



**Formycon Group**  
*key financial figures*

**2023**

**2022**

**77.7**

Revenue  
in € Million

**42.5**

Revenue  
in € Million

**1.5**

EBITDA  
in € Million

**-15.9**

EBITDA  
in € Million

**13.3**

Adjusted EBITDA  
in € Million

**-28.8**

Adjusted EBITDA  
in € Million

**75.8**

Net Income  
in € Million

**36.0**

Net Income  
in € Million

**38.9**

Working Capital  
in € Million

**14.0**

Working Capital  
in € Million

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

## About Formycon



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



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

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



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



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



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

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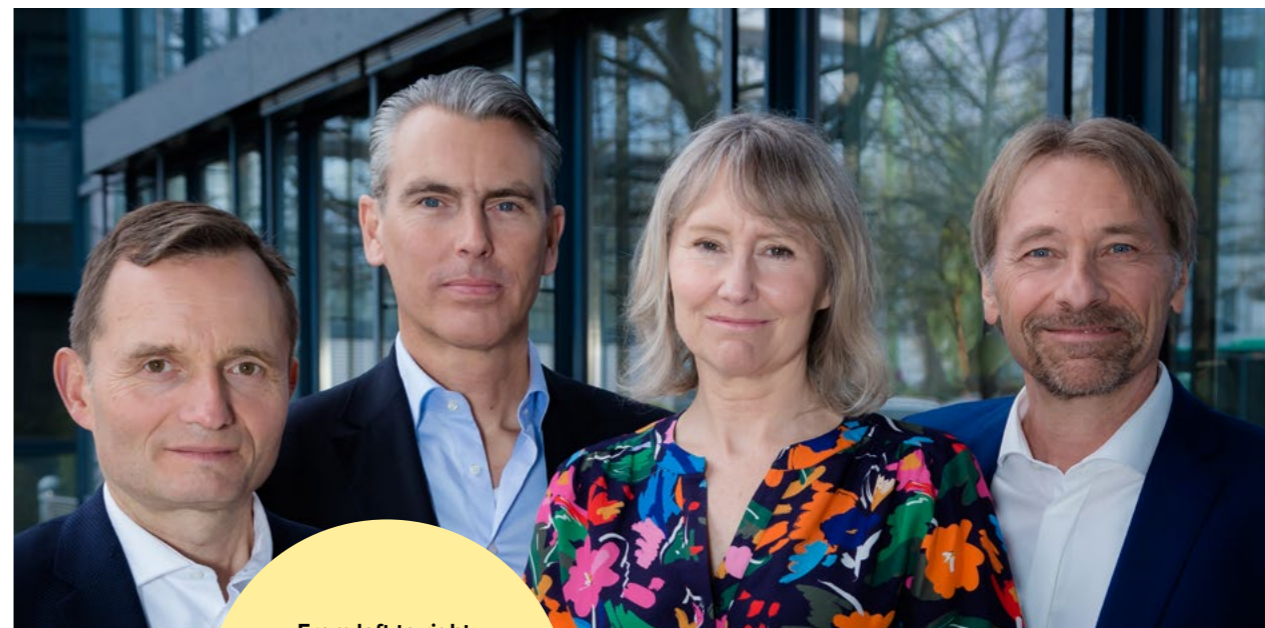
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To our  
shareholders

## An interview with our **Executive Board**



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

***Let's together look back upon 2023, a year in which Formycon was able to announce a number of major advances, particularly in its biosimilars development. From your standpoint, what were the highlights?***

**Dr. Stefan Glombitza, CEO:** „Biosimilars are making modern medicine more democratic. What I mean by this is that all patients should have access to the best possible therapy – and in particular, to highly effective biopharmaceuticals. Formycon has set itself the goal of becoming a driving force in this global transformation.

Toward this goal, we have achieved a number of important milestones over the past two years: in 2022 with the first regulatory approvals of our Lucentis® biosimilar FYB201 as well as our first market launches in Europe and the United States; →



→ then in 2023 with the achievement of key development milestones in our pipeline projects, as well as the increasing market success of FYB201. With FYB201 we have, in important markets, been gaining significantly higher share than our competitors.”

**You mentioned key milestones in Formycon’s pipeline projects last year. What were these specifically?**

**Dr. Stefan Glombitza, CEO:** “First of all, we managed to initiate the formal drug approval process in both the U.S. and Europe for our two late-stage drug candidates FYB202 [ candidate biosimilar to Stelara®] and FYB203 [candidate biosimilar to Eylea®]. Also in 2023, both of these successfully completed the validation phases with the respective authorities. Assuming that the review process follows the schedule, we expect FDA approval in the United States during 2024 and EMA approval in

the European Union in late 2024 to early 2025. Another highlight of 2023 was the successful completion of the preclinical development work for FYB206, our candidate biosimilar to Keytruda®. Based on a promising preclinical data package, we were able to coordinate our further project strategy and a detailed clinical study program with the respective regulatory authorities. We expect to be in a position to recruit the first oncology patients into our clinical trials as planned in the course of 2024, which is the next major step toward approval.

Our two most recently launched development projects, FYB208 and FYB209, also made good progress. So in sum, we achieved all of the relevant development milestones that we set out to achieve in 2023 – and within our planned timeframes.“

**For the submissions of FYB202 and FYB203, it seems that the approval**

**application packages had to be created in a short timeframe and largely in parallel. How did you manage this?**

**Dr. Andreas Seidl, CSO:** “This was indeed a remarkable achievement, and it once again underlines the unique expertise and extraordinary capability of our teams in this critical phase of the development process. Last year we managed to submit a total of five approval applications to various regulatory authorities. We are talking about multiple modules with numerous documents, adding up to tens of thousands of pages for each application. The superb interdisciplinary collaboration, the excellent preparation work and, last but not least, the experiences from previous submissions all came into play here. This shows once again that our specialization and intense focus in biosimilars is a competitive strength and that we are able to operate on an equal footing even with major pharmaceutical companies.

In the case of FYB203 [aflibercept], we demonstrated comparable efficacy to the reference drug Eylea® in phase III clinical trials by improving visual acuity in patients with neovascular, or ‘wet’, nAMD [age-related macular degeneration]. We had already successfully completed the phase III clinical

trials for FYB202 [ustekinumab] back in August 2022. The results of the expanded phase I pharmacokinetics study further demonstrated bioequivalence to the reference drug Stelara® for all primary endpoints.”

**Weren’t clinical trials for Formycon’s innovative COVID-19 drug FYB207 also supposed to start in 2023?**

**Dr. Andreas Seidl, CSO:** “That was our original plan. However, we had to react to the changing COVID-19 environment. The pandemic numbers were already significantly down at the start of the year, and in May the WHO declared an official end to the global health emergency. This, of course, was a very good thing, but it also entirely changed the situation for us with regard to this innovative drug development project. As a result, we made the decision, at least for the time being, to pursue the development of FYB207 only in focused areas and in a very resource-sparing way through to preclinical proof of concept. In other words, our COVID-19 blocker project has been essentially put on hold. Should the pandemic come back, or should substantial government funding be made available to prepare for future pandemics, we are able to restart activities at any time. At the moment, however, →



**What is a biosimilar?**

Biosimilars are follow-on products to biopharmaceutical drugs whose market exclusivity has expired. Biopharmaceuticals are produced in living cells using state-of-the-art biotechnology. Because of the way in which these products are created and manufactured, a biopharmaceutical from a different provider cannot be identical, and in fact there are even slight differences from batch to batch. Although a biosimilar can inherently not be identical to the reference drug, it is extremely similar, with close comparability in terms of the drug’s safety, efficacy and quality. These provide the basis for the regulatory approval of biosimilar drugs in the world’s most stringently regulated markets, such as the European Union, the United Kingdom, the United States, Japan, Canada and Australia

*More about biosimilars starting from page 30*



**In the case of a biosimilar, how are phase I and phase III clinical trials different?**

The clinical comparison of a biosimilar to the reference drug generally involves includes phase I and phase III clinical trials with the study objective of excluding potential product-related and clinically relevant differences affecting pharmacokinetics (absorption, distribution, metabolism and excretion), therapeutic efficacy, and safety, including immunogenicity (i.e. the body’s immune response to the active ingredient).

The phase **I pharmacokinetics (PK) study** examines the bioequivalence of the biosimilar and reference drug in a homogeneous and sensitive study population, if possible in healthy volunteers. Bioequivalence means that a biosimilar and reference drug do not differ





from each other in terms of bioavailability (active ingredient concentration over time in the bloodstream after drug administration), or at least not to a clinically relevant extent (<20%).

In the **phase III study**, the clinical efficacy and safety (including immunogenicity) of the biosimilar is compared to the reference drug. These clinical efficacy trials are carried out in a sensitive patient population with a statistically sufficient number of participants. The primary efficacy endpoint should ideally measure the pharmacological activity of the drug (efficacy) with minimal dependence upon patient or disease-related factors. Appropriate equivalence ranges for the primary efficacy endpoint are established based on knowledge of the reference drug's efficacy for the selected indication as well as clinical judgment. While these equivalence ranges may represent the most significant difference in terms of efficacy, they are not significant in actual clinical practice.

Before the start of clinical trials, there is close consultation with the relevant regulatory authorities as to the appropriate phase I and III study designs and the determination of which studies are actually required.

→ we see no reason to do so. Especially since our strategic and scientific focus is one hundred percent on the development of biosimilars.”

***There aren't many pure-play biosimilar companies around the world. Do you find that Formycon's total focus on biosimilars also plays a role when it comes to partnering your pipeline projects?***

**Nicola Mikulcik, CBO:** “I think that we offer a uniquely attractive combination of several different strengths: our clear focus on biosimilars, our expertise, our reliability when it comes to achieving development milestones and sticking to timelines, the high quality of our products – these are all essential to a successful partnership. Our attractiveness was recently demonstrated by the signing of the global commercialization partnership for FYB202 with Fresenius Kabi. We were able to conclude these agreements early in 2023, meaning even before completion of clinical development. The settlement agreement with Johnson & Johnson to clear the way for the U.S. market launch was also an important milestone and, assuming approval by the FDA,

should enable market entry within the first launch group no later than April 15, 2025. Commercialization agreements for the European market space and Canada have now also been signed.

In the case of FYB203, our license partner Klinge Biopharma is currently in discussions with several renowned marketing partners.”

***FYB201 has established itself very 'quickly in some markets and somewhat more slowly in others. How do you assess the progress?***

**Nicola Mikulcik, CBO:** “We are, of course, especially pleased about the high market shares that FYB201 was able to achieve during 2023 in the U.S. and the UK. In the first 15 months following the U.S. market launch, some 190,000 doses of Cimerli® [FYB201] were administered to patients. This means that, by December of 2023, we captured a market share by volume of about 38%. This speaks for the excellent quality of our product as well as for the performance of the Cimerli® sales team, which is now working under the leadership of Sandoz fol-

lowing the strategic transaction between Coherus and Sandoz in March of 2024.

FYB201 has enjoyed similarly success in the UK, where it's marketed as Ongavia®. Thanks to our successful NHS [National Health Service] tender, our market share as of November 2023 grew to almost 70%. Elsewhere we've also been seeing positive trends for FYB201, especially in the highly fragmented EU market where it's marketed as Ranivisio®.

To understand the big picture here, you need to remember that ranibizumab was the first biosimilar to enter the market in the field of ophthalmology, so the market introduction has required more educational work than in medical treatment areas where biosimilar products are already established and well accepted. What this means is that we need just a bit more patience at the very beginning. Over time, we will increasingly gain share in important markets such as France, Germany, Spain and the Czech Republic. Biosimilars consistently deliver on their value promise of generating major savings for healthcare systems across all therapeutic areas, so there's no question that this will happen.

The first market launches have now taken place in the MENA [Middle East and North Africa] region, and approval applications for FYB201 are also underway in Latin America, where we are currently preparing the market launch together with our regional partners.”

***How will growing revenues from product sales affect Formycon on the financial side?***

**Enno Spillner, CFO:** “The revenues that we've started to generate from actual product sales, along with milestone payments and proceeds from the financing round in February 2023 and from Gedeon Richter's strategic investment at the beginning of 2024, have provided us with the financial resources to steadily build our development pipeline without financial constraints. FYB206, our candidate biosimilar to Keytruda®, is currently the focus of particular attention because of its enormous sales potential. Experts estimate that global sales of pembrolizumab, the active ingredient in Keytruda®, could be as much as 54 billion dollars by 2032. We have therefore prioritized various activities in order to further accelerate development, and we hope that this will bring us further competitive advantage in this market space. This is only possible because we have the financial resources that are required.

More broadly, we have formulated a clear set of objectives: We want to continue our growth, to continually expand our pipeline, and to become sustainably profitable in the foreseeable future. In my view, Formycon is absolutely on the right path. This view is also confirmed by the feedback we have been receiving at international investor conferences.



**FYB201 (ranibizumab) is being launched in more and more markets**

FYB201 is already available in 17 countries worldwide. Depending on the region, it is on the market under different trade names: in the EU and Switzerland FYB201 is called Ranivisio®, in the UK Ongavia®, in the United States Cimerli®, and in Canada Ranopto®. Within the MENA region, FYB201 is available in Jordan as Uptera® and in Saudi Arabia as Ravegza®. In Latin American countries, FYB201 will be called Ranivisio®.

→ On the subject of these investor conferences, over the past year we have significantly increased the number in which we participate in order to improve our international visibility and bring Formycon even more into the conversation. Biosimilars and their enormous growth potential over the coming years is by no means an investing theme that all are fully aware of. Every year, biologics with billions of dollars in annual global sales lose their exclusivity. By 2032, that will be around 45 such products with an estimated combined market size of more than 200 billion dollars per year. And so far we're only talking about the blockbuster drugs.

Let me make a final point: It's not just the business opportunity that is extremely attractive. Equally important to us is that, through biosimilars, we can make a contribution to improving access to modern and effective therapies for many patients around the world who have until now been underserved. That's also a goal for Formycon, and it's something that really motivates us."

***You've touched upon the societal role of biosimilars, so let's talk about these issues more broadly. How has Formycon been addressing the challenges of ESG Environmental, Social, Governance?***

**Enno Spillner, CFO:** "Even though we aren't required to comply with the CSRD [EU Corporate Sustainability Reporting Directive] until fiscal year 2025, which means starting in 2026, last year we launched our own "Formycon's Road to Sustainability" initiative, which we've been pursuing with real commitment. In our first year, we've already attained the first major milestone, which is the materiality analysis. Needless to say, the subject of "access to medicines" is a significant social issue globally. This will be a lengthy process, and we choose to call it our "Road to Sustainability" because it's a roadmap for what lies ahead – but already we've been learning a lot from each other in interdisciplinary groups, and we've been redefining our self-image and corporate culture.

At Formycon, we maintain a corporate culture that recognizes and promotes the strength of diversity. We are committed to a world in which every person – regardless of origin, gender, religion or other characteristics – enjoys the same opportunities and rights. Particularly in this day and age, we emphatically stand by these values, which are essential for us as individuals, for our company, and for our future."

***That's an uplifting statement on which to bring this interview to a close. Dr. Glombitza, now that 2024 is already in full swing, what are your expectations for 2024?***

**Dr. Stefan Glombitza, CEO:** "I would first like to underscore what Enno Spillner just said. We think it's important and valuable to expressly articulate what should actually be self-evident: With our diverse staff from over 30 different countries, we at Formycon have a wealth of different experiences, perspectives and ideas which collectively contribute to our company and our success. This is an immensely valuable resource, and together with our extraordinary in-house expertise across all stages of biosimilar development and our agile and entrepreneurial mindset, it is one of the great strengths of #TeamFormycon.

And on that note, we would like to once again say a heartfelt 'thank you' to our entire team for their hard work and commitment. We would also like to thank our shareholders for their continued trust in us and in the work that we do each day.

As to our expectations for 2024, I would like to mention just three highlights: the start of clinical studies for FYB206, the launch of our new FYB210 development project, and the regulatory approvals of FYB203 and FYB202 within the United States (in Europe early 2025). In any case, 2024 promises to be no less exciting than the past year, and I am really looking forward to the coming weeks and months."

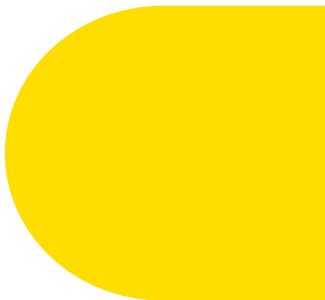
***Our thanks to all four of you for taking the time to talk with us.*** ←



**WHAT IS ESG?**

Environmental, Social and Governance, or "ESG", is an expression which first came to prominence in a 2004 United Nations report called "Who Cares Wins." The central premise is that investment decisions based upon ESG criteria should have a positive impact not only on society at large but also on the financial markets. Today, ESG sustainability criteria are steadily being integrated into more and more companies throughout Europe, in particular through the reporting requirements of the EU Corporate Sustainability Reporting Directive (CSRD), which raises sustainability reporting to the same level as financial reporting. The aim is to provide transparency on sustainability and corporate responsibility at a company-by-company level.

*More on ESG and Formycon's commitment to sustainability starting from page XX*



## Report of the Supervisory Board

### *Dear Shareholders,*

Formycon is able to look back upon yet another eventful and successful year. In my capacity as Chair of the Supervisory Board of Formycon AG, I am pleased to provide you with this overview of the Supervisory Board and its work during fiscal year 2023.

#### **Composition of Supervisory Board**

As established by the prevailing Articles of Association (Satzung) of Formycon AG, the Supervisory Board consists of four members:

and its shareholders, Dr. Strüngmann explained that he had joined the Supervisory Board in the context of Athos's important portfolio transaction with Formycon in order to support the success of the strategic transaction and subsequent changes in Formycon Group while also representing the interests of Athos as an anchor investor. His decision to step down from the formal role of Supervisory Board member due to his own time constraints does not in any way mean that he no longer feels deeply connected to Formycon Group, and both he and Athos will remain in close contact with the

#### **Composition of Supervisory Board**

<b>Name</b>	<b>Role</b>	<b>In office since</b>	<b>Elected until</b>
Dr. Olaf Stiller	Chair of Supervisory Board	2010	2025
Peter Wendeln	Deputy Chair of Supervisory Board	2010	2025
Klaus Röhrig	Member of Supervisory Board	2020	2025
Wolfgang Essler	Member of Supervisory Board	2023	2028

The composition of the Supervisory Board during 2023 changed compared to the prior fiscal year. During the proceedings of the Annual General Meeting held in presence form on July 25, 2023, Wolfgang Essler, Chief Representative (Generalbevollmächtigter) of Athos KG, was elected as a new member of the Supervisory Board by a large majority following the resignation of Dr. Thomas Strüngmann with effect from the end of the Annual General Meeting. In a personal letter to Formycon

management and Supervisory Board of Formycon. In the future, Dr. Strüngmann will, with the benefit of his long experience and expertise, continue his support and commitment to Formycon. Wolfgang Essler, who now takes lead responsibility for representing Athos, brings an extraordinary track record of knowledge and achievement, particularly in the areas of corporate development and transformation, strategic transactions, capital markets and finance.





### Cooperation between Executive Board and Supervisory Board

Throughout the entire fiscal year, the Supervisory Board, under my chairmanship, duly performed the tasks and duties incumbent upon it under German law and under the Company's Articles of Association. The Board intensively considered the operational and strategic development of Formycon AG, regularly advising the Executive Board as to its management of the Company and continuously monitoring this management. The Supervisory Board was involved in all decisions of fundamental importance. In my capacity as Chair of the Supervisory Board, I was available for discussions with investors pertaining to the Supervisory Board and its activities. The Supervisory Board received regular reports from the Executive Board in accordance with its informational obligations in both written and oral form, providing comprehensive and timely information about all business developments and events of substantive importance. These reports fully met the requirements established by the Supervisory Board in terms of both content and scope. On the basis of these reports, the current development status of the Company's six biosimilar candidates and COVID-19 drug, the Company's financial position and orga-

nizational alignment, and business events of key importance were discussed. Furthermore, regular consultations were held with the Executive Board on matters of the Company's strategy, business and financial planning, and business performance. The Supervisory Board also examined the Company's risk situation and risk management and its compliance with legal requirements and ethical norms.

The Supervisory Board was promptly and directly informed by the Executive Board of, and involved with, all important events and developments of material significance to the Supervisory Board's assessment of the Company's financial condition and business performance and to the corporate management of Formycon AG. In addition, I, in my capacity as Chair of the Supervisory Board, held regular interim discussions with the Executive Board to discuss current business performance as well as individual topics and decisions of particular importance. In this way, I was regularly and extensively informed between meetings.

The cooperation between the Supervisory and Executive Boards during the fiscal year thus met the standards for responsible and goal-oriented action in every respect.

#### Attendance at regular quarterly meetings of the Supervisory Board

Date	March 21, 2023	April 25, 2023	September 26, 2023	December 07, 2023
Meeting	Regular meeting	Regular meeting	Regular meeting	Regular meeting
Format	Presence format	Virtual format	Presence format	Hybrid format
Dr. Olaf Stiller	✓	✓	✓	✓
Peter Wendeln	✓	✓	✓	✓
Klaus Röhrig	✓	✓	✓	✓
Dr. Thomas Strüingmann (until July 25, 2023)	✓	✓		
Wolfgang Essler (since July 25, 2023)			✓	✓

### Supervisory Board meetings and main topics of discussion

In the course of the four regular quarterly board meetings during the fiscal year, all business matters and pending decisions requiring concurrence of the Supervisory Board under governing law or under the Company's Articles of Association were discussed in depth before being voted upon. All members of the Supervisory Board were in attendance at the meetings during which they held office, some of which took place by way of video or telephone conferences in lieu of presence meetings. The Executive Board was also present at, or otherwise participated in, these meetings in order to discuss issues and answer questions.

In these meetings, the Supervisory Board discussed, among other topics, the following regularly recurring agenda items:

- Progress reports on the Company's biosimilar drug development projects and sales reports on the FYB201 product following its approval and market launch
- Specific discussions of the upcoming submissions for approval of product candidates FYB202 and FYB203 to the respective regulatory authorities along with the decision to strategically deprioritize the FYB207 project
- Corporate planning, financial performance and adequacy of the Company's financial resources
- Consideration of potential financing alternatives as well as assessment of the capital increase
- Discussions of general corporate strategy and strategic alignment, including vertical vs. horizontal integration along the value chain

- Current and future development of the Company's business areas
- Human resources and planning

Central core themes of the meetings also involved ways to ensure and strengthen the Company's competitiveness and strategic concepts for its future growth. Further discussion topics of particular importance included:

- design and review of the goals defined and agreed in writing (Zielvereinbarung) with the Executive Board, and
- approval of the agenda for the Annual General Meeting.

In conjunction with the approval of the annual financial statements and quarterly financial reports, discussions specifically focused on key details of accounting valuations and the resulting consequences for Company's capital structure, in particular the long-term value of acquired assets.

Where agenda items concerning the Executive Board were discussed or voted upon, or where closed discussion or votes of the Supervisory Board were otherwise required, members of the Executive Board were excluded from these meetings or portions of meetings.

#### Audit committee

In order to effectively carry out its oversight duties relating to the auditing of the Company's financial statements and processes, the Supervisory Board formed an Audit Committee consisting of the following three members:

#### Audit committee

Name	Role
Klaus Röhrig	Chair of the Audit Committee
Dr. Olaf Stiller	Member of the Audit Committee
Peter Wendeln	Member of the Audit Committee

The Audit Committee held three meetings during fiscal year 2023, in which all members of the Audit Committee participated either virtually or in person. With the Company's appointed auditor present, the Audit Committee reviewed and discussed the annual financial statements of the Formycon AG parent entity, the consolidated financial statements of the Group, and the combined management report. The Committee also reviewed and discussed the annual report and audit reviews thereof.

The Audit Committee recommended that the Supervisory Board propose KPMG AG Wirtschaftsprüfungsgesellschaft (Munich office) to the 2023 Annual General Meeting as the auditor for both the consolidated financial statements in accordance with IFRS and the financial statements of Formycon AG in accordance with German statutory accounting (HGB). The Audit Committee accordingly issued the audit mandate to the elected auditor for fiscal year 2023, determined the focus of the audit process, and agree on the auditor's fee.

The Committee's activities also included oversight of the selection, independence, qualifications and effectiveness of the auditor. In doing so, the Committee focused in particular on its quality assessment of the audit process.

Finally, the Audit Committee reviewed the Company's accounting process and business risks and was regular informed on compliance issues.

#### **Audit of the financial statements and consolidated financial statements**

The consolidated financial statements of Formycon Group as of December 31, 2023 in accordance with International Financial Reporting Standards (IFRS), including the combined management report, and the financial statements of Formycon AG

(parent company only) as of December 31, 2023 in accordance with the German Commercial Code (Handelsgesetzbuch, HGB), including the combined management report, were properly examined, along with the underlying bookkeeping, by the Munich office of KPMG AG Wirtschaftsprüfungsgesellschaft, the audit firm appointed by the Annual General Meeting for fiscal year 2023, which has provided its respective unqualified audit opinions. The appointed audit firm further determined that the Executive Board has enacted appropriate measures for risk monitoring, as required under sec. 91 para. 2 of the German Stock Corporation Act. Risks which might jeopardize the Company's continued existence were not identified.

The annual financial statements of Formycon AG and combined management report for the Formycon Group were prepared in accordance with German statutory accounting regulations. The consolidated financial statements for Formycon Group were prepared in accordance with IFRS as applicable within the European Union and in accordance with the additionally applicable German statutory provisions pursuant to sec. 315e para. 1 of the Commercial Code. The proposals of the Executive Board as to the the financial statements, the combined management report and the auditors' reports were made available to all members of the Supervisory Board with adequate advance time and were discussed and examined in detail at the Audit Committee meeting of April 16, 2024.

A representative of the appointed audit firm attended the meeting in which the financial statements and audit thereof were reviewed and discussed, reporting in considerable depth on the primary results of the audit and answering questions of the Audit Committee relating thereto. Advance copies of the audit reports and other documents relating to the annual financial statements and consolidat-

ed financial statements were provided to the Audit Committee to facilitate comprehensive review and discussion.

All transactions requiring concurrence of the Supervisory Board under governing law or under the Company's articles of incorporation were examined by the Audit Committee on its behalf before reaching a decision on such concurrence.

Based upon its own examining review, the Audit Committee found no cause to raise any objections to the financial statement documents which it reviewed, including also the concluding statement of the Executive Board. Upon recommendation of the Audit Committee, the Supervisory Board approved the unconsolidated and consolidated financial statements for fiscal year 2023 as presented to it. The annual financial statements of Formycon AG and consolidated financial statements of Formycon Group have been adopted accordingly.

#### **Conflicts of interest among Supervisory and Executive Board members**

During fiscal year 2023, no conflicts of interest were reported involving Supervisory Board or Executive Board members.dern gemeldet.

#### **Changes in composition of Executive Board**

By the resolution of the Supervisory Board, the following changes were made to the composition of the Executive Board of Formycon AG:

Chief Financial Officer (CFO) Dr. Nicolas Combé, who had departed from the Executive Board as planned upon expiry of his term of office on June 30, 2022, remained available in an advisory capacity as interim CFO until March 31, 2023.

By the resolution of the Supervisory Board of September 6, 2022 and with effect from April 1, 2023, Mr. Enno Spillner was appointed Executive Board member and Chief Financial Officer (CFO) for a term of three years.

#### **Our gratitude to all those who have made this possible**

On behalf of the entire Supervisory Board, I would like to thank the members of the Executive Board for the solid cooperation and successful management of the Company through the many challenges of the past fiscal year.

We would also like to thank our entire staff for their extraordinary commitment and their impressive achievements. Through your dedication and efforts, Formycon's pipeline has matured and expanded, and important milestones have been attained.

Finally, we would like to once again extend our special thanks to our partners, who have likewise continued to play a vital role in Formycon's success.

Munich, April 2024

Dr. Olaf Stiller  
*Chair of Supervisory Board*

## Formycon on the stock market

### Shares and the capital markets

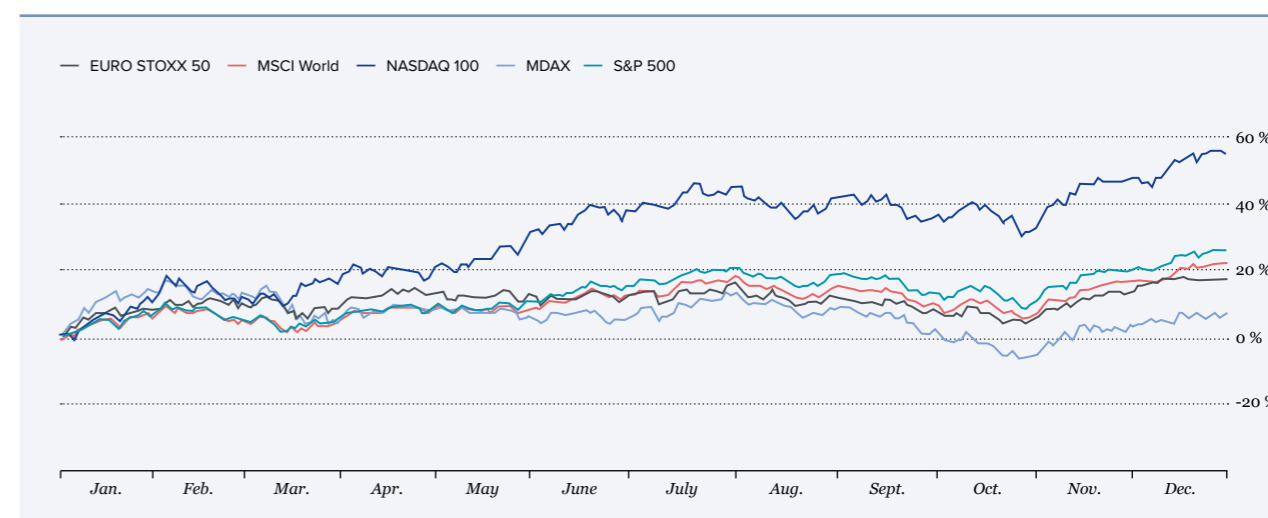
#### German and international stock market environment

Contrary to early expectations, 2023 turned out to be an exceptionally good year for stocks. Gains were posted on the most of the world's equity markets, and the MSCI World international equity index ended the year up 22%.<sup>1</sup> Leading benchmark indexes such as Dow Jones 30 and Germany's DAX 40 reached new all-time highs. The favorable market environment was fueled, in particular, by the prospect of lower inflation rates and thus falling key interest rates. In addition, investors were enthused by the growth potential of artificial intelligence.

In terms of market sectors, technology stocks were among the major outperformers, following the disappointment of the preceding year. In the United States, the world's largest equity market, the

resurgence of tech stocks drove up the technology-heavy Nasdaq 100 by approx. 54%.<sup>2</sup> The other major U.S. benchmarks likewise benefited, with the Dow Jones 30 gaining 14% for the year and the S&P 500 up 24%.<sup>3</sup>

In Europe as well, growth stocks stood out during 2023, contributing to healthy gains in the major indexes. For the year as a whole, the Euro Stoxx 50 index of Eurozone stocks rose by some 19%.<sup>4</sup> Within Europe, the German stock market was one of the best performers, and the country's DAX 40 benchmark index reached an annual high of 16,794 points in mid-December before closing the year at 16,752 points, corresponding to full-year gain of 20%.<sup>5</sup> Within Germany's small-cap sector, the MDAX index of medium-sized companies rose by 8%, while Germany's TecDAX index of technology stocks posted an annual gain of 14%.<sup>6</sup>



<sup>1</sup> <https://www.finanzen.net/index/msci-world/historisch>  
<sup>2</sup> [https://www.finanzen.net/index/nasdaq\\_100/historisch](https://www.finanzen.net/index/nasdaq_100/historisch)  
<sup>3</sup> [https://www.finanzen.net/index/dow\\_jones/historisch](https://www.finanzen.net/index/dow_jones/historisch),  
[https://www.finanzen.net/index/s&p\\_500/hochtief](https://www.finanzen.net/index/s&p_500/hochtief)

<sup>4</sup> [https://www.finanzen.net/index/euro\\_stoxx\\_50/historisch](https://www.finanzen.net/index/euro_stoxx_50/historisch)  
<sup>5</sup> <https://www.finanzen.net/index/dax/historisch>  
<sup>6</sup> <https://www.finanzen.net/index/mdax/historisch>,  
<https://www.finanzen.net/index/tecdax/historisch>

## Performance of Formycon shares

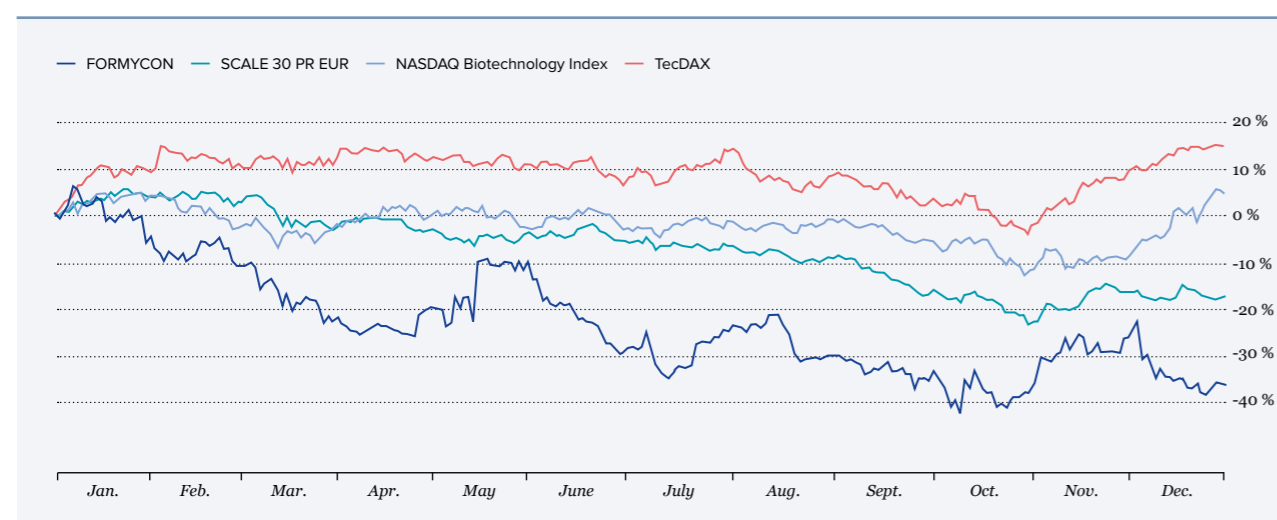
Compared to the broader market, the biotechnology sector generally underperformed during 2023. Although the sector's powerful value drivers remain in place, investors were preoccupied over the past year with temporary influencing factors, in particular a reduced emphasis on the healthcare sector with the end of the global pandemic as well as market attention on tech stocks and on sustainably profitable companies. In this context, the Nasdaq Biotechnology Index, which includes pharmaceutical and other biotech stocks, achieved an increase of 4%.<sup>1</sup>

Moreover, smaller emerging companies tend to be more affected by interest rate changes due to their typically greater dependence upon debt financing. The Frankfurt Stock Exchange's Scale 30 Index, which includes the most liquid stocks among Germany small- to medium-sized companies such as Formycon, fell by 16% during 2023.<sup>2</sup>

In this weak environment for biotech stocks and Scale 30 stocks, Formycon shares were unable

to extend the robust upward momentum of the prior year. Our shares ended the year with a closing price of € 56.40 in Xetra trading, marking a full-year price decline of 35%, a disappointment following the 47% gain in Formycon shares during 2022.

The stock market began 2023 on a high note, and Formycon shares reached a price of € 92.00 on January 9, which was not only the year high but a new all-time high. Over the rest of the year, however, Formycon shares fell in line with the broader markets for our two primary benchmark indices, Scale 30 and Nasdaq Biotechnology. While our shares saw short-term boosts from positive news regarding advances in our biosimilar projects, particularly the successful completion of clinical development of our FYB2022 biosimilar candidate and the settlement agreement with Johnson & Johnson for the commencement of marketing of FYB202 in the United States, as well as the initial sales performance of our Lucentis® biosimilar FYB201/Cimerli® in the United States, these have not yet translated into a sustained positive influence on our share price.



<sup>1</sup> [https://www.finanzen.net/index/nasdaq\\_biotechnology/historisch](https://www.finanzen.net/index/nasdaq_biotechnology/historisch)

<sup>2</sup> [https://www.finanzen.net/index/scale\\_30/historisch](https://www.finanzen.net/index/scale_30/historisch)

## 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	Oddo BHF Corporates & Markets AG M.M. Warburg & Co.

## Formycon shares: Performance information

in Euro	2023	2022
Opening price (Xetra) on Jan. 2, 2023 / Jan. 3, 2022	87,00	59,30
Closing price (Xetra) on Dec. 29, 2023 / Dec. 30, 2022	56,40	85,40
Average price (Xetra closing price)	67,25	69,10
Market capitalization as of Dec. 31	905.390.610	1.291.997.385
<b>in shares</b>		
Total shares traded (on all trading venues)	3.815.854	3.620.234
Daily average shares traded (on all trading venues)	14.964	14.087
Total shares issued as of Dec. 31	16.053.025	15.128.775



### Shareholder structure

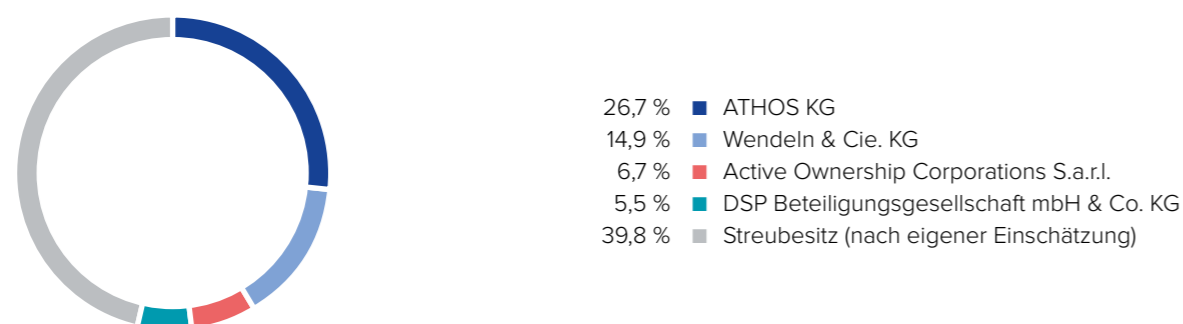
If certain voting rights thresholds are exceeded, the relevant shareholders are required, under German law, to file a notification thereof with the respective issuing company as well as with the German Federal Financial Supervisory Authority (BaFin). According to sec. 33 para. 4 of the German Securities Trading Act (Wertpapierhandelsgesetz), however, this provision regarding voting rights thresholds does not apply to all domestic issuers. The term “issuer” is restricted to those issuing companies whose shares are listed on an organized market within the meaning of sec. 2 para. 11 of the Act. Thus, these provisions of the Securities Trading Act do not extend to companies which, like Formycon, are listed in the unofficial regulated market (Freiverkehr), or “Open Market”,<sup>1</sup> as these companies are not legally considered to be listed on an official exchange.

Under sec. 20 of the German Stock Corporation Act (Aktiengesetz), however, entities owning more than one fourth (25%) of the shares of a stock

corporation with registered offices in Germany are subject to notification requirements. Through its entry as part of the 2022 capital increase transaction with a major capital contribution in kind, Athos KG indirect shareholding of more than 25% of the Company’s share capital and continued to be Formycon’s largest shareholder during fiscal year 2023. ATHOS KG and the relevant direct and indirect entities thereunder provided notification to Formycon and published an announcement in the Federal Gazette in accordance with sec. 20 para. 1 of the Stock Corporation Act.<sup>2</sup>

As of the close of fiscal year 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 as of Dec. 31, 2023



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

### Reporting of securities transactions by company executives (directors’ dealings)

During fiscal year 2023, no member of the Executive Board or Supervisory Board conducted any securities transaction subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR).

### Scale (Open Market) market segment

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

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

### Subscribed capital

As of Jan. 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 corresponded to approx. 6.02% of the Company’s shares already outstanding at the time of issuance.

In September and November of 2023, a total of 14,250 shares were subscribed and newly issued to employees under the Stock Option Plan 2015 and by the authority granted by resolution of the Annual General Meeting of June 30, 2015 (Conditional Capital 2015). By its respective resolutions of September 11, 2023 and October 24, 2023, the Supervisory Board accordingly amended Section 4 of the Company’s Articles of Incorporation (Satzung), which specifies the amount and division of the Company’s registered capital as well as conditional capital.

The registered capital of Formycon AG thus amounted to a total of € 16,053,025.00 as of Dec. 31, 2023.

## Annual General Meeting

The Annual General Meeting of Formycon AG was held on July 25, 2023 in presence form. The participating shareholders followed the various recommendations of the Executive Board and Supervisory Board, approving all resolutions proposed by management with large voting majorities. During the proceedings, the Executive Board provided shareholders with a detailed informative presentation about the Company's key developments over the fiscal year and answered all questions. In addition, the Executive Board's two newest members presented themselves to shareholder: Dr. Andreas Seidl, appointed to the Executive Board as Chief Scientific Officer (CSO) with effect from July 1, 2022, and Enno Spillner, appointed to the Executive Board as Chief Financial Officer (CFO) with effect from April 1, 2023.

Wolfgang Essler, Chief Representative (Generalbevollmächtigter) of Athos KG, was elected as a new member of the Supervisory Board by a large majority following the resignation of Dr. Thomas Strüngmann with effect from the end of the Annual General Meeting. In a personal letter to Formycon and its shareholders, Dr. Strüngmann explained that he had joined the Supervisory Board in the context of Athos's important portfolio transaction with Formycon in order to support the success of the strategic transaction and subsequent changes in Formycon Group while also representing the interests of Athos as an anchor investor. His decision to step down from the formal role of Supervisory Board member due to his own time constraints does not in any way mean that he no longer feels deeply connected to Formycon Group, and both he and Athos will remain in close contact with the management and Supervisory Board of Formycon. In the future, Dr. Strüngmann will, with the benefit of his long experience and expertise, continue his support and commitment to Formycon. Wolfgang Essler, who now takes lead responsibility for representing Athos and enjoys its complete trust, brings

an extraordinary track record of knowledge and achievement, particularly in the areas of corporate development and transformation, strategic transactions, capital markets and finance.

## Investor relations

Professional dialog with investors and with the international capital markets forms an important component of Formycon's investor relations program. During fiscal year 2023, Formycon's senior management and investor relations department presented the Company at a number of investor conferences within Germany and abroad, including the following:

- Unicredit & Kepler Cheuvreux: German Corporate Conference (Frankfurt)
- Stifel European Healthcare Summit (Bordeaux)
- Metzler Small & Mid-Cap Day (Frankfurt)
- H.C. Wainwright Virtual Ophthalmology Conference
- Jefferies Pan European Mid-Cap Conference (London)
- Montega HIT – Hamburg Investor Day (Hamburg)
- Spring conference / Equity Forum (Frankfurt)
- Berenberg & Goldman Sachs: German Corporate Conference (München)
- Hauck & Aufhäuser Stockpicker Summit (Mallorca)
- Jefferies London Healthcare Conference (London)
- Jefferies Global Healthcare Conference (New York)
- Deutsche Börse Equity Forum (Frankfurt)

During fiscal year 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	Alexander Neuberger
First Berlin Equity Research GmbH	Simon Scholes
Hauck Aufhäuser Lampe Privatbank AG	Alexander Galitsa
Kepler Cheuvreux	Nicolas Pauillac
SRH AlsterResearch AG	Alexander Zienkowitz
M.M. Warburg	Dr. Christian Ehmann

Formycon also participated in a number of virtual and international roadshows, including in Zurich, Madrid, Luxembourg and London.

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 Dec. 31, 2023, seven analysts were regularly providing equity research coverage on Formycon AG.

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

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

### Formycon AG

Sabrina Müller

*Director Investor Relations & Corporate Communications*

Phone +49 89 864 667 149

[ir@formycon.com](mailto:ir@formycon.com)



**Formycon**  
*Sustainable.*  
Growth.  
Potential.



# Formycon – Expertise *from* *the very* **start**

*Formycon is a successful, independent, “pure play” developer of biosimilars. The company’s track record speaks for itself: With an approved biosimilar product that is rapidly establishing itself in more and more markets around the world, two biosimilar candidate drugs pending approval with large target markets, three further candidates in the development pipeline, and countless development milestones achieved across the entire value chain, the biosimilar specialist based in the outskirts of Munich can stand proudly among far larger pharmaceutical developers. Formycon’s remarkable success is due first and foremost to the extraordinary expertise of its staff and to its agile corporate culture focused on sustainable long-term growth.*

Formycon’s mission is to improve patient access to vital modern medicines. Toward this end, the company has dedicated itself entirely to the development of biosimilar drugs. Biosimilars are follow-up products to biopharmaceuticals whose legal protection periods have expired. They are used to treat serious and chronic diseases, such as autoimmune diseases and cancer.

#### **Greater cost efficiency and improved patient access**

When biosimilars enter the market, they create competition and thus improve cost efficiencies in the treatment of the relevant medical condition, thereby broadening access to the treatment. For healthcare systems and insurers, the savings from biosimilars mean that more patients can be treated with alternative, equally effective biopharmaceuticals than was previously affordable.



The high treatment cost of patented biopharmaceuticals – on average 15 times higher<sup>1</sup> compared to therapy with purely chemical, synthetically produced drugs – means that, even in wealthy countries like Germany, patients often only become eligible for biopharmaceutical-based treatment after long waiting times and when all other options have been exhausted.

#### Development risk reduced by high success rate

Compared to an innovative biopharmaceutical, a major difference in the development of a biosimilar is that the key reference points along the path of its development are already largely pre-established through the selection and analysis of the reference drug.



*„Through its biosimilars, Formycon is making an important contribution to making healthcare more democratic because, with the increasing availability of biosimilars, more and more people are gaining access to modern biopharmaceutical-based treatments.“*

**Dr. Stefan Glombitza**  
CEO of Formycon AG

Biopharmaceutical active ingredients are highly complex molecules, which means that their development is technically demanding, cost-intensive and time-consuming. Depending on the active ingredient, the development budget for a biosimilar drug is typically in the range of USD 150 to 300 million over a timeframe of seven to ten years. In the case of an innovative biopharmaceutical, however, the development cost is significantly higher and the timeframe far longer. This is due in large part to the greater complexity and challenges of clinical trials that an innovative biopharmaceutical must undergo in order to obtain regulatory approval.

Because biopharmaceutical active ingredients are manufactured in living cells, a biosimilar can inherently not be absolutely identical to the reference drug. Biosimilar development is about producing a preparation that is as similar as possible to the reference drug, which means that there is a relatively high probability, even at the outset of development, that the biosimilar will ultimately meet all of the approval criteria established by the regulatory authorities.

<sup>1</sup> "Aktueller Begriff: Biosimilars", Research Services of the German Bundestag, July 2023, <https://www.bundestag.de/resource/blob/958060/3e214dc926a30f919fdde9130fdb8801/Biosimilars-data.pdf>



*„At Formycon, the whole is more than the sum of its parts, because our analytical data gives us the opportunity not only to prove the similarity of an active ingredient, but also to provide patients with an highly effective drug.“*

**Nicole Bleasdale**  
Senior Project Leader

In the case of innovative drug development, the probability of ultimate success is far lower. In fact, only about one in twelve innovative drug candidates in preclinical development ever reaches approval.<sup>1</sup>

#### **The importance of selecting the right candidates**

In biosimilar development, the very first step, which is the selection of the active ingredient to be developed, is of particular importance. This enormously consequential decision must take numerous factors into account which, considering the biosimilar's lengthy development timeframe and the expected commercial life cycle upon approval, extends well beyond ten years and even as far as 30 years into the future.

At Formycon, an experienced interdisciplinary team is responsible for selecting candidates. The active ingredient candidate FYB210, for which development work is scheduled to begin in 2024, is currently under final evaluation. The team analyzes a broad range of medical, scientific, economic, legal

and, last but not least, strategic questions: How is the therapeutic area expected to develop? What innovations can be expected within this area? Will the active ingredient continue to play an important role in the future? How complex is the molecule? What capabilities and resources are required for development? What requirements are there for the manufacturing process? How complex will the design and implementation of clinical trials be? What is the intellectual property situation? What is the expected sales trajectory of the reference drug until its patent protection ends and biosimilars can enter the market? How many competitors can we expect? And finally, where can we as a company make the most effective and profitable use of our strengths?

#### **Extraordinary experience combined with maximum agility**

Our more than 230 committed employees spanning the areas of Product Development, Scientific and Preclinical/Clinical Affairs, Business Operations and Administration/Enabling Functions are united by one common goal: improving healthcare access

for patients around the globe – patients who are suffering from various diseases, often quite serious, who cannot now be adequately treated because of the lack of affordable treatment options.

The particular strength of Formycon lies in the extraordinary scientific expertise and combined years of experience of our biosimilar experts – from the very start of each development project.

#### **Diversity and internationality**

Formycon employs a diverse staff from more than 30 different countries. Throughout all of our offices, laboratories and functional areas, we stand out for our lively team spirit and agile, entrepreneurial working style. We are proud of our people and our organization, which has grown steadily over the years, and of the values we live by, specifically including openness, tolerance, reliability, appreciation and mutual trust.

<sup>1</sup> Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)

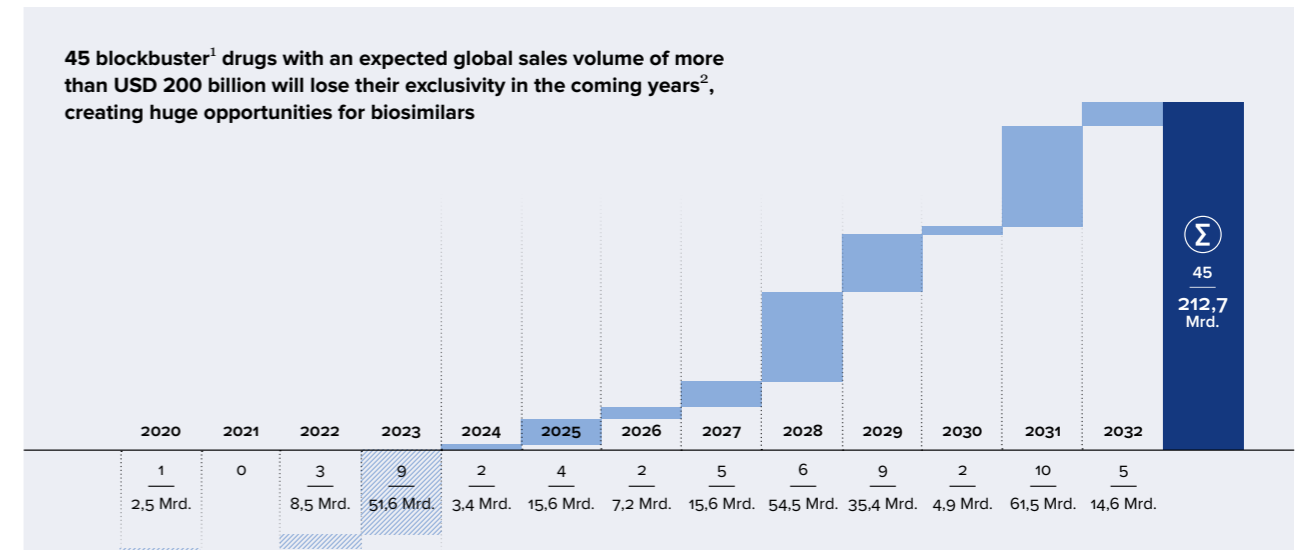
# The *transformative* potential of biosimilars

Since this new drug class first came into existence almost 20 years ago, the biosimilars phenomenon has been truly remarkable. With more than 80 approved biosimilar products in the European Union and 48 in the United States, and with medium to high double-digit annual growth rates, biosimilars are currently the fastest growing segment of the overall pharmaceutical market. As more and more biopharmaceuticals lose their patent protection in the coming years, the rapid growth of these follow-on products is forecast to continue. Over the next few years, many of the world's top-selling biologics will lose their market exclusivity and will be confronted with competition from biosimilars. The combined annual sales for blockbuster<sup>1</sup> refer-

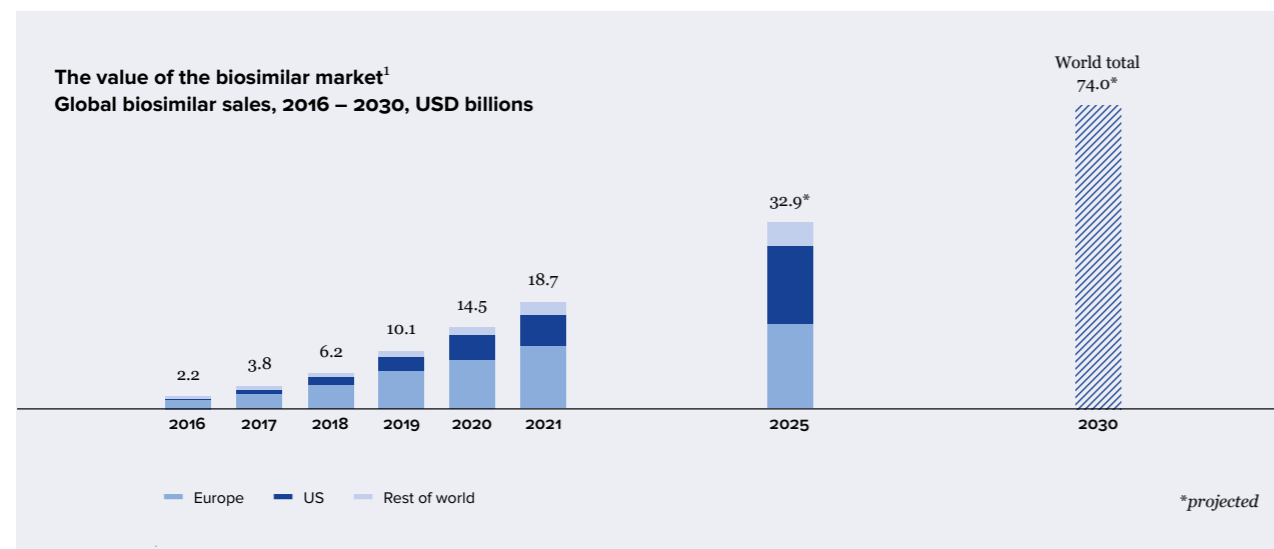
ence drugs for which legal protection will expire by 2032 is more than USD 200 billion.

In addition to this loss of market exclusivity over the coming years for many important reference biologics, demographic factors such as increasing global life expectancy and the growing prominence of chronic diseases will further expand the growth potential for biosimilars.

For all of us at Formycon, this enormous market potential is both validation and motivation: It validates the past decisions we have made and the work we have done to achieve our strong existing position in the biosimilars segment, and it



<sup>1</sup> A blockbuster is defined as a drug with annual sales of more than USD 1 billion.  
<sup>2</sup> McKinsey & Company, "Three imperatives for R&D in biosimilars", August 2022



motivates us to further strengthen and expand this position.

With its development pipeline, Formycon is already addressing extraordinarily attractive markets in the areas of ophthalmology, immunology and immuno-oncology. For the biosimilar candidates FYB202, FYB203 and FYB206, combined sale revenue for the three respective reference drugs was approx. USD 45.0 billion in 2023, compared to USD 40.4 billion in 2022. Particularly in the case of FYB206, significant continued growth market is expected for pembrolizumab (reference drug Keytruda®) over the coming years as the range of approved oncological indications is expanded and

the incidence of cancer continues to increase. In its most recent World Cancer Day publication on February 4, 2024, the World Health Organization (WHO) predicted 35 million new cancer diagnoses by 2050, corresponding to an increase of 77%. It is especially important to all of us at Formycon that we are able, through our development work, to contribute to the effective and cost-efficient treatment of these and other seriously and chronically ill patients.

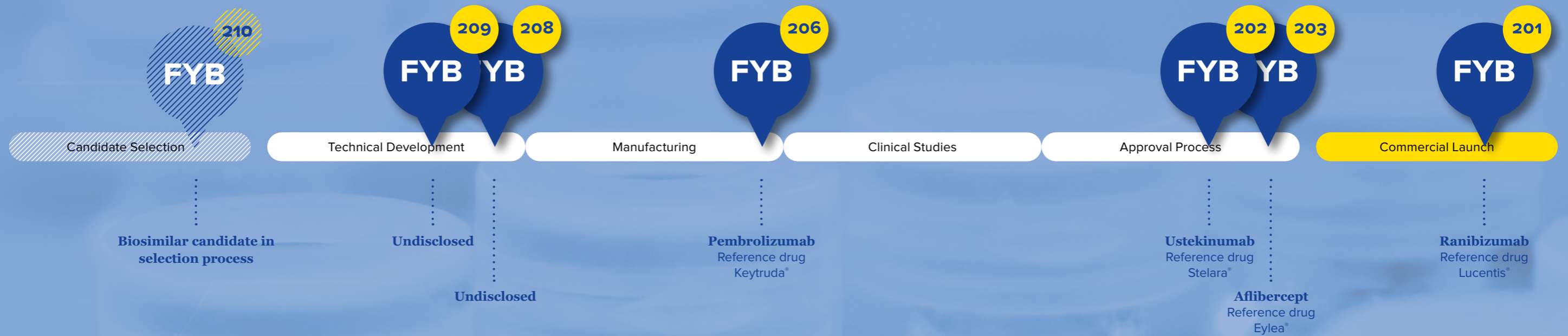
With our as yet unannounced biosimilar candidates FYB208 and FYB209 in early development, and soon also FYB210, Formycon intends to tap opportunities in further promising markets.

# Formycon — *Pipeline*

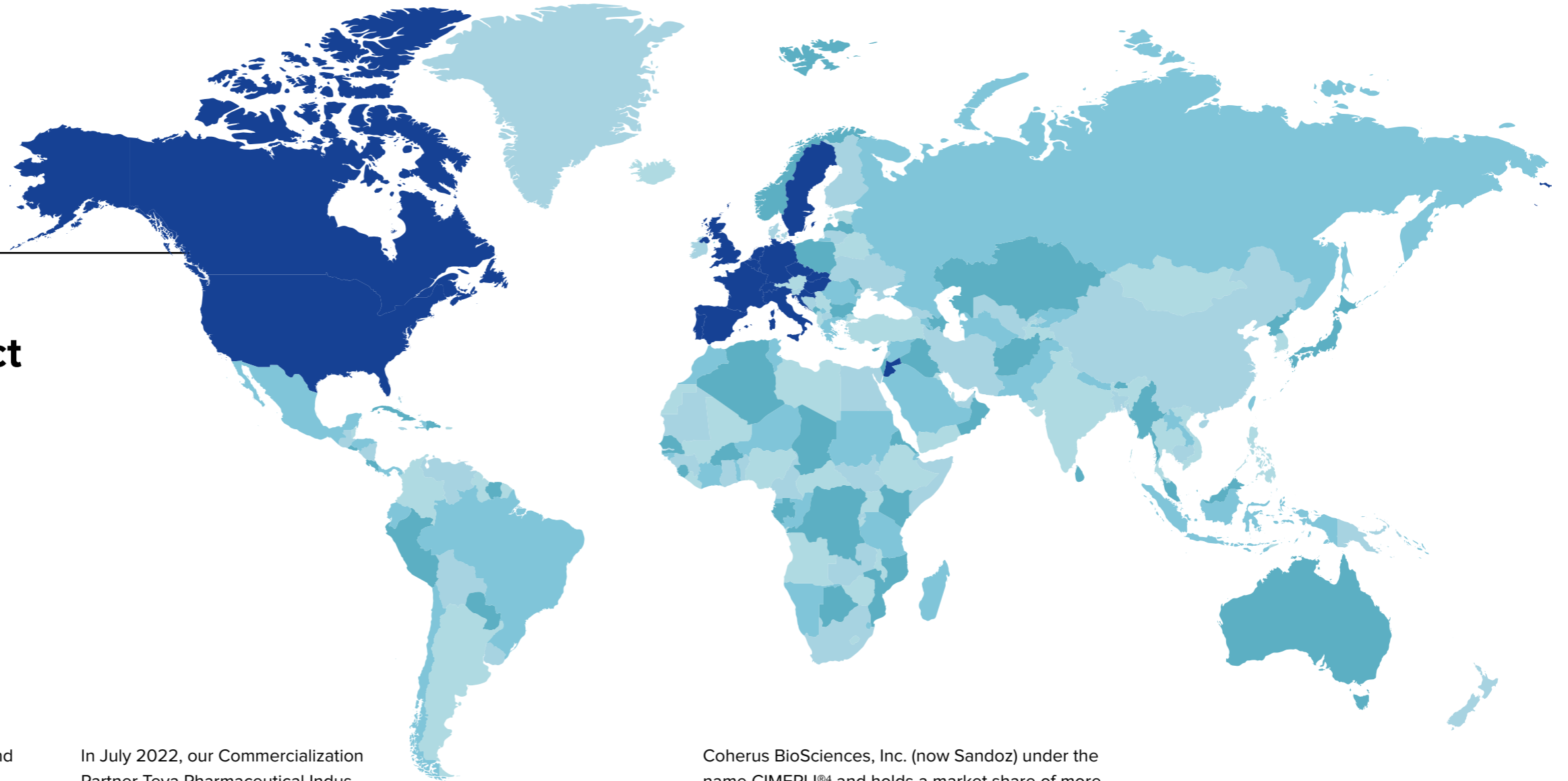
<sup>1</sup> McKinsey & Company, "Three imperatives for R&D in biosimilars", August 2022



# Development status of the Formycon biosimilar candidates



## FYB201 – our first commercial product



Since its initial regulatory approval in the second half of 2022, FYB201 (ranibizumab) has been sequentially entering markets around the world. Today, the biosimilar is approved and commercially available in a total of 17 countries<sup>1</sup>, including the United States, the UK, Switzerland, Canada, Jordan, and various markets within the European Union. These countries are shown in blue on the world map.

In July 2022, our Commercialization Partner Teva Pharmaceutical Industries Ltd. successfully launched FYB201 under the name Ongavia<sup>®2</sup> in the United Kingdom as the first market. The market share has reached more than 60% meanwhile. In all other major markets in Europe the product has been launched successively under the name Ranivisio<sup>®3</sup>. The market launch in the United States took place in October 2022, where FYB201 was first marketed by

Coherus BioSciences, Inc. (now Sandoz) under the name CIMERLI<sup>®4</sup> and holds a market share of more than 40%. The product was acquired by Sandoz in March 2024.

Over the coming months, further regional approvals and market launches are planned in the Middle East and North Africa (MENA) and Latin America regions.

<sup>1</sup> The countries where FYB201 is available today are shown in blue on the world map

<sup>2</sup> Ongavia<sup>®</sup> is a registered trademark of Teva Pharmaceutical Industries Ltd.

<sup>3</sup> Ranivisio<sup>®</sup> is a registered trademark of Bioeq AG

<sup>4</sup> Cimerli<sup>®</sup> is a registered trademark of Coherus BioSciences, Inc.

## FYB201 – Lucentis® Biosimilar



### FYB201

Nonproprietary name (INN)	Ranibizumab		
Reference drug	Lucentis® (Genentech, Inc.)		
Active ingredient group	VEGF inhibitor		
Indications	<b>Ophthalmology</b> <ul style="list-style-type: none"> <li>— Neovascular ("wet") age-related macular degeneration (nAMD)</li> <li>— Diabetic macular edema (DME)</li> <li>— Choroidal neovascularization (CNV)</li> <li>— Proliferative diabetic retinopathy (PDR)</li> <li>— Macular edema following retinal vein occlusion (RVO)</li> </ul>		
Project status	Commercially available		
Business model	50% Formycon project via participation in Bioeq AG (joint venture of Formycon AG 50% and Polpharma Biologics Group B.V. 50%)		
Commercialization partner(s)	<b>USA</b> Sandoz AG <i>(until Feb. 2024: Coherus BioSciences Inc.)</i>	<b>EU / other Territorien:</b> Teva Pharmaceutical Industries Ltd.	<b>MENA Region:</b> MS Pharma
Initial market launch	July 2022		
Description	<p>Ranibizumab is used in the treatment of various eye diseases in adults which cause damage to the retina, thereby impairing vision. In these diseases, a protein called vascular endothelial growth factor ("VEGF") causes excessive blood vessels to form within the retina, resulting in a progressive loss of central vision. In many cases, this process leads to a severe visual impairment or even blindness.</p> <p>Due to the increasing ageing in our society, the proportion of the population affected by age-related macular degeneration ("AMD") has increased significantly over recent years and decades. Today, AMD is the leading cause of blindness in developed countries among people over 50.</p>		
Ranibizumab market	Ranibizumab is among the most widely used established anti-VEGFs today. In 2023, Lucentis® generated global sales of around USD 2.0 billion.		

Lucentis® is a registered trademark of Genentech, Inc.

## FYB202 – Stelara® biosimilar candidate



### FYB202

Nonproprietary name (INN)	Ustekinumab	
Reference drug	Stelara® (Johnson & Johnson)	
Active ingredient group	Immunosuppressant (interleukin inhibitor)	
Indications	<b>Immunology</b> <ul style="list-style-type: none"> <li>— Psoriasis</li> <li>— Crohn's disease</li> <li>— Ulcerative colitis</li> </ul>	
Project status	Pending FDA and EMA approval	
Business model	100% Formycon	
Commercialization partner(s)	<b>Key global markets</b> Fresenius Kabi	<b>Secondary marketing rights in Germany as well as parts of the MENA and Latin America</b> Formycon
Planned market launch	Starting from 2025*	
Description	<p>Ustekinumab, a human monoclonal antibody which targets the cytokines interleukin-12 and interleukin-23, is used for the treatment of several different serious inflammatory diseases.</p> <p>In August 2023, Formycon and its Commercialization Partner Fresenius Kabi announced the conclusion of a settlement agreement with Johnson &amp; Johnson for the United States. The settlement allows Fresenius Kabi and Formycon to launch their product FYB202, once approved by the FDA, in the United States no later than on April 15, 2025. Furthermore, in March 2024 Formycon and Fresenius Kabi announced the conclusion of a settlement agreement with Johnson &amp; Johnson for the EU and Canada, whereas the precise settlement date is not published due to confidentiality.</p>	
Ustekinumab market	Global sales of this relatively new drug were around USD 10.9 billion in 2023, with growth continuing at a rapid rate (source: Johnson & Johnson, Annual Report FY 2023). The potential use of ustekinumab for other therapeutic indications offers additional revenue potential.	

\*According to settlement with Johnson & Johnson in the USA for April 15, 2025 at the latest. Settlement agreement reached for Europe and Canada - terms not published. Stelara® is a registered trademark of Johnson & Johnson



## FYB203 – Eylea® biosimilar candidate



### FYB203

Nonproprietary name (INN)	Aflibercept
Reference drug	Eylea® (Regeneron Pharmaceuticals Inc.).
Active ingredient group	VEGF inhibitor
Indications	<b>Ophthalmology</b> <ul style="list-style-type: none"> <li>– Neovascular (“wet”) age-related macular degeneration (nAMD)</li> <li>– Diabetic macular edema (DME)</li> <li>– Choroidal neovascularization (CNV)</li> <li>– Proliferative diabetic retinopathy (PDR)</li> <li>– Macular edema following retinal vein occlusion (RVO)</li> </ul>
Project status	Pending FDA and EMA approval
Business model	Out-licensed to Klinge Biopharma GmbH
Commercialization partner(s)	–
Planned market launch	Launch is expected in the first countries within the next two years depending on progress of litigation
Description	<p>Aflibercept is a recombinant human fusion protein which works by binding to vascular endothelial growth factor (VEGF-A), as well as to placental growth factor (PLGF). Through this action, aflibercept suppresses the formation of blood vessels in the retina, which otherwise impair vision. Like Lucentis®, Eylea® is injected directly into the vitreous body of the eye.</p> <p>Due to their different mechanisms of action, aflibercept and ranibizumab complement each other very well in clinical practice. Some patients respond better to aflibercept, while others see more benefit from ranibizumab.</p>
Aflibercept market	Together, aflibercept and ranibizumab make up more than 90 percent of the world market for anti-VEGF therapies. Demographics are a key long-term driver because, as people grow older, so does the spread of age-related eye diseases and thus the demand for effective treatment options. In 2023, Eylea® alone generated around USD 9.2 billion in sales.

Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.

## FYB206 – Keytruda® biosimilar candidate



### FYB206

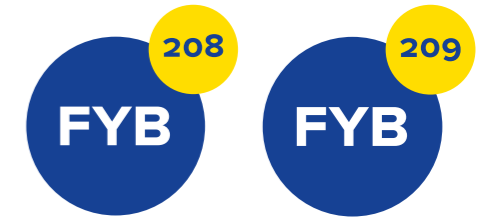
Nonproprietary name (INN)	Pembrolizumab
Reference drug	Keytruda® (Merck Sharp & Dohme LLC)
Active ingredient group	Immune checkpoint inhibitor
Indications	<b>Immuno-oncology</b> <ul style="list-style-type: none"> <li>– Advanced melanoma</li> <li>– Non-small cell bronchial carcinoma</li> <li>– Hodgkin’s lymphoma</li> <li>– Urothelial carcinomas</li> <li>– Tumors in the head and neck area</li> <li>– Other tumor diseases</li> </ul>
Project status	Technical development
Business model	100 % Formycon
Commercialization partner(s)	–
Planned market launch	in the United States and the EU after loss of exclusivity of the reference drug
Description	<p>The active ingredient pembrolizumab is a humanized monoclonal antibody that belongs to the group of immune checkpoint inhibitors and is used to treat a variety of tumors. Pembrolizumab binds to the PD-1 receptor and specifically blocks the interaction between PD-1 and its ligand PD-L1. This helps the immune system to activate the body’s own cellular anti-tumor immune response and kill melanoma cells, for example.</p> <p>The specific mechanism of PD-1 blockade is not limited to one type of cancer but is effective in numerous oncological indications. In addition to advanced melanoma (black skin cancer), pembrolizumab is indicated for non-small cell lung cancer and classical Hodgkin’s lymphoma (malignant disease of the lymphatic system). Non-small cell lung cancer is one of the most common cancer indications worldwide. In Germany alone, 50,000 people are diagnosed with the disease every year.</p>

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC

Description	<p>Following the initial scientific advice meetings with EMA and FDA, we scaled up the manufacturing process to commercial scale at the end of 2022. For this purpose, we secured GMP (Good Manufacturing Practice) manufacturing capacity at an experienced and established manufacturer at an early stage. The start of clinical development Phase I and Phase III with enrollment of first patient is expected during 2024.</p> <p>It is the intention to stay longer on the value chain and to conduct first clinical steps on Formycon's own behalf. Thus, significant investment is foreseen for this project and partnering is likely to take place e.g. after a successful completion of Phase I in 2026, contributing significantly to the mid- and long-term sustainability and value creation of Formycon.</p>
Pembrolizumab market	In 2023, the reference market for Keytruda® was reported to be over USD 25.0 billion in sales worldwide.



## FYB208/FYB209 – undisclosed biosimilar candidates



### FYB208 / FYB209

Nonproprietary name (INN)	undisclosed
Reference drug	undisclosed
Active ingredient group	undisclosed
Indications	Immunology
Project status	Technical development
Business model	100% Formycon
Planned market launch	in the United States and the EU after loss of exclusivity of the reference drug

# Highlights – 2023

## **Global commercialization partnership for FYB202 (Stelara biosimilar candidate)**

At the beginning of 2023, Formycon announced the signing of a global licensing agreement for FYB202 with Fresenius Kabi AG, a healthcare leader providing medicines and medical technologies around the world. Under the arrangement, Fresenius Kabi will, upon successful approvals by the respective regulatory authorities, launch FYB202 in key global markets. With the signing of the agreement, Formycon received an upfront payment and will receive 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 future 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 newly issued shares, corresponding to approx. 6.02% of the Company's registered capital, were placed with institutional investors using an accelerated book-building 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. The net issuance 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.

## **Successful completion of clinical development phases for FYB202 (candidate biosimilar to Stelara®) and FYB203 (candidate biosimilar to Eylea®)**

During fiscal year 2023, Formycon was able to report the achievement of important further development milestones within its project pipeline. Specifically in the case of the FYB203 project, these were positive interim results from the MAGELLAN-AMD phase III clinical trials on the drug's efficacy and tolerability. In the case of FYB202 project, the announced milestone was the successful completion of the extended phase I clinical study to compare pharmacokinetics, thus completing the clinical development program. This milestone also triggered success payments in the amount of € 15 million.





*„The clinical trials show for the first time what improvements in clinical symptoms we can achieve for patients with our biosimilars - and that our work is important.“*

**Andrey Trukhmanov**  
Clinical Development Manager

**Submission of regulatory filings for FYB203 (candidate biosimilar to Eylea®) to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA)**

The application for approval of FYB203 was submitted to the U.S. FDA at the end of June 2023, in line with Formycon's original schedule. At the end of August, Formycon announced that the application for approval had been accepted by the FDA for review ("file acceptance") and that the target date for the FDA's processing of the application had been set for June 2024. In November, Formycon and its license partner Klinge Biopharma GmbH announced that an application for approval was likewise submitted to the European Medicines Agency, whose acceptance for review was confirmed in late December 2023.

**Submission of regulatory filings for FYB202 (candidate biosimilar to Stelara®) to the U.S. FDA and European Medicines Agency**

Based upon the previous submission of FYB202 to the European Medicines Agency, the EMA's acceptance of the renewed application for the review and approval of FYB202, together with Fresenius Kabi, was announced at the end of September 2023. The FDA's acceptance of the approval application ("file acceptance") was announced on November 30, 2023, with an expected target date for processing the application at the end of September 2024.

# Sustainability and social responsibility

Already today, Formycon's biosimilars are having a positive impact towards the Sustainable Development Goals (SDGs) of the United Nations: Through our business model, we aim to provide as many patients as possible with affordable, cost-effective and high-quality biosimilars, thereby increasing availability of modern treatments to combat serious diseases while helping to relieve the cost burden on healthcare systems worldwide.

Moreover, Formycon sees harmony and balance between the impact of its business activities, not only upon its staff but upon society at large, and the needs and expectations of key stakeholders as an issue of central importance and corporate responsibility. Formycon thus bases its business decisions upon the principles of responsible corporate management and sustainable action.

#### 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. In addition to these measures, Formycon has also implemented a "whistleblowing" tool that allows employees to confidentially report any potential violations of the Code of Conduct or appli-

cable laws and regulations which they may become aware of. In this way, the tool helps to create an environment in which ethical behavior can be promoted and in which any breaches can be effectively detected, addressed and tracked.

#### Management culture and leadership

In Formycon's view, good corporate management means that leadership, employee engagement, the long-term sustainability of good management, business success and ultimately financial success are all directly interrelated. For this reason, Formycon 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".

#### 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 exchan-



*„From my very first day at Formycon, I was – and today still am – part of a strong team that supports each other and where everyone interacts at an equal level, regardless of whether I am dealing with my colleagues in IT or with the Management Board.*

#### Patrick Stevens

Trainee IT specialist for systems integration

ges among staff, including a new section on the company's intranet called "FOR\_MY\_Queers\_Community". We also offer our own LGBTQIA+ podcast series on topics such as diversity and international LGBTQIA+ rights, which serves not only to provide information but also to sensitize our entire staff and to promote understanding and mutual respect.

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 Dec. 31, 2023, the percentage of women in Formycon's second level of management (Vice President, Senior Director, Director and Asso-

ciate Director) was 42.9%, while for all management positions the percentage was 36.2%.

#### 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 .

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 and Clinical Career Path for its research staff as well as a Managerial Career Path for staff in the regulatory affairs, quality management and pro-

ject 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 during 2023 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 fiscal year, 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 not only health examinations required by law but also such additional services as annual flu vaccinations, individual advice and assistance on workplace ergonomics, and first-aid courses for staff.

#### **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. Following our initial 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.



# Formycon — *Road to* Sustainability

## **Formycon — Setting high standards for our sustainability performance**

Formycon's mission is clear: We are committed to using our business model to make affordable, high-quality biopharmaceutical follow-on products (biosimilars) available to as many people as possible. This is our contribution to fighting serious diseases and reducing the burden on healthcare systems worldwide. But our mission goes beyond the development and supply of biosimilars; we are committed to sustainability and responsible action towards nature and society in every facet of our business. Developing a comprehensive sustainability strategy is not only a response to regulatory requirements or market expectations but states a conscious commitment to society and the environment. By embedding sustainability into our business processes, we are reducing our environmental footprint, promoting social justice, and ensuring responsible corporate governance. In this sense, we view sustainability as an integral part of our identity as a highly specialized biosimilar developer.

## **Materiality analysis - identifying our most important sustainability topics**

As part of our efforts to integrate sustainability into our business activities, we developed our first sustainability strategy in 2023. At the heart of this processes, we carried out a materiality analysis based on the principle of double materiality. Using this method, we systematically identified all sustainability matters that are important to our company and then addressed them in our sustainability strategy. In preparation for future legal requirements, we voluntarily conducted the materiality analysis in accordance with the key requirements of the Corpo-

rate Sustainability Reporting Directive (CSRD). This EU directive requires large companies in Europe to disclose comprehensive sustainability information on an annual basis in the future. A sustainability matter is material if it represents either an actual or potential negative or positive impact of our business on the environment and people, or if it creates or may create financial risks or opportunities for the success of our business.

The materiality analysis started with a long list of 25 potentially material environmental, social and governance (ESG) matters. We identified the topics based on the European Sustainability Reporting Standards (ESRS), complemented by additional relevant sustainability standards, frameworks and industry-specific standards. We considered our entire value chain, as not only our direct business activities, but also upstream and downstream processes in the supply chain have a significant environmental and social impact. For all potentially material sustainability topics, we identified and assessed our impacts, financial opportunities and risks in an iterative process with an interdisciplinary team.

#### Engaging in dialog with our stakeholders

A cornerstone of our responsible conduct is the space for open exchange and feedback. In this spirit, we involved both external and internal stakeholders in our materiality analysis. We conducted a comprehensive employee survey, inviting our employees to assess working conditions, the opportunities for personal and professional development, and the status quo of equal opportunity and diversity at Formycon. Our employees were also invited

to make suggestions for improvement. Additionally, we conducted one-on-one interviews with business partners and investors to discuss our company's current sustainability performance and their expectations for the future. We were pleased to find that both our employees and our stakeholders share our values of sustainability. Together, we see great potential to further strengthen our sustainability efforts through collaboration and the creation of synergies.

#### Formycon's material sustainability topics

Through the internal analysis of our sustainability topics and reflection with our stakeholders, we were able to define the key sustainability issues for Formycon.

## Environment

### Environment

- Climate change mitigation
- Climate change adaption
- Circular economy
- Biodiversity and ecosystems
- Water

## Social

### Employees

- Equal treatment and equal opportunities
- Training and skills development
- Working conditions
- Health and safety

### Social aspects in the value chain

- Workers in the value chain

### Patients

- Access to products and high-quality information
- Product safety and quality
- Responsible marketing

## Governance

### Business conduct, including

- Corporate culture
- Compliance and integrity in business conduct
- Corruption and bribery
- Protection of whistleblowers
- Lobbying
- Management of relationships with suppliers



*„Taking responsibility together – not just for our projects but on a larger scale with regard to social and environmental issues – is an important step towards a more sustainable future. I’m glad that such high importance is placed on sustainability themes at #TeamFormycon.“*

**Qiyun Tang**

Associate Manager Regulatory Affairs

From an impact perspective, climate change mitigation was identified as particularly important. This is due to greenhouse gas emissions and the high energy consumption resulting from the development, production, and distribution of our biosimilars along our value chain. In addition to the mitigation of climate change, we are also committed to the preservation of biodiversity. To achieve this, the responsible use of water and the strengthening of the circular economy are integral parts of our business model.

Our top priorities also include patient safety and the quality of our medicines. We believe that our greatest opportunity - both for the success of our company and our contribution to society - is to improve access to affordable medicines worldwide. Our employees work towards this goal every day, making it essential for us to provide them with good working conditions, support their professional development and ensure their safety and health at work.

#### **Our Sustainability Strategy – Focus on Responsible Action**

To meet our environmental and social responsibilities, we developed a comprehensive sustainability strategy in 2023 that addresses our material topics and guides our actions through 2030.

Key objectives for protecting our environment include the consistent reduction of greenhouse gas emissions in our operations and the enhancement of resource-efficient and material-efficient processes. To this end, we are developing a climate strategy to minimize our carbon footprint. At the same time, we aim to expand our environmental and energy management system and achieve ISO 14001 and ISO 50001 certification by 2026. We will also work with our strategic business partners to integrate sustainability criteria into our existing partnerships and consider these criteria in the selection of new strategic partners. This goes hand in hand with the development of our Supplier Code of Conduct in 2024 in which we define our values for an ethical collaboration with our partners.

For the benefit of patients, we will strive to maintain the high quality and safety of our products and

increase their availability worldwide. As we continue to develop our products, we also want to make them easier for patients to use.

We strive to build long-term, trusting partnerships with our employees. To this end, we are expanding our training opportunities, setting annual personal development goals and integrating employee training metrics into our management performance targets. At the same time, we aim to reduce work-related injuries and illnesses among our own employees to zero and plan to have our occupational health and safety management system certified to ISO 45001 by 2027.

We are committed to transparency and continuous improvement in all areas of our sustainability efforts. Regularly updating our materiality analysis and adjusting our targets and measures accordingly will help us to develop our sustainability performance while ensuring our long-term economic success. By integrating sustainability holistically into our business model, we are making a significant contribution to the health and well-being of current and future generations.



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## Combined Management Report

*This Combined Management Report covers the reporting period from January 1, 2023 to December 31, 2023 and encompasses the management reports for both Formycon Group (hereinafter also “Formycon” or the “Group”) and Formycon AG. Unless otherwise noted, the presentation of business performance and financial figures relevant to corporate management, both actual and forecasted, are for Formycon Group.*

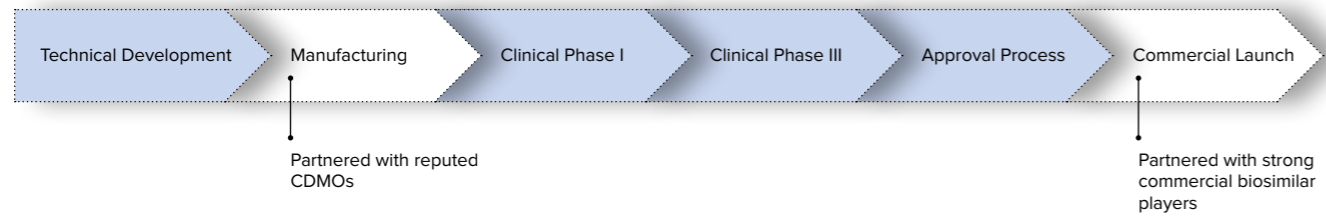
*Information which applies solely to the Formycon AG parent entity is specifically marked as such.*

## *Basic information about Formycon Group*

Formycon is an independent company specialized in the development of high-quality biosimilar drugs for the global market, with current projects spanning indications in various areas, particularly ophthalmology, immunology and immuno-oncology. Formycon is able to cover all technical stages of the biopharmaceutical development chain starting with the selection of highly promising biosimilar candidates, through 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.

For the manufacturing and commercialization of its products, Formycon relies upon strong and trustworthy partners around the world. With its FYB201 project, Formycon achieved successfully regulatory approval of a biosimilar product that is already being marketed in the United States and Canada, Europe, the Middle East and North Africa (MENA), and other geographical regions. A further five biosimilar drugs candidates are currently in the Group’s development pipeline, two of which are already well advanced in the approval process. Formycon’s long-term and sustainable growth strategy is built upon steady expansion of its product portfolio through the targeted selection of new biosimilar candidates, the development of these projects, and their ultimate commercial success through commercialization partnerships, either partly or in their entirety.

The biosimilar value chain

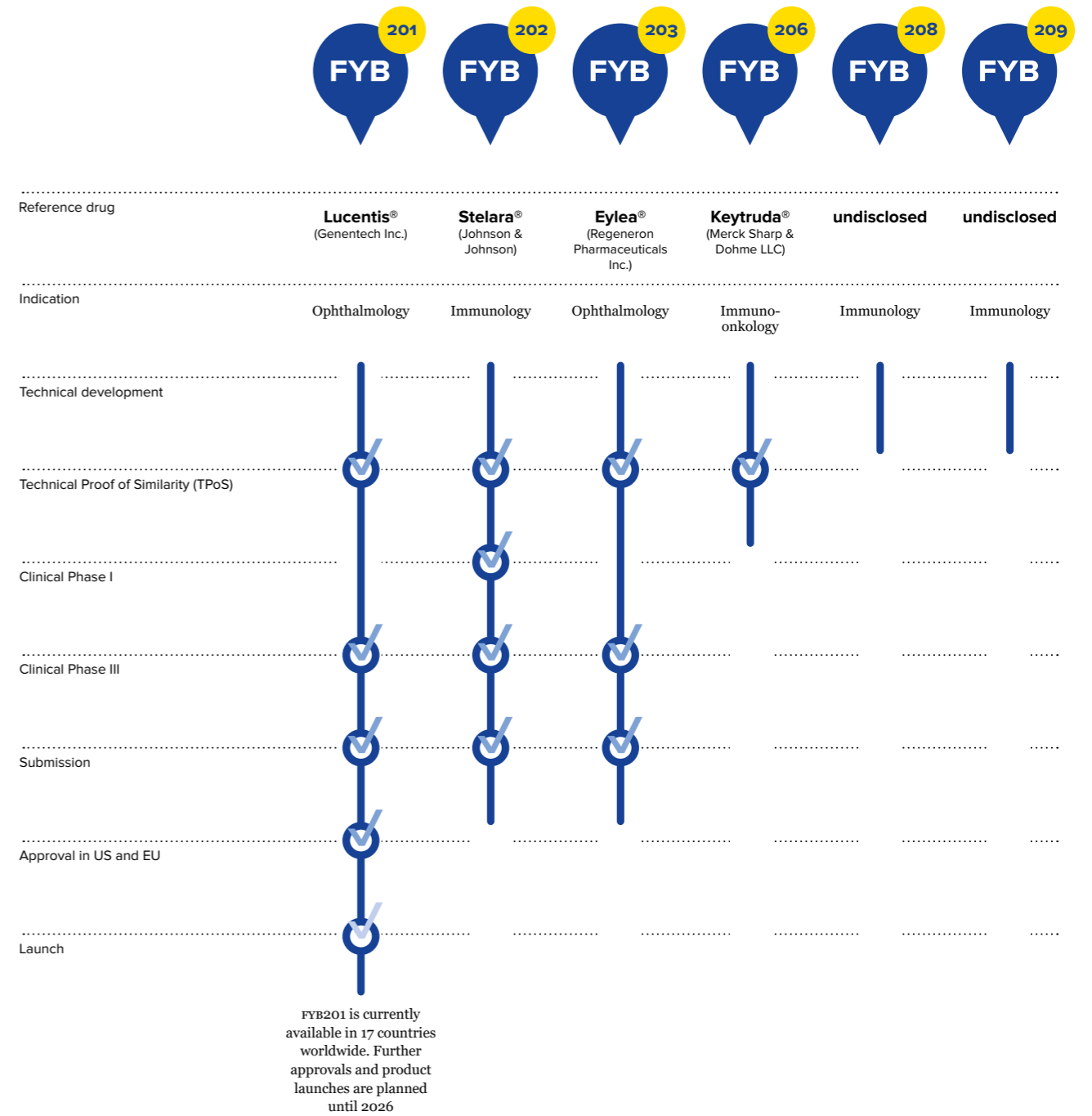


Since the 1980s, biopharmaceuticals have been revolutionizing the treatment of serious diseases such as cancer, diabetes, rheumatism, multiple sclerosis and acquired blindness. Starting from the mid 2010s, patents on many of these powerful biopharmaceuticals began expiring, and over the next nine years, many more of these biotech drugs will lose patent protection, including 45 blockbuster drugs<sup>1</sup> with combined annual sales estimated at more than USD 200 billion.

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

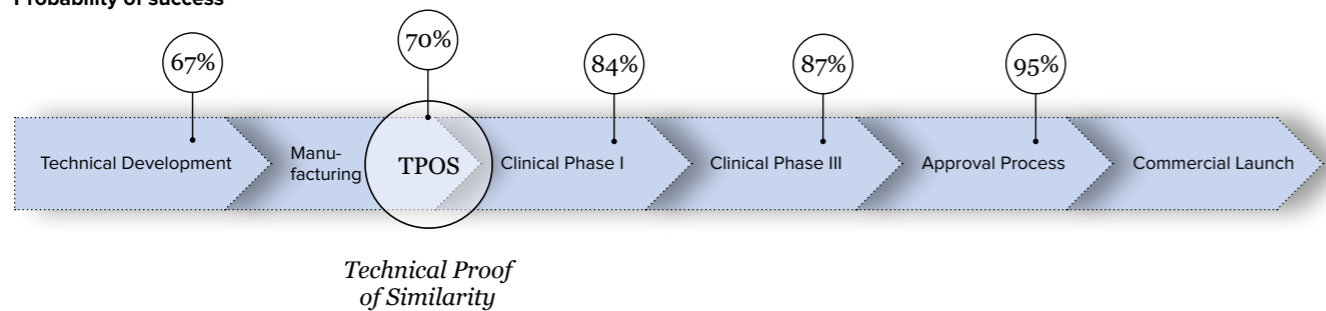
**Produkt pipeline**

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



<sup>1</sup> Blockbuster ist hier definiert als ein Medikament mit einem Jahresumsatz von mehr als 1 Milliarde Dollar im Spitzenjahr, wobei die Analyse auf dem Zeitpunkt des Ablaufs des US-Patents basiert. Quelle: EvaluatePharma-Datenbank, April 2022; Presseberichte; McKinsey-Analyse

**Biosimilar development  
Probability of success**



Formycon’s FYB207 project involved the development of an innovative COVID-19 fusion protein based upon its extensive experience in the development of biopharmaceuticals and intended as a contribution to the global fight against the pandemic. With the epidemiological situation since greatly changed, Formycon reevaluated and deprioritized this project under consideration of economic and strategic factors and has, for the time being, essentially placed it on hold.

In order to maintain the attractive platform which was created and to ensure that development work could be resumed at any time, particularly in the event of a resurgence of the COVID-19 pandemic, Formycon continues to pursue patent applications and scientific advice meetings with the respective authorities and to evaluate the possibility of government or other funding. In terms of its own resources, Formycon’s current plan is to invest into FYB207 only minimally and selectively. It must also be recognized that the current strategic focus of potential partners is generally on other priorities and therefore that an attempted out-licensing deal would, at present, not likely be successful.

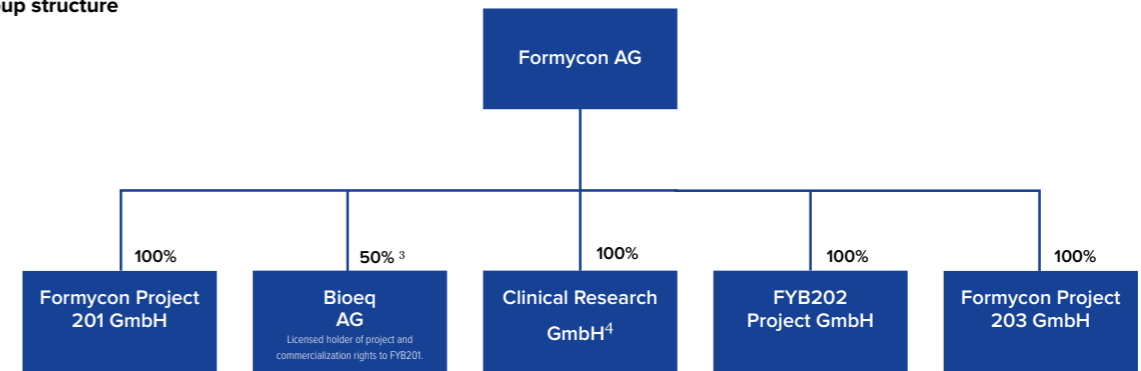
**The probability of a biosimilar being approved is very high**

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 including the regulatory approval process of typically seven to ten years, the research and development process for an entirely new biological entails an exploratory approach and thus a significantly higher level of development risk along with significantly longer development times and vastly higher development costs.

The probability of success, i.e. that a biosimilar will be approved, remains high throughout the course of its development, as illustrated above.<sup>1</sup> In the case of the development of an innovative drug, the success rate is dramatically different, with only one in twelve projects in preclinical development, on average, reaching final approval.<sup>2</sup>

<sup>1</sup> The path towards a tailored clinical biosimilar development, Schiestl et. al 2020  
<sup>2</sup> Paul, S.M., et al.: Nature Reviews Drug Discovery 9, 203–214 (2010)

**Group structure**



**Business objective and strategy**

Formycon’s guiding objective is to further expand its position as a global yet highly specialized and focused player in the rapidly growing market for biosimilars, thereby developing into a sustainably profitable biosimilars company which will remain a leader over the long term.

With the help of biosimilars from Formycon, ever more patients around the globe will be able to 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.

**Group structure**

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

<sup>3</sup> The remaining 50% of Bioeq AG is owned by Polpharma Biologics BV.  
<sup>4</sup> Bioeq GmbH was legally renamed to “Clinical Research GmbH” with effect from Dec. 19, 2023.

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.

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.

**Executive Board members and allocation of responsibilities**



**Dr. Stefan Glombitza**  
CEO (Chief Executive Officer)

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

**Areas of responsibility:**  
Corporate Strategy and Product Development

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



**Nicola Mikulcik**  
CBO (Chief Business Officer)

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

**Areas of responsibility:**  
Business Operations

- Business Development and Licensing
- Supply Chain and Logistics
- Intellectual Property Litigation
- Procurement



**Dr. Andreas Seidl**  
CSO (Chief Scientific Officer)

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

**Areas of responsibility:**  
Scientific and Pre-/Clinical Affairs

- Preclinics, Bioanalytics and Scientific Affairs
- Clinical Development and Operations
- Intellectual Property



**Enno Spillner**  
CFO (Chief Financial Officer)

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

**Areas of responsibility:**  
General Administration / Enabling Functions

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

**Management and oversight**

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

The Supervisory Board of Formycon AG is elected by the Annual General Meeting. As of Dec. 31, 2023, it consisted of four members.

**Remuneration of Executive Board and Supervisory Board**

The remuneration of Executive Board members includes both fixed and variable components, as described in Note 27 to the Consolidated Financial Statements. Formycon has not yet published a separate remuneration report. The remuneration of Supervisory Board members, which was most recently determined at the 2018 Annual General Meeting, is € 25,000 per fiscal year for the Chair of the Supervisory Board and € 20,000 for other members. In addition, each Supervisory Board member receives an attendance fee of € 1,500 per Supervisory Board meeting, whereby the total amount of attendance fees may not exceed € 6,000 per fiscal year.

**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 the U.S. Food and Drug Administration (FDA).

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

Contract development and manufacturing organizations (CDMO) or "contract manufacturers" are important partners within the value chain for biosimilars development and play a critical role for Formycon, including in the production of active ingredients. 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./Sandoz AG<sup>1</sup>.

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.

<sup>1</sup> In early 2024, the commercialization rights to FYB201 were transferred from Coherus BioSciences, Inc. to Sandoz AG.



Oncology, a field of medicine in which some 19.3 million new cases were reported worldwide during 2020, currently dominates the areas of application for biosimilars worldwide, and by the year 2040, the number of new cancer cases globally is forecast to exceed 30.2 million.<sup>1</sup> At the same time, the number of disease areas in which biosimilars are approved and in active use is steadily increasing. The growth in recent and expected biosimilar approvals is particularly striking for indications in immunology and ophthalmology. A study in the UK found that one in ten people suffer from some kind of autoimmune disease.<sup>2</sup> According to the Global Autoimmune Institute, the most common diagnoses are psoriasis, Crohn's disease, lupus, and type 1 diabetes.<sup>3</sup> The global market for autoimmune disease therapeutics is forecasted to grow from USD 137,557 million in 2023 to USD 205,585 million by the end of 2033, which is an average annual growth rate (CAGR) of 4.1% over these ten years.<sup>4</sup>

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 expires, thereby ending its exclusivity, biosimilar drugs may be brought to market. The reduced costs of effective treatment through new competition from biosimilars not only helps to relieve the burden on the world's health providers such as statutory health insurers: They also make it possible to bring these powerful treatments to more patients, thereby also opening entire new markets.

### Competitive situation

Internationally published studies predict average annual growth rates (CAGR) for the global market for biosimilars over the next decade (2023 through

2032) in excess of 14%.<sup>5</sup> Despite substantial barriers to market entry due to high development costs (approx. € 150 to 300 million per biosimilar development project), long development cycles (seven to ten years), and the specialized expertise required for biosimilars development, there are a number of international competitors in this attractive market segment. In addition to major pharmaceutical corporations such as Amgen, Biocon, Biogen, Fresenius Kabi, Pfizer, Samsung Bioepis and Sandoz but also smaller companies specializing in biosimilars such as Alvotect, Celltrion and XBrane. (These are just examples and are listed in alphabetical order.)

Because of Formycon's positioning as an independent developer, situations may arise in which such a company, particularly a major pharmaceutical name, is a competitor for one or more products at the same time that it is a commercialization partner for one or more biosimilar development projects. For each of its biosimilar development projects, Formycon seeks out the most suitable commercialization partner, not only for the area of indication but also for the relevant region, and to distinguish itself from 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 advancement and expansion of its project pipeline so that it is able to bring new biosimilars to market at regular intervals. In parallel with this strategic thrust,

Formycon is pursuing an organizational growth strategy so that it has the resources to compete as a leading and sustainably profitable pharmaceuticals company, specifically within the biosimilars segment. In order to achieve this strategic vision, the Executive Board is open to considering cooperation arrangements and integration in selected areas of the manufacturing process as well as to building 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 competitors, particularly large pharmaceutical companies with biosimilar ambitions, above all in the high level of agility and flexibility in its operational activities. In biopharmaceutical development, it is important to align structures, processes and behaviors along the value chain in such a way as to foster an integrated 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 238 committed employees, Formycon currently has the capacity and resources to develop multiple biopharmaceutical projects in parallel.

### Financial performance indicators

In managing Formycon Group, the Executive Board relies upon a defined set of key financial performance indicators. Up until now, these have primarily been revenue, EBITDA, net profit/loss, and working capital.

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

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

<sup>1</sup> <https://de.statista.com/statistik/daten/studie/1201649/umfrage/prognostizierte-anzahl-neuer-krebsfaelle-weltweit/>

<sup>2</sup> Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: a population-based cohort study of 22 million individuals in the UK, *The Lancet*

<sup>3</sup> <https://www.autoimmuneinstitute.org/articles/about-autoimmune/autoimmune-disease-basics/>

<sup>4</sup> Autoimmune Disease Therapeutics Market: Global Industry Analysis 2017-2022 and Opportunity Assessment 2023-2033, *Future Market Insights 2023*

<sup>5</sup> *Globe Newswire* (source: Market.us), "Biosimilars Market is Anticipated to Grow at a CAGR of 14.1% from 2023-2032 due to Increasing Incidences of Chronic Diseases", Feb. 28, 2023

<b>Key financial performance indicators</b> in accordance with IFRS in € Million			
	2021	2022	2023
<b>Revenue</b>	36,6	42,5	<b>77,7</b>
<b>EBITDA</b>	-12,4	-15,9	<b>1,5</b>
<b>Adjusted EBITDA</b>	-12,4	-28,8	<b>13,3</b>
<b>Working capital</b>	29,5	14,0	<b>38,9</b>

In the future, Formycon AG will limit itself to announcing specific guidance forecasts with regard to the above key performance indicators for the current fiscal year only. Any guidance or announced expectations for subsequent financial years are thus no longer valid. Formycon holds a portfolio of partnered biosimilar candidates which, even after successful transfer to licensed or cooperation partnerships, generate revenue for Formycon from development work performed, advance payments, milestone payments and license payments. As the pipeline of development projects matures, Formycon expects the proportion of revenue from milestone payments and license payments from product sales to further increase.

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

As already noted, Adjusted EBITDA additionally includes Formycon's participation in earnings from Bioeq AG, which is under joint control. Bioeq AG's earnings, in turn, result solely from the operational success of our FYB201 product. Because this holding is under joint control and therefore necessarily accounted for at equity, earnings from this Formycon product are not included in operating income and is therefore also excluded from EBITDA, which is derived and calculated from reported operating profit (EBIT). Adjusted EBITDA, in contrast, includes earnings from FYB201.

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

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

# Report on business performance

## General economic conditions

The economic situation in Germany deteriorated during 2023. Economic activity suffered from elevated inflation rates and financing costs. In addition, demand was weakened, both in the domestic market and abroad. Against the backdrop of these generally unfavorable conditions, the German economy slipped into recession in the first half of the year. For the year as a whole, real (price-adjusted) GDP fell by 0.3% compared to 2022.<sup>1</sup>

Economic output slackened in individual sectors, particularly in the manufacturing sector where output declined by 2.0%, primarily due to lower energy production.<sup>2</sup> Expansion continued in the service sector, although at a slower rate than in the prior two years. The weakness in German production and economic activity was also reflected in foreign trade, where real (price-adjusted) imports fell by 3.0% compared to the preceding year.<sup>3</sup> Exports for full-year 2023 declined by 1.8%, primarily due to the slowdown in the global economy.<sup>4</sup>

Private consumer spending likewise declined in 2023 and therefore contributed less to Germany economy than in the previous year. It is thought that the decline of 0.8% was largely due to the lingering effects of the inflationary spike, particularly in consumer prices.<sup>5</sup> For the year as a whole, year-on-year inflation was 5.9%, one percentage point below the comparable figure for the previous year but still at a high level.<sup>6</sup>

Despite the weak economy, Germany's labor market remained largely stable during the year under review. On an annual average basis, the number of employed people with a workplace in Germany increased by 0.7%<sup>7</sup>, with the slight increase almost entirely driven by the service sector. The unemployment rate during 2023 averaged 5.7%, compared to 5.3% in the prior year.<sup>8</sup>

## General industry conditions

Specifically within Germany's chemical-pharmaceutical industry, 2023 was a challenging year. The weakened general economic environment and unfavorable structural conditions hampered business development and led to capacity utilization below the normal range. According to figures from the German Chemical Industry Association (VCI), production fell by 11%, particularly in the chemicals sector.<sup>9</sup> The generally far more stable pharmaceutical sector also posted a decline of 3%, although it should be borne in mind that the preceding years benefitted from the temporary boom in COVID-19 vaccinations.<sup>10</sup>

By international comparison, pharmaceutical companies in Germany continue to be confronted with high costs and other unfavorable location factors in Germany as well as increasingly strict regulations, notably including the German Statutory Health Insurance Financial Stabilization Act (GKV-Finanzstabilisierungsgesetz). At the same time, these challenges to Germany's competitiveness are also being recognized by political leaders and policy makers. In

order to address these, and to strengthen domestic security of supply, a national pharmaceutical strategy was adopted in December 2023, with a range of measures designed to make Germany more attractive as a pharmaceutical production location and reduce reliance upon pharmaceutical imports.

Furthermore, since the end of 2023, a committee of the European Medicines Agency (EMA) has been discussing the need to reassess current requirements for dedicated clinical efficacy and safety studies for biosimilars, with the aim of simplifying the development and evaluation process while maintaining the highest standards of safety and effectiveness.

The EMA is thus addressing the need to keep the biosimilar pathway attractive for Europe's biopharmaceutical industry while also ensuring future access for European patients to safe and effective biologics. Public consultation on the EMA's concept paper runs from Feb. 1 to April 30, 2024.<sup>11</sup>

## Developments in the global biosimilars market

Once again, the worldwide market for biosimilars grew significantly in 2023, reaching a total estimated market size of USD 21.2 billion.<sup>11</sup> All indications point to continued expansion in the future. The global biosimilars market is expected to grow to USD 74 billion by 2030.<sup>12</sup>

This growth dynamic in the global market spans all geographic regions. IQVIA, a leading global pro-

vider of advanced analytics, technology solutions, and clinical research services to the life sciences industry, expects biosimilar sales to grow to USD 49 billion in 2027 in the United States alone.<sup>13</sup> With CAGR rates of 26% this year and next, the U.S. market, which we have been serving since 2022 with our Lucentis® biosimilar, remains one of the fastest growing.<sup>14</sup>

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

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.<sup>16</sup>

Within Europe, annual sales of biosimilar preparations are expected to achieve an average annual growth rates of 8% over this same period.<sup>17</sup> In addition to Germany, the UK and France are among the most rapidly expanding national markets. For the

<sup>1-5,7</sup> [https://www.destatis.de/DE/Presse/Pressemitteilungen/2024/01/PD24\\_019\\_811.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2024/01/PD24_019_811.html)  
<sup>6</sup> [https://www.destatis.de/DE/Presse/Pressemitteilungen/2024/01/PD24\\_020\\_611.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2024/01/PD24_020_611.html)

<sup>8</sup> <https://de.statista.com/statistik/daten/studie/1224/umfrage/arbeitslosenquote-in-deutschland-seit-1995/>  
<sup>9-10</sup> <https://www.vci.de/presse/pressemitteilungen/stuermische-zeiten-fuer-die-branche.jsp>

<sup>11</sup> <https://gabionline.net/policies-legislation/ema-concept-paper-towards-a-tailored-clinical-approach-in-biosimilar-development?>  
<sup>12,15</sup> <https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars>

<sup>13</sup> <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>

<sup>14</sup> Research and Markets - Biosimilar Market by Drug Class, Indication, Region

<sup>16</sup> Healthcare Supply Chain Institute / Institut der deutschen Wirtschaft Köln - Produktion von Biosimilars – Wer Reshoring möchte, muss Offshoring vermeiden

decade from 2021 to 2031, IQVIA expects the UK market to grow by 213% and the French market to grow by 260%.<sup>1</sup>

Within Europe, a further 110 biopharmaceuticals are also expected to lose intellectual property protection by the end of 2032, with the Loss of Exclusivity (LoE) potential in the time range between 2030 and 2032 amounting to roughly € 30 billion.

Over the next 10 years, the largest numbers of LoE opportunities for biosimilars are expected to be in the areas of oncology (24%), immunology (11%) and blood disorders (10%).<sup>2</sup>

#### Summary statement by Executive Board on expected future development

Formycon Group can look back on a very successful financial year in a number of different respects, especially clinical development, regulatory aspects, commercial industry partnerships, product sales, and capital structure. Significant progress was made in biosimilar development projects, and the Group's key performance financial indicators for fiscal year 2023 were also well above the preceding year. In addition to the first significant commercialization revenues following the launch of FYB201 in the UK, the United States and individual EU countries as well as revenues from development services for Formycon's out-licensed biosimilar candidates, full-year consolidated revenues of € 77,696K include, in particular, significant milestone payments from the commercialization partnership for FYB202 with Fresenius Kabi AG. These milestone payments resulted from the successful closing of the global commercialization agreement with Fresenius Kabi AG as well as from successful completion of phase I clinical trials for FYB202.

The sharp rise in consolidated EBITDA to € 1,518K was primarily due to the increase in revenue less attributable cost of sales. Formycon Group's liquidity position also remained strong with € 27.0 million as of Dec. 31, 2023, due in large part to the gross issuance proceeds of approx. € 70.1 million from the capital increase in February 2023.

The global biosimilars market continues to grow dynamically and is expected to reach a value of USD 74 billion by 2030.<sup>3</sup> Formycon can also be satisfied with the market launch of its first biosimilar product, FYB201. In the United States, Formycon's sales partner Coherus BioSciences, Inc., was able to successfully bring CIMERLI®, the brand name for our biosimilar to Lucentis®, into this large and critically important market and has already secured significant share against competitors in the biosimilar market space. 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, U.S. sales of CIMERLI® have significantly increased as a result. According to our marketing partner Coherus BioSciences, Inc.,<sup>4</sup> CIMERLI® sales in the United States totaled USD 125.4 million in 2023.<sup>5</sup> Following the strategic realignment of Coherus at the close of 2023 and beginning of 2024, the marketing rights for CIMERLI® were in March 2024 transferred to Sandoz AG, which will henceforth take over the distribution of CIMERLI® in the USA. The Coherus ophthalmological sales team was also assumed by Sandoz.

The submission of FYB203 for approval to the EMA took place according to schedule at the end of 2023. The approval documents for FYB202, our

candidate biosimilar to Stelara®) were likewise submitted to regulatory authorities as planned during the third quarter. Efforts on the FYB206 project, our candidate biosimilar to Keytruda®, were concentrated on preparations for entry into the clinical trial phase, which is scheduled to begin in 2024.

With the lifting in May 2023 by the World Health Organization (WHO) of the COVID-19 global health emergency, the framework conditions for FYB207, our innovative COVID-19 biopharmaceutical candidate, were significantly changed. The project was thus re-evaluated based on financial and strategic factors, with the result that the development of the innovative FYB207 drug will, for the time being, be pursued only in certain specific areas through to the preclinical proof of concept benchmark, and in a way which stringently conserves our resources. In this way, should the framework conditions change and COVID-19 once again become a global health-care priority, Formycon will be able to immediately resume active development work on this project.

During fiscal year 2023, Formycon Group generated consolidated revenue of € 77,696K compared to € 42,497K in the prior fiscal year. The increase in reve-

<sup>1</sup> [https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/artikel-in-der-fachpresse/2023/know-how\\_iqvia\\_mahp\\_01-2023.pdf](https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/artikel-in-der-fachpresse/2023/know-how_iqvia_mahp_01-2023.pdf)

<sup>2</sup> <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void>

<sup>3</sup> McKinsey & Company, "Three imperatives for R&D in biosimilars", August 2022

<sup>4</sup> The commercialization rights for CIMERLI were transferred from Coherus BioSciences, Inc. to Sandoz AG on March 1, 2024.

<sup>5</sup> <https://investors.coherus.com/news-releases/news-release-details/coherus-biosciences-reports-fourth-quarter-full-year-2023>



## Financial performance

nue is largely due to significant milestone payments realized from the FYB202 project under the new partnership with Fresenius Kabi and recognition of expected future revenue from success-based payments thereunder as contract assets in the amount of € 37,672K. At the same time, revenue from the FYB201 and FYB203 development partnerships declined due to the lower activity level in these projects. Not included in revenue are government grants received for the FYB207 project in the amount of € 2,914K (prior year: € 5, 407K), which are accounted for as an offset to expenses.

EBITDA for the fiscal year was € 1,518K, compared to EBITDA of negative € 15,866K in fiscal year 2022, with the improvement due first and foremost to the increase in revenue, along with offsetting increases in cost of goods sold, along with lower research and development expenses. At the same time, general and administrative expenses were higher, mainly due to the increase in staff during both the current and previous fiscal years. Adjusted EBITDA additionally includes the contribution from Formycon's investment participation from Bioeq AG in the amount of € 11,811K (2022: neg. € 12,932K), resulting in full-year Adjusted EBITDA of € 13,329K (2022: neg. € 28,798K). Full-year net profit was € 75,795K (2022: € 35,992K), which includes a non-cash gain from the revaluation at fair value of the conditional purchase price payment obligations for the shareholding in Bioeq AG. The fair value of the FYB201 project was also reassessed during the fiscal year based upon budget planning for 2024 and subsequent years as well as prevailing market rates. As a result of this reassessment, the fair value of Formycon's shareholding in Bioeq AG was reduced by € 31,173K, which served to reduce earnings, while at the same time the decrease in the fair value of the conditional

purchase price obligations to Athos in the amount of € 99,321K generated a gain to earnings (likewise non-cash) in the amount of € 68,148K. 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 (at fair value) of the contingent purchase price payments under the strategic acquisition transaction.

During 2023, Formycon Group continued to vigorously drive 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. In addition, a marketing agreement was concluded on February 1, 2023 with Fresenius Kabi covering the FYB202 product, which was an unfinished development project at the time of conclusion. The agreement encompasses transfer of the product license, certain success-related payments until regulatory approval by the FDA and EMA, and finally license payments from subsequent product sales. As a result of this agreement, € 37,672K of revenue was recorded during the fiscal year, of which € 25,000K was realized in cash. With the conclusion of this agreement, development costs starting from the date of the agreement were no longer capitalized as unfinished intangible assets but rather recorded as cost of sales, resulting in a significant increase in cost of sales.

The commencement during the reporting period of development work on Formycon's two 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 were capitalized starting from demonstration of technical proof of similarity (TPOS) and thus, in contrast to the previous year, were no longer included in research and development expenses. Moreover, costs for the FYB207 project during the fiscal year were significantly less than in the preceding year. Through the combination of these effects, research and development expenses were, in total, significantly lower than in fiscal year 2022.

The Group ended the fiscal year with an equity ratio of 56.5% (Dec. 31, 2022: 42%). The Group's non-current assets are largely covered by equity and non-current liabilities for conditional purchase price payment obligations, which is suggestive of a healthy balance sheet structure. More than one third of current assets are in the form of liquid and near-liquid assets. The increase in customer contract assets is mainly due to the recognition of expected future revenue from success-based payments under the marketing agreement with Fresenius Kabi.

Current liabilities include loans from Formycon shareholders to Formycon AG (shareholder loans) in the amount of € 20,485K (including accrued interest) and the current portion of the conditional purchase price payments in the amount of € 27,179K. As in the past, cash and cash equivalents as well as working capital, the Group's key liquidity indicators, remained adequate, with current assets of € 67,147K offset by current liabilities (excluding current portion

of shareholder loans and current portion of conditional purchase price) of € 21, 255K. The Group did not have any bank loans during the period. During the fiscal year, € 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 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 Dec. 31, 2023, the Group held cash and cash equivalents in the amount of € 27,035K (Dec. 31, 2022: € 9,820K) and working capital (including cash and cash equivalents) in the amount of € 38,889K (Dec. 31, 2022: € 13,975K). The increase over the prior year is due in large part to the capital increase transaction. Reference is made to the Consolidated Statement of Cash Flows.

## Financial management

### Principles and objectives

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

### Liquidity management

Toward this end, expected cash flows from the Group's individual projects are regularly analyzed and updated so that Formycon is at all times able to maintain an overview of expected future project spending needs. With its five-year planning horizon, the Group is well able to anticipate changing needs and to take measures as necessary, thereby proactively managing its liquidity. Liquidity is centrally monitored 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 FYB206 project. Substantial and necessary items of property, plant and equipment, primarily laboratory equipment, are typically financed through lease agreements.

## Formycon AG

In addition to the above review of the consolidated financial performance of Formycon Group, this section provides an overview of the financial performance specifically of the Formycon AG parent entity, the financial statements of which have been prepared for fiscal year 2023, as in prior years, in accordance with the German Commercial Code (Handelsgesetzbuch, HGB). The complete financial statements with related documents are published separately. As Formycon Group's parent company, Formycon AG determines the Group's overall strategic management, financial management, and communications with the capital markets and with shareholders. Formycon AG is an active operating company engaged in the business of biosimilars development at one location, which is its headquarters in the Munich suburb of Martinsried/Planegg. Formycon AG generates its revenue from the provision under so called "FTE agreements" of research and development services for biosimilar candidates initiated by Formycon and subsequently out-licensed or developed through partnerships, as well as from upfront and milestone payments and license payments from product sales. In the current phase of Formycon's corporate development, its biosimilar products are marketed solely via commercialization partners.

### Profitability of Formycon AG in accordance with German statutory accounting (HGB)

During fiscal year 2023, the Formycon AG parent entity generated revenue of € 37,917K compared to € 28,257K in the prior fiscal year, which was sub-

stantially generated from passing on the costs of the FYB202 and FYB203 development projects internally within the Group. Not included in revenue are government grants received for the FYB207 project in the amount of € 2,914K (prior year: € 5,703K), which are accounted for as an offset to expenses. Full-year EBITDA amounted to negative € 30,031K (prior year: neg. € 22,205K), while the net loss for the period was € 166,147K (2022: net income of € 65,755K). The decline in EBITDA primarily resulted from an increase in development expenses for projects FYB206 through FYB209, for which the costs are borne entirely by Formycon AG, as well as increased staff costs resulting from organizational growth during the fiscal year as well as the preceding fiscal year. The revenues achieved, as well as operating costs and EBITDA for the year, were in line with the Executive Board's expectations for the year. The drop from 2022's reported net income to 2023's net loss was largely the result of two factors: firstly, a non-recurring gain in the previous year in the amount of € 89,995K resulting from the Company's exit from FYB 202 GmbH & Co. KG, and secondly, the initial recognition under German statutory accounting (HGB) of the conditional purchase price payment obligations resulting from the 2022 acquisition transaction for the shareholdings in Bioeq AG and FYB202 Project GmbH. In the first step, the shareholdings were revalued during 2023, directly on the balance sheet and thus without affecting profit or loss, and in the second step, these were written down, with a corresponding loss. Thus, as a result of this change, the Company reported write-downs of financial assets in the amount of €

<sup>1</sup> An FTE (Full Time Equivalent) is a calculatory figure that measures the working time or the time value that a full-time employee provides. The total number of FTEs indicated corresponds to the number of notional full-time positions that result from the actual existing positions, taking into account the different working time models.

177,015K, offset to a small extent with higher interest income in the amount of € 36,993K.

During 2023, Formycon AG continued to consistently drive forward with the development of its biosimilar projects according to its defined business model. As a result of the out-licensing deals for FYB201 signed in late 2013 and for FYB203 in 2015, the company continued to post significant revenue during the period. Under the terms of these deals, the Formycon AG parent entity received ongoing payments for its product development services provided on behalf of the respective licensees. Under this arrangement, Formycon AG passes on the billable project development expenses for FYB201 and FYB203 to its wholly-owned subsidiaries Formycon Project 201 GmbH and Formycon Project 203 GmbH, which in turn invoice the respective licensee.

Through the creation of a joint venture with Aristo Pharma GmbH in 2017, Formycon had transferred the intellectual property rights for its FYB202 biosimilar project to joint venture entities FYB 202 GmbH & Co. KG and FYB 202 Project GmbH. For this project Starting from that point, Formycon AG continues began to pass on the costs of its project development services for the project to its now 100% subsidiary FYB202 Project GmbH. With effect from May 1, 2022, Formycon AG acquired 100% of the shares in FYB202 Project GmbH. The arrangement under which Formycon AG passes the costs of its development services to FYB202 Project GmbH, now its 100% subsidiary, remains unchanged.

#### **Balance sheet structure of Formycon AG in accordance with German statutory accounting (HGB)**

As of Dec. 31, 2023, the equity capital ratio for the Formycon AG parent entity was 46.7%, compared to 89.2% at the close of the prior fiscal year. Non-current assets are more than covered by equity capital and the provision for conditional purchase price payment obligations, which is suggestive of a healthy balance sheet structure. The Group's current assets consist almost completely of cash, cash equivalents and marketable securities and thus involve negligible risks.

Compared to the prior-year close, financial assets increased from € 487,717K to € 719,966K, primarily due to the recognition of earn-out conditional payment obligations (in "Other provisions"), as explained in the separate financial statements for Formycon AG in accordance with German statutory accounting (HGB), and the related write-up of financial assets. At the same time, current assets increased from € 21,608K to € 53,884K, due to the cash proceeds of the capital increase carried out during the fiscal year as well as an increase in advance payments for development services from € 3,656K to € 9,690K. At the same time, receivables from affiliated companies increased by € 10,138K to € 17,357K.

The total amount of the increase in "Other provisions" was € 370,173K, to a new year-end total of € 376,857K, mainly due to this first-time recognition of a provision for the conditional purchase price obligations resulting from the acquisition of shares in Bioeq AG and FYB202 Project GmbH in the preceding fiscal year. € 20,000K of the outstanding shareholder loan was repaid during the fiscal year, with the remaining € 20,000K included in current liabilities as of the reporting date.

#### **Financial position of Formycon AG in accordance with German statutory accounting (HGB)**

The financial position of the Formycon AG parent entity remains stable. As in the past, the Company's unconsolidated key liquidity indicators, cash and cash equivalents as well as working capital, were adequate, with current assets of € 53,884K offset by current liabilities of € 73,674K including the current portion of conditional purchase payment obligations. The Company did not have any bank loans during the period. To ensure the adequacy of Formycon's financial resources, key shareholders of Formycon AG provided the company with a credit line during 2022 in the amount of up to € 68,000K. Following the repayment of € 20,000K during the fiscal year, the amount of the available credit line is now € 48,000K, of which € 20,000K was outstanding as of Dec. 31, 2023. As of the fiscal year end, the Company held unconsolidated cash and cash equivalents in the amount of € 21,494K. In line with the change in operating income, unconsolidated net cash flow from operating activities declined during the fiscal year to € 36,844K compared to € 29,495K in the previous year. Because of the large payments (investment outflows) in the previous year for the acquisition of the shareholdings in FYB202 Project GmbH, Bioeq GmbH and Bioeq AG, net cash outflows for investing activities were reduced from € 31,088K to € 2,906K. Net unconsolidated cash flow from financing activities during 2023 was positively impacted by the Company's capital increase transaction and negatively by the paydown of the shareholder loans, such that the net cash inflow from investing activities was € 57,203K compared to € 42,375K in the preceding fiscal year. In total, the Company's liquidity position increased by € 17,454K, to € 21,494K as of Dec. 31, 2023 compared to € 4,040K at the prior-year close.

## Other non-financial aspects

### Staff

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

every day, thereby forming the basis for Formycon's success.

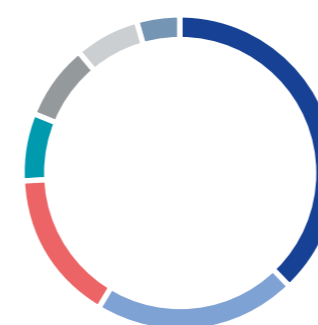
As of Dec. 31, 2023, Formycon Group employed a total headcount of 238 persons (Dec. 31, 2022: 205). The average staffing during fiscal year 2023 compared to the prior-year period is shown below, divided by functional area and including percentage change, and expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff:

Unaudited information

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

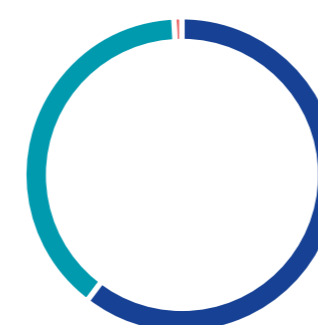
	2023	2022	Change
Research and development	161.6	137.1	+17.9%
Business operations	9.7	8.4	+15.5%
General and administrative	25.6	16.1	+59%
<b>Total</b>	<b>196.9</b>	<b>161.6</b>	<b>+21.8%</b>

### Educational level of Formycon staff



- 37,9 % ■ Doctorate
- 14,9 % ■ Master's
- 6,7 % ■ Diplom (Master's equiv.)
- 5,5 % ■ Bachelor's
- 7,7 % ■ Vocational training (technical)
- 6,8 % ■ Vocational training (administrative)
- 4,3 % ■ Degree or certification not (yet) completed

### Diversity of Formycon staff



- 60,5 % ■ Female
- 38,7 % ■ Male
- 0,8 % ■ Not specified

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



**Division of second-level management by gender**



**Division of all management positions by gender**



Staff expenses for Formycon AG during fiscal year 2023 were € 21,542 K (2022 € 17,076K), with the increase due primarily to the greater average number of employees.\*

Formycon Group’s workforce is highly qualified, particularly in terms of educational level, and training is also a company priority. As of Dec. 31, 2023, 81% of the Group’s employees have completed a university degree, which in the case of 38% is a doctoral degree. Since 2022 Formycon has been cooperating with the regional chamber of commerce (IHK) in offering technical vocational training positions for young people, under which it currently employs one trainee as an IT specialist for systems integration.\*

As to gender diversity, some 60% of the Group’s workforce is female. The employee average age as of Dec. 31, 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 32 different countries, reinforces its self-image as a truly global organization and biopharmaceutical company.\*

**Research and development**

Because Formycon has been, over the past fiscal year as in the preceding years, and remains today focused primarily on the development of its own biosimilar projects, out-licensed projects, and those under development through partnerships, the Group’s activities are essentially limited to research and development 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 Dec. 31, 2023, a total of 161.6 group employees were, on a full-time equivalent (FTE) basis, working in research and development (Dec. 31, 2022: 137.1). During the reporting period, consolidated group research and development costs of € 19,790K 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 during the prior 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 capitalized development costs for pending projects acquired as part of the acquisition transaction, the total book value of these capitalized development costs as of Dec. 31, 2023 was € 507,428K.\*

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% (2022: 83.5%\*) of all hours worked were project-related. Over this same period, 14.5% (2022: 13.6%\*) of hours worked were performed by employees who are not assigned to the research and development area.

\* Unaudited information.

## Report on risks and opportunities

### Risk strategy and policies

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

### Risk management system

Formycon, one of the few independent developers of 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. Regular reviews of this system further ensure that it is constantly improved and that, as circumstances change, changes are likewise made to the system promptly and in accordance with evolving needs.

Risk management is a cornerstone of Formycon Group's governance, ensuring compliance not only with legal and regulatory requirements but also with general principles of sound corporate governance. Good risk management strives to recognize risks 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. Findings from these ongoing risk management monitoring and review processes are promptly presented to the Executive Board as necessary, which examines strategically significant risks and available routes of action to mitigate them. The Executive Board, in turn, reports its findings to the Supervisory Board.

In parallel with these ongoing risk monitoring processes, the Group may also 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, workplace safety, financial risks, and operational risks.

## Risks

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

### Strategic risks

Compared to the development of an entirely new biopharmaceutical, the financial investment required for the development of a biosimilar drug is considerably less. Nevertheless, the development of a biosimilar may cost in the range of € 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 immunological 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 – and the trend is continuing upward.

At the same time, however, the high cost of these powerful treatments, which in some cases may

exceed € 100,000 per patient per year, is a major burden on healthcare system costs. The political will to act as a result of these cost pressures could also, by increasing the pressure on biopharmaceutical prices, impact Formycon's business environment.

#### **Environmental protection, health protection, and workplace safety**

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

#### **Financing and liquidity risks**

Formycon's liquidity situation and equity capitalization remain stable, and the Group's liquidity position is particularly satisfactory for a company 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. As a result of this paydown, the total line was reduced to € 48 million, so that the company now has a remaining and unused available credit line of € 28 million.

The possibility cannot be entirely excluded, however, that such one or more development partnerships could be terminated for reasons not under Formycon's control. Such an event could have a material adverse impact on the Group's profit and

loss accounts as well as on its financial planning. At the present time, Formycon assesses this risk as very low.

Formycon will continue to fund its future development pipeline projects from its own financial resources, with the aim of moving these into attractive partnership arrangements, in whole or in part, starting from a certain product development stage. With its strong financial footing, Formycon is well positioned to overcome future financial risks as these may arise. The Group's existing financial resources should be sufficient to largely cover its short- to medium-term capital needs. This, however, cannot be used to infer any sort of assurance as to the availability of long-term financial resources. There are, at present, no identifiable fundamental risks which would jeopardize the Group's near-term continued existence. The failure of current or future development projects could, however, result in fundamental risks, depending on the relevance of the respective project to Formycon Group as a whole.

#### **Organizational risks**

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

#### **Patent risks**

Formycon Group's success, competitive position and future revenues depend upon its ability to navi-

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

The possibility of patent infringements, even if only alleged, is an inherent risk in biosimilar development because of the large number of potentially relevant patents which must be considered. Disputes with competitors or other patent owners, or defense against lawsuits claiming patent infringement, may pose a considerable financial burden. Particularly in the U.S., such legal actions can be very expensive. In the worst case, such a dispute could result in restrictions on, or even the prohibition of, the marketing of one or more products 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, for this reason, established a health management system to mitigate the impact of staff absences resulting from illness.

#### **General risks associated with the development of biosimilars**

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

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

With this in mind, Formycon plans all steps of product development with the greatest possible care and, to the extent feasible, with reasonable time

allowances for delays that might arise. Preclinical and clinical studies as well as the extensive program of analytical characterization take place in close consultation with the respective authorities and with assistance and expert advice from outside specialists. Notwithstanding this, the results or outcome of any such study cannot be completely predicted in advance.

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

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

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

With the takeover and integration of Bioeq GmbH in May of 2022, Formycon expanded the scope of its drug development capabilities to include clinical development and the direct management of clinical trials. Bioeq GmbH, a legally separate subsidiary

of Formycon Group which has since been legally renamed to "Clinical Research GmbH", continues to serve, as it did before its acquisition by Formycon, in the role of "clinical trial sponsor" for Formycon-developed biosimilar candidates and thus as the official contracting entity for these clinical trials. In its role as clinical trial sponsor, Clinical Research GmbH bears not only financial risks but also the risk of liability towards participating patients or other test subjects. With the acquisition of Clinical Research GmbH as a subsidiary company belonging to Formycon Group, these risks are effectively assumed by Formycon.

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

As clinical trial sponsor, Clinical Research GmbH is, moreover, obligated to comply with detailed and rigorous regulatory requirements for good clinical practice (GCP) when conducting clinical trials of medicinal products for human use under the EU Clinical Trials Regulation, which apply to clinical trials worldwide and which serve to protect patients and ensure the integrity and correctness of the data and findings generated through the trials. The clinical

trial sponsor, participating study centers and other parties involved in the clinical trials process are regularly subject to GCP inspections by local health authorities to ensure compliance with these GCP regulatory requirements.

#### **Legal risks**

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

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



### Regulatory and political risks

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

### Competitive risks

The current aim of Formycon is to launch its products, through its respective partners either entirely or in part, upon expiry of patent protection on the reference product in the respective market. Due to Formycon's positioning as an independent player within the biosimilars market space, situations may arise in which a commercialization partner, such as a partner company named in this report, is also a competitor. In each market, Formycon must compete not only with the manufacturer of the reference drug, who might attempt to defend its market position and establish barriers to market entry (e.g. through life-cycle management), but also with other biosimilar producers. These include not only major pharmaceutical corporations such as Amgen, Biocon, Biogen, Fresenius Kabi, Pfizer, Samsung Bioepis, and Sandoz but also smaller and highly specialized biosimilars companies such as Alvotech,

Celltrion and Xbrane. The competition situation in each specific case will depend upon the pricing of the reference drug as well as the pricing of any new competitors in the market. It is, in addition, entirely possible that the manufacturer of the originator product might reduce its pricing upon the market entry of new and competing biosimilars, or seek to enter into discount agreements with health insurers or other major buyers 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 geopolitical events

The military conflict between Russia and Ukraine involves risks that cannot yet be assessed but which, in particular, have a bearing upon the cost and availability of energy in Germany and may make raw materials and preliminary products as well as services which are important to Formycon more expensive or potentially even scarce. Formycon strives to mitigate these risks through a long-term sourcing strategy based upon strategic partners and transparent pricing. However, the possibility cannot be ruled out that delays or interruptions in development projects could occur as a result of a potential scarcity of resources or rationing of energy, or that the development costs thereof could become significantly greater. The recruitment of patients for clinical studies could also be significantly impacted by the conflict in Eastern Europe, which could have the effects of increasing competition for participating study patients, of delaying clinical studies, or of otherwise increasing costs.

In addition, the Islamist militant group Hamas launched a surprise attack on Israel from the Gaza Strip on October 7, 2023. The ongoing war between Hamas and Israel currently represents one of the greatest geopolitical risks which could potentially impact Formycon's current and future markets. There is significant uncertainty about the extent and duration of disruptions which could directly or indirectly arise as a result of these conflicts, as well as their ultimate impact on the global economy. There can therefore be no guarantee that the Group's projects will not experience delays or interruptions due, for example, to potential resource shortages, energy rationing, or other adverse impacts to Formycon's development projects and the costs thereof.

## 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, the Group’s high degree of integration along with its agility, and finally the quality and scientific expertise of the service providers and advisors on which Formycon additionally relies.

Within this core business area and market, Formycon sees no change in its favorable future outlook. Demographic trends, particularly in Western countries, point to a continued increase in the proportion of the population over 55 years of age. This demographic segment has a higher incidence of requiring intensive medical treatment. In addition, the life expectancy is increasing around the world, meaning that long-term treatments, in particular recurring drug administrations, are often possible or even medically necessary over longer remaining lifespans.

Formycon established its position in the highly promising market for biosimilars development at an early stage and, with its comprehensive expertise, is able to exploit the potential of this fast-growing market. Formycon’s business model is scalable. The continued growth of both the market environment and Formycon own business and organization shows that Formycon Group is on the right path with its corporate strategy.

### Overall risk assessment by Executive Board

Compared to the prior-year period, there have been no fundamental changes in the risks described above. With regard to the general risks associated with the development of biosimilars described above, the Executive Board has reviewed its assessment of the risk level of this category, in particular in view of the fact that certain regulatory authorities have expressed reservations arising from audits of production facilities of individual contract development and manufacturing organizations (CDMOs), as well as of certain competitors of Formycon. The Executive Board has determined that this risk should, in accordance with the criteria of the risk matrix, continue to be assessed as “medium”.

### Summary risk matrix

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

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

	Probability of occurrence (PoO)		
	< 25 %	25 – 75 %	> 75 %
< € 10 million	Low	Low	Medium
€ 10 – 50 million	Low	Medium	High
> € 50 million	Medium	High	High

## *Report on risks relating to the use of financial instruments*

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

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

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

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

## *Report on outlook for Formycon Group*

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

### **Future development of Formycon Group**

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

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

It is planned to invest the expected cash inflows from these product sales primarily into the expansion of Formycon's development pipeline. In doing so, we will have achieved key conditions necessarily to further strengthen Formycon's position as

a global player in the biosimilars market segment and to further build the Formycon organization into a leading and sustainably profitable pharmaceutical company within this rapidly growing segment.

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

### **Product developments**

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

Following the successful submissions in 2023 to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of applications for regulatory approval of FYB203, the candidate biosimilar to Eylea®, applications were likewise submitted to both authorities for FYB202, Formycon's candidate biosimilar to Stelara®. Assuming the approval of these two biosimilars in 2024 through early 2025, Formycon expects to report accrued revenue in 2024 for expected milestone payments in 2024/2025 as well as for expected revenue from sales of the two biosimilars starting from the second quarter of 2025. In addition, Formycon expects to

be able to move FYB206, the immuno-oncology candidate biosimilar to Keytruda®, into the clinical trial phase during 2024 and to recruit and begin treatment of the first study patients.

The two newest biosimilar candidates FYB208 and FYB209 are both in the early development stage. In the second half of 2024, Formycon hopes to launch development of an additional biosimilar candidate (FYB210) as the next step towards a broad and sustainable project pipeline.

### 2024 financial outlook for Formycon Group

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

#### Revenue

Thanks to the steady progress in establishing Ranivisio®, Ongavia® and CIMERLI® (region-specific trade names for FYB201, the biosimilar to Lucentis®) in key global markets, as well as further planned market launches in various other territories, Formycon expects further increases in contributions to the Group’s 2024 revenue and earnings from its participation in product sales. In addition, assuming successful regulatory approval, further mile-

stone payments are expected during 2024 for the FYB202 project. Because part of these expected milestone payments were already recognized and reported in fiscal year 2023 as accrued revenue for an expected success-based milestone payment, the full amount of the milestone payments received will not be reflected in 2024 reported revenue.

On an overall basis, we expect reported consolidated revenue for full-year 2024 to be in the range of € 55 to 65 million, which is below the past year’s level. This is primarily due to the effect of the milestone revenue accrual described above, to declining revenue for development compensation payments for the largely completed projects FYB201 and FYB203, and finally to our conscious decision not to partner the biosimilar candidate FYB206 in 2024 as originally planned, which would have generated revenue from milestone payments, but instead to develop the project independently through to completion of phase I clinical trials, thereby creating greater long-term value for our shareholders.

#### EBITDA

Formycon’s value creation is fundamentally based upon its development pipeline. The Group will therefore continue to invest significantly into its advancing product pipeline, including FYB208, FYB209 and the soon-to-be-launched FYB210 project. Because of the capitalization of development expenditures, the FYB206 project does not flow through EBITDA. Overall, EBITDA for full-year 2024 is expected to be in the range of negative € 15 million to 25 million, due to the significant non-capitalized development investments combined with the lower expected revenue for 2024.

#### New key financial performance indicator: Adjusted EBITDA

Adjusted EBITDA additionally includes Formycon’s at-equity participation in earnings from Bioeq AG, which is expected to be approx. € 10 million in the current fiscal year. Bioeq AG generates earnings solely from the operational success of our approved FYB201 product. Because Bioeq AG is under joint

#### Key financial performance indicators in accordance with IFRS in € million

	2022 actual	Outlook for 2023 per Annual Report 2022	Updated guidance for 2023	2023 actual	2023 variance analysis	2024 forecast
<b>Revenue</b>	42.5	“Significant increase”	75.0 to 85.0	<b>77.6</b>	Revenue in line with updated guidance	<b>55.0 to 65.0</b>
<b>EBITDA</b>	-15.9	“At prior-year level”	-15.0 to -5.0	<b>1.5</b>	Lower than expected investment expenses, in particular for FYB207	<b>-15.0 to -25.0</b>
<b>Adjusted EBITDA</b>	n/a	n/a	n/a	<b>13.3</b>	Newly introduced performance indicator 2023 at-equity earnings in line with expectations	<b>-5.0 to -15.0</b>
<b>Working capital</b>	14.0	“At prior-year level”	15.0 to 25.0	<b>38.9</b>	Full-year profit plus cash proceeds from capital increase	<b>10.0 to 20.0</b>

control and therefore accounted for at equity, earnings resulting from sales of the FYB201 product are not included in Formycon Group’s operating income. By additionally including these earnings, Adjusted EBITDA provides a broader measure of income and thus a more meaningful reflection of operating performance.

With this amount factored in, Formycon anticipates Adjusted EBITDA for the fiscal year in the range of negative € 15 to negative € 5 million.

#### Working Capital

Beyond the effect of net income, Formycon anticipates a negative impact to working capital from investments into project FYB206 and from the planned partial paydown 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 be in the range of € 10 to 20 million.



## 2024 financial outlook for Formycon AG

### 2024 outlook Key financial performance indicators for Formycon AG

Revenue	At prior-year level
EBITDA	At prior-year level
Working capital	Slight decrease

#### Revenue

Wir erwarten Umsatzerlöse aus der internen Weiterbelastung der Entwicklungsprojekte auf Vorjahresniveau.

#### EBITDA

EBITDA is likewise expected to remain in line with the prior-year level. Projects FYB201, FYB202 and FYB203 are expected to be roughly EBITDA-neutral to the unconsolidated parent company, as expenses incurred are passed on internally within the Group. EBITDA will continue to be impacted by other product development investments, particularly into Formycon's own projects FYB207, FYB208 and FYB209. Operating income from the success of the FYB201 project is received through the profit transfer agreement with Formycon Project 201 GmbH and thus falls outside the scope of EBITDA.

#### Working capital

Beyond the effect of net income, Formycon anticipates a negative impact to working capital from the planned partial paydown of the remaining shareholder loan, but this has already been offset by the proceeds of the capital increase carried out in February. It is therefore expected that working capital will decrease only slightly.

#### Summary statement by Executive Board on expected future development

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

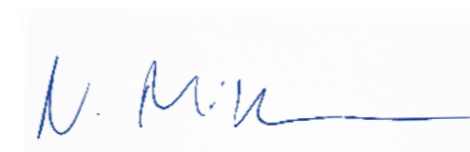
In parallel with this strategic thrust, Formycon is pursuing an organizational growth strategy so that we have the resources to compete as a leading and sustainably profitable pharmaceuticals company, specifically within the biosimilars segment. In order to achieve this strategic vision, the Executive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

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

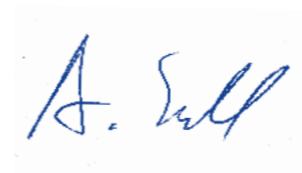
Martinsried/Planegg, Germany, April 16, 2024



Dr. Stefan Glombitza



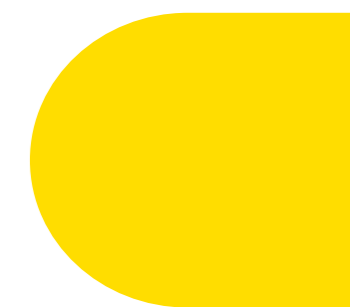
Nicola Mikulcic



Dr. Andreas Seidl



Enno Spillner



## Consolidated Financial Statements of Formycon Group for the period from January 1, 2023 to December 31, 2023

### Consolidated Statement of Financial Position as of December 31, 2023 in €K

	explanatory note	Dec. 31, 2023	Dec. 31, 2022
<b>Assets</b>			
<b>Non-current assets</b>			
Goodwill	19	44,534	44,534
Other intangible assets	19	508,403	488,439
Right-of-use (ROU) assets	18	9,300	8,916
Property, plant and equipment	18	3,027	2,600
Investment accounted for using the equity method	20	167,044	186,406
Financial assets	20	90,907	92,300
Deferred tax assets		-	-
<b>Total non-current assets</b>		<b>823,215</b>	<b>823,195</b>
<b>Current assets</b>			
Inventories		467	571
Trade and other receivables	25	11,612	14,314
Contract assets	9	16,561	1,161
Other financial assets		6	-
Prepayments and other assets	25	11,335	4,636
Income tax receivables		131	-
Cash and cash equivalents		27,035	9,820
<b>Total current assets</b>		<b>67,147</b>	<b>30,502</b>
<b>Total assets</b>		<b>890,362</b>	<b>853,697</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Subscribed capital	21	16,053	15,129
Capital reserve	21	412,871	343,419
Accumulated loss carryforward	21	-1,968	-37,960
Period income (loss)	21	75,795	35,992
<b>Total equity capital</b>		<b>502,751</b>	<b>356,580</b>
<b>Non-current liabilities</b>			
Non-current lease obligations	26	7,815	7,594
Other non-current liabilities	24	187,690	319,339
Deferred tax liabilities	16	122,800	119,518
<b>Total non-current liabilities</b>		<b>318,305</b>	<b>446,451</b>
<b>Current liabilities</b>			
Provisions		387	-
Current lease obligations	26	1,186	925
Other current liabilities	23	51,349	38,315
Trade payables	25	16,319	11,318
Current income tax liabilities	16	65	108
<b>Total current liabilities</b>		<b>69,306</b>	<b>50,666</b>
<b>Total liabilities</b>		<b>387,611</b>	<b>497,117</b>
<b>Total equity and liabilities</b>		<b>890,362</b>	<b>853,697</b>

**Consolidated Statement of Comprehensive Income for the period from January 1, 2023 to December 31, 2023** in €K

	explanatory note	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Revenue	9	77,696	42,497
Cost of sales	10	-54,391	-30,425
Research and development expenses	11	-9,162	-16,912
Selling expenses	12	-841	-1,442
Administrative expenses	12	-13,283	-11,446
Other expenses	12	-389	-347
Other income	12	1	347
<b>Operating profit/loss (EBIT)</b>		<b>-369</b>	<b>-17,728</b>
Income from investments accounted for using the equity method	13	-19,362	76,844
Finance income	13	102,210	432
Finance expense	13	-2,962	-22,952
Change in Impairments based on the expected credit loss model	13	-447	
Net finance income		79,439	54,324
<b>Profit before tax</b>		<b>79,070</b>	<b>36,596</b>
Income tax expense	16	-3,275	-604
<b>Profit (loss) / Comprehensive income (loss) for the period</b>		<b>75,795</b>	<b>35,992</b>
Basic (undiluted) earnings per share (in €)	14	€ 4.76	€ 2.62
"Average number of shares outstanding (without dilution)"		15,915,789	13,715,221
Diluted earnings per share (in €)		€ 4.72	€ 2.59
"Average number of shares outstanding (with dilution)"		16,048,616	13,883,874

**Consolidated Statement of Changes in Equity for the period from January 1, 2023 to December 31, 2023** in €K

	explana- tory note	Sub- scribed capital	Capital reserve	Accumu- lated loss carry- forward	Period income (loss)	Total equity
<b>as of Jan. 1, 2022</b>		<b>11,065</b>	<b>82,785</b>	<b>-24,669</b>	<b>-13,290</b>	<b>55,891</b>
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	15	-	535	-	-	535
Shares issued through exercise of stock options		64	1,699	-	-	1,763
Period income (loss)		-	-	-	35,992	35,992
<b>as of Dec. 31, 2022</b>		<b>15,129</b>	<b>343,419</b>	<b>-37,960</b>	<b>35,992</b>	<b>356,580</b>
Appropriation of prior-year income (loss)		-	-	35,992	-35,992	-
Capital increase against cash contributions		910	69,160	-	-	70,070
Costs of capital increase		-	-1,736	-	-	-1,736
Effect of stock options granted	15	-	1,624	-	-	1,624
Shares issued through exercise of stock options		14	404	-	-	418
Period income (loss)		-	-	-	75,795	75,795
<b>as of Dec. 31, 2023</b>		<b>16,053</b>	<b>412,871</b>	<b>-1,968</b>	<b>75,795</b>	<b>502,751</b>

**Consolidated Statement of Cash Flows for the period from January 1, 2023 to December 31, 2023** in €K

	explanatory note	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Profit (loss) for the period		75,795	35,992
<b>Adjustments for non-cash items:</b>			
Depreciation and amortization	18, 19	1,887	1,862
Net finance income	13	-79,439	-54,324
Effect of stock options	15	1,624	535
Net loss (gain) arising from disposals of non-current assets	18, 19	41	36
Other non-cash transactions		-46	-
Income tax expense	16	3,275	604
<b>Changes in operating assets and liabilities:</b>			
Decrease (increase) in inventories		104	-363
Decrease (increase) in trade and other receivables	25	2,696	3,217
Decrease (increase) in contract assets	9	-15,400	-137
Decrease (increase) in other financial assets		-	150
Decrease (increase) in prepayments and other assets	25	-6,699	-4,008
Increase (decrease) in other liabilities	25	1,094	655
Increase (decrease) in trade payables	25	4,999	-2,766
Increase (decrease) in current provisions		387	-
Income taxes paid	16	-166	-331
<b>Net cash used for operating activities</b>		<b>-9,848</b>	<b>-18,878</b>
Investments in intangible assets	19	-20,167	-26,208
Investments in property, plant and equipment	18	-1,029	-551
Investments in financial assets	20	-	-11,419
Acquisition of subsidiaries less cash and cash equivalents acquired	7	-	1,108
Proceeds from issuance of debt	20	3,300	-
Interest received	13	516	2
<b>Net cash used for investing activities</b>		<b>-17,380</b>	<b>-37,068</b>
Proceeds from issuance of shares	21	70,488	1,763
Costs relating to issuance of shares	21	-1,736	-
Inflows from the assumption of financial liabilities	23, 24	-	40,000
Payment of lease liabilities	26	-1,103	-908
Inflows for the payment of financial liabilities	23, 24	-23,137	-
Interest paid	13	-69	-118
<b>Net cash from financing activities</b>		<b>44,443</b>	<b>40,737</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>17,215</b>	<b>-15,209</b>
<b>Cash and cash equivalents as of Jan. 1</b>		<b>9,820</b>	<b>25,029</b>
<b>Cash and cash equivalents as of Dec. 31</b>		<b>27,035</b>	<b>9,820</b>

## Notes to the Consolidated Financial Statements for the period from January 1, 2023 to December 31, 2023

### 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. Basis of accounting

These Consolidated Financial Statements (hereinafter also the “Financial Statements”), presented here in translation from the German original, have been prepared in accordance with International Financial Reporting Standards (IFRS) as endorsed within the European Union. The provisions of sec. 315e of the

German Commercial Code (Handelsgesetzbuch, HGB) were taken into account as applicable. These Financial Statements were released for publication by the Company’s Management Board (Vorstand) on April 16, 2024.

During the fiscal year, the following standards and interpretations were mandatorily applied for the first time:

- IFRS 17 (“Insurance Contracts”): IFRS 17 replaces IFRS 4 and, for the first time, establishes uniform requirements for the recognition, measurement, presentation of, and notes to insurance contracts, reinsurance contracts and investment contracts with discretionary participation. There have been no material effects on these Financial Statements.
- Amendments to IAS 1 (“Presentation of Financial Statements”) and IFRS Practice Statement 2 (“Making Materiality Judgements”) regarding “Disclosure of Accounting Policies”: Under the amended IAS 1, only “material” information regarding accounting policies must be disclosed in the notes to the financial statements. For the information to be material, the accounting policy must be related to material transactions or other events and there must be a reason for its disclosure. The changes to Practice Statement 2, in turn, describe how the concept of materiality should be applied to the disclosure of accounting policies. This means that the focus will henceforth be on company-specific disclosures instead of generic disclosures. There have been no material effects on these Financial Statements.
- Amendments to IAS 8 (“Accounting Policies, Changes in Accounting Estimates and Errors”)



regarding “Definition of Accounting Estimates”: The amendments to IAS 8 clarify how companies can better distinguish changes in accounting policies from changes in estimates. For this purpose, IAS 8 now defined an “accounting estimate” as being related to an uncertainty in the valuation of a financial figure in the financial statements. In addition to input parameters, a company also uses measurement methodologies to determine an estimate, which may be methodologies for estimation or valuation. There have been no material effects on these Financial Statements.

- Amendments to IAS 12 (“Income Taxes”) regarding “Deferred Tax related to Assets and Liabilities arising from a Single Transaction”: The amendments to IAS 12 address existing uncertainties in the accounting of deferred taxes in connection with leases as well as with disposal or restoration obligations. When assets and liabilities are recorded for the first time, the existing “initial recognition exemption” (IAS 12.15) is applied under certain conditions, meaning that, in such exceptional cases, deferred taxes are not recognized. In practice, there has been uncertainty as to whether this exception also applies to leases and disposal or restoration obligations. A narrow amendment has now been made to IAS 12 to ensure uniform application of the standard. The amendment clarifies that this “initial recognition exemption” no longer applies to transactions in which equal amounts of deductible and taxable temporary differences arise on initial recognition, even if the other previously valid requirements are already met. This is therefore a reverse exception to the “initial recognition exemption” for these narrowly defined cases. The changes mean that deferred taxes must be recognized, for example, on leases recognized by the lessee and on disposal or restoration obligations. There have been no material effects on these Financial Statements.
- Amendments to IAS 12 (“Income Taxes”) regarding “International Tax Reform - Pillar Two Model Rules”: The amendments introduce a temporary but mandatory exception to the accounting of deferred taxes resulting from the introduc-

tion of global minimum taxation. In addition, the amendments stipulate specific disclosure requirements for affected companies so that users of the financial statements are able to understand the degree to which a company is affected, in the current period as well as in the future, by the minimum taxation. There have been no material effects on these Financial Statements.

Formycon does not plan early application of the following new or amended standards and interpretations, which will only become mandatory in subsequent fiscal years. Unless otherwise stated, the effects of these changes on the Financial Statements are currently under review.

Already endorsed by the European Union:

- Amendments to IAS 1 (“Presentation of Financial Statements”) regarding “Classification of Liabilities as Current or Non-current” and “Non-current Liabilities with Covenants”: The amendments to IAS 1 adopted in January 2020 provide for certain limited adjustments to the assessment criteria for classifying liabilities as current or non-current. The amended standard clarifies that this classification also depends upon whether the company has the right, as of the reporting date, to postpone the settlement of the liability for at least 12 months following the end of the reporting period. If such a right exist, the liability is classified as non-current. The right to postpone the settlement of the liability must be substantial. If the company must fulfill certain conditions in order to exercise such a right, these must be fulfilled as of the balance sheet date; otherwise, the liability is classified as current. When classifying a liability, it is irrelevant whether management intends or expects that the liability will actually be settled within 12 months of the balance sheet date. The determining criterion for the classification is the right existing as of the balance sheet date to postpone the settlement of the liability by at least 12 months. This also applies in the event of settlement within the adjustment period. The January 2020 amendments were

supplemented by a further amendment to IAS 1 published in October 2022 (after the date of initial application of the changes had already been postponed from January 1, 2022 to January 1, 2023 due to changes in July 2020). This further amendment addresses the classification of liabilities subject to additional conditions, or “covenants”. The IASB makes it clear that additional conditions that must be met before or on the balance sheet date can have an impact on the classification as current or non-current. However, additional conditions that only have to be met subsequent to the balance sheet date have no influence on the classification. Instead of being taken into account as part of the classification, such subsequent conditions must be disclosed in the notes to the financial statements. This is intended to enable users of the financial statements to assess the extent to which non-current liabilities could potentially become repayable within 12 months. The amendments to IAS 1 must be applied in their entirety to reporting periods beginning on or after January 1, 2024. Early application of the amended standard is permitted. The Group currently assumes that there will be no material impact on its consolidated financial statements.

- Amendments to IFRS 16 (“Leases”) regarding “Lease Liability in a Sale and Leaseback”: The amendments to IFRS 16 govern the accounting of lease liabilities from sale and leaseback transactions and stipulates that a lessee must measure the lease liability following a sale in such a way that there is no recognition of any amount of gain or loss relating to the retained right of use. The newly added paragraphs include explanation different possible approaches with concrete examples, such as variable lease payments. The amendments to IFRS 16 must be applied to fiscal years beginning on or after January 1, 2024. Early application of the amended standard is permitted. The Group currently assumes that there will be no material impact on its consolidated financial statements.

Pending endorsement by the European Union:

- Amendments to IAS 7 (“Statement of Cash Flows”) and IFRS 7 (“Financial Instruments: Disclosures”) regarding “Supplier Finance Arrangements”: The amendments affect disclosure requirements related to supplier financing arrangements (also known as supply chain financing, trade payables financing or reverse factoring arrangements). The new regulations supplement requirements already contained in other standards and explicitly prescribe the following appendix information:
  - Terms and conditions of supplier financing agreements,
  - The carrying amounts of liabilities subject to such agreements for which suppliers have already received payment from the finance providers, including specification of the balance sheet item under which these liabilities are included,
  - The range of due dates, and
  - Information on liquidity risk.
- The amended standard is to be applied to reporting periods beginning on or after January 1, 2024, subject to adoption into EU law. Early application of the changes is permitted but requires EU endorsement. The Group currently assumes that there will be no material impact on its consolidated financial statements.
- Amendments to IAS 21 (“The Effects of Changes in Foreign Exchange Rates”) regarding “Lack of Exchangeability”: The amendments concern the determination of the exchange rate in the event of a long-term lack of convertibility, an issue which has until now not been addressed by IAS 21. With these amendments, IAS 21 additionally includes:
  - Requirements for assessing whether a currency can be converted to another currency,
  - Statements on determining the exchange rate if such conversion is not possible, and
  - Additional disclosure requirements relating thereto.

- The amended standard is to be applied to reporting periods beginning on or after January 1, 2025, subject to adoption into EU law. Early application of the changes is permitted but requires EU endorsement. The Group currently assumes that there will be no material impact on its consolidated financial statements.
- Amendments to IFRS 10 (“Consolidated Financial Statements”) and IAS 28 (“Investments in Associates and Joint Ventures”) regarding “Sale or Contribution of Assets between an Investor and its Associate or Joint Venture”: The amendments address a known inconsistency between the provisions of IFRS 10 and IAS 28 (2011) in the event of the sale or contribution of assets to an associate or joint venture. According to the existing IFRS 10, a parent company must recognize the full amount of the gain or loss from the sale of a subsidiary in the income statement if control is lost. In contrast, the existing IAS 28.28 requires that the gain on a sale transaction between an investor and an investment valued at equity - be it an associate or joint venture - only be recognized in the amount of the share held by the others in this company. In the future, it is proposed that the entire gain or loss from the transaction should only be recognized if the assets sold or contributed constitute a “business operation” within the meaning of IFRS 3. The new standard would apply regardless of whether the transaction is structured as a share deal or asset deal. However, if the assets do not constitute a business operation, only a proportionate recognition of profits would be permitted. The date of initial application of the changes has been indefinitely postponed by the IASB.

### 3. Functional currency and presentation currency

These Financial Statements are presented in euros, the Company’s functional currency. Unless otherwise stated, all amounts in euros presented herein have been rounded to the nearest thousand euros (EUR thousandthousand).

### 4. Use of judgements and estimates

In preparing these Financial Statements, the Management Board has made judgements and estimates that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to estimates are recognized prospectively.

#### Judgements

Judgements exercised by the Management 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 (see Note 26 “Leases”)
- 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 19 “Goodwill and other intangible assets”)
- Identification of multiple performance obligations under the development partnerships for purposes of revenue recognition (see Note 9 “Revenue”) and separation thereof between 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 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 used (see Note 16 “Income tax expense”)

- Acquisition of subsidiaries: Fair value of the consideration transferred (including contingent consideration) and fair value of the assets acquired and liabilities assumed in the previous fiscal year (see Note 7 “Acquisition of subsidiaries”)
- Impairment test of intangible assets and goodwill: Key assumptions underlying the calculation of the recoverable amounts (see Note 19 “Goodwill and other intangible assets”)
- Valuations under IFRS 2 (“Shared-based payment”, specifically including phantom shares): 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 15 “Share-based compensation arrangements”).
- Determination of book value of investment participations in jointly controlled companies: Key assumptions for impairment testing in accordance with IAS 28 “Investments in Associates and Joint Ventures” (see Note 20 “Financial assets”)

#### Measurement of fair values

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

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

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

- Level 2: Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

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

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

- Valuation of intangible assets acquired during the previous fiscal year for the purpose of determining and allocating the purchase price (see Note 7 “Acquisition of subsidiaries”),
- Valuation of conditional purchase price payments in determining and allocating the purchase price (see Note 25 “Financial instruments”),
- Valuation of obligations arising from share settled as well as cash-settled share-based compensation arrangements (see Note 15 “Share-based compensation arrangements”),
- Impairment testing of unfinished internally generated intangible assets (see Note 19 “Goodwill and other intangible assets”), and
- Impairment testing of financial assets (see Note 20 “Financial assets”).

### 5. Group structure

In addition to the Formycon AG parent entity, Formycon Group also includes, as of December 31, 2023, the following 100% owned and fully consolidated subsidiaries:

- Formycon Project 201 GmbH

- (Martinsried/Planegg, Germany)
- Formycon Project 203 GmbH (Martinsried/Planegg, Germany)
- FYB202 Project GmbH (Martinsried/Planegg, Germany)
- Clinical Research GmbH (until Dec. 31, 2023: Bioeq GmbH, Holzkirchen, Germany)

Furthermore, Bioeq AG (Zug, Switzerland), which is under joint control by Formycon, is included in these Financial Statements using the equity method.

## 6. Accounting and valuation methods

### Basis of valuations

These Financial Statements have been prepared based on the principle of historical cost. Exceptions to this are the valuations of the contingent consideration component of the Athos transaction during the previous fiscal year (see Notes 7 “Acquisition of subsidiaries”, 23 “Other current liabilities” and 24 “Other non-current liabilities”) and of obligations arising from cash-settled share-based compensation arrangements, which have both been carried out at fair value. Equity-settled share-based payment arrangements granted to employees are likewise measured at fair value as of the grant date (see Note 15 “Share-based compensation arrangements”).

In their preparation, and for all periods therein, the Group has, unless otherwise stated, consistently applied the following accounting policies.

### Basis of valuations

### Business combinations

The Group accounts for business combinations using the acquisition method provided that the set of activities and assets acquired meets the definition of a “business” and that the Group has acquired control thereof. In determining whether a particular

set of activities and assets is a “business”, the Group assesses whether the set of activities and assets acquired includes at least one “input”, meaning “an economic resource (e.g. non-current assets, intellectual property) that creates outputs when one or more processes are applied to it” (per IFRS 3 “Business Combinations”), and one substantive process and whether the presumed “business” is able to provide goods or services to customers.

The consideration transferred for the acquisition and the identifiable assets and liabilities acquired thereby are generally measured at fair value. Any goodwill arising from the transaction is tested annually for impairment. Any gains on acquisitions below market value are recognized immediately as profit. Unless relating to the issuance of debt or equity securities, transaction costs are expensed as incurred.

In determining the amount of consideration transferred for the acquisition, any amounts paid for the fulfillment of pre-existing obligations are excluded. Any profit or loss arising therefrom is recognized as such.

Any consideration transferred for the acquisition in the form of a contingent future obligation is measured at fair value at the time of the business combination. Finally, all other contingent consideration is measured at fair value at each reporting date, with any subsequent changes in the fair value of the contingent consideration recognized as profit or loss.

### Subsidiaries

Subsidiaries are companies under the Group’s control. The Group controls an entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are consolidated into these Financial Statements from the date control begins until the date such control ends.

### Loss of control

If the Group loses control of a subsidiary, it derecognizes the assets and liabilities of the subsidiary

from its consolidated statement of financial position (balance sheet), along with any related non-controlling interests or other equity components. Any resulting gain or loss is recognized in profit or loss. If an interest in the former subsidiary is retained, it is measured at fair value as of the date control over the subsidiary is lost.

### Financial assets accounted for using the equity method

The Group’s financial assets (investments) accounted for using the equity method include a shareholding in a joint venture.

A joint venture is an arrangement in which the Group has joint control, whereby the Group has rights to the net assets of the arrangement, rather than rights to its assets and obligations for its liabilities.

Shares in joint ventures, which are accounted for using the equity method, are initially recognized at acquisition cost, including transaction costs. Subsequent to this initial recognition, these Financial Statements include the Group’s share of the comprehensive income of the financial assets accounted for using the equity method until the date upon which such significant influence or joint control ends.

### Consolidation of intragroup transactions

In preparing these Financial Statements, balances and transactions between the Company and consolidated subsidiaries thereof, as well as any unrealized intercompany income and expenses (other than income and expenses arising from foreign currency transactions), have been eliminated. In the case of companies accounted for using the equity method (associates and joint ventures), any unrealized gains on transactions have been offset against the investment asset, but not by more than the Group’s investment in the respective company. Unrealized losses have been analogously offset (i.e. added to the investment asset), but only where

there is no indication of impairment.

### Transactions in foreign currencies

Business transactions in foreign currencies are converted into the functional currency of the respective Group company at the spot rate on the date of the transaction.

Monetary assets and liabilities denominated in a foreign currency as of the reporting date are translated into the functional currency at the closing rate for the period. Non-monetary assets and liabilities measured at fair value in a foreign currency are translated at the exchange rate in effect at the time the fair value was measured. Non-monetary items measured at historical cost in a foreign currency are translated at the exchange rate prevailing on the transaction date. Currency translation differences are recognized in period profit and loss and included within finance costs.

### Revenue from contracts with customers

The Group generates revenue by granting licenses for the marketing of products once development has been completed. Depending on the contractual design, these licenses may include marketing rights for certain regions, sublicensing rights for certain regions, and/or rights to develop, manufacture and register the products. In some cases, the Group may retain certain rights. The Group subsequently receives license revenue for the granted rights based upon product sales within the licensed territories. If the amount can be reliably determined, the Group recognizes the revenue at the time the license is granted. As a rule, however, such license revenues depend upon actual product sales and thus the amount generated thereby can only be reliably determined over time. The corresponding license revenue is allocated as variable consideration to the separate performance obligation of granting a license.

These license agreements may also include upfront payments, which are likewise allocated to the relevant license grant performance obligation. Revenue from such upfront payments is recognized



at the time the license is granted.

In addition the company generates revenues from the provision of development and other services to assist with the completion of product development through to market approval. These other services may include, for example, the organization of clinical studies and the preparation of approval documents. The customer agreement may provide for ongoing reimbursement of costs or defined milestones. Services rendered but not yet been invoiced are reported as contract assets. In the case of ongoing reimbursements, the regular payments are recognized against contract assets as received, whereas milestone payments are only recognized against contract assets provided that the relevant milestones have been achieved. Revenue is recorded over the development period using the cost-to-cost method. Associated costs are recognized in profit or loss as they are incurred.

In some cases, a single customer contract may combine different kinds of performance obligations, such as both the granting of a license and the provision of development services.

The transaction price of the contract is allocated to the respective individual performance obligations based upon their individual values. Development services are valued using cost plus an appropriate margin as well as residual value considerations. The license is granted on the basis of the residual value considerations if the individual values are not observable.

Specific conditions may be attached to Milestones and Upfront payments. The assessment of the fulfillment of such conditions has an impact on the revenue recognized. Currently the fulfillment of such conditions is assessed to be highly probable.

Once product sales are generated, license revenues become due and payable to the Group with relative-

ly short payment terms.

### **Employee benefits**

#### **Short-term employee benefits**

Short-term employee benefit obligations are expensed as the employee performs the related work services. In cases where the Group has an obligation to pay a future amount as a result of service rendered by the employee, whether legally binding or constructive, and where the obligation can be reliably estimated, a liability is recognized for the amount expected to be paid.

#### **Equity-settled share-based compensation**

Share-based compensation payments to employees settled by the physical delivery of shares are recognized as an expense in the amount of their fair value upon the grant date, with a corresponding increase in equity, over the vesting period of the awards. The amount recognized as an expense is adjusted to reflect the number of granted shares for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized is based on the number of granted shares that meet the related service and non-market performance conditions at the vesting date. In the case of share-based payments with non-vesting conditions, the fair value of the share-based payment as of the grant date is measured to reflect such conditions, but with no subsequent true-up for differences between expected and actual outcomes. Further explanation may be found under Note 15 ("Share-based compensation arrangements").

#### **Cash-settled share-based compensation**

The fair value of amounts payable to employees under cash-settled stock appreciation rights (SARs) is recognized as an expense with a corresponding increase in liabilities, beginning with the period during which the respective employees become unconditionally entitled to payment. The liability

is remeasured at each reporting date and at the settlement (payout) date based upon the fair value of the SARs. Any changes in the liability are recognized in profit or loss. Further explanation may be found under Note 15 ("Share-based compensation arrangements").

#### **Defined contribution plans**

Obligations to make contributions to defined contribution plans are expensed as the employee performs the related work services. Prepaid contributions are recognized as an asset to the extent that there is a right to a refund of, or reduction in, future payments.

#### **Termination benefits**

Benefits arising from the termination of employment are expensed as of the date on which the Group can no longer withdraw the offer of such benefits, or the date on which the Group recognizes costs for a restructuring, whichever is earlier. If these benefits are not expected to be settled in full within 12 months of the reporting date, they are discounted appropriately.

#### **Government grants**

Government grants to fund the future purchase of assets are initially recognized as deferred income at fair value if there is reasonable assurance that they will be received and that the Group will meet the conditions attached to the grant. Once such government grant is actually used to fund the acquisition of the asset, the deferred income is then amortized over the period of the asset's useful life and recognized in profit and loss as other income.

Grants which compensate the Group for expenses incurred are recognized as a reduction in expense in the period(s) in which the relevant expenses are recognized, unless the grant conditions are not met until after the related expenses have been recognized. In this case, the grant is recognized in the period during which the entitlement arises.

The Group is currently receiving grants to cover research and development expenditures incurred in connection with the development of the FYB207 project. Accordingly, the grants are recorded as a reduction in research and development expenses, (see Note 11 "Research and development expenses") and are reflected in the same way as the expenses and presented in the Consolidated Statement of Cash Flows under cash flows from operating activities.

#### **Finance income and finance expense**

The Group's finance income and finance expenses include:

- interest income,
- interest expense,
- gains and losses of investments accounted for using the equity method,
- write-downs of financial assets valued at equity,
- foreign currency gains and losses on financial assets and financial liabilities, and
- gains and losses arising from the measurement of fair value of contingent consideration classified as a financial liability.

Interest income and expenses are recognized in profit or loss using the effective interest method.

The effective interest rate is the interest rate that exactly discounts the estimated future payments or receipts over the expected life of the financial instrument to the net book value of the financial asset, or in the case of a financial liability to the remaining amount thereof.

In calculating interest income and expense, the effective interest rate is applied to the gross book value of the asset, provided that the asset is not credit impaired, or in the case of a financial liability to the remaining amount thereof. In the case of financial assets which have become credit-impaired subsequent to initial recognition, interest income



is, however, instead calculated by applying the effective interest rate to the amortized cost of the financial asset. Should the asset no longer be credit-impaired, the calculation of interest income reverts to the gross basis.

#### Income tax expense

Income tax expense consists of current tax expense and deferred tax expense. Both are recognized in profit or loss, except to the extent that they relate to a business combination or to an item recognized directly in equity or other comprehensive income (OCI). The Group has determined that interest and penalties on income taxes, as well as uncertain tax items, do not meet the definition of income tax expense, and therefore accounts for these in accordance with IAS 37 “Provisions, Contingent Liabilities and Contingent Assets”.

#### Current taxes

Current tax expense is the expected tax liability or tax receivable on taxable income or tax loss for the year, based on tax rates enacted or certain to be soon enacted as of the reporting date, along with any adjustments to tax liability for prior years. The amount of the expected tax liability or tax receivable is the best estimate of the tax amount expected to be paid or received, but also reflecting any tax uncertainties. Current tax receivables and liabilities are only offset (netted) under certain specific conditions.

#### Deferred taxes

Deferred taxes are recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred taxes are not recognized for:

- temporary differences upon initial recognition of assets or liabilities in a transaction which is not a business combination and which affects neither accounting nor taxable profit or loss;
- temporary differences related to investments

in subsidiaries, associates and joint ventures where the Group is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and

- taxable temporary differences arising upon initial recognition of goodwill.

Deferred tax assets are recognized for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognize a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, based on the business plans for individual subsidiaries in the Group. Deferred tax assets are reviewed at each reporting date and reduced to the extent that it is no longer probable that the related tax benefit will be realized; such reductions are reversed when the probability of future taxable profits improves.

The measurement of deferred tax reflects the tax consequences that would follow from the manner in which the Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and deferred tax liabilities resulting from the application of IFRS 16 “Leases” are offset (netted). All other deferred tax assets and deferred tax liabilities are only offset under certain specific conditions.

#### Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is based on the first-in, first-out (FIFO) method of allocation. In the case of manufactured inventories, cost includes an appropriate share of production overheads based on normal operating capacity.

## Property, plant and equipment

### Recognition and measurement

Property, plant and equipment are measured at cost, including any capitalized borrowing costs, less accumulated depreciation and any accumulated impairment losses. Should significant components thereof have different useful lives, these are accounted for as separate items (major components) of property, plant and equipment. Any gain or loss on disposal of an item of property, plant and equipment is recognized in profit or loss.

### Subsequent costs of acquisition or production

Subsequent expenditures are only capitalized if it is probable that the Group will derive additional future economic benefits resulting from the expenditure.

### Depreciation

Depreciation is calculated to fully depreciate the cost of an item of property, plant and equipment less its estimated residual value on a straight-line basis over its estimated useful life. Depreciation is generally recognized in profit or loss.

The estimated useful lives of significant items of property, plant and equipment, for both the current period and prior-year period, are:

- Leasehold improvements: The useful life specific to the asset, not to exceed the remaining term of the underlying lease at the time of the leasehold improvement, i.e. 5-10 years
- Laboratory furnishings and equipment: 7-15 years
- Office furnishings and equipment: 5-10 years

Depreciation methods, useful lives and residual values are reviewed on each reporting date and adjusted as necessary.

## Goodwill and other intangible assets

### Recognition and measurement

#### Goodwill

Goodwill arising from business combinations is measured at cost less any accumulated impairment losses.

#### Research and development

Research expenditures are recognized in profit or loss as incurred.

Development expenditures are only capitalized provided that the expenditure can be measured reliably, that the product or process is technically and commercially feasible, that future economic benefits are probable, and that the Group both intends and has sufficient resources to complete development and to utilize or sell the asset. Any development expenditures not meeting these criteria are recognized in profit or loss as incurred. Capitalized development expenses are valued at acquisition or production cost less accumulated amortization and any accumulated impairment losses.

Formycon develops biopharmaceuticals, in particular biosimilars, with the aim of converting biosimilar candidates into development and marketing partnerships upon attainment of certain defined milestones. Formycon currently has seven projects under active development. For each individual development project, an assessment is made as to whether the criteria for recognition of an internally generated intangible asset have been met.

While innovative drug development projects in phase 3 clinical trials often suffer failures or significant setbacks, the probability of success of a biosimilar candidate in phase 3 clinical comparability trials is significantly higher. Because the efficacy of the originator (reference) biopharmaceutical has already been scientifically proven and recognized by the authorities, and because biosimilar development

focuses on various tests and studies to demonstrate biological similarity to the reference drug already prior to phase 3 clinical testing, one may reasonably conclude, predicated on this already demonstrated similarity, that the likelihood of successfully completing the remaining development of a biosimilar that will bring future economic benefits is very high. It should be noted that more than 95% of biosimilar candidates entering phase 3 clinical trials are, upon completion thereof, proved similar to the reference drug. It is also notable that 78% of biosimilars entering phase 1 clinical trials are ultimately licensed upon completion of development work.

The many activities which Formycon undertakes to develop a biosimilar candidate may be broadly divided into the following six development steps:

- Market research: assessment of market situation, identification of possible drug targets, project planning
- Initial analysis: development of the analytical method panel, characterization of reference molecule, definition of quality target, commencement of cell line development
- Development phase: cell line development, bio-similar manufacturing process development
- Preclinical testing: in vivo studies generally not necessary, but comprehensive physiochemical and bioanalytical testing leading to technical proof of similarity (TPoSo)
- Phase I clinical trials: testing on healthy volunteers to demonstrate biological similarity to the reference product
- Phase III clinical trials: study to demonstrate the similarity of the biosimilar to the reference product in patients (similar efficacy, safety and immunogenicity)

TPoS is generally the point following completion of pre-clinical testing at which Formycon is able to demonstrate, based on the results thereof, that the asset resulting from the development fulfills the criteria of IAS 38.57 and thus that all subsequent development expenditures may be deemed part of the cost of generating the asset and capitalized accordingly. Each project is, however, individually assessed as to whether the criteria have been met.

The costs to be allocated are determined as costs directly attributable to development; because the assets are qualifying assets within the meaning of IAS 23, these costs also include related borrowing costs. The capitalization of development expenditures is terminated upon regulatory approval, except for subsequent development expenditures which generate an additional economic benefit with respect to the related asset.

#### Other intangible assets

Other intangible assets acquired by the Group that have finite useful lives are measured at cost less accumulated amortization and any accumulated impairment losses.

#### Subsequent expenditures

Subsequent expenditures relating to goodwill and intangible assets are capitalized only to the extent that they generate an additional economic benefit with respect to the related asset. All other expenditures, including expenses for internally generated goodwill and brand names, are recognized in profit or loss as incurred.

#### Amortization

Intangible assets are amortized on a straight-line basis over the respective estimated useful life. The amortization begins from the day the respective assets are first used, or in the case of development projects, from the day of initial regulatory approval of the drug in question. The amortization is generally recognized in profit or loss. Other than through impairment, goodwill is not amortized.

The estimated useful lives are:

- Patents and trademarks: based on the term of the corresponding legal protection (5-10 years)
- Capitalized development costs (both acquired and internally developed): up to 18 years

Amortization methods, useful lives and residual values are reviewed on each reporting date and adjusted as necessary.

### Financial instruments

#### Recognition and initial measurement

Trade receivables and debt securities issued are initially recognized from the date they arise or are issued. All other financial assets and financial liabilities are initially recognized when the Group becomes a party to the contractual terms of the instrument.

A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus or minus, for an item not at FVTPL (i.e. fair value with changes in value through profit or loss), transaction costs directly attributable to its acquisition or issue. Trade receivables without a significant financing component are initially recognized at the transaction price.

#### Classification and subsequent measurement

##### Financial assets

Upon initial recognition, a financial asset is classified and measured as:

- an instrument at amortized cost,
- an FVOCI debt instrument (i.e. an investment in a debt instrument measured at fair value with changes through other comprehensive income),
- an FVOCI equity investment (i.e. an equity investment measured at fair value with changes through other comprehensive income), or
- an FVTPL instrument.

Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

A financial asset is measured at amortized cost if it meets both of the following conditions and is not designated as an FVTPL instrument:

- It is held within a business model whose objective is to hold financial assets in order to collect contractual cash flows.
- The contractual terms of the financial asset give rise, on specified dates, to cash flows that are solely payments of principal and interest on the principal amount outstanding.

A debt investment is classified as an FVOCI instrument if it meets both of the following conditions and is not designated as an FVTPL instrument:

- It is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets.
- Its contractual terms give rise, on specified dates, to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Upon initial recognition of an equity investment that is not held for trading, the Group may irrevocably elect to present subsequent changes in the fair value of the investment in OCI. This election is made individually for each investment.

All financial assets not classified as measured at amortized cost or FVOCI as described above are measured at FVTPL. This includes all derivative financial assets. Upon initial recognition, the Group may irrevocably designate a financial asset that otherwise meets the requirements to be measured at amortized cost or at FVOCI as an FVTPL instrument

if doing so eliminates or significantly reduces an accounting mismatch that would otherwise arise.

#### Financial assets:

##### Business model assessment

The Group makes its assessment of the objective of the business model in which a financial asset is held through an assessment of each individual portfolio. The information considered includes:

- the stated objectives for the investment, including whether management's strategy focuses on earning contractual interest income, maintaining a particular interest rate profile, matching the duration of the financial assets to the duration of any related liabilities or expected cash outflows, or realizing cash flows through the sale of the assets;
- how performance results are evaluated and reported to the Group's management;
- the risks that affect the performance of the business model (and the financial assets held within that business model) and how those risks are managed;
- how managers of the business are compensated – e.g. whether compensation is based on the fair value of the assets managed or the contractual cash flows collected; and
- the frequency, volume and timing of sales of financial assets in prior periods and expectations about future sales activity.

##### Financial liabilities: Classification, subsequent measurement, and gains and losses

Financial liabilities are classified and measured at amortized cost or FVTPL. A financial liability is classified at FVTPL if it is classified as held for trading, is a derivative, or is designated as such upon initial recognition.

Financial liabilities at FVTPL are measured at fair value, with net gains and/or losses, including interest expense, recognized in profit or loss.

Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign currency translation differences are recognized in profit or loss. Any gain or loss upon derecognition is also recognized in profit or loss.

With the exception of the obligation to pay contingent consideration under the Athos transaction, all of the Group's financial liabilities are measured at amortized cost.

#### Derecognition

##### Financial assets

The Group derecognizes a financial asset when its contractual right to receive cash flows from the financial asset expires, or when it transfers its right to receive contractual cash flows in a transaction in which either the Group transfers substantially all of the risks and rewards associated with ownership of the financial asset are transferred, or when the Group, although neither transferring nor retaining substantially all the risks and rewards of ownership, does not retain control of the financial asset.

##### Financial liabilities

The Group derecognizes a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognizes a financial liability when its contractual terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognized at fair value.

Upon derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid (including any non-cash assets transferred or liabilities assumed) is recognized in profit or loss.

#### Subscribed capital

Costs directly attributable to the issuance of common shares are recorded as a deduction from equity. Income tax effects relating to the transaction costs of an equity measure are recognized directly in equity in accordance with IAS 12 "Income Taxes".

#### Asset impairment

##### Financial assets (excluding derivatives)

##### Financial instruments and contract assets

The Group recognizes loss allowances for expected credit losses (ECLs) on:

- financial assets measured at amortized cost, and
- contract assets.

The Group also recognizes loss allowances for ECLs on other receivables.

The Group measures loss allowances at an amount equal to lifetime ECLs, except for the following, which are measured at 12-month ECLs:

- debt securities that are determined to have low credit risk at the reporting date, and
- other debt securities and bank balances for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition.

In the case of trade receivables and contract assets, valuation allowances reflect the amount of the expected credit loss over the term.

In determining whether the credit risk of a financial asset has increased significantly since initial recognition and in estimating expected credit losses, the

Group considers reasonable and reliable information which is both relevant and available, including quantitative as well as qualitative information. In addition to well-founded estimates based on analysis, including forward-looking assessments, the Group also considers its own past experience. Should a financial asset be overdue by more than 30 days, the Group assumes that its credit risk has increased significantly. Due to the company's customer structure and contractually agreed payment terms, there have to date been no such delays.

Due to the small number of contract counterparties, the Group assesses each of these with whom there is significant contract exposure through an assessment of each individual portfolio. In each existing case, the Group has assessed the risk of default as extremely low. Thus, subject to materiality considerations, no value adjustments are currently recognized.

The Group considers a financial asset to be in default when:

- the debtor is unlikely to pay its credit obligations to the Group in full, without recourse by the Group to actions such as realizing security (if any is held); or
- the financial asset is more than 180 days past due.

The Group considers a debt security to have low credit risk when its credit risk rating is equivalent to the globally understood definition of "investment grade". The Group considers this to be an S&P rating of BBB- or higher. Lifetime ECLs are the ECLs that result from all possible default events over the expected life of a financial instrument. 12-month ECLs are the portion of ECLs that result from default events that are possible within the 12 months after the reporting date (or a shorter period if the expected life of the instrument is less than 12 months). The maximum period considered when estimating ECLs

is the maximum contractual period over which the Group is exposed to credit risk.

### Non-financial assets

The book value of the Group's non-financial assets, other than inventories and deferred tax assets, is reviewed at each reporting date to determine whether there is any indication of impairment. Should this be the case, an estimate is made of the asset's recoverable amount. Goodwill and intangible assets with an indefinite useful life as well as unfinished internally generated intangible assets (capitalized development costs) are tested annually for impairment. In testing for impairment, assets are grouped into the smallest groupings of assets that generate cash inflows from continued use that are as independent as possible of cash inflows from other assets or cash-generating units (CGUs). Goodwill acquired in a business combination is allocated to the CGU(s), or group(s) of CGUs, expected to benefit from the synergies of the combination.

The recoverable amount of an asset or CGU is the higher of its value in use and its fair value less disposal costs. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate which reflects current market assessments of the time value of money and of the risks specific to the asset or CGU. Should the book value of an asset or CGU exceed this recoverable amount, an impairment loss is recognized.

Impairment losses are included in profit or loss. Impairment losses recognized in respect of CGUs are first allocated to any goodwill allocated to the CGU, then allocated to the book values of the other assets of the CGU (or group of CGUs) on a pro rata basis. Each development project generally corresponds to its own CGU.

Any impairment of goodwill, once recognized, is not reversed. In the case of other (non-goodwill) assets, an impairment loss may only be reversed to the extent that the book of the asset does not exceed the book value, net of depreciation and amortiza-

tion, which would exist had no impairment loss been recognized.

### Leases

The Group enters into lease contracts solely as a lessee. Upon entry into a contract, the Group first assesses whether the contract constitutes a lease or contains a lease component. This is deemed to be the case when the contract entitles the holder to control the use of an identified asset for a period of time in exchange for payment of a fee.

Upon commencement of a lease (or contract containing a lease component), or when a lease (or contract containing a lease component) is modified, the Group allocates the contractual consideration pro rata based on the stand-alone selling prices of the leased assets.

Upon commencement of the lease, the Group recognizes a right-of-use (ROU) asset and a lease liability. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made on or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term, unless the lease transfers ownership of the underlying asset to the Group at the end of the lease term, or unless the cost of the right-of-use asset suggests that the Group will exercise a purchase option. In either of these cases, the right-of-use asset is instead depreciated over the useful life of the underlying asset, which is determined on the same basis as in the case of comparable owned assets. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability. If the lease includes extension options and it is likely that these will be used, these are assumed in the lease term.

The lease liability is initially measured at the present value of the lease payments that are not already paid as of the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate (which is, in fact, the relevant discount rate usually used by the Group). The Group determines its incremental borrowing rate by obtaining interest rates from various external financing sources and makes adjustments as necessary to reflect the individual lease term and type of asset leased.

Lease payments included in the measurement of the lease liability may include:

- fixed payments, including de facto fixed payments;
- variable lease payments that depend upon a benchmark index or rate, initially set according to the index or rate on the commencement date;
- amounts expected to be payable under a residual value guarantee; and/or
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional lease extension period if the Group is reasonably certain to exercise the lease extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is measured at amortized book value using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate; if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee; if the Group changes its assessment of whether it will exercise a purchase, extension or termination option; or if there is a change in the amount of a de facto fixed lease payment. Should the lease liability be remeasured in this way, a corresponding adjustment is made to the book

value of the right-of-use asset, or if the book value of the right-of-use asset has been reduced to zero, it is recognized in profit or loss.

### Short-term leases and leases of low-value assets

The Group has elected not to recognize right-of-use assets and corresponding lease liabilities for leases of low-value assets and short-term leases, including IT equipment. The Group recognizes the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

### Operating profit/loss (EBIT)

Operating profit/loss is net income generated from the Group's continuing sales-generating primary activities plus other income and expenses from operating activities, but excluding finance income and finance costs, participations in the profits and losses of companies accounted for using the equity method, and income taxes.

### Measurement of fair value

"Fair value" is the price at which an asset would, as of the measurement date, be sold, or a liability transferred, in an orderly transaction on the relevant principal market or, if none exists, in the most advantageous market to which the Group has access at that time. The fair value of a liability reflects the risk of non-performance (credit risk).

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.

Where a quoted price in an active market is available, the Group determines the fair value of a financial instrument on the basis thereof. A market is considered "active" when transactions for the relevant asset or liability occur and are reported with sufficient frequency and volume to provide market price information on an ongoing basis.



If there is no quoted price in an active market, the Group uses valuation techniques that maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The chosen valuation technique incorporates all factors which market participants would normally consider when pricing the asset or liability.

Where fair value is to be measured for an asset or liability for which the relevant market price is quoted as a bid/ask price pair, the Group values assets or long positions at the bid price and liabilities or short positions at the ask price.

## 7. Acquisition of subsidiaries in prior fiscal year

On May 1, 2022, Formycon acquired a 100% ownership share of FYB 202 Project GmbH (Berlin, Germany) from FYB 202 GmbH & Co. KG, which upon completion of the transaction was renamed “FYB202 Project GmbH” (without space) and its location of official registration changed to Martinsried/Planegg, Germany; a 100% ownership share of Bioeq GmbH (Holzkirchen, Germany); and 50% of the shares of Bioeq AG (Zug, Switzerland).

Through the transaction, Formycon acquired full rights to FYB202, a candidate biosimilar to Stelara® (ustekinumab), as well as a 50% interest in Bioeq AG, which owns the rights to FYB201, a biosimilar to Lucentis® (ranibizumab). Stelara® is used to treat various serious inflammatory diseases such as moderate to severe psoriasis (psoriasis) and inflammatory bowel diseases such as Crohn’s disease and ulcerative colitis. Lucentis® is used to treat neovascular (“wet”) age-related macular degeneration and other serious eye diseases.

In addition, through the acquisition and organizational integration of long-term partner Bioeq GmbH (“Bioeq”), Formycon was able to expand its expertise and in house resources in a number of areas important for the development, regulatory approval and commercialization of biosimilars.

Formycon contributed its FYB201 project into the partnership with Bioeq AG in 2013, then in 2017

contributed its FYB202 project into the partnership with Aristo Pharma GmbH, an Athos Group company, with the respective partnerships assuming onward development, approval and commercialization. By reacquiring these two biosimilar candidates, Formycon has gained a significantly higher share of future sales revenue upon their respective market introduction. Formycon intends to invest a large part of the anticipated cash inflows into the accelerated expansion of its product development pipeline, thereby enabling it to develop future biosimilar candidates independently and with its own resources. The aim is thus to make a sustainable, ongoing contribution to value creation and to Formycon’s continued future growth.

Through the transaction, important prerequisites were put into place to enable Formycon’s further expansion and to establish Formycon as a global biopharmaceutical player within the rapidly growing biosimilars market. Assuming that regulatory approvals are received as expected and that market launches and out-licensing of its biosimilar candidates take place as planned, Formycon is aiming to achieve a significantly positive EBITDA within the near to medium term.

In the case of FYB202 Project GmbH and Bioeq GmbH, the identifiable assets and liabilities acquired at the time of acquisition included “inputs” (within the meaning of IFRS 3 “Business Combinations”) in the form of the FYB202 biosimilar originally created by the Group and an organized workforce. All of the companies’ necessary marketing and organizational processes were performed by the companies themselves or were outsourced to external service providers. The Group concluded that the acquired inputs and processes together contributed significantly to the ability to generate earnings. The Group thus came to the conclusion that the acquisition of the respective companies meets the IFRS 3 definition of a business combination.

In the case of Bioeq AG, the identifiable assets and liabilities acquired through the transaction included inputs, development processes and an organized workforce. The Group likewise concluded that the inputs and processes acquired together likewise contribute significantly to the ability to generate

earnings and that the acquired company is a “business” within the meaning of IFRS 3. The remaining 50% of the shares of Bioeq AG are held by Polpharma Biologics B.V. (Utrecht, Netherlands). Bioeq AG is a joint venture over which Formycon Group has joint control and in which it has a 50% shareholding. The shares in the company are thus valued at equity in accordance with IAS 28 “Investments in Associates and Joint Ventures” and reported under financial assets. In determining the fair value at the time of acquisition, the provisions of IFRS 3 have been applied by analogy, even though outside the mandatory scope thereof.

### Consideration transferred

The consideration transferred by Formycon for the transactions, valued in accordance with IFRS 3, consisted of 4,000,000 common shares newly issued from the Company’s authorized capital, a cash component, and an earn-out component dependent upon future net cash inflows from the FYB201 and FYB202 projects. The earn-out component was

measured over the next 15 years as a percentage of the net cash inflows after taxes from the respective projects to Formycon AG. This conditional payment obligation is capped at € 677,082 thousand (on an undiscounted basis, of which € 194,052 thousand for FYB202 and € 483,030 thousand for FYB201). The actual amounts were discounted back to the acquisition date of May 1, 2022 until the agreed target amount or the agreed undiscounted maximum was reached. Depending upon actual future net cash inflows, the present values of these future payment outflows could be in line with the estimates in the table below, or they could be as low as zero, while the nominal amount of the payment could be anywhere between zero and the agreed maximum. The common shares issued were valued at the market price on the acquisition date of € 65.60 per share. In the case of Bioeq AG, a loan receivable in the nominal amount of € 82,000 thousand was acquired by Formycon along with the 50% shareholding in the company. Thus, the acquisition costs for the respective transaction components are as follows:

### Consideration transferred in €K

	FYB202 Project GmbH Bioeq GmbH	Bioeq AG	Total
Newly issued common shares (number of shares)	3,330,000	670,000	<b>4,000,000</b>
Newly issued common shares	218,448	43,952	<b>262,400</b>
Fair market value of investment participation indirectly held by Formycon prior to acquisition transaction	114,811		<b>114,811</b>
Debts assumed	8,153		<b>8,153</b>
Cash component	18,763		<b>18,763</b>
Earn-out component	54,115	237,387	<b>291,502</b>
less: Acquisition of loan receivable		-82,000	<b>-82,000</b>
<b>Total consideration paid allocated to respective shareholdings acquired (including prior investment participation at fair market value)</b>	<b>414,290</b>	<b>199,339</b>	<b>613,629</b>

The acquisition of the shares in FYB202 Project GmbH was reported as a step acquisition within the meaning of IFRS 3.41 et seq. The share in FYB 202 GmbH & Co. KG was shown at fair value at the time of acquisition and the resulting profit included in finance income. As part of Formycon's exit as a limited partner of FYB 202 GmbH & Co. KG and the resulting division of assets, Formycon acquired the receivable held by FYB 202 GmbH & Co. KG against Formycon in the amount of € 114,811 thousand, so that this debt was then extinguished as a claim of Formycon against itself ("confusion of debts").

#### Acquisition-related costs

The Group incurred costs of € 717 thousand for legal advice and due diligence in connection with the business combination. These costs were included in administrative expenses.

#### Identifiable assets acquired and liabilities assumed

The recognized amounts of assets acquired and liabilities assumed as of the acquisition date are summarized below.

#### Recognized amounts of assets acquired and liabilities assumed as of the acquisition date in €K

	FYB202 Project GmbH Bioeq GmbH	Bioeq AG, at 50% equity
Intangible assets	460,883	276,054
Property, plant & equipment	50	157
Deferred tax assets	0	3,209
Inventories	0	2,070
Trade and other receivables	14,781	2,173
Cash and cash equivalents	19,871	942
<b>Total assets</b>	<b>495,585</b>	<b>284,605</b>
Equity	369,756	170,226
Non-current liabilities	0	82,156
Current liabilities	6,714	398
Deferred tax liabilities	119,116	31,825
<b>Total equity and liabilities</b>	<b>495,586</b>	<b>284,605</b>

#### Determination of fair values

The valuation methods used to determine the fair value of significant assets acquired under the transaction were as follows:

- Intangible assets: Relief-from-royalty method and residual value method. In the case of patent rights, the relief-from-royalty method measures the present value of estimated future royalty payments that will be spared through the ownership thereof. The residual value method, on the other hand, values these as the present value of the expected future net cash flows generated from the acquired patents and rights.
- Inventories: Market comparison method. The fair value of inventories is measured on the basis of their estimated sales price in the ordinary course of business less the estimated costs of completion and sale along with a reasonable profit margin commensurate to the effort required for completion and sale of the inventories.

#### Provisional determinations of fair value

The fair values of the intangible assets of FYB202 GmbH (full rights to the FYB202 development project) and Bioeq AG (commercialization rights to the FYB201 development project) were provisionally determined as of December 31, 2022. During the fiscal year, there were no further changes to these valuations.

#### Goodwill

Goodwill resulting from the acquisition of the subsidiaries and associate has been measured and recognized as follows, whereby the goodwill of jointly controlled Bioeq AG is already implicitly included in the valuation thereof and thus not reported separately. The recorded goodwill represents, in particular, the know-how in clinical study management and supply chain management which has now been integrated into Formycon AG through the assumption of staff. This goodwill is not tax deductible.

#### Goodwill in €K

	FYB202 Project GmbH Bioeq GmbH	Bioeq AG
Consideration transferred (including prior investment participation at fair market value)	414,290	199,339
Fair value of identifiable net assets	369,756	170,226
Difference (goodwill)	44,534	29,113

**Segments 2023** in €K

	FYB201	FYB202	FYB203	FYB206	FYB207	FYB208	FYB209	Total for reportable operating segments	Remaining amount	Formycon Group
External revenue	14,885	37,356	25,456	-	-	-	-	77,696	-0	77,696
<b>Segment revenue</b>	<b>14,885</b>	<b>37,356</b>	<b>25,456</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>77,696</b>	<b>-0</b>	<b>77,696</b>
Segment profit (loss)	-16,159	12,502	-1,672	-	-2,920	-3,429	-4,173	-15,850	92,092	76,242
Finance income	-	-	-	-	-	-	-	-	102,210	102,210
Finance expense	-	-	-	-	-	-	-	-	-2,962	-2,962
Income from investment participations at equity	-19,362	-	-	-	-	-	-	-19,362	-	-19,362
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-11,275	-24,185	-26,456	-	-2,847	-3,346	-4,072	-72,181	-2,768	-74,949
Other expenses (selling expenses, miscellaneous)	-	-	-	-	-	-	-	-	-1,229	-1,229
Depreciation and amortization	-286	-668	-672	-	-72	-85	-103	-1,887	-	-1,887
Income taxes	-	-	-	-	-	-	-	-	-3,275	-3,275
<b>Assets</b>										
Investment accounted for using the equity method	167,044	-	-	-	-	-	-	167,044	-	167,044
Additions to non-current assets	14,111	3,717	-	16,073	-	-	-	33,902	1,406	35,307

**Segments 2022** in €K

	FYB201	FYB202	FYB203	FYB206	FYB207	FYB208	FYB209	Total for reportable operating segments	Remaining amount	Formycon Group
External revenue	12,125	2,576	27,795	-	-	-	-	42,497	-	42,497
<b>Segment revenue</b>	<b>12,125</b>	<b>2,576</b>	<b>27,795</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>42,497</b>	<b>-</b>	<b>42,497</b>
Segment profit (loss)	-12,870	89,157	637	-6,334	-6,921	-1,034	-1,293	61,342	-25,350	35,992
Finance income	-	-	-	-	-	-	-	-	432	432
Finance expense	-	-	-	-	-	-	-	-	-22,952	-22,952
Income from investment participations at equity	-12,932	89,776	-	-	-	-	-	76,844	-	76,844
Allocated costs (cost of sales, research and development expenses, administrative expenses)	-11,676	-3,092	-26,287	-6,130	-6,699	-1,001	-1,251	-56,136	-784	-56,920
Other expenses (selling expenses, miscellaneous)	-	-	-	-	-	-	-	-	-1,442	-1,442
Depreciation and amortization	-387	-103	-872	-203	-222	-33	-42	-1,862	-	-1,862
Income taxes	-	-	-	-	-	-	-	-	-604	-604
<b>Assets</b>										
Investment accounted for using the equity method	186,406	-	-	-	-	-	-	186,406	-	186,406
Additions to non-current assets	291,639	615,424	-	5,733	-	-	-	912,796	-19,305	893,491

## 8. 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 Management Board, which allocates resources and evaluates segment performance on the basis of the management reports submitted to it. The following segment reporting was prepared in accordance with this definition. In evaluating the performance of the Group's business segments, the Management Board relies upon operating profit/loss as the primary measure of profitability.

The Management 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.

Income and expenses that cannot be assigned to a specific operating segment are substantially the result of the fair value measurement of the contingent purchase price payment obligations. The income from investment participations at equity allocated to the FYB201 segment includes, in addition to Formycon's share earnings from jointly controlled Bioeq

AG, the loss resulting from write-down of the investment participation (see Note 20 "Financial assets"). The Group's business activities take place exclusively within Germany. During the fiscal year as well as the preceding fiscal year, revenues were generated from Athos Group companies (2023: FYB203 operating segment revenue and in 2022 in addition FYB202 operating segment revenue), from Bioeq AG, which is under joint control FYB201/FYB201 operating segment revenue, see Note 27 "Transactions with related persons and companies"), and from Fresenius Kabi (2023: FYB202 operating segment revenue) as marketing partner for the FYB202 project. Thus, all revenue for the fiscal year was generated from these three major customers.

## 9. Revenue

### Revenue streams

During the period, Formycon generated revenue by providing development services to the respective development partners for its partnered development projects FYB201 and FYB203, as well as from FYB202 during the fiscal year 2022 up until and including April 30, 2022, and again during fiscal year 2023 starting from February 1, 2023. These costs include not only product development costs but also costs incurred for the management of clinical studies. In addition, a non-exclusive right of use to the unfinished license for the FYB202 project was transferred to future license partner Fresenius Kabi during fiscal year 2023 with effect from February 1, 2023. As a result of this transfer, revenue of € 10,000 thousand was realized. Finally, with the market launch during fiscal year 2022 of FYB201 in the UK and shortly thereafter in the EU and the USA, Formycon began 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. During the fiscal year, a total of € 4,159 thousand (2022: € 329 thousand) was recognized as license revenue from FYB201.

### Geographical breakdown of revenue in €K

Region	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Germany	25,456	30,372
Switzerland	52,240	12,125
<b>Gesamt</b>	<b>77,696</b>	<b>42,497</b>

### Geographical breakdown of revenue

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

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

### Contract receivables and contract assets

Assets arising from contracts with customers are included as both trade receivables and contract assets. As of the reporting date, such receivables from customers were € 6,757 thousand (Dec. 31, 2022: € 7,766 thousand), while receivables from services not yet invoiced and separately reported as contract assets were € 16,561 thousand (Dec. 31, 2022: € 1,161 thousand). The increase in contract assets in the amount of € 15,400 thousand was mainly (2023: € 12,672 thousand; 2022: € 0 thousand) attributable to services already provided under the agreement for the further development and marketing of FYB202 that have not yet been invoiced to the customer. The remainder of the increase was attributable to additional development services for FYB201 and FYB203 which had not yet been invoiced at year end. There were no contract liabilities.



**Cost of sales** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Cost of materials	-1,554	-2,778
Contract research expenses	-35,676	-24,224
Staff expenses	-11,915	-3,469
Depreciation, amortization and write-downs	-397	-343
Regulatory approval fees	-3,744	0
Other expenses	-1,105	388
<b>Total</b>	<b>-54,391</b>	<b>-30,425</b>

**10. Cost of sales**

Cost of sales includes all costs directly related to generated revenue and thus all costs that can be allocated to the Group's partnered projects. Starting from February 1, 2023, with the conclusion of the marketing agreement with Fresenius Kabi and the associated realization of revenue from performance-related payments using the cost-to-cost method, all further development costs were recorded as the cost of sales. Cost of sales during the fiscal year consisted primarily of the following:

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

**11. Research and development expenses**

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

The 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 Forschungstiftung), 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 € 2,914 thousand (2022: € 5,407 thousand) 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 € 2,097 thousand (2022: € 6,453 thousand).

**12. Other operating income and other operating expenses**

Other operating income consists mainly of income from insurance reimbursements, income from damage claims, and income from other periods.

**Research and development expenses** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Cost of materials	-391	-483
Contract research expenses	-8,038	-16,081
Staff expenses	-2,977	-5,103
Depreciation, amortization and write-downs	-153	-304
Grants received	2,914	5,792
Other expenses	-517	-733
<b>Total</b>	<b>-9,162</b>	<b>-16,912</b>

**Other operating expenses** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Staff expenses	-7,485	-5,950
Marketing expenses	-608	-329
Legal and advisory expenses	-3,304	-4,401
IT expenses	-813	-526
Depreciation, amortization and write-downs	-1,130	-1,392
Other expenses	-1,173	-638
<b>Total</b>	<b>-14,513</b>	<b>-13,235</b>

**Net finance income** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Realized and unrealized gains from foreign currency translation	73	131
Interest income per effective interest method	2,816	302
Investment gain from FYB 202 GmbH & Co. KG	-	89,776
Investment gain from Bioeq AG	11,811	-
Change in fair value of FYB201 conditional purchase price	99,321	-
<b>Finance income</b>	<b>114,021</b>	<b>90,209</b>
Bank fees	-15	-18
Realized and unrealized losses from foreign currency translation	-165	-38
Interest expense from lease liabilities	-80	-68
Interest expense per effective interest method	1	-57
Share of loss from Bioeq AG	-	-12,932
Impairment of investment in Bioeq AG	-31,173	-
Change in fair value of FYB202 conditional purchase price	-2,703	-22,772
Change in Impairments based on the expected credit loss model	-447	-
<b>Finance expense</b>	<b>-34,582</b>	<b>-35,885</b>
<b>Net finance income</b>	<b>79,439</b>	<b>54,324</b>

**Earnings per share**

	Outstanding common shares	Exercisable stock options	Diluted number of common shares
Jan. 1, 2022	11,064,750	192,750	11,257,500
May 16, 2022	15,064,750	192,750	15,257,500
Aug. 16, 2022	15,128,775	128,725	15,257,500
<b>Year average Dec. 31, 2022</b>	<b>13,715,221</b>		<b>13,883,874</b>
Jan. 1, 2023	15,128,775	128,725	15,257,500
Feb. 3, 2023	16,038,775	128,725	16,167,500
Sep. 20, 2023	16,048,525	146,475	16,195,000
Nov. 20, 2023	16,053,025	141,975	16,195,000
<b>Year average Dec. 31, 2023</b>	<b>15,915,789</b>		<b>16,048,616</b>

**13. Net finance income**

The Group's net finance income during the reporting period were as shown on the left.

The acquisition of the shares in FYB202 Project GmbH was reported in the prior fiscal year as a step acquisition within the meaning of IFRS 3.41 et seq. The share in FYB 202 GmbH & Co. KG was thus shown at fair value at the time of acquisition and the resulting gain in the amount of € 89,776 thousand included in net finance income.

The loan impairment are based on the expected credit loss model and primarily the result of value adjustments to loans to companies under joint control (see Note 20 "Financial assets"). The remainder is attributable to the other current financial assets. In the previous fiscal year, such imapriments were not recorded by reason of immateriality.

**14. Earnings per share**

Basic earnings per share are calculated by dividing after-tax earnings attributable to the shares by the number of Formycon common shares outstanding and therefore participating in earnings. Diluted earnings per share are calculated by adding shares which could in the future be issued through the exercise of stock options. The addition of these exercisable but not yet unexercised options results in a dilution in the number of common shares outstanding as shown above.

**Share options issued and outstanding**

	Stock Option Plan 2015	Stock Option Plan 2020
<b>as of Jan. 1, 2022</b>	<b>311,250</b>	<b>101,500</b>
Share options expired - July 2022	-30,000	-30,000
Shares subscribed - July 2022	-64,025	
Share options granted - July 2022		132,500
<b>as of Dec. 31, 2022/Jan. 1, 2023</b>	<b>217,225</b>	<b>204,000</b>
Share options granted - May 2023		25,000
Shares subscribed - August 2023	-9,750	
Shares subscribed - September 2023	-4,500	
Share options granted - October 2023		2,000
Share options granted - December 2023		1,000
<b>as of Dec. 31, 2023</b>	<b>202,975</b>	<b>232,000</b>

**Stock Option Plans**

Stock Option Plan	Tranche	Grant date	Vesting date	Expiry date	Expected exercise date	Expected term	Interest rate	Market price at grant date	Subscription price	Minimum price	Market value of options
<b>2015</b>	<b>1</b>	July 16, 2015	July 16, 2019	July 15, 2025	Nov. 15, 2020	5.63	0.07%	2710	30.98	29.36	8.4058
<b>2015</b>	<b>2</b>	June 28, 2016	June 28, 2020	June 27, 2026	Oct. 29, 2021	5.63	-0.17%	17.51	22.77	22.70	4.7053
<b>2015</b>	<b>3</b>	Oct. 4, 2016	Oct. 4, 2020	Oct. 3, 2026	Feb. 4, 2022	5.63	-0.56%	19.90	19.46	21.42	7.0826
<b>2015 (amended)</b>	<b>4</b>	July 3, 2017	July 3, 2021	July 2, 2027	Nov. 3, 2022	5.63	-0.42%	34.32	36.62	36.16	11.1178
<b>2015 (amended)</b>	<b>5</b>	Feb. 28, 2018	Feb. 28, 2022	Feb. 27, 2028	July 1, 2023	5.63	-0.11%	33.10	31.73	34.95	11.1551
<b>2015 (amended)</b>	<b>6</b>	Apr. 1, 2018	Apr. 1, 2022	Mar. 31, 2028	Aug. 2, 2023	5.63	-0.04%	32.20	31.74	35.04	10.6511
<b>2015 (amended)</b>	<b>7</b>	July 1, 2018	July 1, 2022	June 30, 2028	Nov. 1, 2023	5.63	-0.11%	35.00	36.07	39.33	10.3722
<b>2015 (amended)</b>	<b>8</b>	July 10, 2019	July 10, 2023	July 9, 2029	Nov. 9, 2024	5.63	-0.33%	30.40	32.83	36.04	8.0761
<b>2020</b>	<b>1</b>	Dec. 16, 2020	Dec. 16, 2024	Dec. 15, 2030	Apr. 18, 2026	5.38	-0.78%	58.40	47.57	38.32	22.2827
<b>2020</b>	<b>2</b>	Oct. 19, 2021	Oct. 19, 2025	Oct. 18, 2031	Feb. 19, 2027	5.34	-0.68%	53.30	51.72	57.71	18.1448
<b>2020</b>	<b>3</b>	Dec. 9, 2021	Dec. 9, 2025	Dec. 8, 2031	Apr. 11, 2027	5.34	-0.58%	53.60	49.78	55.00	18.9723
<b>2020</b>	<b>4</b>	Aug. 1, 2022	Aug. 1, 2026	July 31, 2032	Feb. 11, 2028	5.53	0.93%	83.00	75.12	82.06	32.6618
<b>2020</b>	<b>5</b>	May 12, 2023	May 12, 2027	May 11, 2033	Oct. 13, 2028	5.53	2.38%	78.60	71.04	78.90	39.3118
<b>2020</b>	<b>6</b>	Oct. 1, 2023	Oct. 1, 2027	Sep. 30, 2033	Oct. 12, 2029	6.03	2.53%	58.30	61.34	67.74	27.7102
<b>2020</b>	<b>7</b>	Dec. 1, 2023	Dec. 1, 2027	Nov. 30, 2033	Oct. 15, 2029	6.03	2.54%	67.20	56.51	63.94	35.8599

**15. Share-based compensation arrangements****Description of share-based compensation arrangements**

On July 1, 2015, the Group introduced, and subsequently amended on April 27, 2017, and introduced again on December 10, 2020, stock option plans which enable eligible staff (including members of the Management Board) to purchase shares in the Company. Under these two stock option plans, the holders of options granted thereunder have the right, once the options are exercisable, to purchase shares at a subscription price set on the option grant date. Currently, these programs are limited to Management Board members and other eligible employees. The key contractual terms of the stock option plans are as follows: All options are to be settled through subscription and physical delivery of newly issued shares. Under both of the plans, the conditions for exercise of the options are that the re-

levant beneficiary must have remained in the Group for a period of four years following the grant date and that the stock market price must be at least 10% above the subscription price set at the time of the grant. The subscription price is determined as the average of closing prices of Formycon AG shares in Xetra trading during the 60 days before the option grant. In both plans, the options have a term of ten years.

Conditional capital for the issuance of up to 715,260 options (Stock Option Plan 2015) and up to 724,000 options (Stock Option Plan 2020) was established by resolutions of the Annual General Meeting. The number of options issued and outstanding during the reporting period and during the comparable prior-year period was as follows.

In measuring the fair values as of the grant date for reporting these share-based compensation arrangements (stock options with subscription and physical delivery of new shares upon exercise), the following

**Key terms and parameters for SARs (phantom stock plan)**

Waiting period	4.00 years
Contractual term	10.00 years
Expected term	5.85 years
Grant date	Dec. 11, 2023
Vesting date	Dec. 11, 2027
Expiry date	Dec. 10, 2033
Expected exercise date	Oct. 15, 2029
Market price at grant date	€ 62.30
Subscription price	€ 58.08
Minimum price	€ 64.19
Historical volatility	49.68%
Expected dividend yield	0.00%
Market value per option	€ 31.46

valuation parameters were used: For both plans, a share price volatility of between 0.35% and 0.43% was assumed based on historical data, along with beneficiary reduction (staff turnover) of approx. 3% and zero dividends. The outstanding stock options have a weighted average remaining term of 1.33 years.

During fiscal year 2023, the total current expense for share-based compensation payments under these stock option plans was € 1,624 thousand (2022: € 536 thousand). As of December 31, 2023, the impact of these share-based payments on the capital reserve account was € 6,509 thousand (Dec. 31, 2022: € 4,885 thousand).

In addition to the above two share-settled stock option plans, a cash-settled “phantom stock” plan was approved by the Supervisory Board during the fiscal year, under which members of the Management Board and certain other employees were granted stock appreciation rights (SARs) to shares in Formycon AG, i.e. subscription rights to phantom shares which are never actually issued. Each SAR

entitles the holder to receive a cash payment equal to the difference between the share market price upon the actual exercise date and the subscription price determined at granting. The term of the SARs is ten years from the grant date, subject to a four-year vesting period. The current share market price for purposes determining the share price appreciation is determined as the average unweighted closing price of Formycon shares in Xetra trading (or a comparable successor trading system) during the 60 trading days preceding the actual exercise date, with the right to payout upon exercise subject to a minimum 10% share price appreciation.

During the fiscal year, a total of 109,250 phantom shares were issued and, based upon the above parameters (specifically including the waiting period), were valued at € 44 thousand and recorded as an expense. Because this is a cash-settled share-based compensation arrangement (see Note 6 “Accounting and valuation methods”), a corresponding liability has been recognized and included under other long-term liabilities.

**Income tax expense** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Current tax expense	-8	202
Deferred tax expense		
from valuation at equity	-258	-3,601
from differing asset valuations	-4	40
from capitalization of certain leases as right-of-use (ROU) assets and corresponding liabilities from lease obligations	-36	-33
from accounting for cash-settled share-based compensation arrangements	-12	
from capitalization of certain internally generated intangible assets	8,664	7,137
Other	-110	
from deferred taxes on tax loss carry-forwards	-4,962	-3,142
<b>Total tax expense</b>	<b>3,275</b>	<b>604</b>

**16. Income tax expense****Components of income tax expense**

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

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



**Deferred tax assets and deferred tax liabilities** in €K

	Dec. 31, 2023		Dec. 31, 2022	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Valuation of participation in affiliate	431		172	
Valuation of non-current assets		91		95
Right-of-use (ROU) assets and corresponding leasing obligations	74		38	
Arising from purchase price allocation to capitalized assets		119,116		119,116
Capitalization of internally generated intangible assets		15,801		7,137
Non-current liabilities relating to share-based compensation arrangements	198	76		
Tax loss carryforwards - Formycon AG corporate tax (Körperschaftsteuer)	15,499		11,659	
Tax loss carryforwards - Formycon AG trade tax (Gewerbesteuer)	9,573		5,580	
Tax loss carryforwards - FYB202 Project GmbH	5,980		5,203	
Offset (netting) of deferred tax assets and liabilities	-12,284	-12,284	-6,830	-6,830
Valuation adjustment to deferred tax assets	-19,470		-15,822	
<b>Total</b>	<b>-</b>	<b>122,800</b>	<b>-</b>	<b>119,518</b>

**Reconciliation of expected income tax expense to reported total tax expense** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Profit before tax	79,070	36,596
Tax rate	26.68%	26.68%
<b>Expected income tax expense</b>	<b>21,096</b>	<b>9,764</b>
Tax-free income and non-taxable expenses from the valuation of financial instruments	-20,454	-13,401
Taxes for prior years	-121	
Other	-221	-154
Non-recognition of deferred tax assets on tax losses	3,022	4,396
<b>Total tax expense</b>	<b>3,275</b>	<b>604</b>

**EBITDA and adjusted EBITDA** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
EBIT	-369	-17,728
Depreciation of property, plant and equipment	564	664
Depreciation of right-of-use (ROU) assets	1,122	1,033
Amortization of intangible assets	201	165
<b>EBITDA</b>	<b>1,518</b>	<b>-15,866</b>
At-Equity Result Bioeq AG	11,811	-12,932
<b>adjusted EBITDA</b>	<b>13,329</b>	<b>-28,798</b>

**17. EBITDA and Adjusted EBITDA**

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

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

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

## 18. Property, plant and equipment (PP&E) and right-of-use (ROU) assets

### Right-of-use (ROU) assets

Capitalized right-of-use (ROU) assets include rights to use leased space for the Company's headquarters, technical equipment and machinery, and vehi-

cles leased for employee use. During the prior fiscal year, the Company's leased headquarters space was expanded and the lease term (for all leased space) extended until 2032 (five years fixed plus

five years optional). An exercise of the lease extension option is assumed in the lease term because the Company believes it likely that the option will be exercised.

#### Property, plant and equipment (PP&E) and right-of-use (ROU) assets: Reconciliation of book value in €K

2022	Right-of-use (ROU) assets	Leaseholds	Leased technical equipment and machinery	Leased other equipment and furnishings	Property, plant and equipment	Leasehold improvements	Technical equipment and machinery	Other equipment and furnishings
Cost of acquisition as of Jan. 1, 2022	7,652	5,771	1,678	203	6,657	613	4,081	1,963
Additions due to business combinations	-	-	-	-	50	-	50	-
Additions	4,212	3,948	178	86	551	31	117	403
Disposals	-43	-	-	-43	-735	-	-526	-209
Cost of acquisition as of Dec. 31, 2022	11,821	9,719	1,856	246	6,523	644	3,723	2,157
Accumulated depreciation as of Jan. 1, 2022	-1,915	-1,203	-611	-101	-3,963	-367	-2,492	-1,104
Additions	-1,033	-763	-185	-85	-664	-57	-364	-243
Disposals	43	-	-	43	704	-	510	194
Accumulated depreciation as of Dec. 31, 2022	-2,905	-1,966	-796	-143	-3,923	-424	-2,345	-1,154
Net book value as of Jan. 1, 2022	5,737	4,568	1,067	102	2,694	246	1,589	859
Net book value as of Dec. 31, 2022	8,916	7,753	1,060	103	2,600	220	1,378	1,003

#### Property, plant and equipment (PP&E) and right-of-use (ROU) assets: Reconciliation of book value in €K

2023	Aktivierete Nutzungsrechte	Leaseholds	Leased technical equipment and machinery	Leased other equipment and furnishings	Property, plant and equipment	Leasehold improvements	Technical equipment and machinery	Other equipment and furnishings
Cost of acquisition as of Jan. 1, 2023	11,821	9,719	1,856	246	6,523	644	3,723	2,157
Additions	1,506	683	705	118	1,029	7	423	599
Disposals	-125	-	-	-125	-189	-	-	-189
Cost of acquisition as of Dec. 31, 2023	13,202	10,402	2,561	239	7,363	651	4,146	2,567
Accumulated depreciation as of Jan. 1, 2023	-2,905	-1,966	-796	-143	-3,923	-424	-2,345	-1,154
Additions	-1,122	-838	-203	-81	-564	-57	-282	-225
Disposals	125	-	-	125	151	-	-	151
Accumulated depreciation as of Dec. 31, 2023	-3,902	-2,804	-999	-99	-4,336	-481	-2,627	-1,228
Net book value as of Jan. 1, 2023	8,916	7,753	1,060	103	2,600	220	1,378	1,003
Net book value as of Dec. 31, 2023	9,300	7,598	1,562	140	3,027	170	1,519	1,339

**Goodwill and other intangible assets: Reconciliation of book value** in €K

2022	Goodwill	Total intangible assets	Licenses and similar rights	Software	Prepayments for intangible assets
Cost of acquisition as of Jan. 1, 2022	-	1.217	323	813	81
Additions due to business combinations	-	460.883	460.882	1	-
Additions	44.534	26.998	26.820	148	30
Disposals	-	-19	-8	-11	-
Cost of acquisition as of Dec. 31, 2022	44.534	489.079	488.017	951	111
Accumulated amortization as of Jan. 1, 2022	-	-490	-47	-443	-
Additions	-	-165	-42	-123	-
Disposals	-	14	5	9	-
Accumulated amortization as of Dec. 31, 2022	-	-641	-84	-557	-
Net book value as of Jan. 1, 2022	-	727	276	370	81
Net book value as of Dec. 31, 2022	44.534	488.438	487.933	394	111

**Goodwill and other intangible assets: Reconciliation of book value** in €K

2023	Goodwill	Total intangible assets	Licenses and similar rights	Software	Prepayments for intangible assets
Cost of acquisition as of Jan. 1, 2023	44.534	489.079	488.017	951	111
Additions	-	20.167	19.807	360	-
Disposals	-	-11	-	-11	-
Rebookings	-	-	-	111	-111
Cost of acquisition as of Dec. 31, 2023	44.534	509.235	507.824	1.411	-
Accumulated amortization as of Jan. 1, 2023	-	-641	-84	-557	-
Additions	-	-201	-38	-163	-
Disposals	-	9	-	9	-
Accumulated amortization as of Dec. 31, 2023	-	-833	-122	-711	-
Net book value as of Jan. 1, 2023	44.534	488.438	487.933	394	111
Net book value as of Dec. 31, 2023	44.534	508.402	507.702	700	-

## 19. Goodwill and other intangible assets

### Capitalized development expenditures

As part of the business combination, all rights to the FYB202 project, which is still under development, were reacquired by Formycon and recognized accordingly. From May 1, 2022 until January 31, 2023, all costs for the further development of the project, both external and internal, were also capitalized as eligible development expenditures. As of December 31, 2023, the capitalized book value of this pending development project was thus € 485,128 thousand. Starting from February 1, 2023, all subsequent development costs were expensed as incurred and included in cost of sales.

In the case of the FYB206 development project, the technical proof of similarity (TpoSo) milestone was reached in the middle of the year 2022. Upon attainment of TpoSo, the Group's policy (see Note 6 "Accounting and valuation methods") is to capitalize all subsequent internal and external development costs. As of December 31, 2023, the amount of capitalized development expenditures for this project was € 21,815 thousand (Dec. 31, 2022: € 5,742 thousand).

During the fiscal year, borrowing costs of € 1,460 thousand (2022: € 790 thousand) under the shareholder loans were allocated to these two qualifying assets, FYB202 and FYB206, and capitalized as part of their acquisition costs.

### Impairment testing

As the part of the business combination involving FYB202 Project GmbH, goodwill of € 44,534 thousand was recognized for the first time. The entire amount of this goodwill was assigned to the FYB202 cash-generating unit (CGU), which corresponds to the FYB202 operating segment. The annual impairment test was conducted upon completion of the Group's budget planning for 2024 and subsequent years and based upon financial figures as of September 30, 2023. The book value of the CGU was accordingly established at € 333,930 thousand, with assets including € 44,534 thousand in goodwill, € 485,128 thousand in internally generated intangible assets (capitalized development costs), and € 52,652 thousand for the conditional purchase price obligation at fair value. The recoverable amount of the CGU for impairment testing was determined using the fair value less cost of disposal (FVLCD) method, and thus at Level 3 in the fair value hierarchy, with fair value determined on the basis of current planning for the FYB202 project using discounted cash flows. The Group's planning is based upon analyses of the market for the original product, internal information regarding potential competitors, market analyses of biosimilar products in general, and internal empirical values developed together with the contractual partner for marketing the product as well as external advisors. Assumptions were made with regard to the overall future market size, the market share for all biosimilars, the market share specifically for FYB202, and price reductions, which are then used as a basis for calculating expected future product sales. For the years 2025 to 2035, annual market sales of the product were thereby estimated at between € 127 and 377 million (2022: between € 56 and 678 million) and assumed to remain unchanged in subsequent years, with these estimates then used as a basis for the further calculations.

tions. The planning period ends in 2040, with no further extrapolations beyond this point. In discounting the future estimated cashflows from the CGU, the Group applied after-tax discount rates of between 11.98% and 13.53% (2022: between 11.35% and 11.53%), depending upon the term and based upon the weighted average cost of capital (WACC) using historical industry weightings, with a possible leverage of 9.9% (2022: 9.9%) and a market risk premium of 8% (2022: 7%). The recoverable amount determined in this way was € 38,428 thousand (2022: € 69,448 thousand) above the book value of the CGU, and thus it was not necessary to recognize any impairment.

Management has determined that two changes in key assumptions could result in a net book value in excess of the recoverable amount: Should the expected free cash flows from the project (which are, in turn, substantially derived from expected future product sales) decrease by 10.32% (2022: 17.25%), or should the applicable WACC increase by 22.18 percentage points (2022: 3.1 percentage points) compared to the rate assumed as of Sept. 30, 2023, the recoverable amount would be just equal to the CGU's book value.

The FYB206 project under development was assigned to the FYB206 CGU with a book value for the CGU of € 21,815 thousand (2022: € 5,742 thousand). Likewise for this CGU, the recoverable amount was determined using fair value on the basis of current planning for the FYB206 project using discounted cash flows. In the case of FYB206, Formycon's planning is based in large part upon its experience with previous biosimilar development projects. Assumptions were likewise made with regard to the overall future market size, the market share for all biosimilars, the market share specifically for FYB206, and price reductions. Initial CGU revenues in the form of milestone payments from

a potential marketing partner are expected from 2028, with commercial market launch anticipated following originator patent expiry in 2029. The planning period ends in 2040, with no further extrapolations beyond this point. For this CGU, Group has applied an after-tax discount rate of 11.9% (2022: 11.53%), likewise based upon the WACC using historical industry weightings, with a possible leverage of 7.5% (2022: 9.9%) and a market risk premium of 8% (2022: 7%).



**Financial assets: Reconciliation of book value** in €K

2022	Investment participation FYB202 GmbH & Co. KG	Investments accounted for using the equity method	Loan to associate Bioeq AG	Total
Book value as of Jan. 1, 2022	23,615	-	-	<b>23,615</b>
Additions from acquisitions	-	199,339	82,000	<b>281,339</b>
Additions	91,149	-	10,300	<b>101,449</b>
Disposals	-114,765	-12,932	-	<b>-127,697</b>
Book value as of Dec. 31, 2022	-	186,406	92,300	<b>278,706</b>

**Financial assets: Reconciliation of book value** in €K

2023	Investment participation FYB202 GmbH & Co. KG	Investments accounted for using the equity method	Loan to associate Bioeq AG	Total
Book value as of Jan. 1, 2023	-	186,406	92,300	<b>278,706</b>
Additions	-	11,811	2,300	<b>14,111</b>
Disposals	-	-	-3,300	<b>-3,300</b>
Write-downs	-	-31,173	-393	<b>-31,566</b>
Book value as of Dec. 31, 2023	-	167,044	90,907	<b>257,951</b>

**20. Financial assets****Shareholdings in associated companies**

During fiscal year 2022, the Group ceased to be a limited partner and shareholder in FYB 202 GmbH & Co. KG, which was a Formycon associate until April 30, 2022. The gain from the ensuing distribution of assets was recognized in period finance income.

**Shareholdings in jointly controlled companies**

During fiscal year 2022, as a component of the transaction described in Note 7 ("Acquisition of subsidiaries"), the Group became a 50% shareholder and co-owner of Bioeq AG (Zug, Switzerland), which is thus jointly controlled by Formycon. For details of the valuation at the time of acquisition, reference is made to the explanation in Note 7.

**Impairment testing**

Group's as part of the Group's updated annual planning as of September 30, 2023, expectations regarding future cash inflows were significantly adjusted due to changed market expectations for the FYB201 project, and on this basis it was determined that the recoverable amount of the netnet investment was likely to be lower than the netnet book value. Accordingly, an impairment test was carried out in accordance with the provisions of IAS 36 ("Impairment of Assets"). The netnet book value of the investment was determined, including the net income for the period of € 1,716 thousand, at € at 184,690 thousand. The recoverable amount of the net investment for impairment testing was determined using the fair value less cost of disposal (FVL COD) method, and thus at Level 3 of the fair value hierarchy, with fair value determined on the

**Key financial details for the accounting of Bioeq AG** in €K

	2023	2022
<b>Formycon share at year end</b>	<b>50%</b>	<b>50%</b>
Non-current assets	144,167	<b>151,794</b>
Current assets	74,147	<b>31,450</b>
Cash and cash equivalents	5,739	<b>7,926</b>
Non-current financial liabilities	-178,000	<b>-184,000</b>
Other non-current liabilities	-1,305	<b>-1,475</b>
Current financial liabilities	-8,991	<b>-3,099</b>
Other current liabilities	-20,142	<b>-20,036</b>
<b>Equity (100%)</b>	<b>15,615</b>	<b>-17,440</b>
<b>Formycon share of equity (50%)</b>	<b>7,808</b>	<b>-8,720</b>
Hidden reserves revealed during initial recognition including Goodwill less accumulated depreciation and impairments	187,337	<b>224,431</b>
Tax effect thereof	-28,101	<b>-29,304</b>
<b>Book value at year end</b>	<b>167,044</b>	<b>186,407</b>
Revenue	101,743	<b>15,412</b>
Depreciation & Amortization	-30,924	<b>-15,326</b>
Operating income (EBIT)	36,091	<b>-24,671</b>
Interest income	35	-
Interest expense	-4,632	<b>-618</b>
Tax Expense	3,472	<b>-1,377</b>
Profit (loss) for the period	23,623	<b>-25,864</b>
<b>Formycon share of profit (loss)</b>	<b>11,811</b>	<b>-12,932</b>

basis of current planning for the FYB201 project using discounted cash flows. The Group's planning is based upon analyses of the market for the original product, internal information regarding potential competitors, market analyses of biosimilar products in general, and internal empirical values developed together with the contractual partners for marketing the product. Assumptions were made with regard to the overall future market size, the market share for all biosimilars, the market share specifically for FYB201, and price reductions, which are then used as a basis for calculating expected future product

sales. For the years 2024 to 2027, annual market sales of the product were thereby estimated at between € 177 and 197 million and reduced in subsequent years by 5% per year, with these estimates then used as a basis for the further calculations. The planning period ends in 2040, with no further extrapolations beyond this point. In discounting the future estimated cashflows from the CGU, the Group applied after-tax discount rates of between 11.98% and 13.53%, depending upon term and based upon the weighted average cost of capital (WACC) using historical industry weightings, with a possible

leverage of 9.9% and a market risk premium of 8%. The recoverable amount determined in this way was € 153153,517 thousand and thus below the net book value, meaning that it was necessary to record an impairment in the amount of € 31,17331,173 thousand. Key financial details for the accounting of Bioeq AG at equity may be found in the following table. In this presentation, adjustments to fair value at the time of acquisition and at the time of the impairment testing as of Sept. 30, 2023, as described in Note 7, have already been taken into account.

#### Loans to jointly controlled companies

As part of the acquisition transaction for the shareholding in Bioeq AG, the Group acquired a loan receivable from Bioeq AG in the amount of € 82,000 thousand. By the end of the prior fiscal year at December 31, 2022, the loan had been increased by a further € 10,000 thousand to € 92,000 thousand within the contractual loan framework amount of € 99,000 thousand through a further loan drawdown. During the 2022 fiscal year, € 300 thousand attributable to the loan was also recorded as interest income. During the 2023 fiscal year, € 3,000 thousand was repaid by Bioeq AG along with the interest due from the preceding year, and a further € 2,300 thousand attributable to the loan was recorded as interest income. The interest rate of the loan is based upon the official circulars published by the Swiss tax authorities for permissible interest rates on cross-border loans with affiliated companies and was approx. 2.5% during the fiscal year. The loan bears interest at the interest rate published by the Swiss Federal Tax Administration (SFTA) in its annually renewed circular on tax-recognized interest rates for advances or loans in foreign currency. During the fiscal year, a loan write-down in the amount of € 393393 thousand was taken based on the expected credit loss (ECL) model.

## 21. Equity

In February of 2023, the Management 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. These new shares corresponded to approx. 6.02% of the Company's shares already outstanding at the time of issuance and were placed with institutional investors using an accelerated bookbuilding process under exclusion of subscription rights. Based on this bookbuilding process to facilitate the private placement, the Management Board, with the approval of the Supervisory Board, set a placement price of €77.00 per new share, thereby generating gross issuance proceeds of € 70,070070 thousand before commissions and other costs. Costs associated with the capital increase transaction in the amount of € 1,736736 thousand were directly posted to the EquityEquity account. Changes to EquityEquity during the reporting period are presented in the Consolidated Statement of Changes in Equity.

#### Number of shares outstanding

As of the end of the reporting period, the Company had registered capital (Grundkapital) of € 16,053,025 (Dec. 31, 2022: € 15,128,775), divided into 16,053,025 bearer shares without par value (Dec. 31, 2022: 15,128,775 shares). All shares have full voting and dividend rights.

#### Authorized Capital 2023

By resolution of the Annual General Meeting of July 25, 2023, the Management Board is authorized, subject to the approval of the Supervisory Board, to increase the Company's registered capital one or more times at any time until July 24, 2028, and by no more than a total of € 8,019,387.00, through the issuance of up to 8,019,387 new no-par-value common bearer shares, against contributions in cash and/or in kind (the "AuthorizedAuthorized Capital 2023"). The Company's shareholders shall, in gene-

ral, be granted subscription rights (which may also be by way of indirect subscription rights pursuant to sec. 186 para. 5 sentence 1 of the Stock Corporation Act). Notwithstanding the foregoing, the Management Board shall be authorized, subject to the approval of the Supervisory Board, to fully or partly exclude the general statutory subscription rights of shareholders in the following specific cases:

- For the exclusion of fractional shares from subscription rights.
- In the case of capital increases against non-cash contributions for the issuance and granting of shares as consideration for the purchase of companies, parts of companies, equity interests in companies, or other assets or rights.
- In the case of capital increases made against cash contributions, provided that the issuance price of the new shares is not significantly lower than the stock exchange price at the time that the issuance price is determined and that the new shares issued under exclusion of subscription rights pursuant to sec. 186 para. 3 sentence 4 of the Stock Corporation Act do not exceed 10% of the Company's share capital, either at the time of entry into effect or at the time of exercise. The calculation of this 10% limit shall include (a) any shares which are issued or sold during the term of this authorization under an exclusion of subscription rights through the direct application of, and in accordance with, sec. 186 para. 3 sentence 4 of the Stock Corporation Act, and/or (b) any shares issued, or which may be issued, to fulfill the Company's obligations arising from the exercise of warrants and/or conversion rights, or other stock option rights or obligations, arising from bonds or profit participation rights, provided that these financial instruments have been issued subsequent to the entry into force of this authorization and under exclusion of subscription rights pursuant to sec. 186 para. 3 sentence 4 of the Stock Corporation Act.
- In the case of capital increases made against cash contributions, insofar as necessary to

grant sufficient shares to holders of bonds or profit participation rights with warrants and/or conversion rights, or involving other stock option rights or obligations, and issued by the Company or by a direct or indirect subsidiary thereof, to the extent that they would be entitled as shareholders upon exercise of the relevant option or conversion right or fulfillment of option or conversion obligation, or following any right to substitute which the Company may have.

- For the granting of shares issued in lieu of cash dividends (scrip dividends), whereby shareholders are offered the option of contributing their dividend entitlement (in whole or in part) to the Company as a contribution in kind against the granting of new shares from Authorized Capital.

The Management Board is authorized, subject to the approval of the Supervisory Board, to determine further details regarding the specific implementation of any such capital increase and issuance of new shares, including the issuance price, as well as regarding the rights of shareholders thereunder. The Supervisory Board is further authorized to amend the Company's Articles of Incorporation to reflect any such increase in registered capital and corresponding decrease in Authorized Capital 2023 in the event of any such full or partial utilization of the Authorized Capital 2023 or in the event of its expiry.

#### Conditional Capital 2022

By resolution of the Annual General Meeting of June 30, 2022, the Company's registered capital has been conditionally increased by a maximum of € 6,497,125.00 (the "Conditional Capital 2022").

This conditional capital increase shall serve for the granting of shares to holders of convertible bonds and/or bonds with attached warrants issued by the Company, or by a group company within the meaning of sec. 18 of the Stock Corporation Act, on the basis of the corresponding authorization resolved by the Annual General Meeting on June 30, 2022 and at any time until June 29, 2027, which become

due upon the exercise of bondholder conversion and/or option rights, or upon fulfillment of conversion or subscription obligations, or upon the exercise by the Company of its optional rights to redeem bonds, in whole or in part, through the granting of Company shares in lieu of cash. The conversion or option exercise price at which the new shares are issued shall be determined in accordance with the authorizing shareholder resolution. Capital increases under the Conditional Capital 2022 shall be carried out only to the extent necessary for the exercise of conversion or option rights, or for the fulfillment by creditors or bondholders of conversion or subscription obligations, or for the exercise by the Company of its optional rights to redeem bonds, in whole or in part, through the granting of new Company shares to holders of convertible bonds and/or bonds with attached warrants as consideration due and only insofar as such consideration due is not granted in the form of cash or existing treasury shares, or as shares of another listed company as substitute consideration. Although newly issued shares should, in principle, participate in profits from the beginning of the fiscal year during which they are issued, any shares newly issued on the basis of a bond conversion or warrant exercise declared prior to the annual general meeting of the Company in which a resolution is passed regarding the application of retained profits from the prior fiscal year shall also be entitled to participate in any dividends declared for the prior fiscal year. To the extent legally permissible, the Board of Management may, with the approval of the Supervisory Board, determine the profit participation of such newly issued shares in deviation from sec. 60 para. 2 of the Stock Corporation Act. The Management Board is authorized, subject to the approval of the Supervisory Board, to determine further details regarding the specific implementation of any capital increases hereunder.

### **Number of subscription rights per sec. 192 para. 2 no. 3 of the Stock Corporation Act**

#### **Conditional Capital 2015**

The Company's registered capital has been conditionally increased by a maximum of € 376,000 for the issuance of a maximum of 376,000 new no-par-value bearer shares (the "Conditional Capital 2015"). The Conditional Capital 2015 serves exclusively to secure subscription rights (stock options) granted to members of the Management Board and Company employees, as well as executives and employees of Company subsidiaries and associated companies, under the authority granted by resolution of the Annual General Meeting of June 30, 2015 to issue such stock options at any time up to and including June 29, 2020 (the "Stock Option Plan 2015"). This capital increase is conditional upon such subscription rights having been issued and upon the exercise of such subscription rights by the holders thereof, and further provided that the Company does not grant treasury shares or provide a cash settlement in fulfillment of such subscription rights. The newly issued shares shall participate in profits from the start of the fiscal year for which, at the time of their issuance, no resolution has yet been taken by the Annual General Meeting as to the application of retained profits. The Management Board is authorized, subject to approval of the Supervisory Board, to determine further details regarding the specific implementation of any such contingent capital increase. In the case of such subscription rights (stock options) being granted to Management Board members, the Supervisory Board is similarly authorized. The Supervisory Board is further authorized to amend the Company's articles of incorporation to reflect such utilization of conditional capital.

A total of 14,250 stock options were granted during the fiscal year under the Conditional Capital 2015.

As of the period closing date, a total of 202,975 stock options remained issued under the Conditional Capital 2015 and not either expired or exercised.

#### **Conditional Capital 2020**

The Company's registered capital has been conditionally increased by a maximum of € 724,000 for the issuance of a maximum of 724,000 new no-par-value bearer shares (the "Conditional Capital 2020"). The Conditional Capital 2020 serves exclusively to secure subscription rights (stock options) granted to members of the Management Board and Company employees, as well as executives and employees of Company subsidiaries and associated companies, under the authority granted by resolution of the Annual General Meeting of December 10, 2020 to issue such stock options at any time up to and including December 9, 2025 (the "Stock Option Plan 2020"). This capital increase is conditional upon such subscription rights having been issued and upon the exercise of such subscription rights by the holders thereof, and further provided that the Company does not grant treasury shares or provide a cash settlement in fulfillment of such subscription rights. The newly issued shares shall participate in profits from the start of the fiscal year for which, at the time of their issuance, no resolution has yet been taken by the Annual General Meeting as to the application of retained profits. The Management Board is authorized, subject to approval of the Supervisory Board, to determine further details regarding the specific implementation of any such contingent capital increase. In the case of such subscription rights (stock options) being granted to Management Board members, the Supervisory Board is similarly authorized. The Supervisory Board is further authorized to amend the Company's articles of incorporation to reflect such utilization of conditional capital.

28,000 stock options were granted during the fiscal year, and thus as of the period closing date, a total of 232,000 stock options were issued thereunder and not either expired or exercised.

## 22. Capital management

The Group's policy is to maintain a strong capital base so as to maintain investor, creditor and market confidence and to sustain future development of the business. Management regularly monitors liquidity and the Equity ratio in order to ensure their adequacy. During the prior fiscal year, a significant long-term debt position was created for the first time arising from the business combination transaction described in Note 7 ("Acquisition of subsidiaries") and the associated financing by key shareholders. This financing arrangement serves to facilitate the Group's medium-term to long-term strategy and to enable Formycon to continue its development projects independently without necessarily having to rely on the support of external partners. At the same time, the equity ratio has fallen significantly as a result of the new long-term debt, although it should be recognized here that this long-term debt is provided exclusively by Formycon shareholders. During the fiscal year, the equity base was further strengthened through the capital increase against cash contributions, thus significantly increasing the Group's equity ratio.

## 23. Other current liabilities

The amount of the shareholder loan includes accrued interest. The loan was granted to the Group by key shareholders (or affiliates thereof) to facilitate the strategic transaction. The loan is a revolving credit line originally in the amount of € 68,000 thousand with a term of 24 months from the first drawdown. Interest is charged on drawdowns at a rate of 6%, which can be repaid at any time. During the fiscal year, € 20,000 thousand was repaid along with the interest amount due and by that credit line was reduced to € 48,000 thousand. Interest due is payable at the end of each calendar quarter. As of the reporting date, € 20,000 thousand of this credit line remained drawn by the Group and outstanding.

### Equity ratio in €K

	2023	2022
Equity	502,751	356,580
Non-current liabilities	318,305	446,451
Current liabilities	69,306	50,666
<b>Liabilities and equity</b>	<b>890,362</b>	<b>853,697</b>
<b>Equity ratio</b>	<b>56,5%</b>	<b>41,8%</b>

### Other current liabilities in €K

	Dec. 31, 2023	Dec 31, 2022
Shareholder loans	20,485	20,790
Current portion of conditional purchase price	27,179	14,935
Staff-related liabilities	2,684	1,293
Taxes	194	465
Other current liabilities	806	833
<b>Total</b>	<b>51,349</b>	<b>38,315</b>



## 24. Other non-current liabilities

Other non-current liabilities include the conditional purchase price payments relating to the acquisition of subsidiaries during the preceding fiscal year in the amount of € 187,644 thousand (Dec. 31, 2022: € 299,339 thousand) along with obligations under cash-settled equity-based compensation arrangements in the amount of € 44 thousand.

## 25. 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 during the preceding fiscal year as partial consideration for the acquisition of the shareholdings in FYB202 Project GmbH and Bioeq AG (see preceding Notes 7, 23 and 24), which is measured at fair value. For all financial assets and liabilities except for the shareholder loan to Bioeq AG, which is at a non-market interest rate, book value is an adequate approximation of fair value. The book values and fair values of the Group's financial assets and liabilities are summarized on the right side. In the prior fiscal year, the book value for all financial assets and liabilities represented a reasonable approximation of their

respective fair value, and thus the fair values were not specifically disclosed.

The contingent purchase price payment obligations for the shares in Bioeq AG are measured at fair value based on level 3 input factors under the fair value hierarchy (see 6 "Accounting and valuation methods"). At the time of the business combination transaction in 2022, the contingent purchase price payments were originally valued at € 291,502 thousand but at a fair value of € 214,824 thousand as of the reporting date (Dec. 31, 2022: € 314,274 thousand). The difference between these figures in the amount of € 96,618 thousand (2022: € 22,772 thousand) has been included in finance income (finance costs). During the fiscal year, € 2,832 thousand under the conditional purchase price obligations were paid.

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 rates used to discount the conditional purchase price payments ranged from 11.1% to 11.8%. The estimated fair value would increase if the expected cash flows occurred earlier or if the risk-adjusted discount rates were lower. A 1% decrease (increase) in the discount rate would result in an increase (decrease) in fair value of € 10,142 thousand (€ 9,326 thousand), which would have to be recognized as profit or loss.

Advance payments in the amount of € 11,335 thousand (Dec. 31, 2022: € 4,636 thousand) are mainly advance payments for development services.

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

	Book value at Dec. 31, 2023	Fair value at Dec. 31, 2023	FV category
Financial assets not carried at fair value			
Financial assets	90.907	82.765	3
Trade and other receivables	11.612		3
Contract assets	16.561		3
Cash and cash equivalents	27.035		3
Financial liabilities carried at fair value			
Current portion of conditional purchase price	27.179	27.179	3
Non-current portion of conditional purchase price	187.645	187.645	3
Financial liabilities not carried at fair value			
Shareholder loans	20.485		3

**Liquidity risk** in €K

as of Dec. 31, 2023	due within 1 year	1-2 years	2-3 years	3-4 years	4-5 years	> 5 years	Total	Book value
Lease obligations	7,652	5,771	1,678	203	6,657	613	4,081	1,963
Shareholder loan	-	-	-	-	50	-	50	-
Conditional purchase price payments	4,212	3,948	178	86	551	31	117	403

**Liquidity risk** in €K

as of Dec. 31, 2022	due within 1 year	1-2 years	2-3 years	3-4 years	4-5 years	> 5 years	Total	Book value
Lease obligations	989	1,010	943	895	829	4,136	8,802	8,802
Shareholder loan	20,790	20,000	-	-	-	-	40,790	40,790
Conditional purchase price payments	15,749	53,692	60,125	61,891	46,972	404,930	643,359	643,359

**Risk management**

For a description of the methods, processes, responsibilities and objectives of Formycon's risk management system, please refer to the respective section of the combined Management Report. The Group has exposure to the following risks arising from financial instruments:

- Credit risk
- Liquidity risk
- Foreign currency risk

**Risk management framework**

The Management Board of Formycon AG has overall responsibility for the establishment and oversight of the Group's risk management framework. Toward this end, the Management Board has appointed staff members responsible for managing and further developing the Group's risk management policies. These staff members report regularly to the Management Board on their activities. The risk manage-

ment policies and systems are regularly reviewed to reflect changes in market conditions and in the Group's activities.

**Credit risk**

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet its contractual obligations. In the case of Formycon, credit risk arises principally from the loan receivable, from trade receivables, from contract assets, and from the Group's holdings in cash and cash equivalents. The carrying amounts of financial assets and contract assets represent the maximum potential credit exposure.

In determining whether the credit risk of a financial asset has increased significantly since its initial recognition and in estimating expected credit losses, the Group considers information that is available without undue cost or effort. This includes both quantitative and qualitative information and analysis based on the Group's historical experience and an appropriate credit assessment, which also incorporate forward-looking information. In addition to

external credit ratings where available, this information may also include credit agency information and industry information.

During the fiscal year, write-downs in the amount of € 447,447 thousand were recorded based on the expected credit losses (ECL) for loans of the same credit rating. In the prior fiscal year, no such impairment losses on financial assets were recognized because the total calculated ECL amount was immaterial (see also Note 6 "Accounting and valuation methods").

**Liquidity risk**

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Group's objective when managing liquidity is to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Group's reputation.

The remaining contractual maturities of financial liabilities as of the reporting date are shown below. The amounts are gross and undiscounted and include contractual interest payments but not the impact of netting agreements.

**Foreign currency risk** in €K

as of Dec. 31, 2023	USD	GBP	CHF	JPY
Bank accounts	368			
Trade payables	52	1	294	84
Net risk exposure	-316	1	294	84

**Foreign currency risk** in €K

as of Dec. 31, 2022	USD	GBP	CHF	JPY
Bank accounts	365	-	-	-
Trade payables	761	51	194	254
Net risk exposure	396	51	194	254

**Foreign currency risk**

To the extent that there is a mismatch between the currencies in which purchase and credit transactions are denominated and the functional currency of the relevant consolidated company, the Group is exposed to transactional foreign currency risk. The functional currency of consolidated companies is, in all cases, the euro (€). The transactions from which such foreign currency risk may arise are primarily denominated in U.S. dollars (USD), British pounds (GBP) and Swiss francs (CHF), as well as to a small extent Japanese yen (JPY). In addition, the Group holds bank accounts denominated in USD. As of the reporting date, the net foreign currency risk reflected in Group's balance sheet (for each of the currencies, in thousands) was as shown above.

A hypothetical strengthening or weakening of the euro, U.S. dollar, British pound, Swiss franc or Japanese yen relative to the other currencies would, as of December 31, have influenced the valuation of financial instruments denominated in foreign currencies and would have affected the equity account and profit or loss account according. A 10% change in the USD/EUR exchange rate would result in a gain/loss of € 6 thousand (2022: € 37 thousand), while a 10% change in the CHF/EUR exchange rate would result in a gain/loss of € 28 thousand (2022: € 20 thousand). This analysis assumes that all other influencing factors, especially interest rates, remain unchanged.

**Lease liabilities** in €K

as of Dec. 31, 2023	due within 1 year	1-2 years	2-3 years	3-4 years	4-5 years	> 5 years	Total
Current lease obligations	1,186						<b>1,186</b>
Non-current lease obligations		1,166	1,089	1,028	978	3,555	<b>7,815</b>

**Lease liabilities** in €K

as of Dec. 31, 2022	due within 1 year	1-2 years	2-3 years	3-4 years	4-5 years	> 5 years	Total
Current lease obligations	925						<b>925</b>
Non-current lease obligations		1,050	986	935	864	3,759	<b>7,594</b>

**26. Leases**

The Group enters into lease contracts solely as a lessee. These contracts include the Group's leased head offices in Martinsried/Planegg on the outskirts of Munich, leased property, plant and equipment primarily for laboratory purposes, and leased vehicles for certain staff members. For information about the capitalization of right-of-use assets, see Note 18 "Property, plant and equipment (PP&E) and right-of-use (ROU) assets".

Interest expenses of € 80 thousand (2022: € 69 thousand) were incurred during the fiscal year and recognized in the income statement (Consolidated Statement of Comprehensive Income). In addition, administrative expenses during the fiscal year included lease payments for low-value assets not

recognized as right-of-use assets with corresponding lease liabilities in the amount of € 19 thousand (2022: € 66 thousand).

The following table provides an overview of the maturities of the Group's lease liabilities:

**Remuneration to Management Board** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Short-term employee benefits	1,678	1,363
Post-employment benefits	-	625
Stock options granted	136	604
<b>Total</b>	<b>1,814</b>	<b>2,592</b>

**Administrative expenses** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Short-term employee benefits	1,678	1,363
Post-employment benefits	-	625
Stock option expenses	998	89
<b>Total</b>	<b>2,676</b>	<b>2,077</b>

**27. Transactions with related parties****Key management personnel and members of Supervisory Board**

The Group's key management personnel are the members of the Management Board of Formycon AG. During the reporting period, remuneration to Management Board members was as shown above. During the fiscal year, remuneration to members of the Supervisory Board was € 109 thousand (2022: € 96 thousand).

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

**Related companies**

Since the acquisition by Athos in 2022 of a shareholding in Formycon AG along with representation on the Supervisory Board, Athos Group companies have been recognized as related companies.

Bioeq AG, an entity jointly controlled by Formycon, is likewise recognized as a related company.

During the reporting period, sales revenue in the amount of € 40,34140,341 thousand (2022: € 30,497 thousand) was recognized with related companies, of which € 14,88514,885 thousand (2022: € 7,211 thousand) was with jointly controlled Bioeq AG. Out of the Group's total trade receivables on the closing balance sheet, receivables in the amount of € 6,471 thousand (Dec. 31, 2022: € 7,808 thousand) were due from related companies. The balance sheet also includes a loan receivable from Bioeq AG

**Average number of employees (FTE) during the reporting period**

	2023	2022
Research & development	162	137
Business operations	10	8
General & administrative	25	16
<b>Total</b>	<b>197</b>	<b>161</b>

**Staff expenses calculated in accordance with total cost method** in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Wages and salaries	18,853	9,599
Expenses for social security contributions	3,247	1,653
Expenses for retirement contributions	275	140
<b>Total</b>	<b>22,377</b>	<b>11,393</b>

in the nominal amount of € 91,300 thousand (Dec. 31, 2022: € 92,300 thousand) including accrued interest.

In addition to the sales revenue and trade receivables resulting from these development partnerships, the Group has also received loans from key shareholders (see Note 23 "Other current liabilities"). In addition, Formycon has liabilities relating to conditional purchase price payments to Athos Group companies resulting from the business combination transaction. As of the reporting date, the amount of this recorded liability was € 214,824214,824 thousand (Dec. 31, 2022: € 311,181 thousand), while finance income during the fiscal year included € 96,618 thousand (2022: finance expenses of € 22,77222,772 thousand) arising from the fair value measurement of these obligations.

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

**28. Other information****Remuneration**

During the fiscal year, the members of the Supervisory Board received total remuneration of € 109 thousand (2022: € 96 thousand), while total remuneration to members of the Management Board, within the meaning of sec. 285 no. 9 of the Commercial Code, was € 1,814814 thousand (2022: € 2,592 thousand), of which € 604604 thousand (2022: € 846 thousand) was success-based, and including 25,000 stock options and 60,000 phantom stock options with a fair value of € 136136 thousand.



## Consolidated financial statement auditor fees per sec. 314 para. 1 no. 9 of the Commercial Code in €K

	Jan. 1 – Dec. 31, 2023	Jan. 1 – Dec. 31, 2022
Audit services	582	389
Tax advisory and other services	0	0
<b>Total</b>	<b>582</b>	<b>389</b>

**29. Subsequent events**

Upon entry into the commercial register on February 8, 2024, the Company's registered capital was increased by € 1,603,877.00 through a partial utilization of the Authorized Capital 2023. The new shares were issued as part of a capital increase by a strategic investor at an issuance price of € 51.65 per share and thus a total cash contribution to the Company in the amount of € 82,843,475.00. Subsequent to the capital increase, the Company's

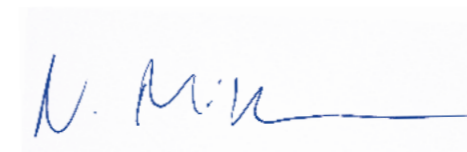
registered capital was € 17,656,902.00. The excess of the issuance price over the imputed nominal value of € 1.00 per share is included in the capital reserve account.

The shareholder loans, including accrued and current interest, were repaid in full with payment of March 28, 2024. At the same time, the loan facility in the amount of € 48,000 thousand was extended by 12 months until May 31, 2025.

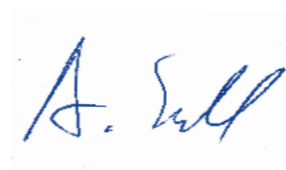
Martinsried/Planegg, Germany, April 16, 2024



Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl



Enno Spillner

## Independent Auditor's Report

To Formycon AG,  
Planegg-Martinsried, Germany

### Opinions

We have audited the consolidated financial statements of Formycon AG, Planegg-Martinsried, and its subsidiaries (the Group), which comprise the consolidated statement of financial position as of December 31, 2023, and the consolidated statement of profit or loss and OCI, the consolidated statement of changes in equity and the consolidated statement of cash flows or the financial year from January 1, 2023 to December 31, 2023, and notes to the consolidated financial statements, including a summary of significant accounting policies. We have also audited the combined management report of the Company and the Group (the "combined management report") of Formycon AG for the business year from January 1 to December 31, 2023.

In accordance with German legal requirements, we have not audited the content of those components of the combined management report specified in the "Other Information" section of our auditor's report.

In our opinion, on the basis of the knowledge obtained in the audit,

- the accompanying consolidated financial statements comply, in all material respects with IFRSs as adopted by the EU, and the additional requirements of German law pursuant to Section 315e (1) HGB [Handelsgesetzbuch] and, give a true and fair view of the assets, liabilities and financial position of the Group as of December 31, 2023 and of its financial

performance for the fiscal year from January 1 to December 31, 2023 in accordance with these requirements and

- the accompanying combined management report as a whole provides an appropriate view of the Group's position. In all material respects, this combined management report is consistent with the consolidated financial statements, complies with German legal requirements, and appropriately presents the opportunities and risks of future development. Our opinion on the combined management report does not cover the content of those components of the combined management report specified in the "Other Information" section of the auditor's report.

Pursuant to Section 322 (3) sentence 1 HGB, we declare that our audit has not led to any reservations relating to the legal compliance of the consolidated financial statements and the combined management report.

### Basis for the Opinions

We conducted our audit of the consolidated financial statements and of the combined management report in accordance with Section 317 HGB and German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW).. Our responsibilities under those requirements and principles are further described in the section "Auditor's Responsibility for the Audit of the Consolidated Financial Statements and the Combined Management Report" of our auditor's report. We are independent of the group entities in accordance with German commercial and professional law, and have fulfilled our other German

professional responsibilities in accordance with these requirements. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion on the consolidated financial statements and on the combined management report.

#### Other Information

The Board of Management and the Supervisory Board are responsible for the other information. The other information comprises the following components of the group management report, whose content was not audited:

- information extraneous to management reports and marked as unaudited.

The other Information includes also the remaining parts of the annual report. The other information does not include the consolidated financial statements, the combined management report information audited for content and our auditor's report thereon.

Our opinions on the consolidated financial statements and the combined management report do not cover the other information, and consequently we do not express an opinion or any other form of assurance conclusion thereon.

In connection with our audit, our responsibility is to read the other information and, in so doing, to consider whether the other information

- is materially inconsistent with the consolidated financial statements, with the combined management report information audited for content or our knowledge obtained in the audit, or
- otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### Responsibility of the Board of Management and the Supervisory Board for the Consolidated Financial Statements and the Combined Management Report

The Board of Management is responsible for the preparation of consolidated financial statements that comply, in all material respect, with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Section 315e (1) HGB and that the consolidated financial statements, give a true and fair view of assets, liabilities, financial position, an financial performance of the Group in compliance with these requirements.

In addition, the Board of Management is responsible for such internal control as the Board of Management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. The Board of Management is further responsible for such internal control as the Board of Management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error (i.e. manipulation of the accounting system or misstatement of assets).

In preparing the consolidated financial statements, the Management Board is responsible for assessing the Group's ability to continue as a going concern. They also have the responsible for disclosing, as applicable, matters related to going concern. In addition, it is responsible for financial reporting based on a going concern basis of accounting unless there is an intention to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Furthermore, the Board of Management is responsible for the preparation of the combined management report that, as a whole, provides an appropriate view of the Group's position and is, in all material respects, consistent with the consolidated financial statements, complies with German legal requirements, and appropriate presents the opportunities and risks of future development. In addition, the Board of Management is responsible for such arrangements and measures (systems) as they have considered necessary to enable the preparation of the combined management report that is in accordance with the applicable German legal requirements, and to be able to provide sufficient appropriate evidence for the assertions made in the combined management report.

The Supervisory Board is responsible for overseeing the Group's financial reporting process for the preparation of the consolidated financial statements and the combined management report.

#### Auditor's Responsibility for the Audit of the Consolidated Financial Statements and the Combined Management Report

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and whether the combined management report as a whole provides an appropriate view of the Group's position and, in all material respects, is consistent with the consolidated financial statements and the knowledge obtained in the audit, complies with German legal requirements and appropriately present the opportunities and risks of future development, as well as to issue an auditor's report that includes our audit opinions on the consolidated financial statements and the combined management report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Section 317 HGB and German Generally Accepted Standards for the Financial Statements Audit promulgated by the Institut der Wirtschaftsprüfer (IDW) will always detect a material

misstatement. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements and the combined management report.

We exercise professional judgment and maintain professional scepticism throughout the audit. We also

- Identify and assess the risks of material misstatement of the consolidated financial statements and of the combined management report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than the risk of not detecting a material misstatement resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit of the consolidated financial statements and of arrangements and measures (systems) relevant to the audit of the combined management report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of these systems.
- Evaluate the appropriateness of accounting policies used by the Board of Management and the reasonableness of estimates made by the Board of Management and related disclosures.
- Conclude on the appropriateness of the Board of Management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's

ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in the auditor's report to the related disclosures in the consolidated financial statements and in the combined management report or, if such disclosures are inadequate, to modify our respective opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's opinion. However, future events or conditions may cause the Group to cease to be able to continue as a going concern.

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements present the underlying transactions and events in a manner that the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Group in compliance with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Section 315e Abs. 1 HGB.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express opinions on the consolidated financial statements and on the combined management report. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.
- Evaluate the consistency of the combined management report with the consolidated financial statements, its conformity with [German] law, and the view of the Group's position it provides.
- Perform audit procedures on the prospective information presented by management in the combined management report. On the basis of sufficient appropriate audit evidence we evaluate,

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.  
Munich, April 18, 2024

**KPMG AG**

Wirtschaftsprüfungsgesellschaft

[Original German version signed by:]

*gez. Hutzler*

Wirtschaftsprüfer

*gez. Ratkovic*

Wirtschaftsprüfer

**Imprint**

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