formycon®

Formycon. The Biosimilar Experts.

Half-Year Report 2023

Formycon. The Biosimilar Experts.
www.formycon.com

Key financial Figures

	H1 2023	H1 2022
Revenue in € Million	**43,8**	**17,6**
EBITDA in € Million	**7,3**	**-7,6**
Net Income in € Million	**1,8**	**80,0**
Working Capital in € Million	**55,0**	**30,7**

Highlights from the first half of 2023

Jan. / Feb. 2023

Commercialization partnerships for FYB202 and FYB203

Following the signing in January with Coherus BioSciences Inc. of a binding term sheet for the marketing in the United States of FYB203, the candidate biosimilar to ophthalmological blockbuster Eylea®, a global commercialization partnership was concluded in February with Fresenius Kabi AG for FYB202, the candidate biosimilar to immunological blockbuster Stelara®. Secondary marketing rights for FYB202 in Germany and certain parts of the Middle East and North Africa (MENA) and Latin America remain with Formycon.

Feb. 2023

Formycon completes capital increase of more than € 70 million

As part of the capital increase transaction supported by anchor shareholders of Formycon, 910,000 new shares were placed at an issuance price of € 77.00 per share. The net proceeds from the financing round will primarily be used to accelerate ongoing development work for biosimilar candidates FYB202, FYB206, FYB208 and FYB209 through to the approval stage as well as to support Formycon's strategy for organic growth.

April 2023

Enno Spillner appointed CFO and Executive Board member

Enno Spillner, most recently CFO of Evotec SE, was appointed Chief Financial Officer of Formycon AG with effect from the start of second quarter of 2023 and Executive Board member with responsibility for the areas of Finance and Controlling, Communications and Investor Relations, Human Resources, Legal and Compliance and IT.

Mr. Spillner brings more than 23 years of proven expertise and distinguished experience in the biotechnology industry. His track record of success at Evotec notably included the company's successful capital market positioning.

April 2023

Clinical development of FYB202 with expanded PK study completed

Following the successful completion of phase III clinical trials of Stelara® biosimilar candidate FYB202 in late summer 2022, the expanded phase I pharmacokinetics (PK) study was successfully completed in April 2023.

Regulatory approval submissions in Europe and the United States are planned for the third quarter of 2023.

June 2023

FYB203 biologics license application submitted to the FDA

Following attainment of the primary efficacy endpoint in the global comparative phase III clinical trials of Eylea® biosimilar candidate FYB203, a biologics license application (BLA) was formally submitted to the U.S. Food and Drug Administration (FDA) at the end of June. Submission to the European Medicines Agency (EMA) is expected in the second half of 2023, likewise in accordance with Formycon's original plan.

Eylea® ist eine eingetragene Marke von Regeneron Pharmaceuticals Inc.
Stelara® ist eine eingetragene Marke von Johnson & Johnson.

About Formycon

Founded in 2012, Formycon is a Munich-based biotechnology company specializing in the development of biosimilar drugs.

More than 200 employees from 31 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 biopharmaceutical development, particularly biosimilars, Formycon is currently able to develop seven projects in parallel.

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

The combined market size for the reference (originator) drugs to Formycon's FYB201, FYB202, FYB203 and FYB206 biosimilar projects is currently approx. USD 43 billion.

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Letter to Shareholders

Dear Shareholders and Friends of Formycon,

with a successful start to 2023 behind us, we are pleased to be able to give you an encouraging update on our progress at Formycon AG. During the first half of the year, we successfully completed the clinical trials for our next two biosimilar candidates in the final development stage, FYB202 (reference drug Stelara®) and FYB203 (reference drug Eylea®). These favorable results follow upon two major milestones last year: the strategic transaction with ATHOS KG, and the approval and product launch of FYB201, our biosimilar to Lucentis®.

What this means is that Formycon is currently undergoing a crucial transition: from an R&D-centric company into a significant market player in the rapidly growing global biosimilars sector. Thanks to our promising commercialization partnerships, our strong and broad product pipeline, and our agile and powerful organization, we feel well prepared to continue on our successful path as we master this next phase of our company's growth.

The striking increase in Formycon's revenue during the first half of the year largely reflects two positive effects: In addition to two milestone payments received from our FYB202 partner, we have also been seeing the acceleration of revenues from the sale of our first commercial product FYB201, particularly during the second quarter. We will continue to invest in expanding our pipeline to generate sustainable long-term value.

In this exciting phase of our corporate development, we are especially pleased to welcome our new Chief Financial Officer (CFO), Enno Spillner, who has been supporting us with his considerable experience and expertise since April 1, 2023. We are confident that Mr. Spillner will be a great addition to our senior management team and will make a significant contribution to Formycon's continued success.

Growing biosimilars market relieves pressure on healthcare systems

While gross pharmaceutical sales in Germany have doubled since 2006, sales of biopharmaceuticals have quintupled. These sophisticated biological drugs currently account for € 19.5 billion in annual sales, or 34% of total German pharmaceutical sales.[1]

In Germany alone, healthcare providers are already saving an estimated € 1.7 billion each year through the use of biosimilar alternatives[2] – and this number is rising rapidly. As the pharmaceutical market segment with the highest projected growth rates, the global biosimilars business is expected to be worth more than USD 30 billion by 2026. As to the potential annual cost savings to healthcare providers globally through the use of biosimilars, this figure could climb to more than USD 100 billion.[3]

With our superb workforce, our agile corporate structure and our valuable pipeline of projects under active development, we see Formycon as very well positioned in this growth market.

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1 IQVIA: Fokus Biosimilars. Trends und Entwicklungen im deutschen Biopharmazeutika Markt, Q1 2023.
2 AG ProBiosimilars: Grafik des Monats Februar 2023.
3 IQVIA: The Global Use of Medicines 2023: Outlook to 2027.

Dr. Stefan Glombitza
CEO

Nicola Mikulcik
CBO

Enno Spillner
CFO

Dr. Andreas Seidl
CSO

Successful market entry and promising partnerships for FYB201: good news in the U.S., UK and Europe

With our FYB201 project we have developed our first biosimilar drug through to successful approval and commercialization. The success has been particularly striking in the United States, where our commercialization partner Coherus has been able to achieve a market share of roughly 17 percent within just nine months, and the trend continues upward. Sales in the UK have also been satisfying, with market share already at roughly 40% as the result of a successful National Health Service (NHS) tender. Because the EU market is fragmented, country-level product launches of FYB201 will take place sequentially through the end of 2023. We are delighted to have Teva at our side as a strong and capable partner for the UK and all of Europe. Further launches in countries such as Brazil, Canada and Saudi Arabia are planned for 2024.

Successful completion of clinical development phases of FYB202 and FYB203 projects as well as submission of approval documents for FYB203 to U.S. Food and Drug Administration (FDA)

As mentioned above, Formycon was able to report significant advances during the first half of 2023 in two of its biosimilar drug development projects nearing completion. Following positive interim results from the MAGELLAN-AMD phase 3 clinical trials on the efficacy and tolerability of FYB203, the candidate biosimilar to Eylea®, Formycon was able to announce the filing of the biologics license application (BLA) for FYB203 with the U.S. Food and Drug Administration (FDA) on June 29, 2023, in line with the Company's original plan. The FDA generally decides within 60 days of submission whether to accept the application ("file acceptance") for further examination. This period has so far passed without any substantive queries. Submission to the European Medicines Agency (EMA) is expected later this year.

In the case of FYB202, the candidate biosimilar to Stelara®, Formycon was able to announce the successful completion of the expanded phase 1 pharmacokinetics (PK) study, marking a remaining milestone in this development project. Submission of regulatory approval documents in Europe and the U.S. remains planned for 2023.

COVID-19: Changed situation of FYB207 project, focus on biosimilars pipeline

With the lifting of the global health emergency by the World Health Organization (WHO) on May 5, 2023, the COVID-19 pandemic has been declared over – at least for the time being.

These major changes in the external environment have also had an impact on our FYB207 project. After careful consideration not only of scientific but also economic and strategic factors, we have re-evaluated the project. We plan to continue pursuing the innovative COVID-19 project, but in a resource-sparing way and only in certain focus areas. We remain confident in this drug candidate and have created a promising platform, and it is on this basis that we remain committed to moving FYB207 into a strategic development partnership. Formycon will continue to pursue patent applications, scientific advice meetings, and potential opportunities for outside funding options with the aim of ensuring that development work of this novel drug can at any time be quickly moved into the clinical phase or otherwise accelerated as conditions change. However, Formycon's clear focus is on our promising biosimilars pipeline.

Formycon Road to Sustainability: Intensified ESG efforts for a sustainable future

As of the first half of 2023, Formycon has further intensified its engagement with Environmental, Social and Governance (ESG) themes. Formycon is committed to managing and conducting its business activities in a responsible and sustainable manner. This commitment specifically includes further measures to reduce the company's ecological footprint, to promote an inclusive corporate culture, and to embed transparency and ethical behavior into our corporate governance. We believe that this holistic view of important ESG themes will create additional long-term value for Formycon and its stakeholders.

During the first half of 2023, Formycon launched a new "Formycon Road to Sustainability" initiative together with a leading consultancy and with support from anchor investor Active Ownership, with the aim of developing a suitable and meaningful sustainability strategy for Formycon by the end of 2023.

Currently, Formycon is in the stage of materiality analysis and is evaluating actual and potential risks, as well as upside opportunities, in each of the ESG component areas, then assessing these accordingly. In 2024, Formycon Group expects to implement the first of the work packages generated on the basis of the newly developed sustainability strategy.

In fact, Formycon's biosimilars are already having a positive impact towards the Sustainable Development Goals (SDGs) of the United Nations: Our biosimilars help improve access to healthcare by making high-quality biopharmaceuticals available to more patients around the world for the treatment of serious diseases, and through the market competition and lower prices which they bring, they help to relieve the cost burden on the world's healthcare systems.

Successful placement of capital increase to finance further growth and to expand Formycon's biosimilars pipeline

In order to finance the group's continued growth, Formycon AG carried out a capital increase from approved capital amounting to approx. 6% of outstanding shares. The gross issuance proceeds of slightly over EUR 70 million will be primarily used to push forward with the development of our own biosimilar candidates (FYB202, FYB206, FYB208 and FYB209) and to expand our biosimilars development pipeline in support of our organic growth strategy.

Our special thanks go to the many dedicated Formycon employees who made most of the achievements and milestones described above possible, as well as to our valued partners and to you, dear shareholders, for your continued confidence in us and in the work that we do.

Martinsried/Planegg as of August 2023

Yours faithfully –

Dr. Stefan Glombitza

Dr. Andreas Seidl

Nicola Mikulcik

Enno Spillner

Formycon on the Stock Market

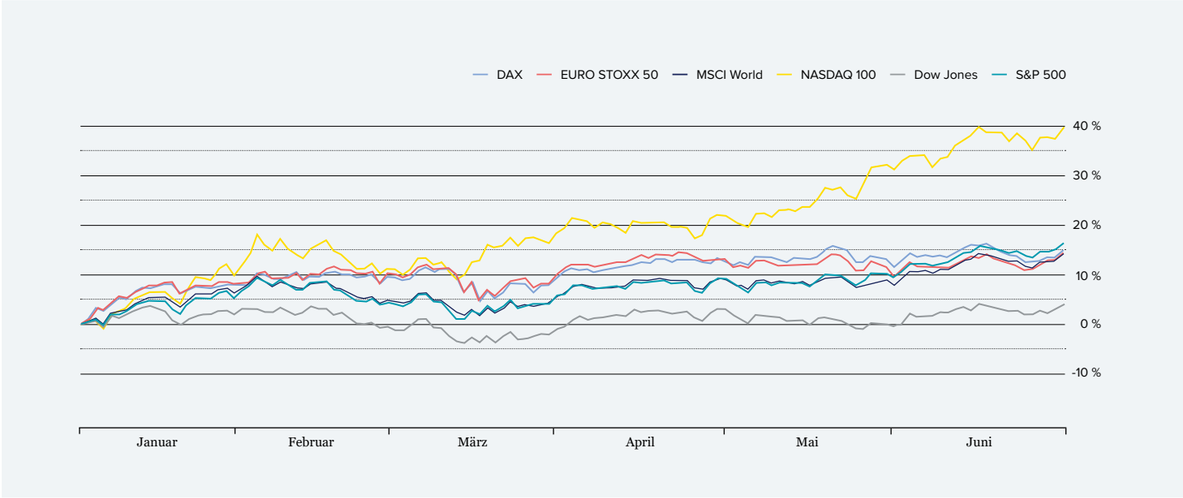
Shares and the capital markets

German and international stock market environment

During the first half of 2023, the world's major stock markets were influenced by a number of factors, both positive and negative. Contrary to the assessment of many analysts, the large-cap market indexes in Europe and the U.S. began the year quite favorably.

Stock market sentiment was initially held back by the disappointingly slow decline in high inflation rates globally. To fight inflation and to prevent inflationary expectations from becoming entrenched, the central banks significantly increased key interest rates during the first half of 2023. The rise in market interest rates reduced the attractiveness of equities relative to bonds while at the same time making new corporate borrowings and refinancings more expensive. On the other hand, the significant drop in energy prices during the first half of 2023 had a favorable impact on energy-intensive companies as well as on households, particularly in Europe. From the close of 2022 to the midpoint of 2023, the DAX 40 German equity index and the geographically broader Euro Stoxx 50 index performed almost identically, with gains of 14 and 15 percent respectively.[1]

Measured in euros, the rise in U.S. stock indices such as the Dow Jones 30 and the S&P 500 was significantly less through early May because the U.S. dollar depreciated by more than five percent against the euro over these first months.[2] These indexes, particularly the Dow Jones 30, subsequently rose sharply as the U.S. dollar stabilized against the euro and as U.S. equity markets outperformed their European counterparts. This



[1] https://www.finanzen.net/index/dax/historisch
[2] https://www.finanzen.net/index/dow_jones/historisch

Performance of Formycon shares

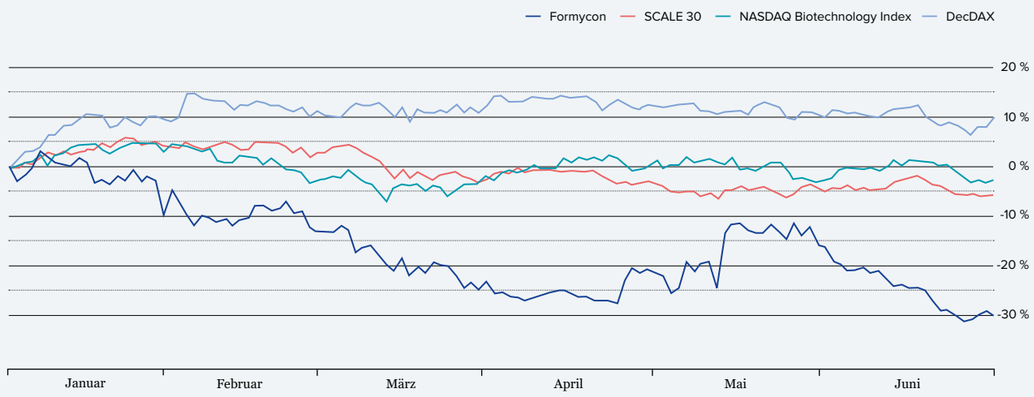
was largely the result of more favorable economic expectations following the lifting of onerous COVID-19 restrictions in China as well as the striking drop in the U.S. inflation rate. Due to the dominant weighting of U.S. companies in the MSCI World index, this global benchmark also performed very favorably starting from the beginning of May so that it was able to end the first half with a gain almost on par with the DAX 40 and Euro Stoxx 50.[1]

During the first half, the Nasdaq 100 benchmark index gained 39 percent in value, more than in any prior six-month period in its history. The top seven stocks in the tech-heavy index (notably including Apple, Microsoft, Alphabet and Amazon) alone contributed over 30 percentage points to the rally, which was particularly fueled by enthusiasm over the potential of artificial intelligence. These large gains also prompted Nasdaq as the exchange operator to carry out a special rebalancing of the index to mitigate distortion through the outsized weighting of these seven technology giants.[2] Compared to the German large-cap index, the German MDAX mid-cap equity index (+ 8%) and TecDax index of German technology stocks (+ 10%) underperformed but still generated gains through the first half of the year.

Following the market price outperformance of the two preceding years, the closing price of Formycon shares on June 30, 2023 was € 62.20, well below the closing price of 2022. Despite the achievement of important business milestones, the price decline over the first half of 2023 was roughly 28%. The Nasdaq Biotechnology Index, which also includes pharmaceutical names, likewise recorded a decline over the same period, which measured in euro terms was -7%.[3] The SCALE 30 index, which measures the market performance of Germany's most actively traded small and medium-sized growth companies, lost 4% in value.[4]

Compared to mature companies, the stock prices of high-growth companies in the biotechnology and biopharmaceutical sectors have recently underperformed due, in particular, to the rapid rise in interest rates. Because of the greater discounting of future cash flows with higher interest rates, companies which generate current profits are now being valued higher relative to growth companies with high future profit potential. During the two years prior to 2023, Formycon shares significantly outperformed the Nasdaq Biotechnology and SCALE 30 benchmark indexes. In the current phase of declining industry-specific market indexes, Formycon's higher price volatility is now being felt in the reverse direction.

Contrary to the direction of the Company's share price, advances in the Formycon product development pipeline during the period were favorable and in accordance with plans. At the beginning of February, the company increased its equity capital through the issuance of new shares, generating gross proceeds (before commissions and other costs) of more than € 70 million. The net proceeds of this transaction will be principally invested into the further development of the Company's own biosimilar project assets.



Formycon shares: Trading information

Ticker symbol	FYB
German securities identifier (WKN)	A1EWVY
ISIN	DE000A1EWVY8
Listed exchange / Market segment	Frankfurt Stock Exchange / Scale (Open Market)
Trading venues	Xetra, Berlin, Düsseldorf, Frankfurt, Hamburg, Munich, Stuttgart, Tradegate
Designated Sponsors	Wolfgang Steubing AG mwb fairtrade Wertpapierhandelsbank AG

Formycon shares: Performance information

In Euro	**H1 2023**	**H1 2022**
Opening price on Jan. 02, 2023 / Jan. 03, 2022 (Xetra)	87,00	58,90
Closing price on June 30, 2023 / June 30, 2022 (Xetra)	62,20	76,50
Average price (Xetra closing price)	74,73	60,35
Market capitalization as of June 30	997.611.805	1.152.453.375
in shares		
Total shares traded (on all trading venues)	2.417.719	2.026.360
Daily average shares traded (on all trading venues)	19.037	16.610
Total shares issued as of June 30	16.038.775	15.064.750

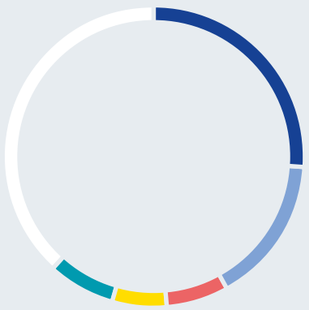
[1] https://www.finanzen.net/index/msci-world/historisch
[2] https://www.tagesschau.de/wirtschaft/boerse/nasdaq-kriterien-dominanz-anleger-etfs-100.html
[3] https://www.finanzen.net/index/nasdaq_biotechnology/historisch
[4] https://www.finanzen.net/index/scale_30/historisch

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. With the completion of the transaction last year, ATHOS KG became the largest shareholder in Formycon AG with an indirect shareholding of more than 25% of the Company's share capital. ATHOS KG and the relevant direct and indirect entities thereunder accordingly provided notification to Formycon and published an announcement in the Federal Gazette in accordance with sec. 20 para. 1 of the Stock Corporation Act.[2]

As of June 30, 2023, and including the effects of the capital increase at the start of 2023, approx. 47% of the Company's shares were held by three family offices: ATHOS KG (indirectly), Wendeln & Cie. KG and DSP Beteiligungsgesellschaft mbH & Co. KG. In addition, 6.7% of shares were held by Active Ownership Group and 6.4% by founders and management. Shares in free float (as defined by Deutsche Börse) were, by the Company's own assessment, 39.8% of total capital.



Shareholder structure[3]

26,7 %	ATHOS KG
14,9 %	Wendeln & Cie. KG
6,7 %	Active Ownership Corporations S.a.r.l.
5,5 %	DSP Beteiligungsgesellschaft mbH & Co. KG
6,4 %	Founders and management
39,8 %	Free float (by the 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
3 Percentages are approximate and rounded accordingly.

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 has, since its introduction throughout the EU in July 2016, been subject to the requirements of the Market Abuse Regulation, replacing key parts of the German Securities Trading Act with the stated goal of promoting the integrity of the financial markets by improving transparency. Under the MAR, the Company 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. Formycon has implemented these requirements, integrating appropriate compliance processes into its existing risk management system as necessary.

Subscribed capital

As of January 1, 2023, the registered capital (Grundkapital) of Formycon AG was € 15,128,775.00, divided into 15,128,775 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 June 30, 2022 (the "Approved Capital 2022"), the Executive Board and Supervisory Board of Formycon AG resolved in February 2023 to increase the Company's registered capital by € 910,000.00, from € 15,128,775.00 to € 16,038,775.00, through the issuance of 910,000 new shares. These 910,000 new bearer shares without par value were placed with institutional investors using an accelerated bookbuilding process at a price of € 77.00 per new share, thereby generating gross issuance proceeds of € 70,070,000.00 before commissions and other costs. These new shares correspond to approx. 6.02% of the Company's shares already outstanding at the time of issuance.

The registered capital of Formycon AG thus amounted to a total of € 16,038,775.00 as of June 30, 2023. For detailed information on the Company's equity capital account, please refer to the Notes to the Financial Statements (see Note 20 "Equity Capital") included in this report

Investor relations

Professional dialogue with investors and with the international capital markets forms an important component of Formycon's investor relations program. During the first half of 2023, Formycon's senior management and investor relations department presented the Company at selected investor conferences, such as the Jefferies Pan-European Mid-Cap Conference, the Deutsche Börse Equity Forum (spring conference), the Hauck & Aufhäuser Stockpicker Summit, the Jefferies Global Healthcare Conference and the Stifel European Healthcare Summit. Formycon also participated in a number of virtual roadshows, including in Zurich, Madrid und Luxembourg.

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, 2023, six analysts were regularly providing equity research coverage on Formycon AG.

During the first half of 2023, the following banks or other research providers published studies on Formycon:

Bank or research provider	Analyst
Jefferies	Brian Balchin
B. Metzler seel. Sohn & Co. KGaA	Tom Diedrich
First Berlin Equity Research GmbH	Simon Scholes
Hauck Aufhäuser Lampe Privatbank AG	Alexander Galitsa
Kepler Cheuvreux	Arsène Guekam
SRH AlsterResearch AG	Alexander Zienkowicz

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/

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
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Senior Manager Corporate Communications & Investor Relations
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ir@formycon.com

Interim Management Report for Formycon Group

January 1 to June 30, 2023

Basic information about Formycon Group

Business activities

This Interim Management Report for Formycon Group covers the reporting period from January 1 to June 30, 2023.

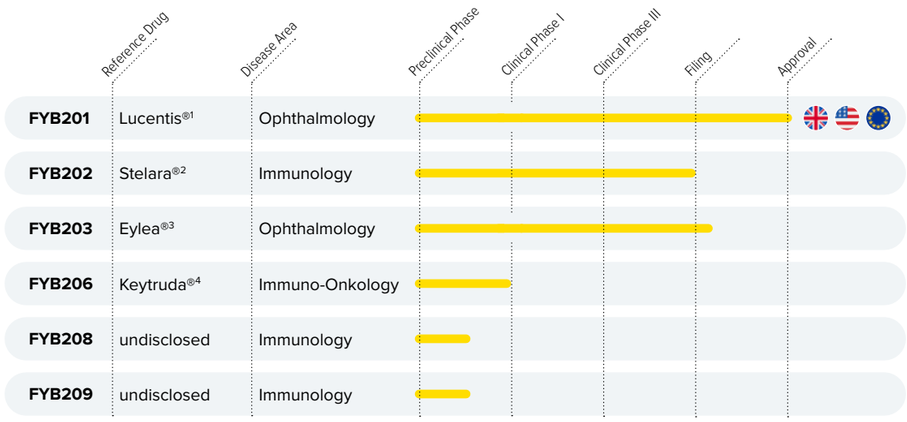
Formycon is a specialized developer of biosimilar drugs with the capabilities and resources to develop multiple biopharmaceutical projects in parallel. The Group's long-term, sustainable growth strategy is built upon steady expansion of the product pipeline through the targeted selection of new biosimilar candidates, the development of these projects, and their ultimate commercial success through commercialization partnerships, either partly or in their entirety.

Since the 1980s, biopharmaceuticals have been revolutionizing the treatment of serious diseases such as cancer, diabetes, rheumatism, multiple sclerosis and acquired blindness. Starting in the mid 2010s, patent protection on many of these powerful biologics began expiring, and these patent runoffs will continue in the coming years. ***Biosimilars are follow-on products to biopharmaceutical drugs whose market exclusivity has expired.*** The approval process in the world's highly regulated markets, such as the European Union, the United Kingdom, the United States, Japan, Canada and Australia, are subject to stringent regulatory requirements which, in particular, ensure that the biosimilar's comparability to the reference product (originator drug) has been proved.

Formycon is able to cover all technical stages of the biopharmaceutical development chain starting with the selection of highly promising candidates, through analysis and cell line development, into preclinical studies and clinical trials, and all the way through to the creation and submission of regulatory approval application documents. In addition, Formycon's core expertise includes beginning-to-end supply chain management along with product logistics.

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 currently has six projects spanning indications in of ophthalmology, immunology and immuno-oncology which are in various stages of development, as shown in the accompanying figure.



Since the start of the coronavirus crisis, Formycon has been pursuing the development of an ***innovative COVID-19 fusion protein*** based upon its extensive experience in the development of biopharmaceuticals and as a contribution to the global fight against the pandemic. With the epidemiological situation now greatly changed, as marked by the declaration of the World Health Organization (WHO) on May 5 that the global health emergency has officially ended, Formycon has reevaluated this project under consideration of scientific, economic and strategic factors.

In order to sustain the attractive platform which has been created, Formycon has decided to continue the innovative COVID-19 project but in a resource-sparing manner, and with the aim of transitioning it into a strategic development partnership. Formycon also is continuing to pursue patent applications and scientific advice meetings with the respective authorities and will regularly evaluate the availability of government or other outside funding so that development activities can be reactivated or accelerated at any time. It must be acknowledged, however, that the current strategic focus of potential partners is generally on other priorities.

Risk profile of biosimilar development compared to innovative biopharmaceutical development

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 six to eight 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.

Business objective and strategy

Formycon's guiding objective is to further expand its position as a global player in the rapidly growing market for biosimilars, thereby developing into a fully integrated pharmaceutical company within the biosimilars market segment.

With the help of biosimilars from Formycon, ever more patients around the globe should gain access to highly effective biopharmaceuticals for the treatment of serious diseases. Through our work, we aim not only to improve care for patients but also to contribute to sustainably relieving the financial burden on healthcare systems.

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1 Lucentis® is a registered trademark of Genentech Inc.
2 Stelara® is a registered trademark of Johnson & Johnson.
3 Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.
4 Keytruda® is a registered trademark of Merck Sharp & Dohme LLC.

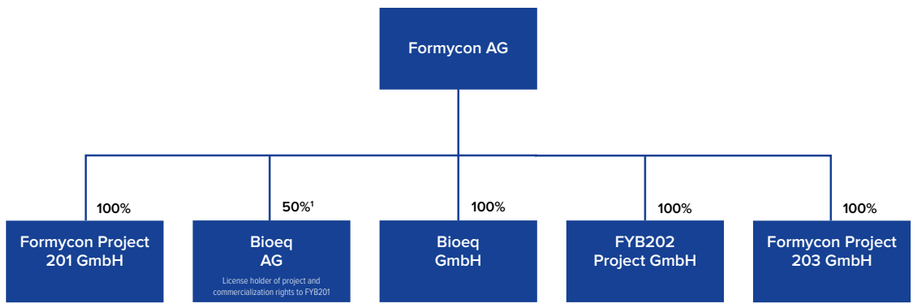
Group structure

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 Bioeq GmbH, as illustrated in the accompanying figure. In addition, Formycon holds a 50% share in 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 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 the Formycon's key target audiences. Subsidiaries and other companies in which Formycon holds investment participations are managed as distinct businesses with their own management teams.

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 activities.



[1] The remaining 50% of Bioeq AG is owned by Polpharma Biologics BV.

Allocation of areas of responsibility among Executive Board members

Dr. Stefan Glombitza
CEO (Chief Executive Officer)

— Since July 1, 2022 (current term of office ends June 30, 2027), 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 Contract Management
— Business Development & Licensing
— Supply Chain and Logistics
— Intellectual Property Litigation
— Procurement

Dr. Andreas Seidl
CSO (Chief Scientific Officer)

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

— Finance and Controlling
— Legal and Compliance
— Human Resources
— Corporate Communications, Investor Relations and Corporate Social Responsibility / ESG
— IT and Digitalization
— Facility/Environment/ Health and Safety

Management and oversight

The Formycon AG parent entity is, as required under the German Stock Corporation Act (Aktiengetz) 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 has consisted 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. As of June 30, 2023, it consisted of four members.

Remuneration of Executive Board and Supervisory Board

The remuneration of Executive Board members includes fixed and variable components. To date, Formycon has not published a separate report on remuneration.

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 guidelines and are periodically examined and audited by regulatory authorities, including also the U.S. Food and Drug Administration (FDA).

With the acquisition of Bioeq GmbH in 2022, 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, Bioeq 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. For the global marketing of biosimilar products, Formycon relies upon commercialization partnerships and cooperation agreements with strong established pharmaceutical players such as Fresenius Kabi AG, Teva Pharmaceutical Industries Ltd. and Coherus BioSciences, Inc.

The 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.

Oncology, a field of medicine in which some 19.3 million new cases are registered every year, currently dominates the areas of application for biosimilars worldwide.[1] Overall, however, the number of disease areas in which biosimilars are available and in active use is steadily increasing. The trend of new and expected biosimilar approvals is, in particular, towards indications in immunology and ophthalmology.

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 the most developed countries. However, once the legal protection period for an originator biopharmaceutical reaches its end, 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.

* through partnerships or cooperation agreements

Competitive situation

Internationally published studies predict average annual growth rates (CAGR) for the global market for biosimilars over the next decade (2023 through 2032) in excess of 14%.[2] Despite substantial barriers to market entry due to high development costs (approx. € 150 to 250 million per biosimilar development project), long development cycles (six to eight years), and the specialized expertise required for biosimilars develop, there are a number of international competitors in this attractive market segment.

In addition to major pharmaceutical corporations such as Amgen, Biocon, Fresenius Kabi, Pfizer, Samsung Bioepis and Sandoz but also smaller companies specializing in biosimilars such as Alvotech 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 both competitor and commercialization partner. 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 in the corresponding section of the "Report on risks and opportunities".

Corporate strategy and management

Formycon's strategic goal is to sustainably expand the scope of its business activities so that it is able to become a leading global developer of biosimilars for the long term. In order to achieve this goal, Formycon will continue to invest heavily into the 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 as an integrated 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 its own commercialization capabilities in certain geographies.

Beyond this guiding 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 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 its competitors, particularly large pharmaceutical companies with biosimilar ambitions, above all in the agility and flexibility of its operational activities. In biopharmaceutical development, is important to align structures, processes and behaviors along the value chain in such a way as to foster an organization 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 225 committed employees, Formycon currently has the capacity and resources to develop seven different biopharmaceutical projects in parallel.

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1 International Agency for Research of Cancer, "Fact Sheet World", https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf

2 Market US / Globe Newswire: Biosimilars market is anticipated to grow at a CAGR of 14.1% from 2023 – 2032 due to increasing incidences of chronic diseases

Financial performance indicators

In managing Formycon Group, the Executive Board relies upon a number of key financial performance indicators. During the first half of 2023 as in previous periods, these were primarily *revenue, EBITDA, net profit/loss, and working capital*.

Key financial performance indicators in accordance with IFRS

In € million	H1 2021	H1 2022	**H1 2023**
Revenue	20.1	17.6	**43.8**
EBITDA	-9.7	-7.6	**7.3**
Net income	-10.6	80.0	**1.8**
Working capital	29.4	30.7	**55.0**

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.

In addition, Formycon has a number of its own biosimilar candidates whose research and development expenses are borne entirely by Formycon. As the Group matures and undertakes more pipeline products for its own account, Formycon anticipates that its future research and development expenses will continue to increase. At the same time, Formycon estimates that the percentage of total revenue from milestone and license payments will increase as the pipeline matures.

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.

Period profit or loss (net income) is another key performance metric. The profit or loss for the current six-month period provides a bottom-line measure of the profit contribution from the Group's businesses and other areas of activity during the period. Net profit/loss is thus likewise a financial key performance indicator of Formycon's overall business model but which takes into account the entirety of income and expenses during the period, including taxes, as well as of any impact which current financial performance might have on the Group's ability to carry out its strategic plan.

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 (receivables, contract assets, securities, and cash and cash equivalents) exceed current liabilities (excluding shareholder loans and the current portion of the conditional purchase price).

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.

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. 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

The German economy has been in recession since the end of the first quarter of 2023. Following a 0.5% decline in the fourth quarter of 2022 compared to the comparable prior-year quarter, the economy again contracted again by 0.3% in the first quarter of 2023. This means that the customary definition of a recession – two consecutive quarters of GDP contraction – has technically been met.[1]

As of the second quarter of 2023, the German Federal Ministry for Economic Affairs and Climate Action (BMKW) continued to see a difficult environment for the country's economy, although the Ministry does not anticipate a prolonged or severe decline in GDP. In understanding the current weakness in the German economy, certain indicators are contradictory: In the first quarter of 2023, investment activity rose sharply by 3.0%, while capacity utilization in the manufacturing sector remained above its long-term average.[2]

Although falling energy prices have served to dampen the rise in consumer prices since German inflation peaked at 10.0% in November 2022[3], increased prices continue to have a real and palpable impact on household disposable income. For the month of June 2023, the German Federal Statistical Office reported an inflation rate of 6.4%[4], slightly higher than for the previous month. On June 15, 2023, the European Central Bank raised the benchmark interest rate for bank refinancings by 0.25 percentage points to 4.00% with the aim of containing general price inflation.[5] Market interest rates, which have risen significantly since the initial rate hike, are increasingly placing a financial burden on both companies and private households with new or re-priced borrowings, such as for investment plans.

[1] Statistisches Bundesamt (destatis) Pressemitteilung Nr. 203 vom 25. Mai 2023
[2] BMWK, Die wirtschaftlichen Lage in Deutschland im Juni 2022
[3] Statistisches Bundesamt (destatis) Pressemitteilung Nr. 529 vom 13. Dezember 2022
[4] Statistisches Bundesamt (destatis) Pressemitteilung Nr. 255 vom 29. Juni 2023
[5] Europäische Zentralbank, Pressemitteilung vom 15. Juni 2023

Internationally, the economic signals are inconsistent. In the United States, the world's leading economy, the economy is showing increasing weakness and thus serving to dampen German exports. On the other hand, China – after finally lifting its onerous COVID-19 restrictions – is supporting world trade with record exports in June along with an increase in imports.[1] Overall, however, the picture is one of global weakness, with the Organization for Economic Cooperation and Development (OECD) forecasting only 2.7% growth for 2023, which would be – excepting pandemic year 2020 – the lowest growth rate in the global economy since the financial crisis of 2008.[2]

Since the spring, business confidence in Germany has once again softened.[3] The weak economy has likewise been having an impact on the country's labor market, with unemployment rising in June 2023 rising by 28,000 compared to the previous month and by 192,000 to 2,555,000 compared to the comparable prior-year month. The unemployment rate increased by 0.3 percentage points to 5.5%.[4]

General industry conditions

The international competition for attracting major investments in pharmaceutical research and development has intensified, because of acute conditions during the COVID-19 pandemic but also because of geopolitical considerations. Pharmaceutical companies are in an extraordinarily competitive race to be the first to gain market approval of new and innovative drugs and are therefore evaluating locations more critically than ever before, particularly in terms of the regulatory and policy environment, in order to optimize their allocation of investment and resources. Although Germany has long been well positioned in this competition because of the country's high quality of science and study management, it has been losing ground significantly over recent years, not only globally but even compared to its European neighbors.

This trend has been reinforced the German Statutory Health Insurance Financial Stabilization Act (GKV-Finanzstabilisierungsgesetz) from the end of last year as well the pending 2023 reforms to EU pharmaceuticals law and the impact which these have on market access, pricing, protection of intellectual property and cost reimbursement, as well as on decreasing the attractiveness of Germany and the EU as a location for pharmaceutical R&D.[5]

Following the shortages experienced during the COVID-19 pandemic and associated disruptions to biopharmaceutical supply chains, European governments and legislatures have come to recognize the importance of ensuring the supply of biopharmaceuticals, including not only reference (originator) drugs but also specifically biosimilars. Within Germany, the first measures are already being taken to reduce dependencies and boost supply chain security. A central policy objective is to strengthen the domestic production of active ingredients and to ensure its resilience, including the reshoring of previously offshored production.[6]

According to a recent IQVIA market report, the German pharmaceutical market, including both clinical and pharmacy sales, generated € 14.5 billion of sales revenue from January to March 2023, a 7.9% rise over the comparable prior-year quarter. Specifically within the pharmacy market, which is the larger of the two channels by volume, sales increased with lower single-digit growth to € 11.6 billion. In looking at German pharmaceutical sales revenue for the first three months of 2023 by drug segment, the biosimilars segment grew somewhat faster than the average.[7] For full-year 2022, biosimilars generated sales of € 2,324 million in Germany, an increase of 7% over the prior year (2021: € 2,182 million). In measuring the market share of biosimilars versus the reference drugs with which they compete (i.e. the potential market space available to biosimilars), the share for biosimilars was 64% in 2022 compared to 60% in 2021.[8] For the first three months of 2023, sales of biosimilars through the pharmacy channel grew to € 550 million, an increase of 7.2% compared to comparable prior-year quarter.[9]

1 IfW Institute for Economic Research – China stützt Welthandel July 5, 2023
2 OECD Economic Outlook, June 2023
3 Ifo Institute – Geschäftsklimaindex sinkt, June 26, 2023
4 German Federal Employment Agency, press release no. 33 of June 30, 2023
5 vfa/Kearney - Pharma-Investitionsstandort Deutschland
6 BMG - GAct to Improve the Supply of Medicines and Avoid Shortages, April 5, 2023
7, 9 IQVIA Marktbericht Classic Entwicklung des deutschen Pharmamarktes im 1. Quartal 2023
8 vfa Biotech-Report 2023: Die automatische Substitution braucht es nicht, June 9, 2023

Developments in the global biosimilars market

The global market for biosimilars has been steadily growing for years and will, according to forecasts, continue to expand at high rates. Recent studies[10] have forecast high annual growth rates (CAGR) of up to 25.9% for the world's biosimilars market over the next four to five years.[11]

Particularly striking growth is being seen in the U.S. market, where biosimilar alternatives are explicitly on the political agenda and have since 2021 been promoted by law. According to IQVIA, sales of biosimilars in the United States are expected to increase from USD 10.2 billion in 2022 to more than USD 38.5 billion in 2027.[12]

In the European market, which together with the American market dominates the global market, biosimilars currently generate annual sales of some € 9 billion.[13] Experts expect average annual growth rates of 8% through 2025.[14]

Over the period through 2028, the smaller Asia-Pacific biosimilars market is forecast to see the highest growth due to low levels of government regulation and increasing collaboration between global leaders and regional providers.[15]

Global competition in the biosimilars market is becoming more intense. Above all, Asian manufacturers from China and India are expanding their expertise in biotechnology-based production and development. However, because of the exacting standards for biosimilar active ingredients to gain regulatory approval, Europe remains the dominant production location due to the high level of expertise required for the production of innovative and technically complex pharmaceuticals. 51% of approved active ingredients are currently produced in Europe.[16]

The high complexity of biosimilars production combined with the high qualifications and expertise required of staff currently continues to offer European manufacturers a certain competitive "moat".

The fundamental long-term drivers for the global biosimilars market are the world's growing population, increasing life expectancy and the rising incidence of diseases which are now treatable, in particular immunological, oncological and ophthalmological diseases. Due to their generally significantly lower prices compared to the reference drugs, biosimilars provide urgently needed financial relief to strained healthcare systems, which are still struggling to recover from the enormous cost impact of COVID-19. Biosimilars offer exceptional opportunities for healthcare providers and insurers to combine cost efficiency with highly effective treatment. In the United States, for example, spending USD 36 billion on biosimilars over the past decade has saved USD 56 billion on reference drugs.[17] In European countries, cost savings from biosimilars through 2022 are estimated at more than € 30 billion.[18]

The development of the biosimilar market is expected to accelerate with the patent expiration of important reference biopharmaceuticals over the coming years. By 2032, more than 55 blockbuster drugs will lose exclusivity in the United States and Europe.[19] According to McKinsey, these drugs together represent an estimated market size of more than USD 270 billion.[20]

10 The Business Research Company (Hrsg.) Biologic & Biosimilar RA Drugs Global Market Report, IMARC Group: Biosimilar Market: Global Industry Trends, Size, Share, Growth, Opportunity and Forecast 2023-2028,
11 IMARC Group: Biosimilar Market: Global Industry Trends, Size, Share, Growth, Opportunity and Forecast 2023-2028
12, 17 IQVIA, Biosimilars in the United States 2023–2027, Jan. 2023
13, 18-19 IQVIA, The Impact of Biosimilar Competition in Europe, December 2022
14, 19 McKinsey & Company, Three imperatives for R&D in biosimilars, August 2022
15 Research and Markets - Biosimilar Market by Drug Class, Indication, Region
16 Healthcare Suppley Chain Institute / Institut der deutschen Wirtschaft Köln - Produktion von Biosimilars – Wer Reshoring möchte, muss Offshoring vermeiden
20 IQVIA, Global Use of Medicines 2023, Jan. 2023

Significant events

Signing of global commercialization partnership with Fresenius Kabi AG for Stelara® biosimilar candidate FYB202

At the beginning of 2023, Formycon, as owner of the exclusive worldwide marketing rights to FYB202 (ustekinumab), announced the conclusion of a global licensing agreement with Fresenius Kabi AG. Upon successful approvals by the respective regulatory authorities, Fresenius Kabi will launch FYB202 in key global markets. Already with the signing of the agreement, Formycon will receive an upfront payment along with subsequent payments contingent upon the achievement of certain regulatory milestone, which are expected to total in the mid double-digit million euro range. In addition, profits from futures product sales will be divided roughly equally. Secondary marketing rights for Germany and for certain parts of the Middle East and North Africa (MENA) and Latin America regions remain with Formycon.

Private placement of capital increase to finance further growth

In February 2023, the Executive Board and Supervisory Board of Formycon AG resolved to increase the Company's registered capital (Grundkapital) by € 910,000.00, from € 15,128,775.00 to € 16,038,775.00, through the issuance of 910,000 new bearer shares without par value (the "New Shares"). The 910,000 New Shares were placed with institutional investors using an accelerated bookbuilding process under exclusion of subscription rights. Formycon anchor shareholders ATHOS KG and Active Ownership Capital, who had previously committed to support the transaction, participated in the capital increase.

Based upon the bookbuilding process carried out as a private placement transaction, the Executive Board, with the concurrence of the Supervisory Board, established a placement price of € 77.00 per New Share, resulting in gross issuance proceeds of € 70,070,000.00 before commissions and other costs. The New Shares, which correspond to approx. 6.02% of the Company's existing share capital, were placed with select investors in Germany and other member states of the European Economic Area who are "qualified investors" within the meaning of article 2(e) of Regulation (EU) 2017/ 1129 (the "Prospectus Regulation") as well as with select investors in certain other jurisdictions. Within the United States, the New Shares were placed exclusively with "qualified institutional buyers" within the meaning of Rule 144A, which provides an exception to the registration requirements under the Securities Act of 1933.

The net proceeds from the capital increase will primarily be used to accelerate the ongoing development of Formycon's own biosimilar candidates (FYB202, FYB206, FYB208, FYB209) through to the regulatory approval stage, to expand the biosimilars pipeline, and to support the Group's organic growth strategy. In addition, Formycon is considering the integration of further assets along the value chain into the Group in order to accelerate the Formycon's organizational development as a highly focused and globally active player in the biosimilars market segment. The capital increase has also served to strengthen the balance sheet, including the partial repayment of the amount drawn and outstanding under the revolving credit line granted by ATHOS and Active Ownership to facilitate the strategic transaction with ATHOS.

Successful completion of clinical development phases of FYB202 and FYB203 projects as well as submission of approval documents for FYB203 to U.S. Food and Drug Administration (FDA)

During the first half of 2023, Formycon was able to report significant advances in two of its biosimilar drug development projects nearing completion. Following positive interim results from the MAGELLAN-AMD phase 3 clinical trials on the efficacy and tolerability of FYB203, the candidate biosimilar to Eylea®, Formycon was able to announce the filing of the biologics license application (BLA) for FYB203 with the U.S. Food and Drug Administration (FDA) on June 29, 2023, in line with the Company's original plan. The FDA generally decides within 60 days of submission whether to accept the application ("file acceptance") for further examination. In the case of FYB202, a candidate biosimilar to Stelara®, Formycon was able to announce the successful completion of the expanded phase 1 pharmacokinetics (PK) study, marking a remaining milestone in this development project. Submission of regulatory approval documents in Europe and the U.S. remains planned for the third quarter of 2023.

Summary statement of Executive Board on business performance and economic environment

Formycon Group can look back with satisfaction upon a successful first half of 2023, with significant progress in its drug development projects as well as six-month consolidated financial performance in line with expectations. In addition to first-time sales revenue from FYB201 following its market launch of in the United Kingdom, the United States, and certain countries in the European Union, as well as revenue from development services provided by Formycon for out-licensed biosimilar candidates, a significant part of first-half consolidated revenue of € 43,789K was from payments under the newly signed partnership with Fresenius Kabi AG for the global commercialization of FYB202. In addition to an upfront payment upon signing of the agreement, Formycon received an additional milestone payment upon successful completion of the expanded phase 1 pharmacokinetics (PK) study for FYB202.

Consolidated six-month EBITDA of € 7,262K reflects this increase in revenue, minus allocated cost of sales. It should be noted that net profit for both the current and prior-year periods includes significant non-cash items resulting from the strategic transaction with ATHOS KG. As of June 30, 2023, Formycon Group held cash and cash equivalents of € 36.9 million, with this solid liquidity position reflecting the capital increase in February, which generated gross issuance proceeds of approx. € 70.1 million.

This dynamic growth can likewise be more broadly seen in the global market for biosimilars. Recent studies are forecasting robust average annual growth rates (CAGR) of up to 25.9% over the next four to five years. Formycon has good reason to be satisfied with last year's market launch of its first biosimilar product, FYB201. The initial success has been particularly striking in the United States, where Formycon's sales partner Coherus BioSciences Inc., which markets the Lucentis® biosimilar under its new trademark CIMERLI™, has already secured significant market share compared to a competing biosimilar. With a permanent reimbursement code (Q-Code) under the Healthcare Common Procedure Coding System (HCPCS) used by Medicare and other payers recently issued for CIMERLI™, the reimbursement process for treating physicians and medical practices is now greatly simplified, and since the second quarter of 2023, sales of CIMERLI™ in the U.S. have significantly increased as a result. According to information released by our marketing partner Coherus BioSciences, Inc., U.S. sales of CIMERLI™ in the second quarter of 2023 were approx. USD 26.7 million[1], compared to approx. USD 6.2 million in the first quarter of 2023.[2]

As to FYB203, the candidate biosimilar to Eylea®, which was filed with the U.S. Food and Drug Administration (FDA) on June 29, 2023, submission of approval documents to the European Medicines Agency (EMA) is likewise planned for 2023 and remains on schedule. The same applies to the submission of approval documents for FYB202, the candidate biosimilar to Stelara®, for which submission to both of these regulatory authorities remains on plan for the third quarter of 2023. As for the development of FYB206, the candidate biosimilar to Keytruda®, preparations are underway for the launch of clinical trials, which are planned for 2024.

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[1] Coherus BioSciences Reports Second Quarter 2023 Financial Results and Business Highlights | Coherus BioSciences, Inc.
[2] Coherus BioSciences Reports First Quarter 2023 Financial Results and Business Highlights | Coherus BioSciences, Inc.

Due to the now greatly changed pandemic situation and, in particular, the WHO's lifting of the COVID-19 global health emergency in May 2023, the innovative COVID-19 development project FYB207 has been re-evaluated under careful consideration not only of scientific but also economic and strategic factors. On the basis of this assessment, Formycon will continue to move forward with FYB207 but in a resource-sparing manner, and with the goal of transferring the project into a strategic development partnership so that it can advance into the clinical development phase. It must be acknowledged, however, that the strategic focus of most potential industrial partners is now on other priorities. Formycon will continue to pursue patent applications, scientific advice meetings, and potential opportunities for outside funding options with the aim of ensuring that development work of this novel drug can be reactivated or accelerated at any time as conditions change.

Financial performance

During the first six months of 2023, Formycon Group generated revenue of € 43,789K compared to € 17,644K in the comparable prior-year period. The sharp increase was mainly due to additional revenue resulting from the changes in the Group's structure and from significant milestone payments realized from the FYB202 project under the new partnership with Fresenius Kabi.

In addition, government funding for the FYB207 project in the amount of € 2,836K (1H 2022: € 4,270K) was received during the period, serving as an offset to R&D expenses. EBITDA for the period was € 7,262K (1H 2022: negative € 7,588K), which reflects the sharp increase in revenue. Net profit for the period was € 1,804K (1H 2022: € 80,031K). Net profit in the prior-year period was extraordinarily high due to the non-recurring gain in the amount of € 88,562K from the revaluation of Formycon's carried investment participation at the time in FYB 202 GmbH & Co. KG, as well as from the valuation of the contingent purchase price payments under the strategic acquisition transaction.

During 2023, Formycon Group has continued to push forward with the development of its biosimilar projects in accordance with its business model. As a result of the out-licensing of FYB201 at the end of 2013 and FYB203 in 2015, Formycon generated significant revenue, as in previous years, through ongoing contractual payments received for development services that Formycon has been providing 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.

The commencement during the reporting period of development work on Formycon's two new biosimilar candidates FYB208 and FYB209 led to an increase in research and development expenses. At the same time, the expenditures for the FYB206 development project are being capitalized and thus no longer included in research and development expenses, thereby resulting in a net decrease compared to the prior-year period.

The Group ended the first half of 2023 with an equity ratio of 47%, unchanged from the prior year (June 30, 2022: 47%). The Group's non-current assets are almost completely covered by equity and non-current liabilities from conditional purchase price payment obligations, which is suggestive of a healthy balance sheet structure. Current assets consist largely of liquidity and near-liquid assets, suggesting a low level of balance sheet risk. The increase in trade accounts receivable and other receivables is mainly due to a receivable from Fresenius Kabi for a contractual milestone payment which was paid in July 2023.

Current liabilities include the loan from Formycon shareholders in the amount of € 20,000K and the current portion of the conditional purchase price payments in the amount of € 36,571K. The financial position of Formycon Group thus continues to be stable. As in the past, key liquidity indicators are adequate, with current assets of € 83,395K offset by current liabilities (excluding current portion of shareholder loans and current portion of conditional purchase price) of € 25,031K. The Group did not have any bank loans during the period. During the first half, € 20,000K of the outstanding amount under the shareholder loan was repaid, leaving another € 20,000K drawn and outstanding as of the reporting date, out of a total current credit line of € 48,000K. To further strengthen the Group's financial structure, 910,000 newly issued shares were privately placed on the capital market at a price of € 77.00 per share in an accelerated bookbuilding process under exclusion of subscription rights.

As of June 30, 2023, the Group held cash and cash equivalents in the amount of € 36,865K (Dec. 31, 2022: € 9,820K) and working capital (including cash and cash equivalents) in the amount of € 54,963K (Dec. 31, 2022: € 13,975K). The increase over to the prior year is due in large part to the capital increase transaction. Reference is made to the Condensed Consolidated Interim 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 at the Group's headquarters in the Munich suburb of Martinsried/Planegg.

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 the 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. Interest rate risks are not significant.

Investment analysis

Significant investments in long-term assets currently consist primarily of capitalized development costs for the FYB202 and FYB206 projects. Substantial and necessary items of property, plant and equipment, primarily laboratory equipment, are typically financed through lease agreements.

Other non-financial aspects

Staff

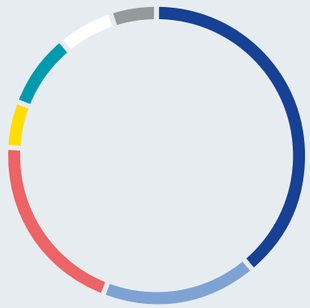
The development of biosimilars is a research-intensive field of activity and therefore requires the expertise of highly qualified and capable employees. For this reason, financial performance indicators alone cannot provide a comprehensive picture of Formycon's value creation potential, and therefore 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, 2023, Formycon Group employed a total headcount of 224 persons (June 30, 2022: 178). The average staffing during the first half of 2023 compared to the prior-year period is shown below, divided by functional area and including percentage change, and expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff:

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

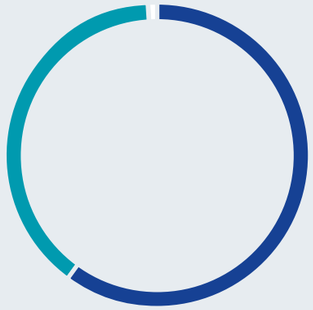
	H1 2023	H1 2022	Change
Research & development	**157.1**	117	+21.3%
Business operations	**9.6**	7	+45.5%
General & administrative	**23.7**	16	+48.1%
Total	**190.5**	152	+25.2%

Educational level of Formycon staff



39 % Doctorate
17 % Master's equiv. (Diplom)
20 % Master's
5 % Bachelor's
8 % Vocational training (technical)
6 % Vocational training (administrative)
5 % Degree or certification not (yet) completed

Gender diversity of Formycon staff



59,4 % Female
40,1 % Male
0,5 % Other

31

Formycon employs staff from a total of 31 different countries.

Staff expenses during the first half of 2023 were € 8,550K (1H 2022: € 7,948K), with the increase due primarily to the greater average number of employees.

The high level of educational and training qualification of Formycon Group's workforce is illustrated in the accompanying figure (data as of June 30, 2023 for this and subsequent workforce-related illustrations).

As can be seen, 81% of the Group's employees have completed a university degree, which in the case of 39% 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 two trainees as IT specialists for systems integration.

As to gender diversity, some 60% of the Group's workforce is female, and 0.5% does not identify as male or female. The employee average age as of June 30, 2023 was 40 years. Formycon is proud of the diverse organization that it has developed over the years. The international diversity of Formycon's staff, from 31 different countries, reinforces its self-image as a truly global organization and biopharmaceutical company.

Sustainability and Corporate Social Responsibility (CSR)

Formycon fully embraces its corporate responsibility to consider the impact of its activities and decisions upon its staff, upon the environment and upon society at large, and to align these with the expectations and needs of Formycon's key stakeholder groups. For this reason, Formycon anchors its business decisions on the principles of Corporate Social Responsibility and on the importance which we as a company place on sustainability.

As of the first half of 2023, Formycon has further intensified its engagement with Environmental, Social and Governance (ESG) themes. Formycon is committed to managing and conducting its business activities in a responsible and sustainable manner. This commitment specifically includes further measures to reduce the Group's ecological footprint, to promote an inclusive corporate culture, and to embed transparency and ethical behavior into its corporate governance. Formycon believes that this holistic view of important ESG themes will create additional long-term value for the Group and its stakeholders. During the first half of 2023, Formycon launched a new "Formycon Road to Sustainability" initiative together with a leading consultancy, with the aim of developing a suitable and meaningful sustainability strategy for Formycon by the end of 2023. Currently, Formycon is in the stage of materiality analysis and is evaluating actual and potential risks, as well as upside opportunities, in each of the ESG component areas, then assessing these accordingly. In 2024, Formycon Group expects to implement the first of the work packages generated on the basis of the newly developed sustainability strategy, including the creation of relevant company policies and the initial implementation of new or adapted processes. New sustainability-related communications will be rolled out in parallel.

It should be noted that Formycon's biosimilars are already having a positive impact towards the Sustainable Development Goals (SDGs) of the United Nations: Our biosimilars improve access to healthcare by making high-quality biopharmaceuticals available to more patients around the world for the treatment of serious diseases, and through the market competition and lower prices which they bring, they help to relieve the cost burden on the world's healthcare systems.

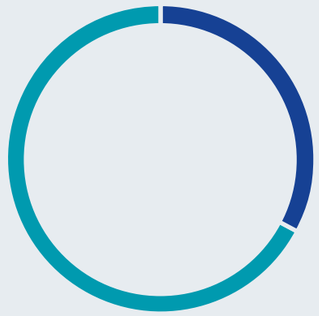
Corporate ethics and Code of Conduct

The business success of Formycon Group depends, among other factors, on the expertise of highly educated and skilled professional staff whose behavior in their decisions and business dealings is built upon a foundation of responsibility and ethical principles. All new employees must familiarize themselves with the German General Equal Treatment Act (Allgemeines Gleichbehandlungsgesetz, AGG) through appropriate training. Starting from 2023, all employees must complete such training on an annual basis. Formycon Group also places great importance upon its Code of Conduct, with which all staff are expected to fully comply. Not only board members and employees but also everyone who acts on behalf of Formycon must comply with this Code of Conduct, regardless of job function, work area or location. Formycon does not tolerate violations of its Code of Conduct or applicable law of any kind, and it is Formycon's policy to properly investigate any instance in which non-compliance is suspected.

Management culture and leadership

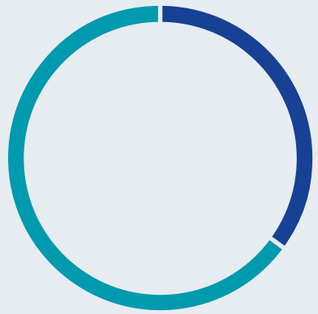
Formycon sees its management culture and good leadership by its managers as a key determinant not only of staff commitment but also long-term sustainability of good management, business success and ultimately financial success. In its corporate culture and management culture, Formycon thus attaches particular importance to a spirit of mutual trust, thereby encouraging a free and open exchange of views spanning the entire organization, across all levels. Formycon views this open, candid and agile work environment as crucial for shared success. The aim is to foster a culture of good management and strong leadership, characterized by values, empowerment and accountability, as essential to achieving Formycon's business goals. Towards this end, Formycon's human resources department offers training courses to all managers at regular intervals to improve their people management skills, while also guiding and coaching them in their day-to-day people management challenges through regular "people management circles."

Division of second-level management by gender



36 % Female
64 % Male

Division of all management positions by gender



35 % Female
65 % Male

Staff recruitment and diversity

Formycon recruits its staff without regard to gender, gender identity, sexual orientation, ethnicity, nationality, age, handicap or other such personal characteristics. The Group's culture is characterized by an affirmative attitude towards integration, respect for diversity and equality of opportunity. Formycon is firmly committed to its policy of non-discrimination in recruitment, hiring, training, promotion and all other such matters, with the goal of fostering an open working environment in which creativity and individuality can thrive. Since 2022, Formycon Group has taken measures to proactively support the its LGBTQIA+ community through new dedicated communication channels for information and for exchanges among staff, including a new section on the company's intranet called "FOR_MY_Queers_ Community".

Over the years, Formycon has been able to recruit outstanding talent and to successfully integrate new staff into the organization. In 2023, Formycon will begin developing an "employer branding" concept, with the objective not only of being perceived by candidates as an attractive employer but also of firmly anchoring the basic principles of its corporate and management culture throughout the Formycon organization.

Formycon has long been deeply committed to equal promotion opportunities for women and have made active efforts to fill its management ranks, including at more senior levels, with excellent female candidates. As of June 30, 2023, the percentage of women in Formycon's second level of management (Vice President, Senior Director, Director and Associate Director) was 36.4%, while for all management positions the percentage was 35.2%.

Formycon's attractiveness as an employer

Formycon strives to be an attractive employer and, specifically with regard to salary structure, orients itself towards the total compensation levels and

models customary within the biotechnology industry. In addition to fixed remuneration, Formycon's compensation structure provides for variable annual remuneration appropriate to organizational level which is linked to the achievement of key company goals. In addition, agreement on individual performance goals serves not only to achieve these overarching corporate goals but also to advance and encourage the personal development of the individual employee. Formycon also regularly reviews its compensation levels and makes adjustments as appropriate based not only upon performance but also general economic conditions, including but not limited to price and wage inflation, as part of Formycon's regular annual salary review process.

In order to help its employees to offset rising consumer prices in Germany and to ease concerns about financial security in an inflationary environment, Formycon is, voluntarily and for the benefit of its valued employees, making full use of the Inflation Compensation Premium (Inflationsausgleichsprämie) enacted into German law last year, which permits but does not require the tax-free payment to each employee of up to € 3,000 in total between October 2022 through the end of 2024 as an inflation relief measure.

Formycon Group has a stock option program for selected managers and staff under which options to buy shares are allocated annually according to set criteria as a long-term incentive component. To further its efforts to attract and retain talent, the Group has implemented an employee referral program which offers incentives to staff who contribute to the recruitment process by recommending suitable candidates.

In addition, Formycon Group offers a range of attractive employee benefits. Formycon's company pension scheme, which was recently amended, is especially worthy of mention in that Formycon offers its participating staff an employer contribution that goes well beyond the customary amount in Germany.

Staff retention and development

In order to maximize the attraction and retention of talent which is so vital to the Group, Formycon pursues a strategy of actively fostering long-term loyalty of its staff throughout the Group's various functional areas which goes beyond monetary incentives. In order to further this strategic aim, Formycon offers individual opportunities for advanced training, not only for present job responsibilities but also to prepare staff for future career progression. Formycon Group has, in addition, established a "scientific career path" for its research staff as well as a "managerial career path" program for staff in the regulatory affairs, quality management and project management areas, thereby fostering career planning within the Group.

Employee satisfaction

Formycon Group places great importance on overall employee satisfaction, which is – along with technical excellence – essential to Formycon's ultimate success. The Group offers opportunities for flexible work arrangements, company pension offerings, programs to promote general health, including a company-subsidized mental health program newly introduced in 2023, a company-subsidized food vending machine, joint team-building events and various other employee benefits. These extensive programs and benefits underscore the sincere regard the Group has for its staff and contribute to high levels of employee loyalty and satisfaction.

To objectively measure the overall satisfaction of its workforce, Formycon again, in its regular two-year cycle, conducted an anonymous survey during 2022 using an external service provider, focusing in particular on any psychological issues which might be adversely affecting its workforce. Although the overall feedback was, as in past years, very positive, follow-up workshops were regularly conducted to identify specific opportunities for improvement, particularly with an eye to making Formycon the best possible place to work – now and long into the future.

Workplace health and safety

Because both productivity and quality depend crucially upon the health and motivation of the people who work at Formycon Group, we believe that effective and efficiently organized workplace health and safety is an important competitive advantage. This means that operational performance can only be maximized if health and safety protections are taken seriously and given highest priority. Formycon is proud to hold the "Systematic Safety" seal of quality from the German Accident Prevention and Insurance Association for the Raw Materials and Chemical Industry (Berufsgenossenschaft Rohstoffe und chemische Industrie). This voluntary audit process to receive the seal of quality included rigorous assessments of Formycon's occupational health and safety management system as well as the effectiveness of its health management system. During the first half of 2023, Formycon recorded one non-critical workplace accident. Through the Group's health and safety guidelines, training courses and regular medical check-ups offered to staff, Formycon pursues the goal of doing everything reasonably possible to prevent workplace accidents and to ensure the continued safety and well-being of the Group's entire workforce.

Formycon attaches great importance to the health of each and every employee. The Group, through its company doctor, offers annual flu vaccinations, eye examinations as provided by Company policy (and as prescribed by Council Directive 90/270/EEC on the minimum safety and health requirements for work with display screen equipment), and individual advice and assistance on workplace ergonomics. Since 2023, Formycon also now offers first-aid courses for staff.

Sustainability as an integral part of corporate development

Formycon's commitment to the United Nations Global Compact

Since 2019, Formycon has been a member of the UN Global Compact, one of the world's largest and most important initiatives for responsible corporate governance, which has set itself the goal of an inclusive and sustainable global economy, supporting companies in aligning their strategies and activities with social and sustainability goals. In addition to the protection of human rights, these also include the elimination of all forms of forced labor, the abolition of child labor, the elimination of discrimination in hiring and employment, and protection of the environment, with a focus on a precautionary approach, the promotion of environmental awareness, and the development and diffusion of environmentally friendly technologies. Formycon stands firmly for global action with responsibility and will maintain this principled commitment long into the future. As a member of the UN Global Compact, Formycon has committed itself to strategically anchoring the theme of sustainability into its business and contributing to the achievement of the UN's Sustainable Development Goals on the basis of the Compact's Ten Principles.

Having its headquarters and laboratories in Germany, Formycon Group already has a high consciousness with respect to human rights, and these standards are formally expressed in the Group's Code of Conduct. Formycon and its business partners, as part of the biopharmaceutical development industry, operate in a highly regulated environment and are already accustomed to regular audits by supervisory authorities. By requiring its suppliers and cooperation partners to cooperate during the past fiscal year with Formycon's initial risk assessment and review process for human rights compliance, Formycon is making every effort to ensure that it is not complicit in any kind of human rights violations anywhere along its value chain.

Following these first steps, Formycon plans to successively increase its ongoing commitment to further sustainability goals and, above all, to continue to integrate the themes of environmental and social responsibility into its corporate management and culture. Towards this worthy end, Formycon launched a new "Formycon Road to Sustainability" initiative in the first half of 2023, together with a leading consultancy, with the aim of developing a suitable and meaningful sustainability strategy for Formycon by the end of 2023. It should be noted that Formycon's biosimilars are already having a positive impact towards the Sustainable Development Goals (SDGs) of the United Nations: Our biosimilars improve access to healthcare by making high-quality biopharmaceuticals available to more patients around the world for the treatment of serious diseases, and through the market competition and lower prices which they bring, they help to relieve the cost burden on the world's healthcare systems.

Corporate Governance

Corporate governance spans all aspects of managing and monitoring a company. In simple terms, it means consistently good management, which is something we wholeheartedly believe in. The German Corporate Governance Code (Deutsche Corporate Governance Kodex, DCGK) provides a comprehensive rulebook, with principles, recommendations and suggestions for executive boards and supervisory boards of officially listed German companies based on nationally and internationally recognized standards intended to ensure that all listed companies are managed in the interests of stakeholders. The Code, originally published by the German Federal Ministry of Justice in 2002, was most recently recast by the Government Commission on the German Corporate Governance Code (Regierungskommission Deutscher Corporate Governance Kodex), which entered into legal force upon publication in the Federal Gazette on June 27, 2022.

This new Code provides clarify regarding the respective obligations of a company's executive board and supervisory board to ensure the continued existence of the company and its sustainable creation of value (company interest) in accordance with the principles of social market economy, taking into account the interests of the company's shareholders, its workforce and other groups with an interest in the Group (together "stakeholders").[1]

Because Formycon shares trade within the "Open Market" segment,[2] it is not legally subject to the requirements for organized markets within the meaning of the German Securities Trading Act (Wertpapierhandelsgesetz) and it not legally considered to be listed. As such, Formycon is under no obligation to publish a corporate governance statement or declaration of compliance. However, as part of our commitment to transparent communication with our investors, the Executive Board and Supervisory Board of Formycon have taken initial steps to implement the principles, recommendations and suggestions anchored in the Code within our organization to the greatest extent possible with the aim of, in addition to this voluntary report on corporate governance, adding a declaration of compliance over the coming years – likewise on a voluntary basis – into this section of the company's future annual financial statements. Formycon's aim in doing so is to strengthen the confidence of its investors, its employees and the public that it is a well-managed, properly supervised company that can be counted on to do the right thing.

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 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, 2023, a total of 155 group employees were, on a full-time equivalent (FTE) basis, working in research and development (June 30, 2022: 129). During the reporting period, research and development costs of € 21,147K were capitalized, which are costs for the continued development of the FYB202 project acquired through the ATHOS transaction, as well as for the FYB206 project, which attained a development milestone in the previous year whereby future economic benefit can now be assumed with sufficient probability, thus permitting the capitalization of development costs incurred starting from the attainment of this milestone. 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 development costs for pending projects acquired as part of the acquisition transaction and capitalized in 2022, the total book value of these capitalized development costs as of June 30, 2023 was € 500,165K.

[1] Government Commission on the German Corporate Governance Code
[2] Frankfurt Stock Exchange, Open Market

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 2022: 85.1%) of all hours worked were project-related. During the same period, 14.6% (1H 2022: 17.1%) 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 would 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 biosimilar medicines, operates in a dynamic global market with many different participants and influencers. Business success is determined by the identification of profit opportunities, along with the best possible assessment of the many and varied risks associated with these. In order to ensure that this happens, the entire staff of Formycon, up to and including the Executive Board, must adhere to the Group's established risk management system, thereby aiming to ensure that that these risks are handled optimally while at the same time providing the necessary entrepreneurial and operational flexibility. 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.

Formycon's risk management system is a cornerstone of the Group's governance, ensuring compliance not only with legal and regulatory requirements but also with general principles of sound corporate governance. Good risk management strives to recognize potential risks as early and proactively as possible and to suggest suitable countermeasures, whether to prevent the risk from occurring in the first place or to mitigate consequences in the event that the risk nonetheless materializes. The focus is first and foremost upon foundational risks that could have a significant adverse impact on business activities or even jeopardize the Group's continued existence. For this purpose, Formycon has appointed various risk managers who are responsible for risk management in their respective administrative and operational areas.In this way, all risks which are significant and can be anticipated, having first been broken down into the respective administrative and operational areas, are subjected to systematic ongoing monitoring and assessed as to their probability of occurrence and the severity of potential adverse consequences.

The results of risk management monitoring and reviews, along with all relevant information, are presented to the Executive Board following each six-month period. The Executive Board may, if it deems appropriate, conduct its own independent assessment of risk management process and/or of specific key risks. The Executive Board also reports its findings to the Supervisory Board.

In parallel with these ongoing risk monitoring processes, the Group may also decide to assess and report on particular 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; controlling; environmental protection, health protection, and workplace safety; financing and liquidity risks; organizational risks; patent risks; staff risks; risks associated with product development; legal risks; regulatory and political risks; and competitive 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 € 150 to 250 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 six to eight 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, however, 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 2022 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 33% of the total drug market in 2022, equal to approx. € 19 billion in sales revenue[1] – 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.

Financial control

Through its internal control system, Formycon ensures the correctness of its accounts and accounting processes, including the correctness and reliability of its financial reporting as this appears in its financial statements and management report. In this, Formycon relies upon the standards established by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer in Deutschland, IDW) for accounting-related internal control systems and risk management systems.

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. 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 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 € 68 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.

1 IQVIA, "Fokus Biosimilars" newsletter, issue no. 12

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.

Risks to the Group's future financial performance could arise from the general economic environment, in which potential bank insolvencies cannot be ruled out. Formycon invests its liquid assets exclusively with financial institutions with strong and stable ratings and which can be regarded as relatively safe in the event of a financial crisis.

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 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 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.

Patent risks

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 generally involve very high costs. In the worst case, such a dispute could result in restrictions on, or even the prohibition of, the marketing of one or more products on one or more relevant markets, and/or the imposition of sizable fines. Such a legal action could also make it necessary to cease the development, launch, or ongoing 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 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.

General risks associated with the development of an innovative COVID-19 drug

The above risks relating to the development of biosimilars substantially also apply to the development of a new and innovative COVID-19 drug under the FYB207 project. This pending project is now subject to increased risks due to changes in the framework conditions, in particular the recent lifting by the World Health Organization (WHO) of the COVID-19 global health emergency as well as the more challenging prospects for entering into a development partnership (or if so, on worse terms than originally anticipated).

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

With the takeover and integration of Bioeq GmbH, 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, 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, Bioeq GmbH bears not only financial risks but also the risk of liability towards participating patients or other test subjects. With the acquisition of Bioeq GmbH as a subsidiary company belonging to Formycon Group, these risks are effectively assumed by Formycon.

Formycon and Bioeq 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, Bioeq 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. In each such 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. 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 over extended contractually binding periods, in order to retain market share. This would improve its defensive competitive position against a new biosimilar entry and make it more difficult for the biosimilar to 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 the Ukraine war

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.

Special risks relating to the COVID-19 pandemic

The proactive measures taken by Formycon in the very early stages of the COVID-19 pandemic to protect its workforce and avoid infection, and which were continuously adjusted and consistently managed in the following years, proved their worth. From the beginning of the pandemic to the present day, there have been only a few isolated cases of infection within the organization, with no material business impact. On May 5, 2023, the World Health Organization (WHO) declared an end to the global health emergency caused by the SARS-CoV-2 virus. Already on February 2023, Formycon revoked its company policy to protect against COVID-19 infection which had been in place throughout the pandemic.

Although the COVID-19 pandemic is over, at least for the time being, the SARS-CoV-2 virus, like other infectious agents, continues to circulate among the global population, and could theoretically produce other virus variants of concern in the future. With Formycon's proven experience in measures to protect against infection and to transition at short notice to decentralized and mobile work arrangements, Formycon is in a position to quickly and effectively response to any such future health emergencies.

Thus, even if such a pandemic were to occur again, it would be unlikely to have a significant direct impact on business activities, development projects or timelines. However, it must be recognized that such an event could adversely impact Formycon's partners and suppliers, thereby indirectly having an adverse impact.

Opportunities

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

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

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, 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 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".

In addition, the Executive Board has now separately assessed the general risks associated with the development of an innovative COVID-19 drug in view of the change in the epidemiological environment, in particular the WHO's declared end to the global health emergency, which in turn has adversely impacted the interest level of potential development and commercialization partners. For this reason, the Executive Board has decided to separately include this risk category in the risk matrix and, in accordance with its criteria, to assess the risk level of the FYB207 project as "high".

As of the date of this publication, the Executive Board cannot identify any individual or aggregate risks which might endanger the Group's continued existence. Through the use of internal control mechanisms, the Group is in a position to identify changes in its risk exposure at an early stage and to take appropriate action. Furthermore, in view of its financial stability, the Group is well equipped to deal with potential future risks.

Summary risk matrix

Risk	Risk type	Assessed risk level	Change
General risks associated with the development of biosimilars	Strategic	Medium	→
General risks associated with the development of an innovative COVID-19 drug	Strategic	High	↗
Risks relating to clinical trials and to the role of Bioeq 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, and workplace safety	Operating	Low	→
Organizational risks	Operating	Low	→
Staff risks	Operating	Medium	→
Legal risks	Operating	Medium	→
Special risks relating to the Ukraine war	Operating	Low	→
Special risks relating to the COVID-19 pandemic	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 receivables, liabilities 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. No risks are foreseen which might endanger Form con as a going concern.

Report on outlook

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, 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 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 cash inflows from these product sales primarily into the accelerated expansion of Formycon's development pipeline. In doing so, we will have achieved key conditions necessarily to strengthen Formycon's position as a global player in the biosimilars market segment and to further build the Formycon organization into a fully integrated pharmaceutical company within this rapidly growing segment.

2023 financial outlook for Formycon Group

Product developments

For 2023, Formycon anticipates substantial license income determined on the basis of revenue and earnings contributions from sales of FYB201, the biosimilar to Lucentis® now being marketed under the names Ranivisio® [1], Ongavia® [2] and CIMERLI™ [3]. Following the filing with the U.S. Food and Drug Administration (FDA) in the first half of 2023 of the biologics license application (BLA) for FYB203, the candidate biosimilar to Eylea®, submission to the European Medicines Agency (EMA) is planned for the second half of the year. Submissions in the U.S. and EU for the regulatory approval of FYB202, the candidate biosimilar to Stelara®, are likewise planned for later this year. Assuming that approval of both biosimilars is granted in 2024, Formycon expects additional revenues from milestone payments in 2024/2025 as well as from sales starting from the market launch of the two biosimilars, which is planned for the second quarter of 2025. Formycon expects that its immuno-oncological biosimilar candidate FYB206 (reference drug Keytruda®) will move into clinical trials in 2024.

No independent clinical studies are planned for the innovative COVID-19 project FYB207 due to the significantly changed post-pandemic framework conditions. Formycon will continue to pursue FYB207 in a resource-conserving manner and strives to convert the project into a strategic development partnership. As to Formycon's biosimilar candidates FYB208 and FYB209, these are both in early-stage development.

[1] Ranivisio® is a registered trademark of Bioeq AG
[2] Ongavia® is a registered trademark of Teva Pharmaceutical Industries Ltd.
[3] CIMERLI™ is a trademark of Coherus BioSciences, Inc.

Revenue

We expect revenue to end the current fiscal year at between € 75 million and € 85 million (fiscal year 2022: € 42.5 million), with the increase largely from revenue and earnings contributions from sales of Ranivisio®, Ongavia® and CIMERLI™ (each of these being regional brands of the same FYB2021 biosimilar to Lucentis®) and from milestone payments for the FYB202 project.

EBITDA and net profit

Because the Group is still in a growth phase involving intensive investment and product development, EBITDA for the current year is expected to be in the range of negative € 15 million to negative € 5 million, slightly above the prior-year level.

Adjusted to exclude the non-recurring gain in fiscal year 2022 from Formycon Group's past investment in FYB202 GmbH & Co. KG, the consolidated net loss is expected to be considerably less than in the previous fiscal year.

The net loss for the year will be significantly influenced by the fair value remeasurement of the contingent purchase price payments, which in turn depends on external factors, in particular the prevailing interest rates (weighted average cost of capital) used to discount future cash flows. Assuming that the discount rates at the end of the fiscal year remain unchanged compared to June 30, 2023, the Executive Board currently expects a full-year net loss of between € 30 million and € 20 million. A 0.5% increase in the discount rates applied would have the effect of increasing net profit (i.e. reducing net loss) by approx. € 6 million, while a 0.5% reduction would reduce net profit (increase net loss) by approx. € 9 million.

In the case of the FYB201 and FYB202 projects, these are expected to make positive EBITDA contributions in fiscal year 2023 as revenue is generated from these. In case of projects FYB203 and FYB206, these are expected to be roughly EBITDA neutral; the costs incurred for FYB203 are passed on to the development partner, while costs incurred for FYB206 development now qualify for capitalization. Conversely, projects FYB207, FYB208 and FYB209 are expected to make negative EBITDA contributions.

Key financial performance indicators for Formycon Group

in € million	Fiscal year 2022 (actual)	Fiscal year 2023 financial outlook per Annual Report 2022	Fiscal year 2023 current forecast	Key assumptions and causal factors
Revenue	42.5	Significant increase	**75.0** *to* **85.0**	+ Share of FYB201 sales proceeds + FYB202 milestone payments
EBITDA	-15.9	At prior-year level	**-15.0** *to* **-5.0**	– Investments in FYB207, FYB208 and FYB209 + Revenue from FYB201 and FYB202
Net profit (loss)	36.0	At prior-year level excluding non-recurring item	**-30.0** *to* **-20.0**	– Non-recurring item (89,9 Mio. €) in fiscal year 2022 ± Revaluations of conditional purchase payments for FYB202 GmbH & Co. KG
Working capital	14.0	At prior-year level	**15.0** *to* **25.0**	– Investments in FYB202 and FYB206 – Repayment of shareholder loan + Proceeds of capital increase

Working Capital

Beyond the effect of net income, Formycon anticipates a negative impact to working capital from investments into projects FYB202 and FYB206 and from the planned partial repayment of shareholder loans. These outflows have, however, been offset by the proceeds of the capital increase carried out in February. It is therefore expected that working capital will end the current year little unchanged or slightly higher.

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 a focus on biosimilars while maintaining our high standards of performance and quality. To achieve this goal, Formycon will continue to invest heavily into the expansion of our own development 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 an integrated 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.

Martinsried/Planegg,
as of August 17, 2023

Dr. Stefan Glombitza

Dr. Andreas Seidl

Nicola Mikulcik

Enno Spillner

Interim Financial Statements of Formycon Group

January 1 to June 30, 2023

Consolidated Interim Statement of Financial Position

In € K

	Explanatory note	June 30, 2023	December 31, 2022
Assets			
Non-current assets			
Goodwill	12	44,534	44,534
Other intangible assets	12	500,660	488,439
Right-of-use (ROU) assets		9,088	8,916
Property, plant and equipment		2,573	2,600
Investment participations at equity		180,244	186,406
Financial assets		92,450	92,300
Total non-current assets		**829,549**	**823,195**
Current assets			
Inventories		965	571
Trade and other receivables		30,970	14,314
Contract assets	6	8,187	1,161
Prepayments and other assets	12	6,408	4,636
Cash and cash equivalents		36,865	9,820
Total current assets		**83,395**	**30,502**
Total assets		**912,944**	**853,697**
Equity and liabilities			
Equity capital			
Subscribed capital	13	16,039	15,129
Capital reserve	13	411,539	343,419
Accumulated loss carryforward	13	-1,967	-37,960
Period income (loss)		1,805	35,993
Total equity capital		**427,416**	**356,581**
Non-current liabilities			
Non-current lease obligations		7,722	7,594
Other non-current liabilities		269,023	319,339
Deferred tax liabilities	10	126,697	119,518
Total non-current liabilities		**403,442**	**446,451**
Current liabilities			
Provisions		387	-
Current lease obligations		1,086	925
Contract liabilities		1,336	-
Other current liabilities		59,548	38,314
Trade payables		19,721	11,318
Current income tax liabilities		8	108
Total current liabilities		**82,086**	**50,665**
Total liabilities		**485,528**	**497,116**
Total equity and liabillities		**912,944**	**853,697**

Consolidated Interim Statement of Comprehensive Income

In € K

	Explanatory note	Period	
		Jan. 1 – June 30, 2023	**Jan. 1 – June 30, 2022**
Revenue	6	43,789	17,644
Cost of sales		-26,153	-12,317
Research and development expenses	7	-5,170	-7,933
Selling expenses		-437	-1,140
Administrative expenses		-5,543	-4,608
Other expenses		-142	-161
Other income		14	-
Operating profit/loss (EBIT)		6,358	-8,515
Income from investment participations at equity	8	-6,162	88,668
Finance income	8	8,960	5
Finance costs	8	-93	-112
Net finance income		2,705	88,561
Profit before tax		**9,063**	**80,046**
Income tax expense	10	-7,259	-15
Profit (loss) for the period		**1,804**	**80,031**
Other comprehensive income (OCI)			
Comprehensive income (loss) for the period		**1,804**	**80,031**
Basic (undiluted) earnings per share (in €)	13	€ 0.114	€ 6.51
Average number of shares outstanding (without dilution)		15,826,442	12,286,972
Diluted earnings per share (in €)		€ 0.113	€ 6.41
Average number of shares outstanding (with dilution)		15,955,167	12,479,722

Consolidated Interim Statement of Changes in Equity

In € K

	Explanatory note	Subscribed capital	Capital reserve	Accumulated loss carryforward	Period income (loss)	Total equity capital
as of Jan. 1, 2022		**11,065**	**82,785**	**-24,670**	**-13,290**	**55,891**
Appropriation of prior-year income (loss)				-13,290	13,290	**-**
New shares issued as consideration for acquisition transaction		4,000	258,400			**262,400**
Effect of stock options granted			535			**535**
Shares issued through exercise of stock options		64	1,699			**1,763**
Period income (loss)					35,993	**35,992**
as of Dec. 31, 2022		**15,129**	**343,419**	**-37,960**	**35,993**	**356,581**
Appropriation of prior-year income (loss)				35,993	-35,993	**-**
Capital increase through issuance of shares	10	910	69,160			**70,070**
Costs of capital increase			-1,736			**-1,736**
Effect of stock options granted	9		696			**696**
Period income (loss)					1,804	**1,804**
as of June 30, 2023		**16,039**	**411,539**	**-1,967**	**1,804**	**427,415**

Consolidated Interim Statement of Cash Flows

In T €

			Period
	Explanatory note	**Jan. 1 – June 30, 2023**	**Jan. 1 – June 30, 2023**
Comprehensive income (loss) for the period		1,805	80,031
Adjustments for non-cash items:			
Depreciation and amortization	12	904	934
Net finance income	8	-2,705	-88,561
Effect of stock options	9	695	354
Net loss (gain) arising from disposals of non-current assets	12	16	13
Income tax expense	10	7,259	15
Changes in operating assets and liabilities:			
Decrease (increase) in inventories		-394	324
Decrease (increase) in trade and other receivables	6	-16,656	2,999
Decrease (increase) in contract assets	6	-7,026	408
Decrease (increase) in other financial assets		-	-
Decrease (increase) in prepayments and other assets		-1,772	-2,278
Increase (decrease) in provisions		387	
Increase (decrease) in contract liabilities		1,336	
Increase (decrease) in other liabilities		-403	-267
Increase (decrease) in trade payables		8,402	-4,060
Income taxes paid	10	-179	-35
Net cash from operating activities		**-8,331**	**-10,123**
Investments in intangible assets	12	-12,313	-2,156
Investments in property, plant and equipment		-253	-169
Investments in financial assets		-	-4,919
Acquisition of subsidiaries less cash and cash equivalents acquired		-	1,108
Interest received	8	236	51
Net cash from investing activities		**-12,330**	**-6,085**
Proceeds from issuance of shares	13	70,070	-
Costs of issuance	13	-1,736	-
Inflows (outflows) relating to financial liabilities		-20,165	10,000
Payment of lease liabilities		-465	-443
Interest paid	8	2	-136
Net cash from financing activities		**47,706**	**9,421**
Net increase (decrease) in cash and cash equivalents		**27,045**	**-6,787**
Cash and cash equivalents as of Jan. 1, 2023		**9,820**	**25,029**
Cash and cash equivalents as of June 30, 2023		**36,865**	**18,242**

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 2022. In addition, milestone payments received during the reporting period are now being recognized as revenue in the period in which Formycon attained the contractual milestone(s) and in which this attainment was confirmed by the contracting party.

The Group generates revenue from the granting of licenses to drug development assets in progress, which include the licensee's right to further development such assets. Such revenue is realized insofar as it is reliably measurable at the time the license is granted. In addition, the Group generates revenue from the achievement of development milestones under these license agreements, which are recognized in accordance with the cost-to-cost method. The associated expenditures are recognized in profit or loss as incurred, even if these relate to licenses capitalized in accordance with IAS 38 ("Intangible Assets"). Subsequent to the conclusion of a license agreement, expenditures are capitalized only to the extent that these are not related to the achievement of the respective milestones or (on a pro rata basis) to the extent that these are available for possible own use beyond the license granted.

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, 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 2022.

Judgements

Judgements exercised by the Executive Board have an impact on the following specific issues presented herein:

- Lease term: Determination of whether the exercise of lease extension options is reasonably certain
- Internally generated intangible assets: Point in time at which the criteria of IAS 38 ("Intangible Assets") are met, thereby resulting in an obligation to capitalize the asset (see Note 12 "Goodwill and other intangible assets")
- Valuations under IFRS 2 ("Share-based payment"): The determination of the fair value of share-based payment arrangements is based, among other factors, upon future share price volatility and future staff turnover, both of which may have a significant influence on the valuation of the options at the time of issuance. The correctness of these estimates depends upon actual future stock market performance and actual future staff turnover, both of which may deviate from the original estimates used in preparing these Financial Statements and may thus lead to significant corrections in future periods (see Note 9 "Share-based compensation arrangements")
- Identification of multiple performance obligations under the development partnership for purposes of revenue recognition (see Note 6 "Revenue") and separation thereof between provision of development services and granting of license

Assumptions and estimate uncertainties

Significant assumptions and estimates which could result in the risk of necessary adjustments in subsequent reporting periods to the amounts recognized herein have been made in the following specific cases:

- Recognition of deferred tax assets: Availability of future taxable profit against which deductible temporary differences and tax losses carried forward can be utilized (see Note 10 "Income tax expense")
- Determination of the fair value as of the reporting date of contingent consideration arising from the 2022 business combination transaction

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:

— Subsequent valuation (revaluation) of conditional purchase price payments arising from the 2022 business combination transaction

4. Changes in accounting and valuation methods

The accounting principles applied in the preparation of these Financial Statements correspond in full to those used in the preparation of the consolidated financial statements of Formycon Group for the fiscal year ending December 31, 2022.

The amendments to existing International Financial Reporting Standards regarding the classification of liabilities as non-current or current, the disclosure of accounting methods, the definition of estimates and deferred tax assets and liabilities arising from a single transaction, as well as the first-time application of IFRS 17 ("Insurance Contracts"), all of which are to be applied for the first time for fiscal years beginning January 1, 2023, had no effect on the preparation of these Financial Statements.

5. Operating segments

Basis for segmentation

The Group's segments are defined on the basis of the so-called "management approach" as required by IFRS 8 ("Operating Segments"). Accordingly, the segments are determined, and the disclosures for each segment made, based on the criteria that the key decision makers use internally for allocating resources and assessing the profitability of the Group's components. At Formycon, the key decision maker is the Executive Board, which allocates resources and evaluates segment performance on the basis of the management reports submitted to it. The accompanying table "Financial performance by operating segment" was prepared in accordance with this definition. In evaluating the performance of the Group's business segments, the Executive Board relies upon operating profit/loss as the primary measure of profitability.

The Executive Board monitors and directs activities at the level of the Group's individual development projects. Project progress, operational performance and financial performance are reported on a monthly basis along with a deviation analysis from the approved plan for each project. The Group's development projects thus also represent the Group's reportable segments.

The business activity of all segments is biopharmaceutical development. With the exception of FYB207, all of these are biosimilars, and thus the operating activities do not differ significantly between segments. For the purposes of internal reporting, almost all of the Group's costs are allocated to the individual projects.

The Group's business activities take place exclusively within Germany. During the reporting period, revenues were generated from Athos Group companies, from Bioeq AG, which is under joint control, and from an unrelated company. During the reporting period, all revenues were thus generated from three major customers.

Financial performance by operating segment

In € K

	FYB201	FYB202	FYB203	FYB206	FYB207	FYB208	FYB209	Total for reportable moperating segments	Remainder	Total
External revenue	6.082	23.664	14.043					43.789	0	43.789
Segment revenue	**6.082**	**23.664**	**14.043**	**-**	**-**	**-**	**-**	**43.789**	**0**	**43.789**
Segment profit (loss)	-5.254	13.848	-912	-	-1.731	-2.971	-1.253	1.726	78	1.804
Finance income								-	8.960	8.960
Finance costs								-	-93	-93
Income (loss) 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	-9.565	-14.580	-	-1.688	-2.897	-1.222	-34.997	-965	-35.962
Other expenses (selling expenses, miscellaneous)								-	-565	-565
Scheduled depreciation and amortization	-129	-252	-375	-	-43	-74	-31	-904	0	-904
Income taxes								-	-7.259	-7.259
Assets										
Investment participations at equity	180.244							180.244	0	180.244
Additions to non-current assets	150	3.154	-	8.993	-	-	-	12.297	1.139	13.436

6. Revenue

Revenue streams

During the period, Formycon generated revenue by providing development services for its partnered development projects FYB201 and FYB203 to the respective development partners. These costs include not only product development costs but also costs incurred for the management of clinical studies. In addition, since the market launch of FYB201 in the UK and subsequently in the EU and the United States, Formycon has been generating revenue through license income from the granting of exclusive marketing rights to Bioeq AG. Such license revenues are recognized only from the point at which they can be reliably determined. For the first half of 2023, a total of € 1,149K was recognized as license revenue.

In addition, revenue from milestone payments from the newly concluded marketing agreement for FYB202 was recognized during the reporting period in the amount of € 10,000K as consideration for the transfer of the license and € 13,664K for the achievement of development milestones.

Geographical breakdown of revenue

During the period, 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".

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 € 24,684K (Dec. 31, 2022: € 7,766K), while receivables from services not yet invoiced and separately reported as contract assets were € 8,187K (Dec. 31, 2022: € 1,161K). At the same time, recognition of payments received in the amount of € 1,336K was deferred as contract liabilities.

7. Research and development expenses

Formycon Group has, in support of its FYB207 project for development of an innovative COVID-19 drug, 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 € 2,826K (1H 2022: € 4,270K) were offset against the corresponding research and development expenses and thus recognized in profit or loss for the reporting period. During the same period, disbursements from the project sponsors were € 0K (1H 2022: € 1,561K).

8. Finance income/costs

The components of finance income and costs during the reporting period may be found in the accompanying table "Finance income and costs". Period finance income includes € 8,515K resulting from the fair value remeasurement of the contingent purchase price payments under the business combination transaction, primarily due to the change in the risk-free base interest rate during the reporting period and thus the corresponding change in the applicable discount rate.

Geographical breakdown of revenue

In € K

	Jan. 1 – June 30, 2023	Jan. 1 – June 30, 2022
Germany	14,181	12,125
Switzerland	29,608	5,519
Total	**43,789**	**17,644**

Finance income and costs

In € K

	Jan. 1 – June 30, 2023	Jan. 1 – June 30, 2022
Realized and unrealized gains from foreign currency translation	59	51
Interest income per effective interest method	386	-
Change in fair value of conditional purchase price obligations	8,515	-
Investment gain from FYB 202 GmbH & Co. KG	-	89,776
Finance income from investment participations at equity	**8,960**	**89,827**
Bank fees	-7	-8
Realized and unrealized losses from foreign currency translation	-47	-65
Interest expense from lease liabilities	-36	-33
Interest expense per effective interest method	-3	-52
Share of loss from associate Bioeq AG	-6,162	-1,108
Finance costs for investment participations at equity	**-6,255**	**-1,266**
Net finance income	**2,705**	**88,561**

9. Share-based compensation arrangements

During the reporting period, 25,000 share options were newly granted to staff members under the Stock Option Plan 2020, as shown in the accompanying table "Number of stock options issued and outstanding".

The valuation parameters used in measuring the fair values of these share-based compensation arrangements may be found in the accompanying table "Valuation of stock options".

During the reporting period, the total current expense for share-based compensation payments was € 695K (1H 2022: € 354K). As of June 30, 2023, the impact of these share-based payments on the capital reserve account was € 5,580K (Dec. 31, 2022: € 4,885K).

Number of stock options issued and outstanding

	Stock Option Plan 2015	Stock Option Plan 2020
as of Jan. 1, 2022	**311,250**	**101,500**
Options expired - July 2022	-30,000	-30,000
Options exercised and shares subscribed - July 2022	-64,025	
Share options granted - July 2022		132,500
as of Dec. 31, 2022	**217,225**	**204,000**
Share options granted - May 2023		25,000
as of June 30, 2023	**-**	**229,000**

Valuation of stock options

Stock Option Plan	Tranche	Grant date	Vesting date	Years remaining until vesting	Expiry date	Assumed exercise date	Assumed term	Assumed interest rate	Market price at grant date	Subscription price	Minimum price	Market value of options
2020	5	May 12, 2023	May 12, 2027	3.87	Apr. 12, 2033	Nov. 18, 2028	5.53	2.38%	78.60	71.04	78.90	34.6178

10. 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.

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

Components of income tax expense
In € K

	Jan. 1 – June 30, 2023	Jan. 1 – June 30, 2022
Current tax expense	80	15
Deferred tax expense from:		
– valuation at equity	-82	-3,551
– differing asset valuations	-5	2
– capitalization of certain leases as right-of-use (ROU) assets and corresponding liabilities from lease obligations	-26	-34
– capitalization of certain internally generated intangible assets	7,065	544
– the recognition of customer liabilities	-356	-
– valuation adjustments to deferred tax assets	584	3,039
Total tax expense	**7,259**	**15**

Calculation of deferred tax liabilities

In € K

	June 30, 2023		December 31, 2022	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Valuation of participation in affiliate	255		172	
Valuation of non-current assets		90		95
Right-of-use (ROU) assets and corresponding leasing obligations	64		38	
Arising from purchase price allocation to capitalized assets		119,116		119,116
Capitalization of internally generated intangible assets		14,202		7,137
Revenue recognition in accordance with IFRS 15	356			
Tax loss carryforwards – Formycon AG corporate tax (Körperschaftssteuer)	14,514		11,659	
Tax loss carryforwards – Formycon AG trade tax (Gewerbesteuer)	7,537		5,580	
Tax loss carryforwards – FYB202 Project GmbH	2,334		5,203	
Offset (netting) of deferred tax assets and liabilities	-6,711	-6,711	-6,830	-6,830
Valuation adjustment to deferred tax assets	-18,350		-15,823	
Total	**-**	**126,697**	**-**	**119,518**

11. Earnings before interest, tax, depreciation and amortization (EBITDA)

The Executive Board additionally presents EBITDA in the accompanying table "Calculation of EBITDA" because it relies upon consolidated EBITDA as a key performance measure 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 profit (EBIT). 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.

Calculation of EBITDA

In € K

	Jan. 1 – June 30, 2023	Jan. 1 – June 30, 2022
Operating profit (EBIT)	6,358	-8,515
Depreciation of property, plant and equipment	265	354
Amortization of right-of-use (ROU) assets	547	505
Amortization of intangible assets	92	75
EBITDA	**7,262**	**-7,581**

12. Goodwill and other intangible assets

Capitalized development expenditures

All costs for the further development of the FYB202 project, both external and internal, are capitalized as eligible development expenditures. As of June 30, 2023, the capitalized book value of this pending development project was € 485,050K (Dec. 31, 2022: € 481,895K).

In the case of the FYB206 development project, the technical proof of similarity (TPOS) milestone was reached in the middle of 2022. Upon attainment of TPOS, the Group's policy is to capitalize all subsequent internal and external development costs. As of June 30, 2023, the amount of capitalized development expenditures for this project was € 14,735K (Dec. 31, 2022: € 5,742K).

During the reporting period, borrowing costs of € 860K under the shareholder loans were allocated to these two qualifying assets, FYB202 and FYB206, and capitalized as part of their acquisition costs. The prepayments in the amount of € 6,408K (Dec. 31, 2022: € 4,636K) are primarily prepayments for development services.

13. Equity capital

Changes to equity capital 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 € 16,038,775.00, which is divided into 16,038,775 bearer shares without par value.

In February 2023, the Executive Board and Supervisory Board of Formycon AG resolved to increase the Company's registered capital by € 910,000.00, from € 15,128,775.00 to € 16,038,775.00, through the issuance of 910,000 new bearer shares without par value. The newly issued shares were placed with institutional investors using an accelerated bookbuilding process under exclusion of subscription rights.

14. 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 the fiscal year as partial consideration for the acquisition of the shareholdings in FYB202 Project GmbH and Bioeq AG, which are measured at fair value. For all other financial assets and liabilities, book value is an adequate approximation of fair value, and thus there is no there is no separate estimate of fair value.

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, 2022, the contingent purchase price payments were valued at € 314,274K; as of the reporting date, these were valued at € 305,759K. The difference of € 8,515K has been included in finance income. 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 rates ranged from 12.50% to 14.45%.

15. 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. During the reporting period, remuneration accrued to members of the Supervisory Board was € 55K (1H 2022: € 42K).

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 € 20,126K with related companies was recognized, of which € 6,098K was with jointly controlled Bioeq AG. In terms of the closing balance sheet, € 9,638K is recognized under trade receivables. There is also a loan receivable from Bioeq AG in the amount of € 92,450K 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.

€ 20,000K out of the total € 40,000K drawn and outstanding under the shareholder credit line was repaid during the reporting period, along with accrued interest. Thus, out of the total available credit line of € 48,000K, € 20,000K remained drawn and outstanding as of June 30, 2023. This amount is included in current liabilities.
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 € 305,759K, while finance income for the reporting period included € 8,515K arising from the fair value measurement of these obligations.

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

16. 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. However, it should be noted for the sake of completeness that Formycon AG and its commercialization partner Fresenius Kabi announced on August 7, 2023 that they had entered into a commercialization agreement ("settlement") with Johnson & Johnson for FYB202, a biosimilar candidate for Stelara®, in the United States. The agreement ensures that FYB202 may, upon FDA approval, be launched on the U.S. market no later than April 15, 2025.

Martinsried/Planegg,
as of August 17, 2023

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