand (Dec. 31, 2023: € 20,485 thousand) of this loan are outstanding.

Formycon also 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 € 214,890 thousand (Dec. 31, 2023: € 214,824 thousand), while finance expense for the reporting period included € 4,970 thousand (1H 2023: € 8,515 thousand income) arising from the fair value measurement of these obligations.

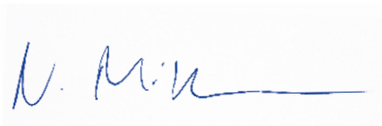
There were no other transactions with related persons or companies during the reporting period.

17. Subsequent events

There have been no events of material significance which occurred following the end of the reporting period and are not reflected in these Financial Statements.

Planegg-Martinsried, Germany, August 08, 2024

Dr. Stefan Glombitza



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Publication date
August 13, 2024

Photography
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