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## Letter to Shareholders





Dr. Stefan Glombitza  
CEO



Nicola Mikulcik  
CBO



Dr. Andreas Seidl  
CSO

Dear Shareholders,

The first half of 2022 is now behind us, and it was indeed a period of challenging circumstances. In addition to the ongoing COVID 19 pandemic, the war in Ukraine has, here in Germany, served to exacerbate supply chain disruptions and inflationary pressures and, in particular, to drive up energy prices and uncertainties – and with social, political and economic consequences which cannot yet be fully foreseen in their entirety but which are, to varying extents, potentially quite serious. Despite this challenging environment, the first half of 2022 was an extraordinary period for Formycon for which we are pleased to be able to report some very positive developments.

#### **Strong position in the high-growth biosimilars market**

The first half of the Company's fiscal year was particularly shaped by two milestone events: firstly, the successful closing of the transaction with ATHOS KG, which will strengthen Formycon's long-term position in the rapidly growing global market for biosimilars, and secondly, the UK regulatory approval of our Lucentis®<sup>1</sup> biosimilar FYB201, which not only serves as a strong validation of the excellent work of the entire team at Formycon and our development partners but also marks our first tangible market contribution to providing future patients with better access to high-quality therapies that are affordable to healthcare systems.

Following the successful pre-license inspection (PLI) by the U.S. Food and Drug Administration (FDA) in the spring and the positive opinion of the Committee for Human Medicine Products (CHMP) of the European Medicines Agency (EMA) in June 2022, we are confident that approvals for FYB201 in the United States and the European Union will have been granted by the time this half-year report is published. Submissions for regulatory approval in other important markets are planned for the second half of the year, along with our first product sales revenue and earnings contributions from the marketing of this Lucentis® biosimilar.

The ATHOS transaction, encompassing not only the acquisition of a 50% share of biosimilar candidate FYB201 and 100% of FYB202 but also strengthening of our staffing, our project development resources and our organization through the acquisition and integration of Bioeq GmbH, will serve to significantly accelerate our growth strategy as we strive to become a fully integrated pharmaceutical corporation with global reach. The first steps towards this strategic aim, and largely attributable to this milestone transaction, may already be seen in the initiation of our two new biosimilar development projects, FYB208 and FYB209, in the first half of the year.



### Growing pipeline of attractive drug candidates to create long-term value

Meanwhile, the global market for biosimilars continues to expand rapidly, with experts projecting annual growth rates of roughly 20% for the years ahead. The increasingly strong position of biosimilars in the market is further evidenced by their steadily increasing share of market supply. For all drugs (excluding insulins) for which there are biosimilar alternatives available, the market share in Germany for 2021 was roughly two thirds, an increase of some ten percentage points over the prior year. Considering also the ever faster market penetration for newly introduced biosimilars, this trend is helping healthcare systems achieve significant cost savings: In Germany alone, biosimilars saved some € 1.5 billion during 2021.<sup>1</sup>

With life expectancies increasing around the globe, the demand for modern biopharmaceutical-based therapies is also increasing. A prime example of this is age-related macular degeneration (AMD), which is projected to afflict 77 million Europeans by 2050.<sup>2</sup> With our development pipeline, we are addressing not only this specific indication but also multiple other important and growing areas of indication, specifically in ophthalmology and immunology.

As the COVID 19 pandemic continues with no end in sight, we are seeing vaccines and other therapies become less effective over time. Even with the currently predominant omicron variant, COVID 19 continues to pose significant health risks, especially among older people. At the same time, the threat of further new virus mutations is likely to intensify worldwide due to social and environmental factors. Through our project to develop an innovative COVID 19 drug offering broad protection against such mutations, we aim to make an important contribution to the prevention and treatment of serious COVID 19 illness.

Details on the current status of our development projects can be found on the following pages.

### Moving forward in the second half under a new leadership team

Events and decisions during the first half of 2022 will play a key role in setting Formycon's future strategic direction, and this also includes important changes in our senior management team: Upon the expiry of their respective terms of office on June 30, 2022, Dr. Carsten Brockmeyer and Dr. Nicolas Combé will step down from their Executive Board positions. Until a suitable successor is chosen, Dr. Combé will, for the time being, continue to serve as Acting Chief Financial Officer.

<sup>1</sup> AG Pro Biosimilars, "Biosimilars in Zahlen 2021", <https://probiosimilars.de/publikationen/biosimilars-in-zahlen/>.

<sup>2</sup> Li JQ, Welchowski T, Schmid M, et al. "Prevalence and incidence of age-related macular degeneration in Europe: a systematic review and meta-analysis", *British Journal of Ophthalmology* 2020;104:1077–1084. <https://bjo.bmj.com/content/104/8/1077>.

Dr. Brockmeyer and Dr. Combé would like to take this opportunity to express their gratitude and best wishes to you, dear shareholders. Both will remain connected to Formycon and provide invaluable future support to Formycon in advisory capacities. The Executive Board surrounding Dr. Stefan Glombitza, who was appointed as Chief Executive Officer (CEO) on July 1, 2022, has been completed since June 1 by the experienced pharmaceutical manager Nicola Mikulcik as Chief Business Officer (CBO). With effect from July 1, 2022, a further new member will be appointed to the Executive Board: renowned biosimilar expert Dr. Andreas Seidl, who will serve as Chief Scientific Officer (CSO).

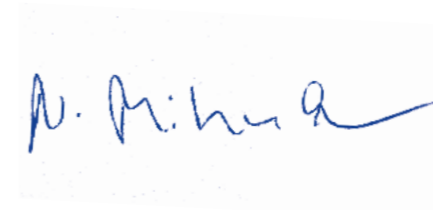
Our special thanks go to our staff, to our partners and to you, esteemed shareholders, for your continued confidence in us and in the work we are doing.

We wish you security and prosperity in these troubled times – and above all, good health!

Martinsried/Planegg, Germany, July 31, 2022



Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

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# B

## Interim Management Report for Formycon Group

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Interim Management Report for Formycon Group for the period from January 1 to June 30, 2022

I Basic information about Formycon Group

Business model

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

Formycon Group (hereinafter also “Formycon” or the “Group”) 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.

Following the successful approval of FYB201, a biosimilar to Lucentis®<sup>1</sup>, our development pipeline now includes five further biosimilar projects and an innovative COVID 19 drug. Of these, two biosimilar projects are in advanced (phase III) stages of clinical development, while the remaining three as yet unannounced biosimilar candidates are in preclinical development.

Formycon’s preferred path is to independently develop its biosimilar drug candidates through to final development stages and then, as they approach market readiness, to transfer them completely or partially to commercialization partnerships for global marketing. The cash flows generated from the sale of these approved and commercialized biosimilar products then provide Formycon with the financial means to further expand its development pipeline. Formycon thus has a promising position and significant growth potential in the rapidly expanding market for biosimilars.

Business objective and strategy

Formycon is positioned as a highly specialized expert in biosimilar drug development and able, with its current resources, to carry out multiple biopharmaceutical projects in parallel. Our strategy for long-term growth is based upon the step-by-step expansion of our project pipeline through the targeted selection of additional biosimilar candidates, their laboratory and clinical development, and their eventual commercialization, preferably through commercialization partnerships.

<sup>1</sup> Lucentis® is a registered trademark of Genentech, Inc.

Scope of business activity

With the help of our biosimilars, ever more patients around the globe will have access to high-quality, important biopharmaceuticals for the treatment of serious diseases. Through our work, we aim not only to improve care for patients worldwide but also to contribute to relieving the financial burden on healthcare systems.

Formycon’s current business activities may be summarized as follows

- The Group’s primary and core business, and the center of its strategy for sustainable long-term growth, is the development of biosimilar medicines.
- At the start of the coronavirus crisis, Formycon initiated development of an innovative COVID 19 fusion protein based upon its extensive experience in the development of biopharmaceuticals and as a contribution to the global fight against the pandemic. In order to maximize the potential and speed of our product development approach, our plan for the innovative COVID 19 project is to transfer it into a strategic global partnership for development and commercialization at an early stage.

These two product development areas are fundamentally different in terms of their respective risk profiles. While biosimilar drug development takes a confirmatory approach, whereby the biosimilar candidate is designed from the start to be comparable to the reference drug and is accordingly managed over the entire development period of typically six to eight years, the research and development process for an innovative originator biopharmaceutical entails an exploratory approach and thus a significantly higher level of development risk.

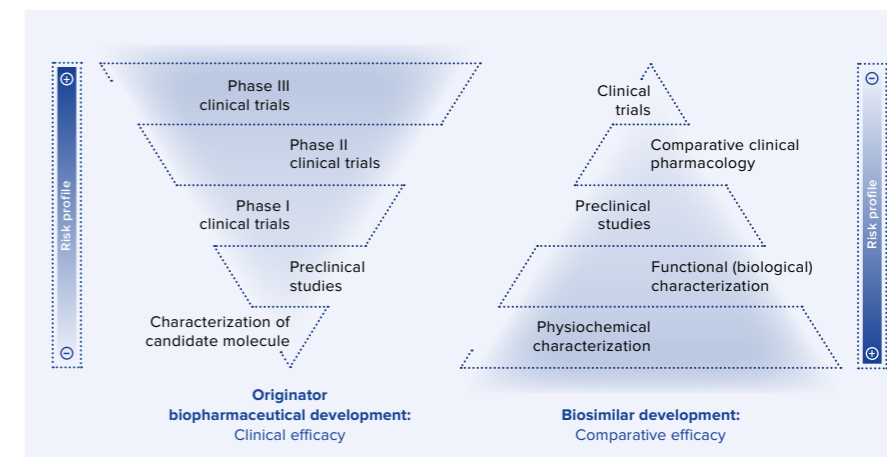


Figure 1: Risk profile for innovative biopharmaceutical development vs. biosimilar development



**As of June 30, 2022, Formycon was working on the following development projects within its principal business of biosimilars:**



FYB201 is a candidate biosimilar to Lucentis® (ranibizumab), an ophthalmic drug used in the treatment of neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases such as diabetic macular edema (DME), diabetic retinopathy (DR), macular edema secondary to retinal vein occlusion (RVO) and myopic choroidal neovascularization (mCNV).

During the first half of 2022, the focus of Formycon’s activities was on the respective pending approval processes at the U.S. Food and Drug Administration (FDA), at the European Medicines Agency (EMA) and in the United Kingdom, where FYB201 received final approval from the Medicines and Healthcare products Regulatory Agency (MHRA) in May 2022. A positive opinion was received from the EMA’s Committee for Medicinal Products for Human Use (CHMP) in June, marking an important step towards final approval in the European Union. FYB201 will be marketed in the UK and Europe by Teva Pharmaceutical Industries Ltd. and in the United States by Coherus BioSciences, Inc.



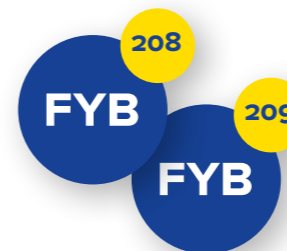
FYB202 is a candidate biosimilar to Stelara® (ustekinumab), a biopharmaceutical used in the treatment of various serious inflammatory diseases, such as moderate to severe psoriasis, Crohn’s disease, and ulcerative colitis. Over the past full year, Stelara® generated global sales revenue of USD 9.1 billion. In addition to completion of treatment of all patients in the phase III clinical trials (“last patient out”), our activities during the first half of 2022 focused on the evaluation of the resulting phase III data regarding the primary efficacy endpoint and on the initiation of an additional phase I comparative pharmacokinetics study.



FYB203 is a biosimilar candidate for Eylea® (aflibercept). Similarly to Lucentis®, Eylea® is used to treat neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases, with 2021 global sales revenue of USD 9.0 billion. April 2022 marked an important development milestone, namely the completion of patient recruitment for phase III clinical trials (“last patient in”).

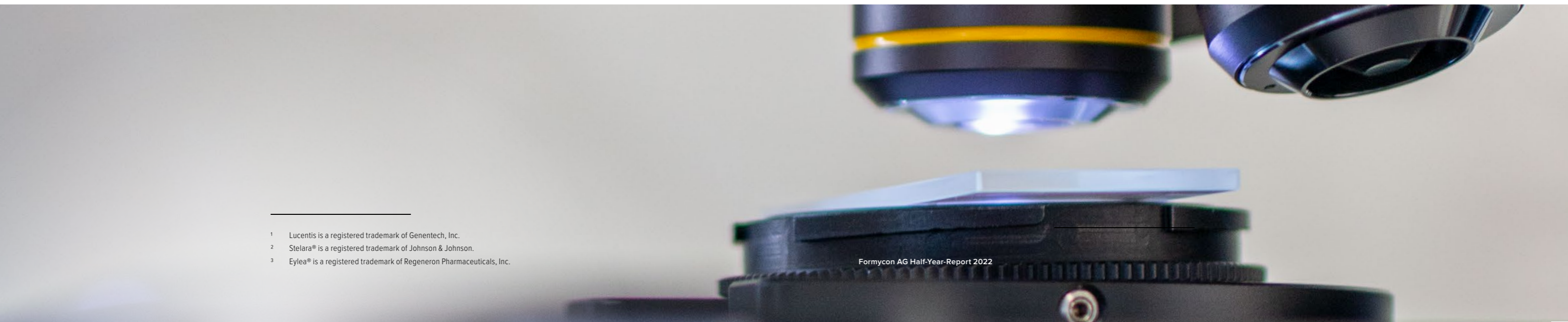


FYB206 is a Formycon-initiated biosimilar candidate in the advanced preclinical stage for which the project rights are 100% owned by Formycon.



FYB208 and FYB209, which commenced during the first half of 2022, are Formycon’s two newest biosimilar development initiatives. Formycon holds 100% of the project rights to both.

<sup>1</sup> Lucentis is a registered trademark of Genentech, Inc.  
<sup>2</sup> Stelara® is a registered trademark of Johnson & Johnson.  
<sup>3</sup> Eylea® is a registered trademark of Regeneron Pharmaceuticals, Inc.



As of June 30, 2022, Formycon was working on the following development project within the area of COVID-19 drug development:



Upon the initial outbreak of the coronavirus pandemic in Europe, and drawing upon Formycon's extensive and clinically validated experience with antibodies and antibody fusion proteins, the Group launched a new project, FYB207, to develop an innovative COVID-19 fusion protein.

For its FYB207 project, Formycon has been working closely with two renowned academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, to develop an efficient antiviral and broad-spectrum SARS-CoV-2 blocker on the basis of a long-acting ACE2-immunoglobulin fusion protein. Through an *in vitro* study, Formycon has already been able to demonstrate that FYB207 completely inhibits the infection of cells while preserving natural enzyme activity and, moreover, that it is able to effectively neutralize all SARS-CoV-2 virus variants tested to date (**alpha, beta, delta and omicron**). Compared to vaccines and neutralizing antibodies, FYB207's active ingredient offers, through its particular biological mechanisms, a maximum of protection against virus breach through mutation.

Formycon holds 100% of the rights to the FYB207 innovative COVID-19 drug development project.

#### A brief explanation of how the COVID-19 fusion protein works

#### SARS-CoV-2 infection pathway

SARS-CoV-2 and other coronaviruses exploit the ACE2 protein (angiotensin-converting enzyme 2) on the surface of human cells as an entry point to infect the respiratory tract. The virus achieves this by using its spike 1 protein to bind to ACE2 on the surface of target cells. After docking, the virus is then absorbed into the cell (Figure 2).

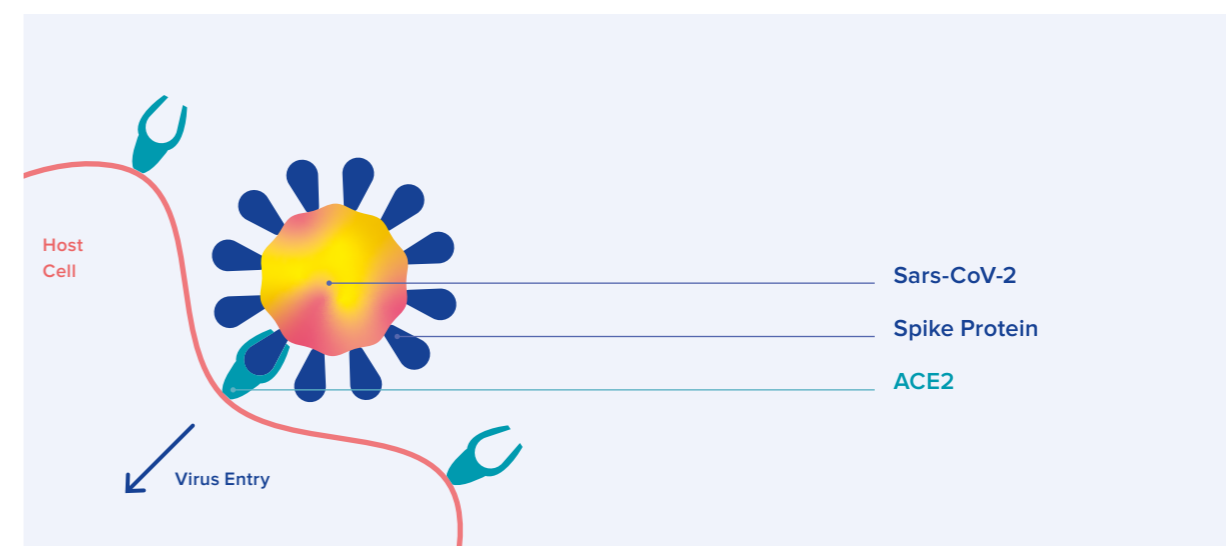


Figure 2 : SARS-CoV-2 infection pathway

#### The FYB207 fusion protein and its unique mechanism of action

Laboratory studies have shown that the introduction of a soluble form of ACE2 blocks the SARS-CoV-2 and earlier SARS-CoV coronaviruses, thereby preventing cells from becoming infected. Formycon has built on this scientific knowledge by linking the human ACE2 protein with the constant portion of the human immunoglobulin G (IgG) protein using computer-aided structural design techniques (Figure 2), thereby creating a highly effective SARS-CoV-2 blocker (FYB207). Formycon has demonstrated, through *in vitro* testing, that FYB207 completely prevents the infection of cells. Because ACE2 is the human receptor for the spike protein used by the SARS-CoV-2 virus to gain entry, FYB207 provides maximal protection even against attempts by the virus to evade the block through mutation (Figure 3). In addition, FYB207 can potentially be used to defend against any other coronaviruses or variants which exploit ACE2 as an entry point for cell infection.

Based on the findings of preclinical studies carried out in 2021, Formycon has been able to make defined proprietary modifications to the FYB207 molecular structure, resulting in a significant improvement in bioavailability.

**Activity of FYB207 in known SARS-CoV-2 variants**

Previously published laboratory studies<sup>1</sup> have shown that FYB207 retains its full anti-viral potential even against the SARS-CoV-2 alpha, beta and delta variants. New laboratory data now further show that the improved drug molecule, in contrast to vaccines and therapeutic antibodies, likewise neutralizes the currently predominant omicron variant with a high level of efficacy.

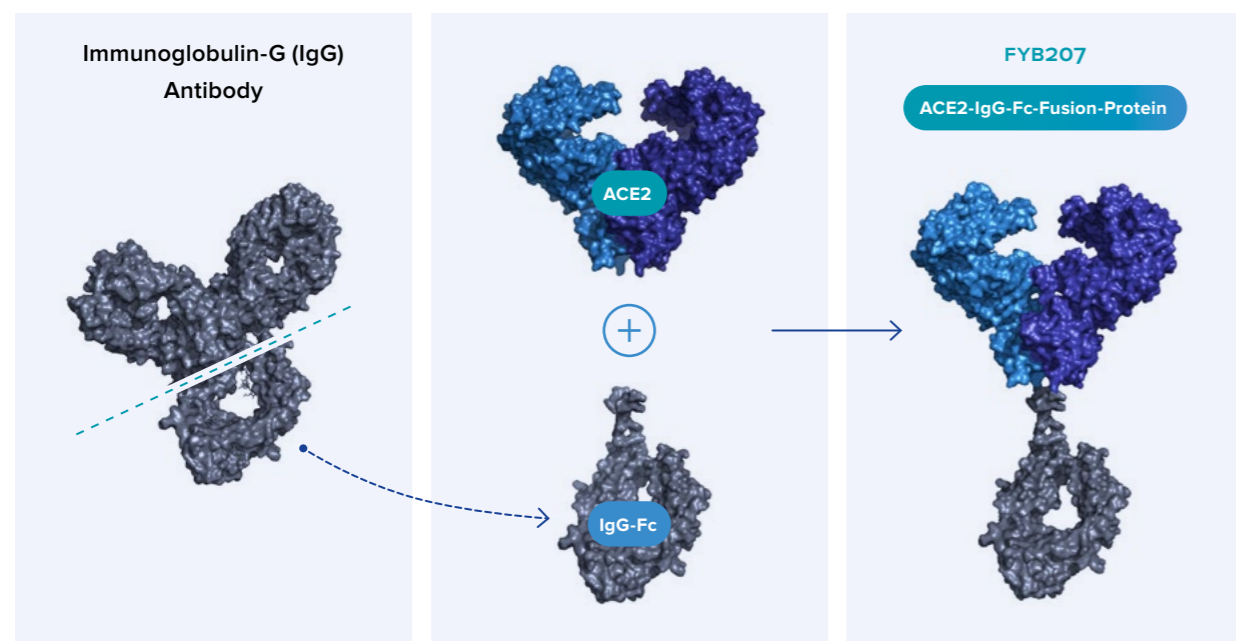


Figure 3: Composition of the FYB207 fusion protein

<sup>1</sup> „Picomolar inhibition of SARS-CoV-2 variants of concern by an engineered ACE2-IgG4-Fc fusion protein“ (<https://doi.org/10.1016/j.antiviral.2021.105197>)

With FYB207, Formycon is thus developing a novel anti-COVID-19 drug which promises to be both effective and long-lasting.

Possible future indications for FYB207 include hospitalized COVID-19 patients, newly infected but asymptomatic COVID-19 patients, and preventive use in risk situations such as care facilities.

Large molecules have specific advantages over small-molecule antiviral drugs, in particular their significantly longer half-life, thus making them potentially suitable for prophylactic use.

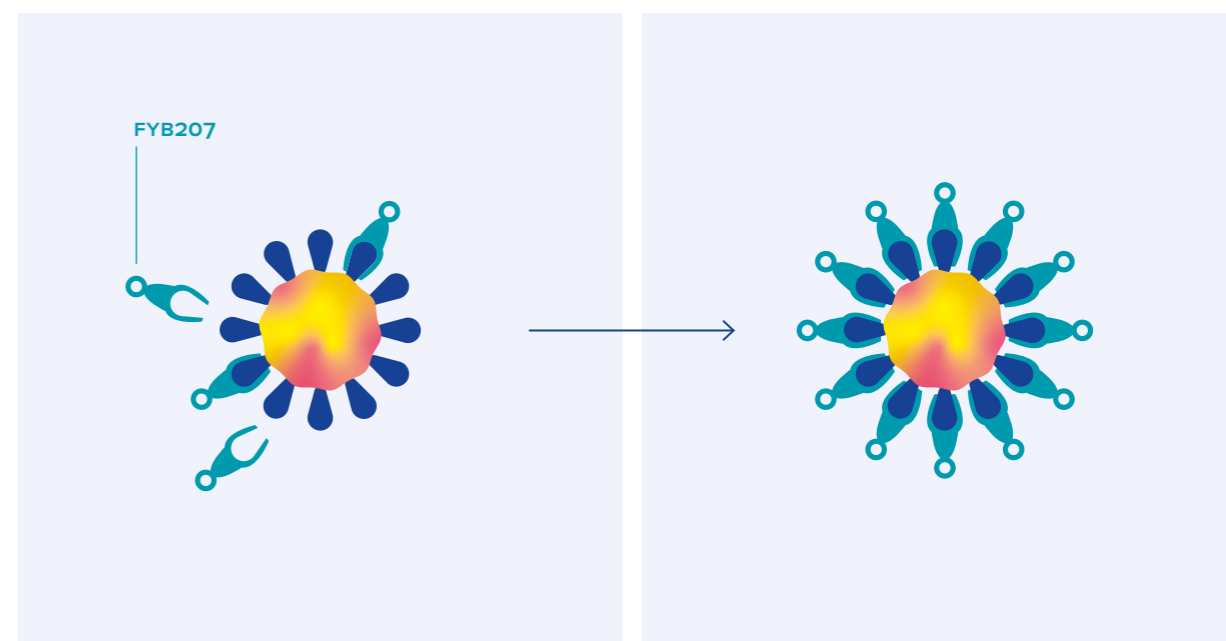


Figure 4: FYB207's mechanism of action

The natural enzyme activity of ACE2 may possibly serve to protect vital organs such as the lungs, and thus another potential indication for FYB207 might be in the treatment of acute respiratory distress syndrome (ARDS) of various etiologies.



**Structure of Formycon Group**

As a result of the strategic transaction concluded during the first half of 2022 with the family office of the Strüngmann family (ATHOS KG), the structure of Formycon Group has undergone changes. Under the transaction, Formycon acquired full rights to FYB202, a candidate biosimilar to Stelara®, and a 50% interest in FYB201, a candidate biosimilar to Lucentis®. In addition, through the acquisition and integration of long-term partner Bioeq GmbH, Formycon has been able to expand its resources and expertise in several areas important for the development, approval and commercialization of biosimilars.

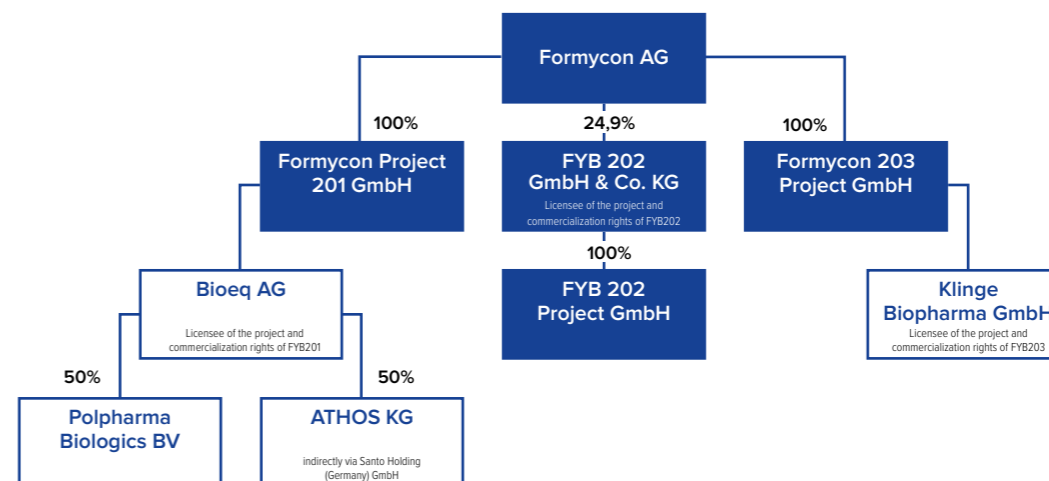
Formycon Group thus now consists of the parent entity, **Formycon AG**, along with its **100%-owned subsidiaries Formycon Project 201 GmbH, FYB202 Project GmbH, Formycon Project 203 GmbH and Bioeq GmbH**. In addition, Formycon owns **50%** of the shares of **Bioeq AG**, a joint venture between **Formycon** and **Polpharma Biologics BV**, which holds the project and commercialization rights to FYB201.

Formycon AG, the parent entity, is a German stock corporation (*Aktiengesellschaft*) listed on the Frankfurt Stock Exchange within the Scale (Open Market) segment for growth companies. Like all companies governed by the German Stock Corporation Act (*Aktiengesetz*), Formycon has a dual board structure with the Executive Board (*Vorstand*) as the managing body. The members of the Executive Board are appointed and monitored by the Supervisory Board (*Aufsichtsrat*). The members of the Supervisory Board of Formycon, of which there were three as of June 30, 2022, are elected by shareholders through the Annual General Meeting.

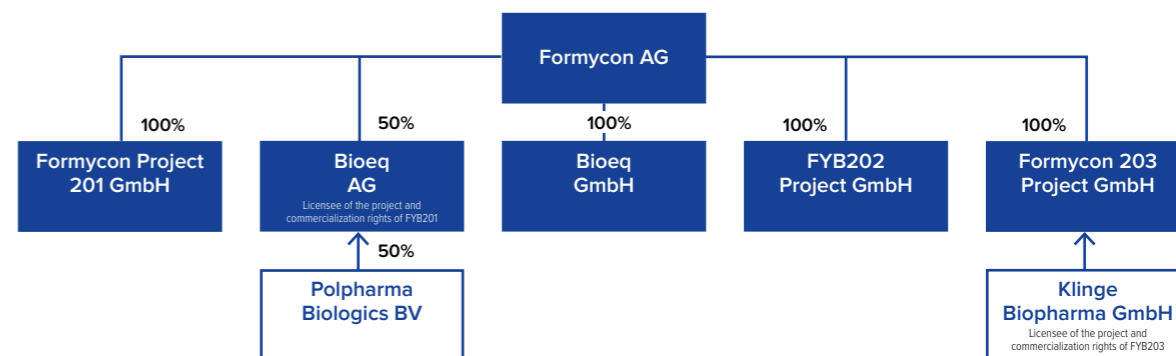
The **corporate structure of Formycon Group** reflects the establishment of dedicated legal entities for certain individual biosimilar projects, particularly in advanced stages of development. Formycon AG performs research and development activities not only for its own projects but also on behalf of its affiliated companies (subsidiaries) and development partners. Reported sales revenue has until now been substantially the result of such development activities whereby Formycon is remunerated by the license or cooperation partners subsequent to transfer of projects into development partnerships.

**Formycon Project 201 GmbH**, a 100%-owned subsidiary and member of Formycon Group, was the first project to be spun off into a separate subsidiary, during fiscal year 2014, and into which all project activities for biosimilar candidate FYB201 were transferred. Formycon's license partner for FYB201 is Bioeq AG, a 50/50 joint venture between Polpharma Biologics BV and Formycon. As the holder of the exclusive product and commercialization rights for FYB201, Bioeq AG has, in turn, commercialization partnerships with Coherus BioSciences, Inc. for the United States, with Teva Pharmaceutical Industries Ltd. for Europe and certain other territories, and with MS Pharma for the Middle East and North Africa (MENA) region. Following the relevant regulatory approvals, these companies will be able to market FYB201 in their respective territories. As part of the strategic transaction with ATHOS KG during the first half of 2022,

Structure of Formycon Group *before* transaction with ATHOS KG:



Structure of Formycon Group *after* transaction with ATHOS KG:



Formycon acquired 50% of the shares of Bioeq AG, which were previously held indirectly by ATHOS KG by way of Santo Holding (Deutschland) GmbH. As consideration for these shares, Santo Holding (Deutschland) GmbH received shares of Formycon AG newly issued from the approved capital against contributions in kind along with a share of future proceeds from the sale of FYB201.

**FYB202 Project GmbH**, likewise a 100% subsidiary and member of Formycon Group, owns the project and commercialization rights to biosimilar candidate FYB202. Prior to the strategic transaction with ATHOS KG, **FYB 202 GmbH & Co. KG**, founded in 2017, was an affiliate within Formycon Group, operating as a joint venture between Formycon (with a 24.9% ownership share) and Aristo Pharma GmbH (75.1%), a Strümgmann Group company. FYB 202 GmbH & Co. KG, in turn, owned 100% of **FYB 202 Project GmbH** until Formycon's acquisition of 100% ownership thereof through the transaction with ATHOS KG. As consideration for the transfer of Aristo's 75.1% ownership share in FYB202 Project GmbH, Aristo Pharma GmbH received shares in Formycon AG newly issued from approved capital against contributions in kind along with a share of future proceeds from the sale of FYB202. Formycon no longer has any ownership share in FYB 202 GmbH & Co. KG.

**Formycon Project 203 GmbH** is also a 100%-owned subsidiary and member of Formycon Group. In 2015, Formycon signed an exclusive worldwide out-licensing agreement for FYB203 with Santo Holding (Deutschland) GmbH. The worldwide marketing rights were subsequently internally shifted within the Santo Group to another Santo entity, Klinge Biopharma GmbH. Formycon will participate in any future proceeds from the sale of FYB203 in the form of royalties.

**Bioeq GmbH** has, as a result of the strategic transaction ATHOS KG, now been fully acquired and integrated as a 100% subsidiary and member of Formycon Group. As consideration for the transfer of its ownership share in Bioeq GmbH, the former shareholder, Klinge Biopharma GmbH, received Formycon shares newly issued from approved capital against contributions in kind. With the takeover of Bioeq GmbH, Formycon has been able to broaden and strengthen its existing organization with complementary experience and expertise in the areas of clinical development, regulatory affairs, business development, commercial affairs, intellectual property and project management. The long-standing partnership between the two companies in ongoing biosimilar projects is expected to facilitate the rapid leveraging of synergies and efficient expansion of the development pipeline. In addition, Bioeq has an established international network for the commercialization of biosimilars as well as extensive expertise in the management of clinical trials. Bioeq GmbH has also previously, before its integration, served as clinical trial sponsor and thus the official contracting entity for clinical trials of Formycon-developed biosimilar candidates.

As to the three biosimilar candidates **FYB206**, **FYB208** and **FYB209** in preclinical development and not yet publicly announced, and to which Formycon owns all rights, Formycon plans to move forward with these as part of its broader growth strategy following the transaction with ATHOS KG and to independently develop each of these projects through to a very advanced stage.

Formycon continues to hold full rights to the **FYB207** project for development of an innovative COVID-19 drug and is actively considering further options for financial and global strategic partnerships.

The current focus of Formycon Group is on research and development activities for its own biosimilar projects, as well as on the development of its COVID-19 drug candidate (FYB207). To the extent that it engages in other business activities, these are primarily in support of these research and development activities.

The future market for Formycon's biosimilar and COVID-19 product candidates is the global pharmaceutical market. Healthcare policy and regulation should therefore be recognized as an important external influence factor.

## II Report on business performance

### General economic conditions

During the first half of 2022, the German economy faced an increasingly difficult environment. In addition to continuing issues resulting from the pandemic, especially disruptions to supply chains, the Ukraine war created new economic burdens. Specifically, the German economy has been significantly impacted by disruption of business activities within the crisis regions, dramatically higher procurement prices, and risks to the country's energy supply.

Already in the first quarter, it became evident that the hoped-for strong economic recovery would likely not materialize in 2022. From January to March, German economic output grew by just 0.2% over the final quarter of 2021. Investment spending, which rose by 4.6% in the construction sector and by 2.5% in the equipment sector, served as the main stabilizing component.<sup>1</sup> As to foreign trade, a divergence was seen, with exports falling by 2.1% compared to the previous quarter while imports rose slightly by 0.9%.<sup>2</sup>

In the months that followed, intensified supply bottlenecks and upward pressure on prices have been creating further uncertainties. In addition, there have been growing concerns about the continuity of Germany's supply of Russian natural gas. Preliminary data from the German Federal Statistical Office (Destatis) suggest that the German economy did not grow at all in the second quarter. According to the figures published in July by the German Federal Ministry for Economic Affairs and Climate Action, some of which are still provisional, incoming orders in the manufacturing sector were 5.3% below the prior-year month in April and 3.1% below in May. Industrial production fell by 3.0% in April and by 1.5% in May versus the respective prior-year months.<sup>3</sup> Growth in exports and imports, on the other hand, exceeded the prior-year months. However, in terms of the value of goods, Germany – which relies heavily on exports – posted a net trade deficit of € 1 billion for the month of May.<sup>4</sup> This was substantially attributable to higher import prices, which were 30.6% higher than in the previous year, with energy imports alone increasing in price by 143.8%.<sup>5</sup>

The inflation rate rose from 4.9% in January to 7.6% in June.<sup>6</sup> These price increases also adversely impacted private consumer spending. Germany's labor market, on the other hand, showed some positive trends, with 2,362,888 people registered as unemployed at the end of June, 250,937 fewer than one year earlier.<sup>7</sup> It should be noted, however, that official unemployment figures have more recently been rising again, due largely to the first-time inclusion of Ukrainian refugees.

<sup>1</sup> German Federal Ministry for Economic Affairs and Climate Action (BMWK), "Ausgewählte Daten zur wirtschaftlichen Lage", July 2022, [https://www.bmwk.de/Redaktion/DE/Downloads/W/wirtschaftliche-lage-in-deutschland-im-juli-2022.pdf?\\_\\_blob=publicationFile&v=4](https://www.bmwk.de/Redaktion/DE/Downloads/W/wirtschaftliche-lage-in-deutschland-im-juli-2022.pdf?__blob=publicationFile&v=4)

<sup>2</sup> German Federal Statistical Office (Destatis), "Gross domestic product: detailed results on the economic performance in the 1st quarter of 2022", press release dated May 25, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/05/PD22\\_215\\_811.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/05/PD22_215_811.html)

<sup>4</sup> German Federal Statistical Office (Destatis), "Exports in May 2022: -0.5% on April 2022", press release dated July 4, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22\\_279\\_51.html;jsessionid=BF6000FC819E656E8F818E45D76B3793.live742](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_279_51.html;jsessionid=BF6000FC819E656E8F818E45D76B3793.live742)

<sup>5</sup> German Federal Statistical Office (Destatis), "Import prices in May 2022: +30.6% on May 2021", press release dated June 30, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/06/PD22\\_274\\_614.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/06/PD22_274_614.html)

<sup>6</sup> German Federal Statistical Office (Destatis), "Inflation rate at +4.9% in January 2022", press release dated February 11, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/02/PD22\\_057\\_611.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/02/PD22_057_611.html)

<sup>7</sup> German Federal Statistical Office (Destatis), "Inflation rate slightly down to +7.6% in June 2022", press release dated July 13, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22\\_296\\_611.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_296_611.html)

<sup>8</sup> German Federal Employment Agency (Bundesagentur für Arbeit), "Monatsbericht zum Arbeits- und Ausbildungsmarkt", June 2022, [https://www.arbeitsagentur.de/datei/arbeitsmarktbericht-juni-2022\\_ba147522.pdf](https://www.arbeitsagentur.de/datei/arbeitsmarktbericht-juni-2022_ba147522.pdf)

### General industry conditions

The German Chemical Industry Association (VCI) reported that the country's chemical-pharmaceutical industry expanded its production by 0.5% in the first half of the year, while industry-wide sale revenue within Germany's third largest industrial sector increased by 22% due largely to higher producer prices. This strong performance was due in no small part to the pharmaceutical sector, which continues to benefit from the pandemic-related industry upswing and has remained unaffected by export restrictions to Russia because of its exemption from sanctions. Excluding pharmaceuticals, production in German's chemical-pharmaceutical industry for the first half of 2022 would have fallen by 3%.<sup>9</sup>

According to a recent market report from IQVIA, a leading information platform for human data science, pharmaceutical revenue to the country's hospital and pharmacy sector was € 13.6 billion during the first three months of 2022, 6.2% above the prior-year quarter. Specifically within the pharmacy sub-sector, which is the larger part by volume, sales increased by 7.1%, a sign that despite the continuing pandemic, visits to doctors and filling of prescriptions at pharmacies have been returning to normal levels. Aggregate sales of biosimilars through pharmacies grew at an even faster rate, rising by 10.7% in the first quarter by sales revenue – and measured in terms of number of package units, the increase over the prior-year quarter was an even more impressive 20.8%.<sup>10</sup>

Since 2012, the number of biosimilar approvals in Europe has increased approximately sixfold. In the past year alone, the European regulator granted nine new approvals. The circumstances arising from the pandemic and from the disruption of global supply chains, which continue to be fragile, have underscored the existential importance of proximal supply of pharmaceuticals to Germany's people, without excessive international dependencies. In the agreement of Germany's new governing coalition published at the end of 2021, the federal government explicitly committed itself to promoting domestic pharmaceutical production, for example by removing bureaucratic hurdles.

With regard to the market opportunity for newly introduced biosimilars, the prospects continue to be promising. According to calculations by IQVIA, patent protection in Germany for seven biopharmaceuticals, representing combined market revenue of € 584 million to pharmacies in Germany alone, will expire this year. By 2025, another 32 biopharmaceuticals will be added with total German pharmacy sales of more than € 2 billion.<sup>11</sup> Newly introduced biosimilars are, upon their regulatory approval and market introduction, expected to gain a large part of this market space. According to the

<sup>9</sup> German Chemical Industry Association (VCI), "Halbjahresbilanz der chemisch-pharmazeutischen Industrie 2022", July 6, 2022, <https://www.vci.de/ergaenzende-downloads/pm-standort-deutschland-bekommt-zunehmend-wettbewerbsproblem.pdf>

<sup>10</sup> IQVIA, "Marktbericht classic, Entwicklung des deutschen Pharmamarktes im ersten Quartal 2022", [https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/publications/iqvia-pharma-marktbericht-classic-q1-2022.pdf?\\_=1659001096958](https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/publications/iqvia-pharma-marktbericht-classic-q1-2022.pdf?_=1659001096958)

<sup>11</sup> IQVIA, "Biosimilars - Marktpräsenz und -entwicklung, 06/2021", <https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/infographic/biosimilars--marktpraesenz-und--entwicklung.pdf>



German Association of Research-Based Pharmaceutical Companies (vfa), biosimilars have been gaining market shares of up to 80% in Germany in the first year after their market launch.<sup>1</sup>

**Developments in the global biosimilar market**

In considering the future potential of the global biosimilars market, the fundamental drivers continue to be the growing world population and the increasing number of patients requiring treatment as people live longer. Both of these trends demand urgent solutions to keep healthcare costs in check while maintaining standards of medical care. In addition, international healthcare systems have been and will continue to be burdened by additional expenses resulting from the COVID-19 pandemic, thereby increasing the urgency of cost containment. Given these budgetary pressures, biosimilars offer ideal opportunities for achieving significant cost efficiencies without compromising the quality of care. In Germany alone, for example, biosimilars are estimated to have saved a total of € 4.19 billion since 2011.<sup>2</sup>

Oncology, a field of medicine in which some 19.3 million new cases are registered every year, currently dominates the areas of application for biosimilars worldwide.<sup>3</sup> Overall, however, the number of disease areas in which biosimilars are available and in active use is steadily increasing. The trend of new and expected biosimilar approvals is, in particular, towards indications in immunology and ophthalmology.

According to expert forecasts, the robust growth within the global biosimilars market will continue into the future. International studies published in the summer of 2022 predict average annual growth rates (CAGR) for the global biosimilars market in excess of 20% over the next four to five years. It should be noted that these research institutions acknowledge the possibility of approval delays resulting from the pandemic as well as obstacles that could arise due to supply chain disruptions and exacerbation of raw material procurement difficulties.

**Sales revenue for biosimilars in Germany in € billion**

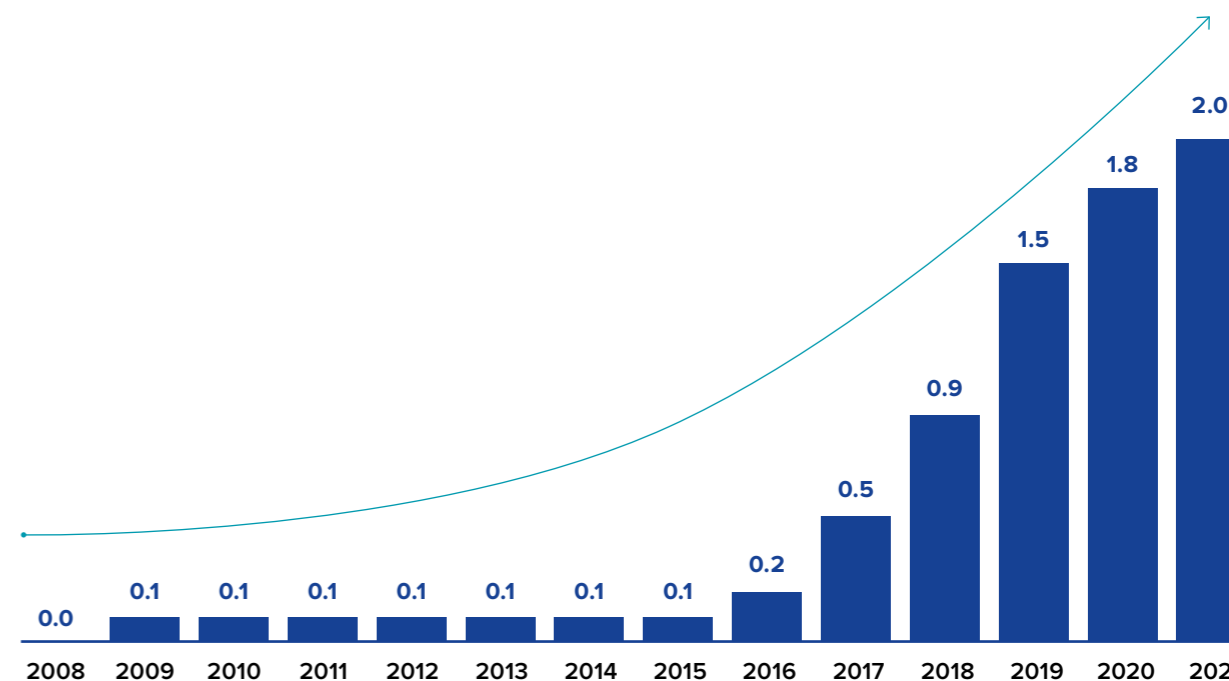


Figure 5: Sales revenue for biosimilars in Germany in € billion

<sup>1</sup> German Association of Research-Based Pharmaceutical Companies (vfa), "Biosimilars: der Wettbewerb funktioniert", press release dated July 7, 2022, <https://www.vfa.de/de/presse/pressemitteilungen/pm-018-2022-biosimilars-der-wettbewerb-funktioniert.html>  
<sup>2</sup> AG Pro Biosimilars, Grafik des Monats März 2022, 28.03.22, <https://probiosimilars.de/grafik-des-monats/maerz-2022/>  
<sup>3</sup> International Agency for Research of Cancer, Fact Sheet World, <https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>



## Chronological review of key developments during the first half of 2022:

### March

In **March**, Formycon announced the **transaction** with **ATHOS KG**, through which Formycon has now acquired **full rights to FYB202**, a candidate biosimilar to Stelara® (ustekinumab), and a **50% interest in FYB201**, a candidate biosimilar to Lucentis® (ranibizumab). Moreover, through the acquisition and **organizational integration** of its long-term partner **Bioeq GmbH**, Formycon has been able to expand its in house expertise and resources in a number of areas important for the development, approval and commercialization of biosimilars.

The transaction between Formycon and ATHOS KG took place at **fair value conditions** jointly determined and **confirmed by independent experts** and based on a valuation of **€ 83.41 per Formycon share**. Payment to ATHOS KG of consideration for the assets acquired (FYB201, FYB202 and Bioeq GmbH) with a total combined transaction value of approx. **€ 650 million** was made in part through the issuance and granting of **shares in Formycon AG** under a non-cash capital increase against contributions in kind, thereby fully utilizing Formycon's existing Approved Capital 2019 in the amount of € 4,000,000.00. In addition, ATHOS KG will receive a **revenue share** (earn-out component) in future product sales of **FYB201 and FYB202** generated by Formycon, through which ATHOS is expected to earn a total participation estimated in the mid three-digit million range.

### May

In **May**, upon fulfilment of conditions precedent, receipt of required official approvals, and entry of the non-cash capital increase into the commercial register, Formycon and ATHOS KG announced the **completion of Formycon's acquisition** of biosimilar assets FYB201 and FYB202 as well as of Bioeq GmbH. Upon completion of this transaction, ATHOS KG became the **largest shareholder** of Formycon, with an ownership stake of approx. **26.6%**.

Also in May, Formycon and its license partner Bioeq AG announced that the **UK Medicines and Healthcare products Regulatory Agency** (MHRA) had granted **UK approval** for FYB201, a biosimilar to Lucentis® (ranibizumab). **Teva Pharmaceutical Industries Ltd.** will be the exclusive **commercialization partner** to market the biosimilar within the UK under the trade name **ONGAVIA®**.

In the middle of May, Formycon released its **audited financial results for fiscal year 2021**. For the year ending December 31, 2021, **total consolidated sales revenue was € 37.0 million**. With **EBITDA of negative € 12.4 million**, an **operating loss (EBIT) of € 13.3 million**, and a **consolidated annual net loss of € 13.5 million**, compared to a net loss of € 5.7 million in the prior fiscal year, the full-year figures were closely in line with expectations. As of December 31, 2021, Formycon Group held **cash and liquid resources of € 18.2 million**.

In this same month, Formycon announced **important changes to its Executive Board**. Firstly, the Supervisory Board appointed **Dr. Stefan Glombitza**, who has been serving as Chief Operating Officer since 2016, as **Chief Executive Officer** with effect from July 1, 2022, thereby assuming the role held until now by Dr. Carsten Brockmeyer, whose term of office as Chief Executive Officer and Executive Board member ended on June 30, 2022. In his new role as Chief Executive Officer, Dr. Glombitza will shape Formycon's strategic direction in an increasingly commercial phase of its corporate development and, together with his team of experts, drive forward with a continuously expanding portfolio of products and development projects. While Dr. Brockmeyer is stepping down from the Executive Board as planned, he will continue to support and guide Formycon Group as scientific advisor and help to ensure the success of the Group's biosimilar candidates and COVID-19 drug project. Secondly, in addition to Dr. Glombitza, **two more experienced pharmaceutical executives** were newly appointed to the Executive Board. The Supervisory Board of Formycon appointed **Nicola Mikulcik** to the Executive Board with effect from June 1, 2022 in the position of **Chief Business Officer (CBO)** and, with effect from July 1, 2022, Dr. Andreas Seidl in the position of **Chief Scientific Officer (CSO)**, each for a term of office of five years.



## June

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In June, Formycon released a **comprehensive development update** spanning all of its projects. In the case of the **FYB201** project, it was announced that the new drug is, upon approval by the UK Medicines and Healthcare products Regulatory Agency (MHRA), is expected to be the first biosimilar to Lucentis® to be marketed anywhere in Europe. It was also announced that the pending approval processes with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are proceeding according to plan.

In the case of the **FYB202** project, the treatment of the last remaining patient in the **phase III clinical trials** (VESPUC-CI study) was successfully completed (“**last patient out**”) and publication of the **primary efficacy endpoint** results announced. In addition, following advance discussion and agreement with both the FDA and the EMA, an additional **comparative phase I pharmacokinetic study** of FYB202 against reference product Stelara® was initiated. Submissions for regulatory approval of FYB202 in Europe and the U.S. are planned for the third quarter 2023, upon availability of these additional pharmacokinetic data.

In the case of the **FYB203** project, the final patient was recruited into the ongoing **phase III clinical trials** (MAGEL-LAN-AMD study) in April (“**last patient in**”). Data on the **primary efficacy endpoint** are expected by the end of the year.

The **FYB206** biosimilar project is advancing according to plan. With convincing results from extensive analytical characterization of the developed molecule, along with significant progress in the development of a manufacturing process, a comprehensive data package is currently being compiled in order to closely coordinate next steps during the second half of the year with both the EMA and the FDA through the scientific advice procedure.

In the case of **FYB207**, Formycon's innovative COVID-19 drug under development, **new laboratory data** showed that the currently dominant **omicron variant** is likewise **neutralized** with a similarly high degree of efficacy. Defined **modifications to FYB207's proprietary molecular structure** were also undertaken within the scope of pending **preclinical studies**, leading to significant **improvements in half-life and efficacy**. In the course of 2022, the preclinical studies should be completed, the manufacturing process adapted to the optimized molecule, and test material produced for stability studies and **clinical trials**. It is currently anticipated that clinical trials will commence in **2023**.

In its reporting of **financial results for the first quarter**, Formycon announced consolidated **sales revenue and other income of € 8.2 million** for the three months ending March 31, 2021. **EBITDA was negative € 4.0 million**, while the **operating loss (EBIT)** and **net loss after tax** for the period were each approx. **€ 4.3 million**, in line with expectations. As of the reporting date, Formycon held **cash and liquid resources**, including short-term trade receivables and other assets, of **€ 24.5 million**. Along with the financial results, the initiation of two further new biosimilar projects was also

announced. The reference molecules for FYB208 and FYB209 were identified and preliminary development activities initiated.

In June, the **EMA's Committee for Medicinal Products for Human Use (CHMP)** issued a **positive opinion** with respect to **FYB201**, thereby recommending the biosimilar to Lucentis® for **approval in the European Union** for treatment of patients with neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases. The **CHMP's scientific assessment report** forms the **decision-making basis** for the European Commission's granting of **central regulatory approval**.

The **Annual General Meeting** of Formycon was held on **June 30, 2022 in virtual form**. Shareholders approved all resolutions with large majorities and received an interesting update from the Executive Board on Formycon's various ongoing development projects.



Shares and the capital markets

German and international stock market environment

During the first half of 2022, equity markets in Germany and around the world were adversely affected by multiple factors. The market downturn started in January with the announcement by the U.S. Federal Reserve of its decision to raise interest rates during 2022, thus bringing an end to its long-standing low-rate policy. The Russian attack on Ukraine followed in February, along with the resulting economic consequences. Other factors weighing on the world's stock markets were high inflation figures, concerns about the economy, China's zero-COVID strategy and production bottlenecks resulting from supply chain disruptions.

The unfavorable environment affected benchmark indexes across virtually all key markets. In the first six months of the year, the MSCI World index lost some 21% of its value.<sup>1</sup> The NASDAQ 100 was hit even harder, losing 30% over the same period.<sup>2</sup> Specifically within the German market, the DAX equity index ended at 12,783.77 points on June 30, 2022, thus ending the first half with a loss of 3,101 points, or almost 20%, compared to the close of 2021.<sup>3</sup> The performance of German blue-chip stocks was thus, on average, almost exactly matched eurozone blue chips more broadly, with the broad EURO STOXX 50 index likewise losing some 20% between January and June.<sup>4</sup>

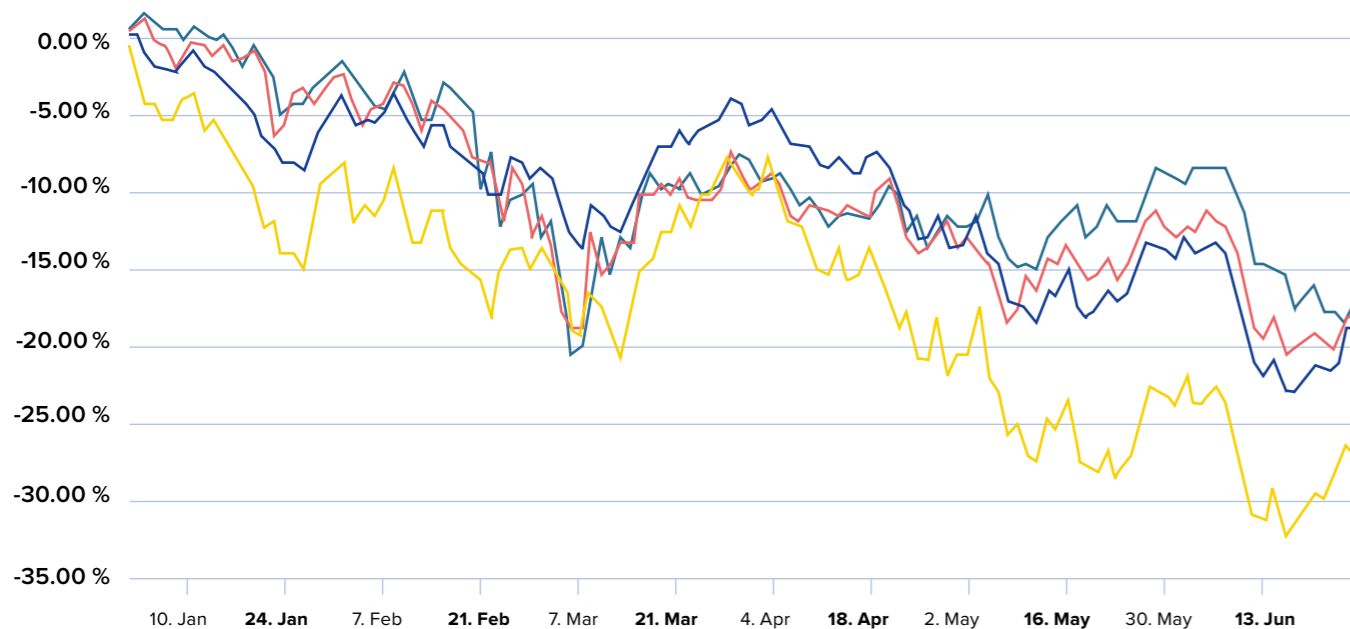


Figure 6: International market environment during the first half of 2022

■ DAX ■ EURO STOXX 50  
■ MSCI WORLD ■ NASDAQ 100

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

In view of the tense situation on the world's stock exchanges, the number of IPOs fell significantly. According to Ernst & Young's global IPO Barometer, a total of 626 companies<sup>5</sup> went public in the first half of 2022, 354 fewer<sup>6</sup> than in the prior-year period. In terms of global issuance, the total value during the first six months was USD 95 billion<sup>7</sup> (1H 2021: USD 198 billion<sup>8</sup>).

Performance of Formycon shares

The performance of Formycon shares during the first half of 2022 was remarkably positive, with a six-month gain of 30% for period ending June 30, 2022. This rise stands in stark contrast to the generally declining stock market environment. Sector benchmarks more closely aligned to Formycon likewise performed poorly during the reporting period, with the Deutsche Börse's Scale 30 Index of the 30 most actively traded shares within Formycon's Scale market segment down 24% from the 2021 close<sup>9</sup> and the biopharmaceutical-dominated NASDAQ Biotechnology Index down 21%<sup>10</sup>.

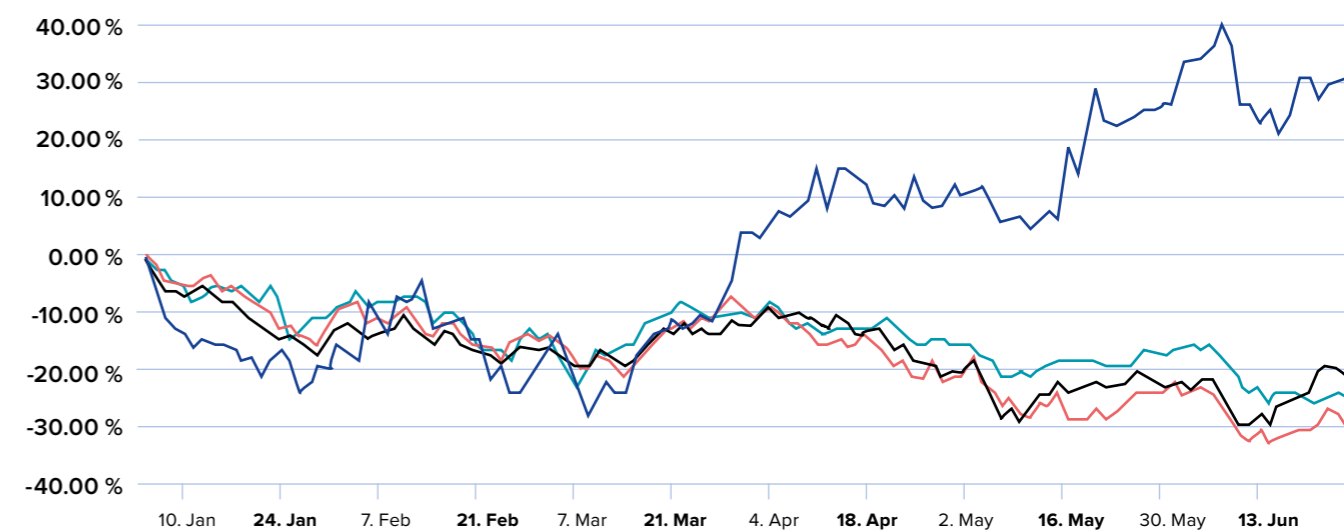


Figure 7: Trading performance of Formycon shares compared to key market benchmarks

■ FORMYCON AG ■ NASDAQ 100  
■ SCALE 30 INDEX ■ NASDAQ BIOTECHNOLOGY INDEX

<sup>5</sup> Ernst & Young, EY Global IPO Update Q1/2022, 28.03.22, [https://www.ey.com/de\\_at/news/2022/03/ey-global-ipo-update-q1-2022](https://www.ey.com/de_at/news/2022/03/ey-global-ipo-update-q1-2022), Ernst & Young, EY Global IPO Update Q2/2022, 30.06.22, [https://www.ey.com/de\\_at/news/2022/06/ey-global-ipo-update-q2-2022](https://www.ey.com/de_at/news/2022/06/ey-global-ipo-update-q2-2022)  
<sup>6</sup> Ernst & Young, EY Global IPO Update Q1/2021, 29.03.21, [https://www.ey.com/de\\_at/news/2021/03/ey-global-ipo-update-q1-2021](https://www.ey.com/de_at/news/2021/03/ey-global-ipo-update-q1-2021), Ernst & Young, EY Global IPO Update Q2/2021, 30.06.21, [https://www.ey.com/de\\_at/news/2021/06/ey-global-ipo-update-q2-2021](https://www.ey.com/de_at/news/2021/06/ey-global-ipo-update-q2-2021)  
<sup>7</sup> Ernst & Young, EY Global IPO Update Q1/2022, 28.03.22, [https://www.ey.com/de\\_at/news/2022/03/ey-global-ipo-update-q1-2022](https://www.ey.com/de_at/news/2022/03/ey-global-ipo-update-q1-2022), Ernst & Young, EY Global IPO Update Q2/2022, 30.06.22, [https://www.ey.com/de\\_at/news/2022/06/ey-global-ipo-update-q2-2022](https://www.ey.com/de_at/news/2022/06/ey-global-ipo-update-q2-2022)  
<sup>8</sup> Ernst & Young, EY Global IPO Update Q1/2021, 29.03.21, [https://www.ey.com/de\\_at/news/2021/03/ey-global-ipo-update-q1-2021](https://www.ey.com/de_at/news/2021/03/ey-global-ipo-update-q1-2021), Ernst & Young, EY Global IPO Update Q2/2021, 30.06.21, [https://www.ey.com/de\\_at/news/2021/06/ey-global-ipo-update-q2-2021](https://www.ey.com/de_at/news/2021/06/ey-global-ipo-update-q2-2021)  
<sup>9</sup> [https://www.finanzen.net/index/scale\\_30/historisch](https://www.finanzen.net/index/scale_30/historisch)  
<sup>10</sup> [https://www.finanzen.net/index/nasdaq\\_biotechnology/historisch](https://www.finanzen.net/index/nasdaq_biotechnology/historisch)

This strong outperformance of Formycon shares was almost entirely during the second quarter of 2022 and largely reflects Formycon's reported progress in expanding its position in the rapidly growing global market for biosimilars. Of particular importance was Formycon's announcement in March, and successful conclusion in May, of the transaction with ATHOS KG. Also in May, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization for FYB201, our biosimilar to Lucentis®.

A more detailed examination versus key market benchmarks shows that, following a somewhat restrained start to the year, Formycon's share price during the reporting period initially moved in line with the broader market, particularly in the weeks between mid-February and early March, a period in which growing uncertainty about Ukraine weighed on the world's stock exchanges. On March 7, Formycon shares reached a first-half low of €43.95, marking the beginning of a subsequent price rally during which, over the following months, Formycon significantly outperformed the broader market. Already by March 30, Formycon's share price exceeded the € 60 mark. Barely three weeks later, it broke the € 70 mark, setting a new price floor for further highs towards the end of the six-month period, and on June 8, Formycon shares reached a new all-time high of € 82.20.

As of the close of first-half trading on June 30, the price of Formycon shares in Xetra trading was € 76.50. With a total of 15,064,750 shares outstanding, Formycon's market capitalization as of June 30, 2022 was thus € 1.15 billion (June 30, 2021: € 697 million with 11,046,500 shares). The total number of shares traded during the first half of 2022 was 2,026,360 (1H 2021: 4,144,437). Some 56% of all shares were traded in the Xetra trading segment, 4% on the Frankfurt Stock Exchange and 40% on other stock exchanges. Across all trading platforms, the average trading volume of Formycon shares per trading day was 16,610 shares (1H 2021: 33,155 shares).

### Formycon shares: Trading information

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

### Formycon shares: Performance information<sup>1</sup>

In €	H1 2022	H1 2021
Opening price on Jan. 3, 2022/Jan. 4, 2021 (Xetra)	58.90	54.60
Closing price on Dec. 30, 2022/Dec. 30, 2021 (Xetra)	76.50	63.10
Average price (Xetra closing price)	60.35	62.82
Market capitalization as of June 30	1,152,453,375	697,034,150
In shares		
Total shares traded (on all trading venues)	2,026,360	4,144,437
Daily average shares traded (on all trading venues)	16,610	33,155
Total shares issued as of June 30	15,064,750	11,064,750



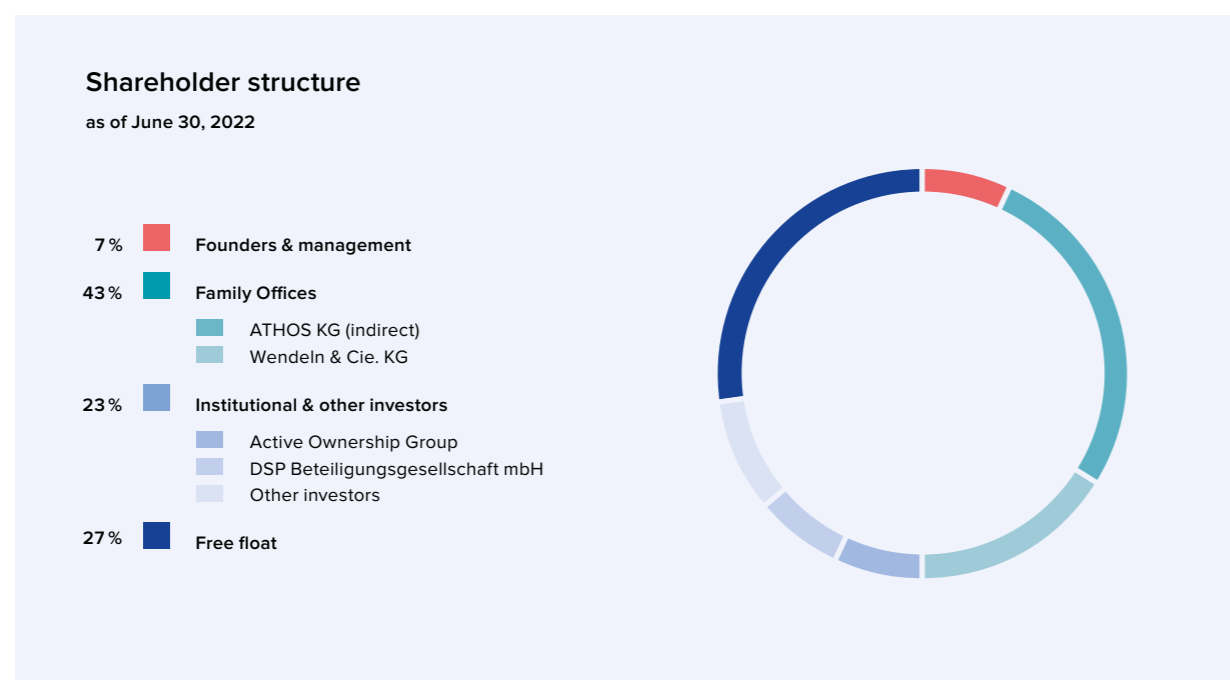


Figure 8: Overview of shareholder structure

### 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. Upon completion of the transaction, ATHOS KG became the largest shareholder in Formycon with an indirect shareholding of 26.6% of its share capital. ATHOS KG and the relevant direct and indirect entities thereunder accordingly provided notification to Formycon and published an announcement in the Federal Gazette in accordance with sec. 20 para. 1 of the Stock Corporation Act.<sup>2</sup>

<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

<sup>3-4</sup> Percentages are approximate and rounded accordingly.

With this change, a total of some 43% of Formycon’s shares are now directly and/or indirectly held by two family offices (ATHOS KG, Wendeln & Cie. KG) with a further approx. 23% held by institutional and other investors<sup>3</sup> (of which the largest are Active Ownership Group and DSP Beteiligungsgesellschaft mbH), while an additional approx. 7% is held by founders and management. The overall shareholder structure of Formycon thus continues to be stable. The remaining approx. 27% of shares are in free float.<sup>4</sup>

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

During the first half of 2022, no members of the Executive Board or Supervisory Board conducted any securities transactions subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR).

### Scale (Open Market) market segment

Formycon’s shares have, since March 1, 2017, been listed in the Frankfurt Stock Exchange’s “Scale” segment for small- to medium-sized companies. The initial listing requirements and ongoing obligations of this Open Market (unofficial regulated) segment are designed to facilitate capital raising for small- to medium-sized companies and to provide access to German and international investors.

Formycon shares were added to the Deutsche Börse’s “Scale 30 Index” of the 30 most liquid shares within the Exchange’s Scale segment in February 2018, soon after the launch of this new market index of Germany’s most actively traded small- to medium-sized companies at the start of 2018. The inclusion of Formycon within the Scale 30 Index was based primarily upon order book turnover on the Xetra and Frankfurt Stock Exchange trading venues as well as its market capitalization. The composition of the Scale 30 Index is regularly adjusted. The index is calculated in real time, is denominated in euros, and is available in both price and performance variants. Since the creation of this select index of the most traded stocks in the Scale segment, these stocks have been gaining greater visibility among investors.

Formycon has, since its introduction throughout the EU in July 2016, been subject to the requirements of the Market Abuse Regulation, replacing key parts of the German Securities Trading Act with the stated goal of promoting the integrity of the financial markets by improving transparency. Under the MAR, Formycon is obligated to publicly release ad hoc announcements of information relevant to its share price, to report securities transactions by its executives (directors’ dealings), and to maintain a registry of Company insiders. Formycon has implemented these requirements, integrating appropriate compliance processes into its existing risk management system as necessary.

**Subscribed capital**

As of January 1, 2022, the registered capital (Grundkapital) of Formycon was € 11,064,750.00, divided into 11,064,750 bearer shares without par value but with an imputed nominal value of € 1.00 per share. Drawing upon the Approved Capital 2019/I resolved by the Annual General Meeting on June 27, 2019, Formycon's share capital was increased by € 4,000,000 to a total of € 15,064,750.00 in conjunction with the transaction with ATHOS KG, with imputed registered capital of € 1.00 per share against contributions in kind.

By resolution of the Supervisory Board on April 26, 2022, Section 4 of Formycon's Articles of Association (Satzung), governing the amount and division of registered capital conditional capital, was amended accordingly, then legally entered into the commercial register (Handelsregister) on May 6, 2022. The registered capital of Formycon thus amounted to a total of € 15,064,750.00 as of June 30, 2022. For detailed information on the Approved Capital and Conditional Capital of Formycon, please refer to the Notes to the Condensed Consolidated Interim Financial Statements (Note 17: "Equity Capital") included in this report.

**Annual General Meeting**

The Annual General Meeting of Formycon was held on June 30, 2022 in virtual format. In the period subsequent to official publication of the meeting agenda in the Federal Gazette on May 20, 2022, agenda item 9 ("Election of new Supervisory Board member") was amended by resolution of the Supervisory Board of Formycon on June 27, 2022 and Dr. Thomas Strümgmann proposed for election as new member of the Supervisory Board.

Shareholders were able to follow the proceedings of the virtual AGM by way of live audio-visual streaming through a specially established AGM portal. 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 Formycon's current biosimilar projects, the development of its new COVID 19 drug, and the transaction with ATHOS KG, answering all of the questions submitted in advance of the meeting.

In addition, shareholders were introduced to two members of the Executive Board newly appointed by the Supervisory Board: Nicola Mikulcik, serving as Chief Business

Officer (CBO) with effect from June 1, 2022, and Dr. Andreas Seidl, Formycon's Chief Scientific Officer (CSO) with effect from July 1, 2022. The Annual General Meeting also approved the expansion of the Supervisory Board from three to four members by a large majority, and Dr. Thomas Strümgmann was elected as the new fourth member thereof with 99.99% of votes represented.

Shareholders were able to exercise their voting rights before or during the virtual AGM through postal voting or authorized proxy voting. A total of approx. 10.7 million shares were voted, representing 70.96% of Formycon's share capital.

**Investor relations**

Professional dialogue with investors and with the international capital markets forms an important component of Formycon Group's investor relations program. During the first six months of 2022, Formycon's senior management and investor relations department presented the Group at selected investor conferences, such as Metzler MicroCap Days, the Jefferies Pan-European Mid Cap Virtual Conference, the Deutsche Börse Equity Forum (spring conference), the Hauck & Aufhäuser Stockpicker Summit, and the Hamburg Investor Day. Through such conferences as well as other outreach activities, notably including non deal roadshows (both virtual and presence) in Milan, Luxembourg and Hamburg, the Group has strived to maintain active contact with existing and potential investors and to increase its visibility on the capital markets. As of June 30, 2022, five analysts were regularly providing equity research coverage on Formycon.



The following analysts published research studies on Formycon during the first half of 2022:

Bank or research provider	Analyst
B. Metzler seel. Sohn & Co. KGaA	Tom Diedrich
First Berlin Equity Research GmbH	Simon Scholes
Hauck & Aufhäuser Privatbankiers AG	Alexander Galista
Kepler Cheuvreux	Arsene Guekam
SRH AlsterResearch AG	Alexander Zienkowitz

Further information about Formycon Group and its investor relations activities may be found in the "Investors" section of Formycon's website <https://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 stands ready to respond to any questions or suggestions:

Formycon AG	
Contact Person	Sabrina Müller Senior Manager Corporate Communications & Investor Relations
Street address	Fraunhoferstr. 15, 82152 Martinsried/Planegg
Phone	+49 89 864 667 149
E-Mail	ir@formycon.com
Web	<a href="https://www.formycon.com/en/investor-relations/shares/">https://www.formycon.com/en/investor-relations/shares/</a>



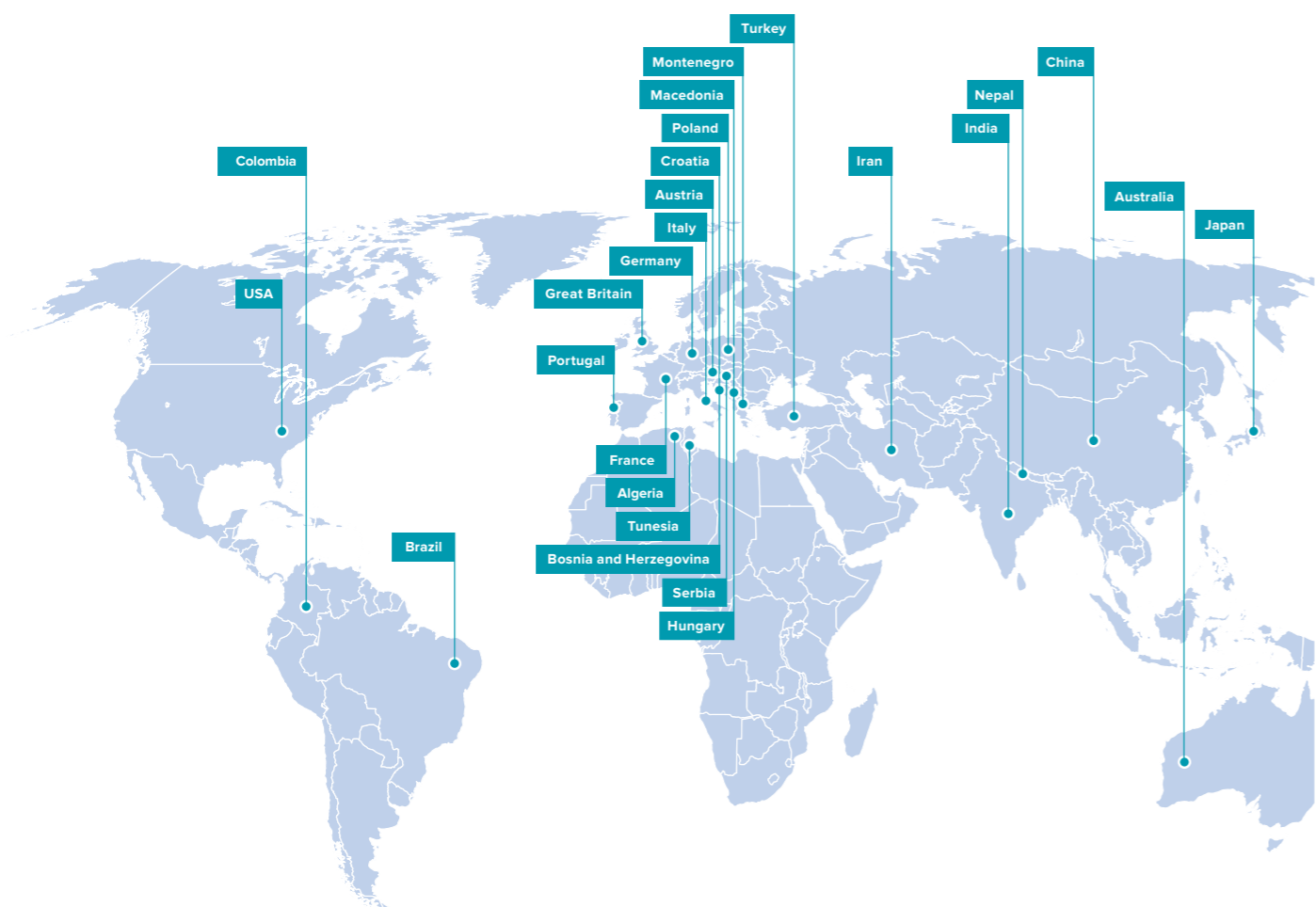
**Staffing and organizational structure**

As of June 30, 2022, a total of 195 persons (prior year: 159), including employees of Bioeq GmbH now integrated into Formycon Group following the ATHOS transaction, were employed at Formycon's offices and laboratories in Planegg on the outskirts of Munich. The average staffing during the six-month current-year and prior-year periods is shown below, divided by functional area, and expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff:

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

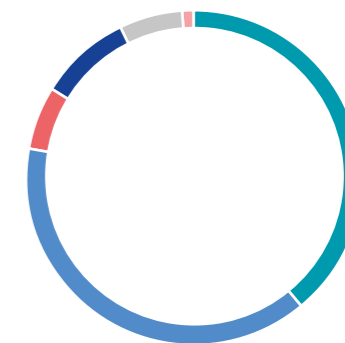
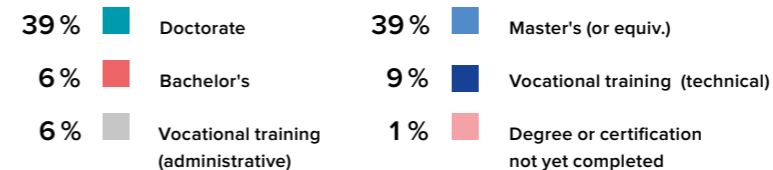
Persons	1H 2022	2H 2021	% increase
Research & development	142	123	+ 15 %
Business operations	11	3	+ 267 %
General & administrative	16	16	+/- 0 %
<b>Total</b>	<b>169</b>	<b>142</b>	<b>+ 19 %</b>

Staff expenses during the first half of 2022 were € 8,088K (1H 2021: € 6,234 K), with the increase due primarily to the greater average number of employees.



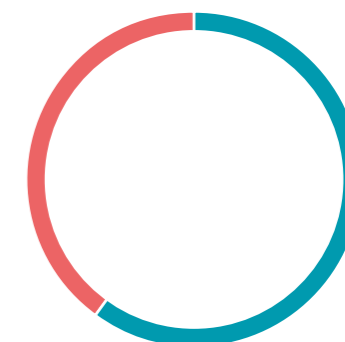
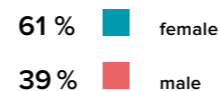
**Educational level of staff**

as of June 30, 2022



**Percentage of total staff by gender**

as of June 30, 2022



New hires during the first half were made, in particular, within the research and development areas of product development and scientific affairs in order to strengthen organizational resources and expertise for further expansion of the Group's development pipeline, which has since begun.

The Formycon Group organization has also been significantly strengthened through the integration of the 17 members of Bioeq staff acquired through the ATHOS transaction at the end of May, thereby adding product development resources and specialized expertise particularly within the areas of clinical affairs, intellectual property, regulatory affairs and commercialization.

In terms of education level, 84% of the Group's total employees have a university degree, and 39% specifically a doctorate. As to gender, 61% are female and 39% male. Formycon is proud of the stable organization and diverse workforce that it has built over the years, with employees from 25 different countries.

**Corporate Social  
Responsibility:  
Our responsibilities  
to our staff and our  
company community**

**Corporate culture and commitment to ethical behavior**

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. This foundation is specifically defined through Formycon's 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 our Company's policy to properly investigate any instance in which non-compliance is suspected.

In its corporate and management culture, 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 and candid work environment as crucial for shared success. By participating in this open dialogue and actively participating in the company, each and every employee can make decisive contributions to Formycon's success.

**Staff recruitment, retention and satisfaction**

Among Formycon's key success factors is the recruiting and retention of highly educated and skilled employees with extraordinary abilities. Formycon recruits its staff without regard to gender, gender identity, sexual orientation, ethnicity, nationality, age, handicap or other such personal characteristics. Our corporate culture is characterized by an affirmative attitude towards integration, respect for diversity and equality of opportunity. Formycon is proud of the steadily growing organization and diverse workforce that it has built over the years, with employees from 25 different countries (Algeria, Australia, Austria, Bosnia and Herzegovina, Brazil, China, Colombia, Croatia, France, Germany, Hungary, India, Iran, Italy, Japan, Macedonia, Montenegro, Nepal, Poland, Portugal, Serbia, Tunisia, Turkije, UK, USA). Despite the particular challenges created by the COVID-19 pandemic, Formycon has been able to recruit outstanding talent and to successfully integrate new staff into the organization.

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 upon general economic conditions, including but not limited to price and wage inflation, as part of Formycon's regular annual salary review process. Formycon Group has a stock option program for management and key staff under which options to buy shares are allocated annually according to set criteria as a long-term incentive component. To further our 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 order to maximize the attraction and retention of talent which is so vital to the Group, Formycon pursues a strategy of actively fostering long-term loyalty of its staff throughout the Group's various functional areas which goes beyond monetary incentives. In order to further this strategic aim, Formycon offers individual opportunities for advanced training, not only for present job responsibilities but also to prepare staff for future career progression. Formycon Group has, in addition, established a "scientific career path" for its research staff as well as a "managerial career path" program for staff in the regulatory affairs, quality management and project management areas, thereby fostering career planning within the Group.

Formycon Group places great importance on overall employee satisfaction, which is – along with technical excellence – essential to the Group's ultimate success. Opportunities for flexible work arrangements, company pension offerings, programs to promote general health, joint team-building events and various other employee 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 regularly conducts anonymous surveys using an external service provider, focusing in particular on any psychological issues which might be adversely affecting its workforce. Although the overall feedback is invariably very positive, follow-up workshops are regularly conducted to identify specific opportunities for improvement, particularly with an eye to making Formycon the best possible place to work – now and long into the future.

**Workplace health and safety**

Against the backdrop of the ongoing COVID-19 pandemic, Formycon promptly took extensive measures to protect its staff from infection to the maximum possible extent. At a very early stage, and even before the COVID-19 crisis fully reached Germany, Formycon took proactive measures by decentralizing its organization. By responding with maximum flexibility, and by adjusting working hours and models around the needs of staff, Formycon was able to meet the requirements of the extraordinary situation while ensuring operational continuity. In addition, the entire Formycon workforce was also promptly equipped with vital protective equipment such as medical-grade mouth and nose protection as well as disinfectants. Finally, we made arrangements so that we were able to offer COVID-19 vaccinations to all employees starting from mid-June 2021 by way of our company doctor. Although the COVID-19 situation appeared to have generally relaxed overall as of early summer 2022, we will continue to closely monitor the ongoing situation so that appropriate measures may be promptly and proactively taken if and as necessary to protect our staff.

Because both productivity and quality depend crucially upon the health and motivation of the people who work in our Company, 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. In 2021, Formycon once again received 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 includes rigorous assessments of a company’s occupational health and safety management system as well as the effectiveness of its health management system. During the reporting period, Formycon recorded no workplace accidents or other reportable incidents (such as commuting accidents). Through our health and safety guidelines, our training courses and the regular medical check-ups which we offer, we pursue the goal of doing everything reasonably possible to prevent workplace accidents and to ensure the continued safety and well-being of our entire workforce.

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**Our responsibilities to patients, to our investors and to the world at large**

**Biopharmaceuticals to meet the needs of patients**

Through the biosimilar drugs which we are bringing to market, we aim to make an important contribution to world healthcare by providing patients with access to high-quality, competitively priced biopharmaceuticals to treat serious diseases. 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, even in the most developed countries. However, once the legal protection period for an originator biopharmaceutical reaches its end, biosimilars may be brought to market, providing a cheaper alternative for patient care. Thus, the reduced costs of effective treatment through new competition from biosimilars not only helps to relieve the burden on health providers such as statutory health insurers: They also make it possible to bring these powerful treatments to more patients.

**Our commitment to the United Nations Global Compact**

Formycon has since 2019 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 our Code of Conduct. Formycon and its business partners, as part of the biopharmaceutical development industry, operate in a highly regulated environment

and are already accustomed to regular audits by supervisory authorities. By requiring our suppliers and cooperation partners to cooperate during 2022 with our initial risk assessment and review process for human rights compliance, we aim to ensure that we as a company are not complicit in any kind of human rights violations throughout our entire value chain.

Following these first steps, Formycon plans to successively increase its ongoing commitment to further sustainability goals and, above all, to continue to integrate the themes of environmental and social responsibility into our corporate management and culture.

**Corporate Governance**

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

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

Because Formycon shares trade within the “Open Market” segment, it is not legally subject to the requirements for organized markets within the meaning of the German Securities Trading Act (*Wertpapierhandelsgesetz*) and it not legally considered to be listed. Although Formycon is therefore under no obligation to publish a corporate governance statement or declaration of compliance, we at Formycon have already implemented and embraced many of the corporate governance principles contained in the Code. In particular, as part of our commitment to transparent communication with our investors, the Executive Board and Supervisory Board of Formycon has taken initial steps to implement the principles, recommendations and suggestions anchored in the Code within our organization to the greatest extent possible with the aim of, in addition to this voluntary report on corporate governance, adding a declaration of compliance over the coming years – likewise on a voluntary basis – into this section of our future annual financial statements. Our aim in doing so is to strengthen the confidence of our investors, our employees and the public that we are a well-managed, properly supervised company that be counted on to do the right thing.

<sup>1</sup> Regierungskommission Deutscher Corporate Governance Kodex

<sup>2</sup> Börse Frankfurt, Open Market



## Research and development

As in previous periods, Formycon Group's activities during the half year ending June 30, 2022, were primarily in the area of research and development.

As of June 30, 2022, 142 staff members (FTE) worked in research and development (1H 2021: 123). During the period, research and development expenditures in the amount of € 2,041K were capitalized (1H 2021: € 0K). This capitalized amount relates solely to certain development costs for the FYB202 project acquired as part of the transaction described above. 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.

## Financial performance

The financial results herein are reported for the period from January 1, 2022 to June 30, 2022. Because of rounding errors, it is possible that the figures cited do not precisely add up to the stated total, or that percentages do not precisely correspond to the absolute figures.

### a) Results of operations

During the first half of 2022, Formycon Group generated consolidated revenue of € 17,644K, compared to € 20,099K in the prior-year period, resulting in six-month consolidated net income of € 80,031K (1H 2021: net loss of € 10,609K). The corresponding cost of sales for the period was € 12,317K (1H 2021: € 15,336K), yielding a six-month consolidated gross profit of € 5,327K (1H 2021: € 4,763K). Additional research and development expenses were € 7,933K (1H 2021: € 11,771K), and government funding for the FYB207 project was received in the amount of € 3,894 thousand (1H 2021: € 35K), which is recognized as an offset to expenses. Sales and marketing expenses for the period were € 1,140K (1H 2021: € 203K), while general and administrative expenses were € 4,608K (1H 2021: € 3,102K). Including other expense and income items, the Group thus reported consolidated EBIT for the reporting period of - € 8,515K (1H 2021: - € 10,485K).

As part of the transaction including acquisition of a 100% share of FYB202 Project GmbH, Formycon exited its holding in FYB 202 GmbH & Co. KG and is no longer a shareholder thereof. The division of assets through this departure from FYB 202 GmbH & Co. KG generated a book (non-cash) investment gain to Formycon in the amount of € 89,730K.

During 2022, **Formycon Group** has continued to 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 Group continued to post significant sales 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 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<sup>1</sup>. Formycon continued to hold a 24.9% stake in the joint venture with Aristo Pharma GmbH until April 30, 2022, bearing a *pro rata* share of accumulated project investments and development costs. With the acquisition of 100% ownership of FYB202 Project GmbH with effect from May 1, 2022, and Formycon's simultaneous exit as a shareholder of FYB 202 GmbH & Co. KG, Formycon has, since this date, been bearing 100% of subsequent project and development costs incurred through its subsidiary FYB202 Project GmbH.

### b) Financial position

The financial position of Formycon Group remains stable, with key liquidity ratios significantly above average, as in prior years. Current assets totaled € 43,364K, compared to total current liabilities of € 20,502K. The Group did not have any bank loans during the period. To ensure the Group's financial resources, a credit line of € 50,000K was made available to Formycon during the reporting period by shareholders thereof, of which Formycon had drawn € 10,000K as of the reporting date. In addition, Formycon has, under the terms of the ATHOS transaction, assumed long-term liabilities arising from the respective earn-out components for FYB201 and FYB202 projects as partial consideration for its acquisition of shares in Bioeq AG and FYB202 Project GmbH.

As of the period closing date, cash and liquid resources amounted to € 18,243K, with marketable securities totaling € 150K, as may be seen on the Condensed Consolidated Statement of Cash Flows. Return on sales (net income/loss before inclusion of income from investment participations divided by consolidated sales revenue) for the period was -48.3% (1H 2021: -52.2%), while EBITDA (operating profit/loss plus depreciation and amortization) was - € 7,581K (1H 2021: - € 9,696K).

### c) Net assets

As of the close of the period, Formycon Group's equity capital ratio was 48.4%, significantly lower than before the transaction with ATHOS KG but still at an above-average level. Non-current assets increased significantly during the period due to the acquisitions under this transaction of a 100% ownership share of FYB202 Project GmbH, a 100% share of Bioeq GmbH, and 50% of the shares of Bioeq AG, along with purchase price allocations relating thereto. In addition, Formycon assumed, as part of the transaction, a loan receivable from Bioeq AG in the nominal amount of € 82,000K. Significant non-current liabilities arising from transaction's earn-out component were also recognized for the first time. Following these changes, more than 50% of non-current assets are now covered by equity capital. The Group's current assets consist almost completely of cash and marketable, highly liquid securities and thus involve negligible risks.

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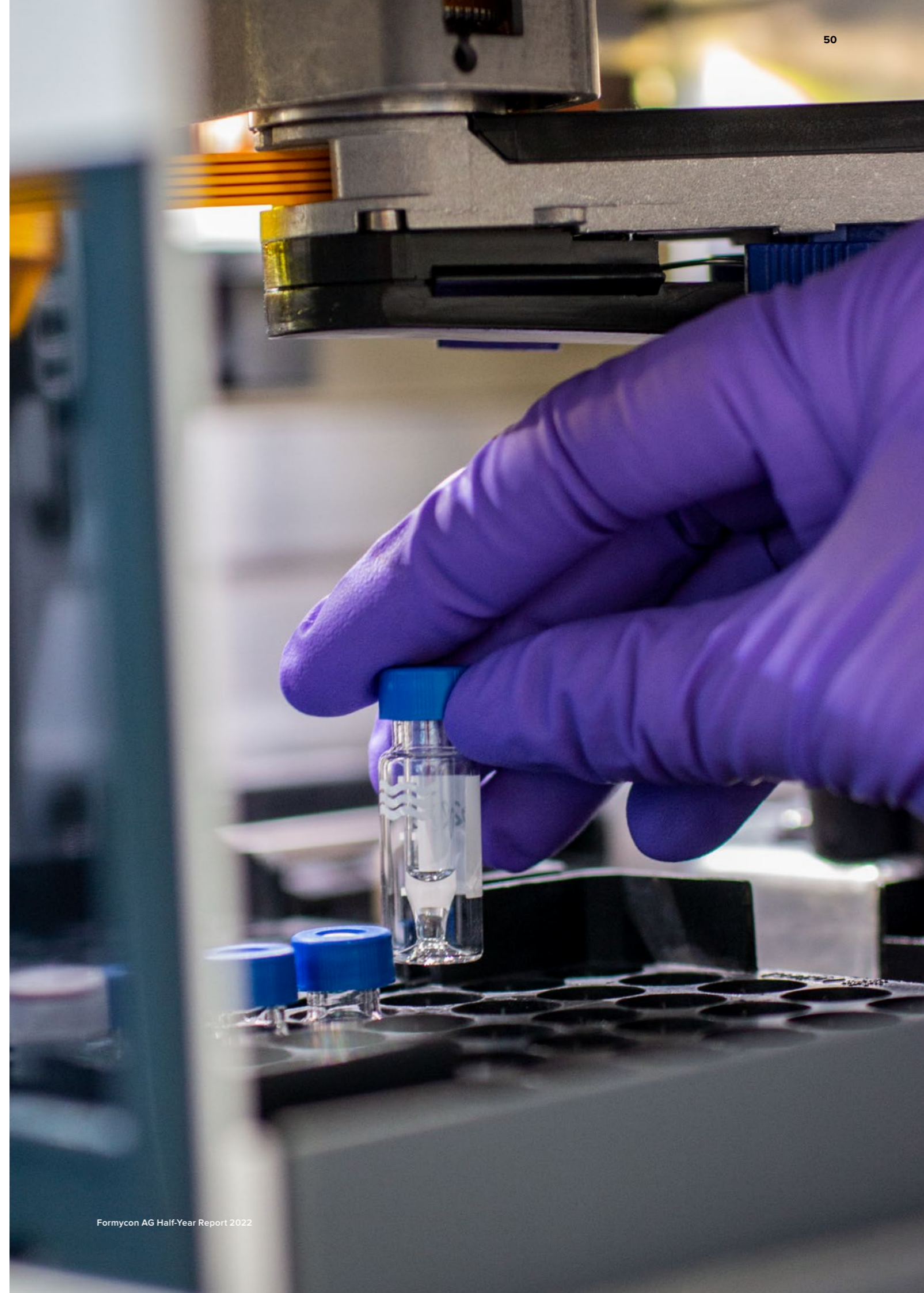
#### Financial and non-financial performance indicators

Because Formycon remains in the product development phase, the informative value of customary financial indicators is necessarily limited. The performance indicators of importance to the Group are those which measure its long-term, sustainable financial strength.

For the first six months of the year, consolidated net cash flow from operating activities was - € 10,122K (1H 2021: - € 7,446K), in line with expectations. Consolidated cash flow from investing activities was - € 6,085K (1H 2021: - € 1,545K), while consolidated cash flow from financing activities was - € 9,421K (1H 2021: - € 309K), reflecting the proceeds of the loans from shareholders. In this way, Formycon has been able to ensure a sufficiently stable level of cash and liquid resources.

As to non-financial performance indicators, please refer to the above “Research and development” section of this report.

Formycon undertakes development for selected clients who see themselves as partners of Formycon and whose interests as to successful product development and subsequent market launch are fully aligned. The cooperative partnership arrangements and congruent objectives suggest a relatively low conflict potential. The Group’s staff works primarily in research and development.





### III Report on outlook

#### Company and development pipeline

Over the past years, Formycon Group has successfully gone through various phases of its development as a business and as an organization, culminating in the Group's significantly increased capitalization and initiation of multiple biosimilar drug development projects in recent years. The focus of fiscal year 2022 is on continuing to execute on the Group's defined strategy and, in particular, driving forward with the further development of its biosimilar candidates and COVID 19 drug (FYB207).

More broadly, Formycon is working to further strengthen the administration and management of its maturing organization and, in parallel with the Group's existing German statutory (HGB) financial accounts, has begun to prepare and publish its consolidated accounts in accordance with International Financial Reporting Standards (IFRS), thereby laying the groundwork for greater international transparency and comparability of financial statements as well as access to international capital markets. With IFRS reporting in place, Formycon is now working towards an uplisting to a more highly regulated stock market segment in order to reach a broader base of potential investors.

As a result of the strategic transaction ATHOS KG, **Bioeq GmbH** has now been fully acquired as a 100% subsidiary of Formycon and organizationally integrated into Formycon Group. With the takeover of Bioeq GmbH, Formycon has been able to broaden and strengthen its existing organization with complementary experience and expertise in the areas of clinical development, regulatory affairs, business development, commercial affairs, intellectual property and project management. The long-standing partnership between the two companies in ongoing biosimilar projects is expected to facilitate the rapid leveraging of synergies and efficient expansion of the development pipeline. In addition, Bioeq has an established international network for the commercialization of biosimilars as well as extensive expertise in the management of clinical trials. Bioeq GmbH has also previously served as clinical trial sponsor and thus the official contracting entity for clinical trials of Formycon-developed biosimilar candidates.



#### FYB201 – biosimilar to Lucentis®

FYB201 is Formycon's biosimilar to ophthalmic blockbuster drug ranibizumab (reference product: Lucentis®). Together with our license partner Bioeq AG, we have been working hand in hand towards the market success of our first approved product. Due to the ongoing COVID 19 pandemic, which again had the effect over the past year of impeding patient access and adversely affecting patient visits to ophthalmological practices, full-year 2021 sales of reference drug Lucentis® rose only slightly over the prior year, from USD 3.5 billion to 3.6 billion.

Following final approval by the UK Medicines and Healthcare products Regulatory Agency (MHRA) in May 2022, the U.S. Food and Drug Administration (FDA) on August 2, 2022 approved FYB201 for **automatic substitution** in the United States as the first

biosimilar to Lucentis®. This makes FYB201 the first and, for a 12-month post-launch period, exclusive interchangeable biosimilar in the U.S. approved for all five Lucentis® indications, providing a new medical treatment option for patients with severe retinal disease. Following the positive opinion of the EMA's Committee for Medicinal Products for Human Use (CHMP) announced in June, the European Commission granted approval for FYB201 on August 26, 2022.

Further applications for the regulatory approval of FYB201 in other attractive markets are planned for submission in due course.

FYB201 was launched in the UK market by our partner Teva Pharmaceutical Industries Ltd. (Teva) in July under the name ONGAVIA®<sup>1</sup>. Within the 27 member states of the European Union as well as Iceland, Norway and Liechtenstein, the newly approved drug will be launched as soon as possible, likewise by Teva, under the name Ranivisio®<sup>2</sup>. The market launch in the U.S. by our partner Coherus BioSciences, Inc. is planned for October 2022 under the trade name CIMERLI™<sup>3</sup>.

In addition, upon regulatory approval, our partner MS Pharma will be responsible for commercializing FYB201 within the Middle East and North Africa (MENA) region.



#### FYB202 – candidate biosimilar to Stelara®

FYB202, Formycon's candidate biosimilar to reference product Stelara® (active ingredient: ustekinumab), targets multiple indications for the treatment of serious inflammatory diseases. In spite of the continued challenging conditions for carrying out clinical studies, phase III clinical trials (the VESPUCCI study) were successfully completed in June and, with the achievement of the primary endpoint, scientifically demonstrated the comparable efficacy of FYB202 relative to reference drug Stelara® in patients with moderate to severe psoriasis vulgaris (plaque psoriasis).

The primary endpoint measures the percentage improvement in the Psoriasis Area and Severity Index (PASI) against baseline at the 12-week point. In addition, the results of the clinical trials did not show any clinically relevant differences in safety or immunogenicity. In the meantime, expanded phase I clinical trials have been initiated on the basis of scientific advice meetings with both the FDA and the EMA. Submissions for regulatory approval of FYB202 in Europe and the U.S. are planned for the third quarter of 2023, once these additional pharmacokinetic data are available.

As a result of the transaction with ATHOS KG successfully completed during the first half of 2022, global commercialization rights to FYB202 are now fully owned by Formycon (prior to transaction: 24.9% co-ownership).

<sup>1</sup> ONGAVIA® is a registered trademark of Teva Pharmaceutical Industries Ltd.

<sup>2</sup> Ranivisio® is a registered trademark of Bioeq AG.

<sup>3</sup> CIMERLI™ is a trademark of Coherus BioSciences, Inc.



#### FYB203 – candidate biosimilar to Eylea®

FYB203, a candidate biosimilar to Eylea® (active ingredient: aflibercept), is – like Lucentis® above – used in the treatment of neovascular age-related macular degeneration (nAMD) along with other serious eye diseases. Global reference drug sales in 2021 were up approximately 12.5% over the prior year, reflecting the increasing number of patients in the 55+ risk group.

As to the ongoing phase III clinical trials (MAGELLAN-AMD study), the final patient was recruited into the study (“last patient in”) in April. The study was designed in consultation with the U.S. FDA, the European Medicines Agency (EMA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) with the aim of facilitating regulatory approval in each of these key regions.

The aim of these randomized, double-blind, multi-center phase III clinical trials is to demonstrate the comparability of FYB203 to the reference product Eylea® in terms of efficacy, safety and immunogenicity in patients with neovascular (wet) age-related macular degeneration. Primary efficacy endpoint data are expected by the end of this year.

FYB201 was out-licensed to our partner Santo Holding (Deutschland) GmbH under a deal signed in 2015. The worldwide marketing rights to the drug were subsequently shifted internally within Santo Group to another Santo entity, Klinge Biopharma GmbH.

Provided that clinical trials reach their successful conclusion and that respective regulatory approval is obtained, we should, by way of our respective commercialization partners, be able to launch FYB203 upon respective expiry of legal protection for the reference product first in the United States in 2024, then in Europe in 2025.



#### FYB206 – biosimilar candidate not yet announced

The FYB206 biosimilar project is advancing according to plan. With convincing results from extensive analytical characterization of the developed molecule, along with significant progress in the development of a manufacturing process, a comprehensive data package is currently being compiled in order to closely coordinate next steps during the second half of the year with both the EMA and the FDA through the scientific advice procedure. A scaling of the manufacturing process to commercial scale is planned for the end of 2022.



#### FYB207 – development of an antibody-based COVID-19 drug

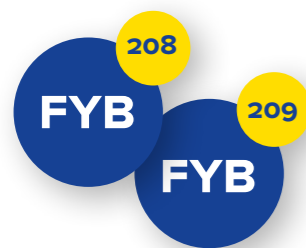
FYB207 is a promising antiviral drug candidate against SARS CoV 2 and variants thereof. It is a fusion protein which links the ACE2 protein (angiotensin-converting enzyme 2) to the constant part of a natural human antibody. Because ACE2 is the entry point for cell infection, the virus is fundamentally unable to overcome an antiviral drug based specifically on this protein. Previously published laboratory studies have already demonstrated that FYB207 is able to retain its full antiviral potential even against the SARS CoV 2 alpha, beta and delta variants. New laboratory data now also show that the currently predominant omicron variant is likewise neutralized by FYB207 with a high level of efficacy.

Thanks to preclinical studies carried out during 2021, Formycon has been able to make modifications to the molecular structure leading to significant improvements in drug half-life and efficacy. The development strategy for an accelerated approval process was already coordinated during 2021 through the scientific advice procedure with both the Paul Ehrlich Institute (PEI) in Europe and with the U.S. FDA.

In a follow-on scientific advice consultation in May 2022, the PEI confirmed its full support for the accelerated development of the improved drug molecule. On this basis, preclinical studies are to be completed in 2022, the manufacturing process is to be adapted to the optimized molecule, and the production of test material for stability studies and clinical trials is to be carried out. Initiation of clinical trials is planned for 2023.

Formycon has extensive expertise and numerous patent applications in the field of fusion proteins against viral diseases, an increasingly important therapeutic area. Together with two renowned academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, Formycon has established a superb scientific reputation in this area, as reflected by the work on FYB207. The extraordinary promise of FYB207 is underscored not only by the extensive government funding received but also its recognition as Most Innovative Product® within the Pharma Trend Image & Innovation Award’s “Leap Innovations”. In view thereof, Formycon is currently evaluating various strategic options to maximally exploit the commercial potential of this platform technology. The exclusive license to develop, manufacture and market FYB207 for the Asia-Pacific region (excluding Japan) previously granted to SCG Cell Therapy Ltd. has, for this reason, been reclaimed. The intensive cooperation with our academic partners toward the ongoing development of FYB207, however, continues apace.





### FYB208 and FYB209 – biosimilar candidates not yet announced

With the aim of continuously expanding its proprietary development pipeline, Formycon initiated two new biosimilar projects during the first half of 2022. The reference molecules for FYB208 and FYB209 were identified and preliminary development activities initiated.

#### Summary and strategic focus

The development of biosimilars is Formycon's strategic focus and the basis for the Group's sustainable, long-term future growth.

With the market launch of its first biosimilar drug in 2022, Formycon is now entering a new phase of its corporate development in which resulting cash inflows are expected to open new growth opportunities for Formycon Group. In addition, through the transaction with ATHOS KG and the associated acquisition by Formycon of a 50% stake in the FYB201 biosimilar candidate and 100% of FYB202, Formycon will enjoy a significantly higher share of future revenues upon approval and market launch. The Group plans to primarily invest the resulting cash inflows into the accelerated expansion of its product development pipeline. The resulting product portfolio will, in turn, create a strong and powerful basis to build Formycon Group's position as a global competitor in the high-growth biosimilars market and to further develop Formycon's organization and resources as a fully integrated pharmaceutical company within this attractive market segment.

The development work on our innovative COVID 19 fusion protein was initiated to contribute to the global fight against COVID 19 by building upon our long and extensive experience in biopharmaceutical development. While Formycon's strategic preference in the case of its biosimilar candidates is to develop these independently through to an advanced stage approaching commercialization, the intention in the case of Formycon's innovative COVID-19 drug project (FYB207) is, in contrast, to enter into a strategic global development and commercialization partnership at an earlier development phase because of the particular advantages of this alternative development approach.

### Financial profile and organization of Formycon

With its financial soundness and its strong portfolio of capabilities, Formycon is well positioned in the market. Through the market launches of FYB201 in the UK, the USA and Europe by the respective commercialization partners during 2022, both planned and already underway, Formycon expects to post its first-ever product sales revenue – and income resulting therefrom – in the second half of the fiscal year.

Formycon has been able to successfully cope with the coronavirus pandemic by taking prompt and proactive measures to protect its staff. The emergency task force established for this purpose quickly worked to develop a comprehensive pandemic policy for the entire organization and remains in regular working contact with senior management as well as the relevant department heads to review the emergency measures taken so far and to improve and strengthen them as necessary. The early-stage decentralization of the Formycon organization by quickly putting into place a new work model focused on flexibility and mobility has proven to be extremely practical as well as effective in ensuring operational continuity. Nevertheless, it must be recognized that the risk of an infection spreading within or otherwise impacting the Group cannot be entirely eliminated and that such an event could have an impact on the Group's business operations, potentially hindering development activities of its biosimilar candidates. In order to counter this risk, the task force team is working on longer-term improvements to protect the health of our staff. For a further discussion of potential risks relating to the ongoing coronavirus pandemic, please refer to the following section ("IV. Report on opportunities and risks").

Revenue for the first half of 2022 was in line with plan. Formycon's operating performance reflects non-capitalized investments into the Group's own FYB202, FYB206 and FYB207 projects as well as the expansion of its development pipeline to encompass the new FYB208 and FYB209 biosimilar projects. Formycon's available liquidity, along with the remaining undrawn and available credit line from shareholders in the amount of € 40,000K, ensure that it has sufficient financial resources to advance these development projects as planned.

## IV Report on opportunities and risks

### 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, for the most part, already scientifically proven and development processes which are largely well established. Because the similarity and comparability of a biosimilar to its reference product must already be demonstrated analytically, the likelihood that the development of the biosimilar will fail in one of the subsequent clinical phases is generally far lower than in the case of innovative biopharmaceuticals.

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

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

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

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

### Risks

#### Principles

Formycon, one of the few independent developers of biosimilar medicines, operates in a global market with many different participants and influencers. Business success is determined by the identification of profit opportunities, along with the best possible assessment of the many and varied risks associated with these. In order to ensure that this happens, the entire staff of Formycon Group, up to and including the Executive Board, must adhere to the Group's established risk management system, thereby aiming to ensure that these risks are handled optimally while at the same time providing the necessary entrepreneurial and operational flexibility. Regular reviews of this system further ensure that it is constantly improved and that, as circumstances change, changes are likewise made to the system promptly and in accordance with evolving needs.

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

In this way, all risks which are conceivable and significant, having first been broken down into the respective administrative and operational areas, are subjected to systematic ongoing monitoring and assessed as to their probability of occurrence and the severity of potential adverse consequences.

The Group's risk review process takes place every six months and is initiated and coordinated by the Legal & Compliance department. The results of the review, along with all relevant information, are presented to the Executive Board following each six-month period. The Executive Board may, if it deems appropriate, conduct its own independent assessment of risk management process and/or of specific key risks. The Executive Board also reports its findings to the Supervisory Board.

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

The risk management system specifically encompasses the following risk areas, which are further described in the following sections: strategic risks; industry and market risks; controlling; environmental protection, health protection, and workplace safety; financing and liquidity risks; organizational risks; patent risks; staff risks; risks associated with product development; legal risks; regulatory and political risks; and competitive risks.

### Strategic risks

Compared to the development of an entirely new biopharmaceutical, the financial investment required for the development of a biosimilar drug is considerably less. Nevertheless, the development of a biosimilar may cost in the range of USD 100 to 200 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.

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. The intended therapeutic applications of Formycon's other biosimilar development projects have not yet been announced.

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. With its advanced-stage biosimilar candidates, Formycon is focused on three of the world's best-selling biopharmaceuticals with combined 2021 global sales revenue of approx. € 21.5 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. Demographic trends around the globe are also playing a key role as populations continue to age and live longer. Older people require more extensive medical care, 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 31.3% of the total drug market in 2021, equal to € 16.1 billion in sales revenue<sup>1</sup> – and the trend is continuing upward.

<sup>1</sup> Statista: Sales of biopharmaceuticals in Germany compared to the total German pharmaceutical market in the years 2007 to 2021.

At the same time, however, the high cost of these powerful treatments, which in some cases may cost € 100,000 per patient per year or more, is a major burden on health-care 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.

### Controlling

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

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

Workplace safety and health, as well as the protection of employees and the environment, is a top priority for Formycon. Formycon therefore places great importance not only on the fulfillment of statutory and regulatory requirements but also on the regular training and further qualification of all of its staff in the relevant aspects of workplace safety. In addition to our biological safety officer, our designated project manager as required under the German Genetic Engineering Act (*Gentechnikgesetz*) and our 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 and senior management 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, Formycon 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 verfügt nach wie vor über eine stabile Liquiditäts- und Eigenkapitalsituation. Insbesondere die Liquiditätslage von Formycon ist für ein Unternehmen, dessen Produkte sich sämtlich in der Entwicklung befinden, ausgesprochen zufriedenstellend. Ungeachtet dessen können sich im operativen Geschäft die Rahmenbedingungen verändern und dadurch finanzielle Risiken entstehen. Da sämtliche Produkte noch nicht zugelassen sind, kann nicht ausgeschlossen werden, dass sich eine oder mehrere Zulassungen verspäten, in einem anderen Umfang oder gar nicht stattfinden. Zudem kann es sein, dass die finanziellen Aufwendungen für die Entwicklung, Zulassung und Markteinführung der Biosimilars höher als budgetiert ausfallen. Nach Zulassung besteht die Möglichkeit, dass die Einnahmen aus Lizenz Erlösen geringer als antizipiert ausfallen.



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 EUR 50 million by a consortium of two major company investors: ATHOS and the healthcare-focused investment group Active Ownership.

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 starting from a certain product development stage.

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

With its strong financial footing, Formycon is well positioned to overcome future financial risks as these may arise. The Group's existing financial resources should be sufficient to cover its short- to medium-term capital needs. This, however, cannot be used to infer any sort of assurance as to the availability of long-term financial resources. There are, at present, no identifiable fundamental risks which would jeopardize the Group's continued existence.

#### **Organizational risks**

Formycon Group'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 state-of-the-art security technology to eliminate or mitigate such risks – for example, relating to cyberattacks or data loss. The Group also regularly conducts maintenance and inspections of its critical equipment by trained personnel or specialized service providers, making changes to equipment as necessary to ensure that it remains at the state of the art.

#### **Patent risks**

The possibility of patent infringements, even if only alleged, is an inherent risk in biosimilar development because of the large number of potentially relevant patents which must be considered. Disputes with competitors or other patent owners, or defense against lawsuits claiming patent infringement, may pose a considerable financial burden. Particularly in the U.S., such legal actions generally involve very high costs. In the worst case, such a dispute could result in restrictions on, or even the prohibition of, the marketing of one or more products on one or more relevant markets, and/or the imposition of sizable fines. Such a legal action could also make it necessary to cease the development, launch, or ongoing marketing of one or more products.

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

#### **Staff risks**

The expertise and many years of experience of its employees are key pillars of Formycon's success. In particular, the development of a biosimilar drug, from early-stage analysis through to regulatory approval, requires highly qualified specialists. Over recent years, Formycon has been able to recruit numerous highly qualified scientists and managers. This demonstrates that Formycon 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 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. The rate of sick leave at Formycon is, compared to other industries in Germany, very low. Formycon has, nevertheless, established a health management system to mitigate the impact of staff absences resulting from illness.

#### **General risks associated with product development**

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 Formycon'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 precise 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 Formycon'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. 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.

The above risks apply not only to the development of a biosimilar candidate but also, and to a very substantial degree, to the development of a new and innovative COVID 19 drug under the FYB207 development project. In the case of FYB207, there is the additional possibility that changes in the global pandemic and in the evolving situation might make it necessary to adjust basic assumptions underpinning the project and that circumstances could result that might lead to a reassessment of the profitability and financial viability of the overall project or could jeopardize the project in its entirety.

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

With the takeover and integration of Bioeq GmbH, Formycon is expanding the scope of its drug development capabilities to include clinical development and the direct management of clinical trials. Bioeq GmbH, a legally separate subsidiary of Formycon Group, continues to serve, as it did before its acquisition by Formycon, in the role of "clinical trial sponsor" for Formycon-developed biosimilar candidates and thus as the official contracting entity for these clinical trials. In its role as clinical trial sponsor, Bioeq GmbH bears not only financial risks but also the risk of liability towards participating patients or other test subjects. With the acquisition of Bioeq GmbH as a subsidiary company belonging to Formycon Group, these risks are effectively assumed by Formycon.

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

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

### Legal risks

Formycon does business in an international environment and in highly regulated markets. There is thus the possibility that Formycon Group could be drawn into legal disputes which might even be unjustified or frivolous, based upon patent law, competitive or antitrust law, tax law or environmental law, or arising from 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. Formycon 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 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, upon expiry of patent protection on the reference product in the respective market. In each such market, Formycon must compete not only with the manufacturer of the reference drug, who might attempt to defend its market position and establish barriers to market entry (e.g. through life-cycle management), but also with other biosimilar producers. The competition situation in each specific case will depend upon the pricing of the reference drug as well as the pricing of any new competitors in the market. It is, in addition, entirely possible that the manufacturer of the originator product might reduce its pricing upon the market entry of new and competing biosimilars, or seek to enter into discount agreements with health insurers or other major buyers over extended contractually binding periods, in order to retain market share. This would improve its defensive competitive position against a new biosimilar entry and make it more difficult for the biosimilar to take share.

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

### Special risks relating to the Ukraine conflict

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 important to Formycon, as well as services, more expensive or potentially even scarce. Formycon strives to mitigate these risks through a long-term sourcing strategy based upon strategic partners and transparent pricing. However, the possibility cannot be ruled out that delays or interruptions in development projects could occur as a result of a potential scarcity of resources or rationing of energy, or that the development costs thereof could become significantly greater.



**Special risks relating to the COVID 19 pandemic**

The proactive measures taken by Formycon in the very early stages of the COVID 19 pandemic to protect its workforce and avoid infection, and which have been continuously adjusted and consistently managed in the two years since, have proven their worth: Formycon’s staff has been able to continue to work on a largely decentralized basis and with minimal disruption. A comprehensive hygiene concept was developed in cooperation with the company doctor and introduced as company policy, through which Formycon also fully complies with applicable government regulations and occupational medical requirements. Where cases of suspected or potential COVID 19 infection have arisen, these have been promptly identified and tested, with no influence thus far on the course of business.

On this basis, and based upon present circumstances, it would thus seem unlikely that an infection outbreak within the Group’s workforce – despite these far-reaching protective measures – would arise that would significantly impact business operations, projects and/or timelines. The possibility also continues to exist that, despite all these measures taken within Formycon, one of its partners or suppliers could be impacted by a COVID 19 outbreak, thereby indirectly impacting the Group.

**Summary risk matrix**

Risk	Risk type	Assessed PoO
Risks associated with product development	Strategic	● Medium
Risks relating to clinical trials and to the role of Bioeq GmbH as clinical trial sponsor	Strategic	● Low
Patent risks	Strategic / Commercial	● Medium
Regulatory and political risks	Strategic / Commercial	● Medium
Industry and market risks	Commercial	● Medium
Competitive risks	Commercial	● Medium
Financing and liquidity risks	Financing	● Medium
Controlling	Operating	● Low
Environmental protection, health protection, and workplace safety	Operating	● Low
Organizational risks	Operating	● Low
Staff risks	Operating	● Medium
Legal risks	Operating	● Medium
Special risks relating to the Ukraine conflict	Operating	● Low
Special risks relating to the COVID-19 pandemic	Operating	● Low

Probability of occurrence (PoO)	
● Low	< 5 %
● Medium	5 – 25 %
● High	> 25 %

### Summary assessment of risks

While there is always a possibility that one or more of Formycon's drug development projects could fail partially or completely for any of various scientific, technological, regulatory, economic or other reasons, this risk is inherently far lower than in the case of the development of an entirely new and innovative biopharmaceutical. The FYB207 project is, in contrast, an innovative project, and thus the associated risks are fundamentally those of any such innovative biopharmaceutical development project. In particular areas, Formycon Group must draw upon the services of outside partners and providers, which necessarily entails dependencies. Risks could thus potentially also arise within areas over which Formycon has no direct management control.

It must, moreover, be fundamentally recognized that the Group faces not only various known and identifiable risks but also unknown risks and uncertainties. These include, but are not limited to, risks associated with research and development, the regulatory approval process, the workings of regulatory and other authorities, the results of clinical trials, changes in laws and regulations, product quality, patient safety and patent disputes. With regards to projects in its pipeline, Formycon provides no representations, warranties or other guarantees that these will receive the regulatory or other related approvals required for market entry, or that these will be profitable and/or successful.

During 2022, the ongoing coronavirus situation has continued to demand that Formycon make significant changes to its organization and work processes, which the Group has been able to successfully achieve – thanks in no small part to the excellent cooperation and support from its staff. There has, however, been no indication to date of any circumstances arising as a result of COVID 19, neither within the organization nor externally, which would significantly impair the Group's business activities. That being said, the possibility can still not be entirely ruled out that the COVID situation in Germany might again worsen, and/or new restrictive measures be imposed, in such a way as to significantly and adversely impact work activities at Formycon.

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### Overall assessment

Compared to the prior-year period, there has been no fundamental change in the risks facing Formycon Group as these relate to its biosimilar development business activities. The risks with regard to FYB207 as an innovative project are comparable to those of any such innovative biopharmaceutical development project.

At present, no risks can be identified which might endanger the Group's continued existence. Through the use of internal control mechanisms, the Group is in a position to identify changes in its risk exposure at an early stage and to take appropriate action. Furthermore, in view of its financial stability, the Group is well equipped to deal with potential future risks.

Over the past year, the Group has continued to comply with requirements and carry out measures made necessary by the COVID 19 pandemic with minimal impact to its organizational function and business processes. As with so many other companies and industries, the coronavirus crisis has presented Formycon with an array of completely new challenges over the past two years. As a biotechnological company with extensive expertise in antibody development, Formycon has striven to turn these challenges into an opportunity by applying its scientific know-how and specialized resources to the FYB207 project, thus rising to the moment as it reaches beyond its core business of biosimilar development.



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

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

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

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

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

No risks are foreseen which might endanger Formycon Group as a going concern.

Martinsried/Planegg, Germany, July 31, 2022



Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl







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## Condensed Consolidated Interim Financial Statements of Formycon Group

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### Condensed Consolidated Interim Statement of Financial Position as of June 30, 2022

In	Section	June 30, 2022	Dec 31, 2021
<b>Assets</b>			
<b>Non-current assets</b>			
Goodwill	XVI	20,910	-
Other intangible assets	XVI	463,692	727
Right-of-use (ROU) assets	XV	9,402	5,737
Property, plant and equipment	XV	2,545	2,694
Financial assets	XVII	283,730	23,615
<b>Total non-current assets</b>		<b>780,279</b>	<b>32,773</b>
<b>Current assets</b>			
Inventories		2	209
Trade and other receivables		21,450	10,914
Contract assets		616	1,024
Other financial assets		150	150
Prepayments and other assets		2,903	616
Cash and cash equivalents		18,243	25,029
<b>Total current assets</b>		<b>43,364</b>	<b>37,942</b>
<b>Total assets</b>		<b>823,643</b>	<b>70,715</b>
<b>Equity and liabilities</b>			
<b>Shareholders Equity</b>			
Subscribed capital	XVIII	15,065	11,065
Capital reserve	XVIII	341,539	82,785
Accumulated loss carryforward		-37,959	-23,749
Profit (loss) for the period		80,031	-14,210
<b>Total shareholders equity</b>		<b>398,676</b>	<b>55,891</b>
<b>Non-current liabilities</b>			
Non-current lease liabilities		8,075	4,406
Other non-current liabilities	XIX	301,502	-
Deferred tax liabilities	XIII	94,888	-
<b>Total non-current liabilities</b>		<b>404,465</b>	<b>4,406</b>
<b>Current liabilities</b>			
Current lease obligations		956	877
Other current liabilities		9,821	1,935
Trade payables		9,636	7,606
Current income tax liabilities		89	-
<b>Total current liabilities</b>		<b>20,502</b>	<b>10,418</b>
<b>Total liabilities</b>		<b>424,967</b>	<b>14,824</b>
<b>Total equity and liabilities</b>		<b>823,643</b>	<b>70,715</b>

### Condensed Consolidated Interim Statement of Comprehensive Income for the period from January 1, 2022 to June 30, 2022

In €K	Section	Period Jan. 1 – June 30, 2022	Period Jan. 1 – June 30, 2021
Revenue	IX	17,644	20,099
Cost of sales		-12,317	-15,336
Research and development expenses	X	-7,933	-11,771
Selling expenses		-1,140	-203
Administrative expenses		-4,608	-3,102
Other expenses		-161	-175
Other income		-	3
<b>Operating profit/loss (EBIT)</b>		<b>-8,515</b>	<b>-10,485</b>
Finance income	XI	89,781	9
Finance expense	XI	-1,220	-130
<b>Financial result</b>		<b>88,561</b>	<b>-121</b>
<b>Profit before tax</b>		<b>80,046</b>	<b>-10,606</b>
Income tax expense	XIII	-15	-3
<b>Profit (loss) for the period</b>		<b>80,031</b>	<b>-10,609</b>
Other comprehensive income (OCI)		-	-
<b>Comprehensive income (loss) for the period</b>		<b>80,031</b>	<b>-10,609</b>
<b>Basic (undiluted) earnings per share (in €)</b>			
		€ 6.51	€ -0.96
<b>Average number of shares outstanding (undiluted)</b>			
		12,286,972	11,035,650
<b>Diluted earnings per share (in €)</b>			
		€ 6.41	€ -0.96
<b>Average number of shares outstanding (diluted)</b>			
		12,479,722	11,170,000

### Condensed Consolidated Interim Statement of Changes in Equity for the period from January 1, 2022 to June 30, 2022

In €K	Subscribed capital	Capital reserve	Accumulated loss carryforward	Profit (loss) for the period	Total shareholders equity
<b>as of Jan. 1, 2022</b>	<b>11,065</b>	<b>82,785</b>	<b>-23,749</b>	<b>-14,210</b>	<b>55,891</b>
Appropriation of prior-year income (loss)	-	-	-14,210	14,210	-
Common shares issued for acquisitions	4,000	258,400	-	-	262,400
Effect of stock options granted	-	354	-	-	354
Profit for the period	-	-	-	80,031	80,031
<b>as of June 30, 2022</b>	<b>15,065</b>	<b>341,539</b>	<b>-37,959</b>	<b>80,031</b>	<b>398,676</b>
<b>as of Jan. 1, 2021</b>	<b>11,000</b>	<b>80,564</b>	<b>-17,105</b>	<b>-6,644</b>	<b>67,815</b>
Appropriation of prior-year income (loss)	-	-	-6,644	6,644	-
Common shares issued upon subscription (exercise of stock options)	46	898	-	-	944
Effect of stock options granted	-	365	-	-	365
Loss for the period	-	-	-	-10,609	-10,609
<b>as of June 30, 2021</b>	<b>11,046</b>	<b>81,827</b>	<b>-23,749</b>	<b>-10,609</b>	<b>58,515</b>

### Condensed Consolidated Interim Statement of Cash Flows for the period from January 1, 2022 to June 30, 2022

In €K	Period Jan. 1 – June 30, 2022	Period Jan. 1 – June 30, 2022
<b>Comprehensive income (loss) for the period</b>	<b>80,031</b>	<b>-10,609</b>
<b>Adjustments for non-cash items:</b>		
Depreciation and amortization	934	789
Financial Result	-88,562	121
Effect of stock options	354	365
Net loss (gain) arising from disposals of non-current assets	13	5
Income tax expense	15	-
<b>Changes in operating assets and liabilities:</b>		
Decrease (increase) in inventories	324	24
Decrease (increase) in trade and other receivables	2,999	-2,604
Decrease (increase) in contract assets	408	105
Decrease (increase) in other financial assets	-	85
Decrease (increase) in prepayments and other assets	-2,276	-50
Increase (decrease) in other liabilities	-267	169
Increase (decrease) in trade payables	-4,060	4,154
Income taxes paid	-35	-
<b>Net cash from operating activities</b>	<b>-10,122</b>	<b>-7,446</b>
Investments in intangible assets	-2,156	-338
Investments in property, plant and equipment	-169	-220
Investments in financial assets	-4,919	-996
Acquisition of subsidiaries net of cash acquired	1,108	-
Interest received	51	9
<b>Net cash from investing activities</b>	<b>-6,085</b>	<b>-1,545</b>
Proceeds from issuance of shares	-	944
Inflows (outflows) relating to financial liabilities	10,000	-
Payment of lease liabilities	-443	-515
Interest paid	-136	-120
<b>Net cash from financing activities</b>	<b>9,421</b>	<b>309</b>
Net increase (decrease) in cash and cash equivalents	-6,786	-8,682
<b>Cash and cash equivalents as of Jan. 1, 2022</b>	<b>25,029</b>	<b>42,009</b>
<b>Cash and cash equivalents as of June 30, 2022</b>	<b>18,243</b>	<b>33,327</b>



## Notes to the Condensed Consolidated Interim Financial Statements for the period from January 1, 2022 to June 30, 2022

### I Reporting entity

Formycon AG (hereinafter also the "Company"), together with its subsidiaries 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)

### II Basis of accounting

These Condensed Consolidated Interim Financial Statements (hereinafter also the "Financial Statements"), presented here in translation from the German original, have been prepared in accordance with IAS 34 ("Interim Financial Reporting"). They are the Group's first-time interim financial statements prepared in accordance with IFRS for the first period thereunder, and the provisions of IFRS 1 ("First-time Adoption of International Financial Reporting Standards") for interim financial statements have been applied accordingly. As interim financial statements, these do not include all of the explanatory notes typically included in full-year financial statements.

An explanation of how the transition to IFRS has affected the presentation herein of the Condensed Consolidated Interim Statement of Financial Position (interim balance sheet) and Condensed Consolidated Interim Statement of Profit or Loss and OCI (interim income statement) may be found under Note 6, including reconciliation calculations for shareholders equity and comprehensive income for the comparable prior-year periods and for shareholders equity at the time of transition to IFRS (January 1, 2020) based upon the previously published accounts in accordance with German statutory accounting (HGB).

### III 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 (€ K).

### IV Use of judgements and estimates

In preparing these Financial Statements, the Company's Executive Board (Vorstand) 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 Executive Board have an impact on the following specific issues presented herein:

- Business combinations: Valuation of acquired assets and liabilities, in particular acquired intangible assets.

#### 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:

- Valuations under IFRS 2 ("Shared-based payment"): The determinations of the fair value of share-based payment arrangements is based, among other factors, on future market prices and volatilities. These estimated amounts depend upon actual future stock market performance as well as actual future staff turnover, both of which may deviate from the original estimates used in preparing these Financial Statements.

#### 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 acquired intangible assets in determining and allocating the purchase price, and
- Valuation of conditional purchase price payments in determining and allocating the purchase price.

## V Group structure

In addition to the parent entity Formycon AG, Formycon Group also includes, as of June 30, 2022, 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) with effect from May 1, 2022
- Bioeq GmbH (Holzkirchen, Germany) with effect from May 1, 2022

In addition, the following associates, over which Formycon wields significant influence, are included in these Financial Statements using the equity method:

- FYB 202 GmbH & Co. KG (Berlin, Germany) until and ending April 30, 2022, based upon a 24.9% ownership
- Bioeq AG (Zug, Switzerland) with effect from May 1, 2022, based upon a 50% ownership

## VI Accounting and valuation methods

### Basis of valuations

These Financial Statements have been prepared based on the principle of historical cost of acquisition or production.

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

### Principles of consolidation

#### 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), 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. If the contingent consideration is classified as an equity instrument, it is not remeasured, and any difference at the time that the obligation is settled is recognized in the equity account. Otherwise, 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 shares in associates and joint ventures.

Associates and joint ventures are companies over which the Group has significant influence, but not control, with regard to financial and operating policies. Shares in associates and 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 expense.

### Foreign currency

### Revenue from contracts with customers

The amount of revenue from a customer contract is determined based on the consideration specified in the contract. The Group recognizes revenue when it transfers control of the contracted good or service to the customer. Revenue is recorded over the course of completion using the cost-to-cost method. Associated costs are recognized in profit or loss as they are incurred.

The Group generates revenue by passing on its internal and external development costs to the sponsor of the respective project. Revenue is recognized at the time the corresponding expenses are recorded. Services rendered but yet been invoiced are reported as contract assets.

### 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.

#### Share-based compensation

Share-based compensation payments to employees are recognized as an expense in the amount of their fair value upon the grant date, with a corresponding increase in shareholders equity, over the vesting period of the options granted. 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 12 ("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

Termination benefits 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.



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**Government grants**

Government grants relating to the future purchase of assets are initially established in the statement of financial position (balance sheet) as deferred income at fair value provided that there is reasonable assurance that they will be granted and that the Group will meet the conditions attached to the grant. Once such government grant is actually used to fund the purchase of the asset, the deferred income is then amortized over the period of the asset's useful life and recognized in the profit and loss account 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.

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**Finance income and finance expense**

The Group's finance income and finance costs include:

- interest income,
- interest expense,
- dividend income,
- gains and losses arising from valuation at equity of financial assets,
- foreign currency gains and losses on financial assets and financial liabilities, and
- losses arising from the measurement at 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. Dividend income is recognized in profit or loss as of the date that the Group has a legal right to receive payment.

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 impaired, or in the case of a financial liability to the remaining amount thereof. In the case of financial assets which have become 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.

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**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 expense also includes any tax liabilities arising from dividends. 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. For this purpose, the carrying amount of investment property measured at fair value is presumed to be recovered through sale, and the Group has not rebutted this presumption.

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.

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### Inventories

Inventories are measured at the lower of acquisition or production 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.

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### Property, plant and equipment

#### Recognition and measurement

Items of property, plant and equipment are measured at cost of acquisition or production, 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 expected useful life. Depreciation is generally recognized in profit or loss. Land is not depreciated.

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

- Leasehold improvements: based on the term of the underlying lease at the time of the leasehold improvement
- 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.

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### 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 five 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, biosimilar manufacturing process development
- Preclinical testing: in vivo studies generally not necessary, but comprehensive physiochemical and bioanalytical testing leading to technical proof of similarity (TPOS)
- 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 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 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
- Capitalized development costs: 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**

Bei der erstmaligen Erfassung wird ein finanzieller Vermögenswert wie folgt eingestuft und bewertet:

- 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 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.



- 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 on an individual basis. 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.

In preparing these Financial Statements, all of the Group's financial assets have been classified as assets measured at amortized cost.

**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.

**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.

**Interest rate benchmark reform**

Should the basis for determining the contractual cash flows of a financial asset or financial liability measured at amortized cost change as a result of interest rate benchmark reform, the Group updates the effective interest rate of the financial asset or financial liability to reflect the change required by the reform. A change in the basis for determining the contractual cash flows is required due to the interest rate benchmark reform if both of the following conditions are met:

- The change is necessary as a direct consequence of the reform.
- The new basis for determining the contractual cash flows is economically equivalent to the previous basis, i.e. the basis immediately before the change.

If changes are made to a financial asset or financial liability which go beyond the changes to the basis for determining the contractual cash flows required by the interest rate benchmark reform, the Group first adjusts the effective interest rate of the financial asset or financial liability to reflect the change required by the interest rate benchmark reform. Only then does the Group apply the policies on accounting for modifications to the additional changes.

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### Subscribed capital

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

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### Asset impairment

#### Financial assets (excluding derivatives)

##### *Financial instruments and contract assets*

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 significantly overdue, the Group assumes that its credit risk has likewise increased significantly.

Due to the small number of contract counterparties, the Group individually assesses each of these with whom there is significant contract exposure. 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.

#### 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 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.

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

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### 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. In the case of real estate leases, however, the Group has elected not to separate the non-lease components and instead to account for the lease and non-lease components as a single lease.

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 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.

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#### **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.

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#### **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.

In most cases, the best and most objective measure of fair value upon initial recognition of a financial instrument is the actual transaction price, meaning the fair value of the consideration transferred or received. Should the Group determine that the fair value upon initial recognition differs from the actual transaction price but that this fair value is neither (a) evidenced by a quoted price in an active market for an identical asset or liability nor (b) based on a valuation technique in which all unobservable input factors can be considered immaterial, then the financial instrument is initially measured at fair value but adjusted to reflect the difference between the fair value upon initial recognition and the transaction price. This difference is subsequently recognized in profit or loss on an appropriate basis over the life of the instrument but no later than when the valuation is wholly supported by observable market data or the transaction is closed out.



## VII First-time adoption of IFRS

These Financial Statements represent the Group's first (interim) financial statements applying IFRS. The accounting and measurement methods described in Note 5 were fully taken into account in preparing these interim financial statements for the period ending June 30, 2022, for all comparative information as of June 30, 2021 and December 31, 2021, and in the opening balance sheet at the date of transition to IFRS, January 1, 2020. In the course of preparing the opening balance sheet, the Group adjusted the values reported using the previously applied accounting standards (German statutory accounting, or "HGB") accordingly. These adjustments are explained in the following tables and related explanations.

The income statement in accordance with HGB was prepared using the cost by nature method, while in applying IFRS the cost by function method has been applied. As a basis for the reconciliation statement, an income statement was first prepared in accordance with HGB using the cost by function method.

### Reconciliation of book value of equity

In €K	Explanatory notes	Jan. 1, 2020	June 30, 2021	Dec. 31, 2021
<b>Shareholder Equity per HGB</b>		<b>48,211</b>	<b>58,809</b>	<b>56,071</b>
Goodwill	h.)	-433	-197	-118
Depreciation periods per useful economic life	a.)	568	332	324
At Equity measurement	c.)	-48	-47	-46
Application of IFRS 16 "Leases"	b.)	-4	-22	-30
Deferred taxes	d.)	-370	-360	-310
<b>Shareholders Equity per IFRS</b>		<b>47,924</b>	<b>58,515</b>	<b>55,890</b>
Total amount of differences		-287	-294	-181

### Explanatory footnotes

- a.) Depreciation periods for property, plant and equipment have been adjusted on the basis of economic useful life. Under HGB, depreciation is based upon statutory tax depreciation tables.
- b.) Leases have been accounted for as right-of-use (ROU) assets in accordance with IFRS 16 (see also Note 6 "Accounting and valuation methods") and are reported separately.
- c.) The Group's 24.9% interest in associate FYB 202 GmbH & Co. KG was measured at equity using the IFRS equity method based upon the company's equity in accordance with IFRS.
- d.) Deferred tax assets arising from tax loss carryforwards have been limited under IFRS to the amount of deferred tax liabilities because it is not possible for the Group to prove that tax loss carryforwards in excess of this amount can be used.
- e.) Certain asset items (in particular, laboratory material) recorded under HGB as inventory have been reclassified as property, plant and equipment because these asset items may be used for more than 12 months.
- f.) Services to customers performed but not yet invoiced are now reported as contract assets rather than as part of inventory.
- g.) The Group maintains an employee participation program in the form of stock options. In the case of exercise by the respective employee, settlement is made by the issuance of common shares.
- h.) The goodwill recognized in the financial statements in accordance with HGB does not meet the recognition criteria under IFRS and has therefore not been taken into account. Amortization thereof in accordance with HGB has been eliminated accordingly.

Reconciliation of balance sheet  
(Condensed Consolidated Interim Statement of Financial Position)

In €K	Explanatory notes	HGB	Change	IFRS
		Jan. 1, 2020		Jan. 1, 2020
<b>Assets</b>				
<b>Non-current assets</b>				
Goodwill	h.)	433	-433	-
Other intangible assets	a.)	198	42	240
Right-of-use (ROU) assets	b.)	-	5,526	5,526
Property, plant and equipment	a.), e.)	3,701	-547	3,154
Financial assets	c.)	20,673	-48	20,625
Deferred tax assets	d.)	370	-370	-
<b>Total non-current assets</b>		<b>25,376</b>	<b>4,170</b>	<b>29,546</b>
<b>Current assets</b>				
Inventories	e.), f.)	371	-321	49
Trade and other receivables		5,133	-	5,133
Contract assets	f.)	-	171	171
Other financial assets		238	-	238
Prepayments and other assets		156	-	156
Cash and cash equivalents		22,116	-	22,116
<b>Total current assets</b>		<b>28,013</b>	<b>-150</b>	<b>27,863</b>
<b>Total assets</b>		<b>53,389</b>	<b>4,020</b>	<b>57,409</b>
<b>Equity and liabilities</b>				
<b>Shareholders Equity</b>				
Subscribed capital		10,000	-	10,000
Capital reserve	g.)	52,239	2,790	55,029
Accumulated loss carryforward		-14,028	-3,077	-17,105
Profit (loss) for the period		-	-	-
<b>Total shareholders equity</b>		<b>48,211</b>	<b>-287</b>	<b>47,924</b>
<b>Non-current liabilities</b>				
Non-current lease liabilities	b.)	1,030	3,477	4,507
Other non-current liabilities		-	-	-
Deferred tax liabilities		-	-	-
<b>Total non-current liabilities</b>		<b>1,030</b>	<b>3,477</b>	<b>4,507</b>
<b>Current liabilities</b>				
Provisions		25	-	25
Current lease liabilities	b.)	-	830	830
Other current liabilities		1,200	-	1,200
Trade payables		2,404	-	2,404
Current income tax liabilities		520	-	520
<b>Total current liabilities</b>		<b>4,148</b>	<b>830</b>	<b>4,978</b>
<b>Total liabilities</b>		<b>5,178</b>	<b>4,307</b>	<b>9,485</b>
<b>Total equity and liabilities</b>		<b>53,389</b>	<b>4,020</b>	<b>57,409</b>

HGB	Change	IFRS	HGB	Change	IFRS
		June 30, 2021	Dec. 31, 2021		June 30, 2021
197	-197	-	118	-118	-
521	48	569	670	57	727
-	6,256	6,256	-	5,737	5,737
3,695	-845	2,850	3,344	-650	2,694
21,669	-47	21,623	23,661	-46	23,615
360	-360	-	310	-310	-
<b>26,442</b>	<b>4,856</b>	<b>31,298</b>	<b>28,103</b>	<b>4,670</b>	<b>32,774</b>
866	-800	66	1,477	-1,268	209
9,563	-	9,563	10,820	94	10,914
-	650	650	-	1,024	1,024
153	-	153	150	-	150
430	-	430	616	-	616
33,327	-	33,327	25,029	-	25,029
<b>44,340</b>	<b>-150</b>	<b>44,190</b>	<b>38,091</b>	<b>-150</b>	<b>37,941</b>
<b>70,782</b>	<b>4,706</b>	<b>75,488</b>	<b>66,194</b>	<b>4,520</b>	<b>70,715</b>
11,047	-	11,047	11,065	-	11,065
77,886	3,940	81,826	78,436	4,349	82,785
-19,954	-3,796	-23,749	-19,954	-3,796	-23,749
-10,170	-439	-10,608	-13,476	-734	-14,210
<b>58,809</b>	<b>-294</b>	<b>58,515</b>	<b>56,071</b>	<b>-181</b>	<b>55,890</b>
851	4,044	4,895	592	3,814	4,406
-	-	-	-	-	-
-	-	-	-	-	-
<b>851</b>	<b>4,044</b>	<b>4,895</b>	<b>592</b>	<b>3,814</b>	<b>4,406</b>
-	-	-	-	-	-
-	956	956	-	877	877
1,704	-	1,704	1,935	-	1,935
9,418	-	9,418	7,597	10	7,607
-	-	-	-	-	-
<b>11,122</b>	<b>956</b>	<b>12,079</b>	<b>9,532</b>	<b>887</b>	<b>10,419</b>
<b>11,973</b>	<b>5,000</b>	<b>16,973</b>	<b>10,124</b>	<b>4,701</b>	<b>14,825</b>
<b>70,782</b>	<b>4,706</b>	<b>75,488</b>	<b>66,194</b>	<b>4,520</b>	<b>70,715</b>

Reconciliation of income statement  
(Condensed Consolidated Interim Statement of Profit or Loss and OCI)

In €K	Explanatory notes	HGB	Change	IFRS
		Jan. 1 – June 30, 2021		Jan. 1 – June 30, 2021
Revenue		20,261	-162	20,099
Cost of sales	a.)	-15,320	-17	-15,336
Research and development expenses	a.)	-11,617	-154	-11,771
Selling expenses		-203	-	-203
Administrative expenses	a.), b.), g.)	-2,625	-476	-3,102
Other expenses	a.)	-625	450	-175
Other income		3	-	3
<b>Operating profit/loss (EBIT)</b>		<b>-10,126</b>	<b>-358</b>	<b>-10,485</b>
Finance income	b), c.)	9	-	9
Finance expense		-129	-0	-130
<b>Financial Result</b>		<b>-121</b>	<b>-0</b>	<b>-121</b>
<b>Profit before tax</b>		<b>-10,247</b>	<b>-359</b>	<b>-10,606</b>
Income tax expense	d.)	77	-80	-3
<b>Profit (loss) for the period</b>		<b>-10,170</b>	<b>-439</b>	<b>-10,609</b>
<b>Other comprehensive income (OCI)</b>		<b>-</b>	<b>-</b>	<b>-</b>
<b>Comprehensive income (loss) for the period</b>		<b>-10,170</b>	<b>-439</b>	<b>-10,609</b>

In €K	HGB	Change	IFRS
	Jan. 1 – Dec. 31, 2021		Jan. 1 – Dec. 31, 2021
Revenue	36,868	-256	36,613
Cost of sales	-26,426	-76	-26,503
Research and development expenses	-16,450	-356	-16,806
Selling expenses	-600	-	-600
Administrative expenses	-5,512	-1,020	-6,533
Other expenses	-1,247	1,000	-247
Other income	75	-	75
<b>Operating profit/loss (EBIT)</b>	<b>-13,293</b>	<b>-708</b>	<b>-14,001</b>
Finance income	39	-	39
Finance expense	-250	4	-246
<b>Financial Result</b>	<b>-211</b>	<b>4</b>	<b>-207</b>
<b>Profit before tax</b>	<b>-13,504</b>	<b>-704</b>	<b>-14,208</b>
Income tax expense	27	-30	-3
<b>Profit (loss) for the period</b>	<b>-13,476</b>	<b>-734</b>	<b>-14,210</b>
<b>Other comprehensive income (OCI)</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Comprehensive income (loss) for the period</b>	<b>-13,476</b>	<b>-734</b>	<b>-14,210</b>

### Simplifications

IFRS 1 ("First-time Adoption of International Financial Reporting Standards") offers first-time adopters a number of exemptions that may be used in preparing the opening balance sheet. The Group has decided to make use of the following exemptions:

- IFRS 3 ("Business Combinations") has not been applied retrospectively but rather starting only from the date of transition.
- IFRS 16 ("Leases") has not been retrospectively applied in full. Both rights of use assets arising from lease agreements and associated liabilities were remeasured as of the date of the opening IFRS balance sheet based on discounted future cash flows. Only in the case of lease agreements that had already been recognized under HGB (lease purchases) the original (HGB) acquisition costs of the respective assets were assumed into the IFRS balance sheet, with depreciation adjusted according to economic useful life.
- IFRIC 1 ("Changes in Existing Decommissioning, Restoration and Similar Liabilities") has not been applied retrospectively.
- IFRS 15 ("Revenue from Contracts with Customers") has not been applied retrospectively to customer contracts already fulfilled.



## VIII Acquisition of subsidiaries

On May 1, 2022, Formycon acquired a 100% ownership share of FYB 202 Project GmbH (Berlin, Germany), which upon completion of the transaction was renamed "FYB202 Project GmbH" and its location of official registration changed to Martinsried, 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<sup>®1</sup> (ustekinumab), as well as a 50% interest in FYB201, a candidate biosimilar to Lucentis<sup>®2</sup> (ranibizumab). Stelara<sup>®</sup> 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<sup>®</sup> 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 has been 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 company, with the respective partnerships assuming onward development, approval and commercialization. By reacquiring these two biosimilar candidates, Formycon gains 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 have been 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 for a significantly positive EBIT-DA by the year 2025.

In the case of FYB202 Project GmbH and Bioeq GmbH, the identifiable assets and liabilities acquired at the time of acquisition include "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 are performed by the companies themselves or have been outsourced to external service providers. The Group has concluded that the inputs and

processes acquired together contribute significantly to the ability to generate earnings. The Group thus has come 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 include inputs, development processes and an organized workforce. The Group has 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. Bioeq AG is a joint venture with Polpharma Biologics B.V. (Utrecht, Netherlands), which holds the remaining 50% of the company's shares. While the Group does not have outright control, it has significant influence over the company. The shares in the company are thus valued at equity in accordance with IAS 28 "Investments in Associates" and reported under financial assets. In determining the fair value at the time of acquisition, the provisions of IFRS 3 have been applied analogously.

### 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 approved 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 is 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 also subject to a cap. 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. The common shares issued have been 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 € 82,000K was contributed by the seller and assumed by Formycon along with the 50% shareholding in the company. This loan bears a market rate of interest, and therefore the market value of the loan corresponds to its nominal value. Thus, the acquisition costs for the respective transaction components are as follows:

Consideration transferred in €K except as otherwise indicated	FYB202 Project GmbH/ Bioeq GmbH	Bioeq AG	Total
Newly issued common shares (number of shares)	3,330,000	670,000	4,000,000
Newly issued common shares	218,448	43,952	262,400
Cash component	141,727	-	141,727
Earn-out component	54,115	237,387	291,502
less: shareholder loan assumed	-	-82,000	-82,000
<b>Total</b>	<b>414,290</b>	<b>199,339</b>	<b>613,629</b>

<sup>1</sup> Stelara<sup>®</sup> is a registered trademark of Johnson & Johnson.

<sup>2</sup> Lucentis is a registered trademark of Genentech, Inc.

### Acquisition-related costs

The Group incurred costs of € 420K for legal advice and due diligence in connection with the business combination. These costs are 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.

in T€	FYB202 Project GmbH & Bioeq GmbH	Bioeq AG, (at 50% equity)
Intangible assets	460,883	276,054
Property, plant & equipment	50	157
Deferred tax assets	-	3,209
Inventories	-	2,070
Trade and other receivables	13,662	2,173
Cash and cash equivalents	19,871	942
<b>Total assets</b>	<b>494,466</b>	<b>284,605</b>
Net Assets	393,381	170,226
Non-current liabilities	-	82,156
Current liabilities	6,197	398
Deferred tax liabilities	94,888	31,825
<b>Total equity and liabilities</b>	<b>494,466</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. In the case of customer relationships, the residual value method values these as the present value of the expected future net cash flows generated therefrom, excluding any cash flows associated with supporting assets.
- 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 Project GmbH (full rights to the FYB202 development project) and Bioeq AG (commercialization rights to the FYB201 development project) have been provisionally determined pending a complete and independent valuation.

To the extent that any new information becomes known within one year of the acquisition date regarding facts and circumstances existent as of the acquisition date that would have led to adjustments to the above amounts, or to additional provisions, the relevant assets and liabilities relating to the business combination will be adjusted accordingly.

### Goodwill

Goodwill resulting from the acquisition of the subsidiaries and associate has been measured and recognized as follows, whereby the goodwill of associate 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.

in €K	FYB202 Project GmbH & Bioeq GmbH	Bioeq AG
Consideration transferred	414,290	199,339
Fair value of identifiable net assets	393,381	170,226
Difference (goodwill)	20,910	29,113

### Financial performance since acquisition

In the case of the acquired subsidiaries FYB202 Project GmbH and Bioeq GmbH, revenue of € 2,321K and a contribution to earnings of negative € 983K have been recorded since the acquisition date. Continuation of the valuation at equity of Bioeq AG has led to a pro rata loss of € 1,108K. This financial performance is in line with expectations at the time of acquisition.

## IX Revenue

### Revenue streams

During the period, Formycon generated revenue exclusively by passing on the external and internal development costs arising from its partnered development projects FYB201 and FYB203, as well as from FYB202 up until and including April 30, 2022, to the respective development partners. These costs include not only product development costs but also costs incurred for the management of clinical studies.

### Geographical breakdown of revenue

During the period, the Group's revenues were generated entirely in Germany and Switzerland as follows:

in €K	Jan. 1 – June 30, 2022	Jan. 1 – June 30, 2021
Germany	12,125	13,751
Switzerland	5,519	6,348
<b>Total</b>	<b>17,644</b>	<b>20,099</b>

### Contract assets

Assets arising from contracts with customers are included in trade and other receivables. As of the reporting date, these included receivables from customers in the amount of € 5,826K (1H 2021: € 9,455K). Receivables from services not yet invoiced, however, are separately reported as customer contracts in the amount of € 616K (1H 2021: € 1,024K).

## X Government grants

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 Forschungsstiftung), an agency of the Bavarian state government, as well as under the Bavarian state government's special "BayTherapie 2020" grant program. Grant awards in the amount of € 3,894K (1H 2021: € 13K) 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 € 1,561K (1H 2021: € 35K).

## XI Finance income/expense

The Group's finance income and finance expense during the reporting period were as follows:

in T€	June 30, 2022	June 30, 2021
Realized and unrealized gains from foreign currency translation	5	9
Investment gain from FYB 202 GmbH & Co. KG	89,776	-
<b>Finance income</b>	<b>89,781</b>	<b>9</b>
Bank fees	-8	-5
Realized and unrealized losses from foreign currency translation	-65	-45
Interest expense from lease liabilities	-33	-11
Interest paid	-6	-69
Share of loss from associate Bioeq AG	-1,108	-
<b>Finance expense</b>	<b>-1,220</b>	<b>-130</b>
<b>Net finance income</b>	<b>88,561</b>	<b>-121</b>

The investment gain from FYB 202 GmbH & Co. KG was generated through the termination of the Group's ownership share in this entity and ensuring distribution of assets on May 1, 2022, as a result of which the Group assumed assets in the amount of € 114,811K. The gain represents the different between this amount and the previous valuation at equity in the book value amount of € 25,035K.



## XII Share-based staff compensation

### 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 Executive 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 Executive 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 relevant 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:

Share options issued and outstanding	Stock Option Plan 2015	Stock Option Plan 2020
	<b>Stand 01.01.2021</b>	<b>376.000</b>
Shares subscribed March 2021	-46.500	-
<b>(options exercised)</b>	<b>329.500</b>	<b>49.000</b>
Shares subscribed October 2021	-18.250	-
Shares granted Oct. / Dec. 2021	-	52.500
as of Dec. 31, 2021	311.250	101.500
<b>as of June 30, 2022</b>	<b>311.250</b>	<b>101.500</b>

*No options expired in either the reporting period or the comparable prior-year period.*

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 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%.

Stock Option Plan	Tranche	Grant date	Vesting date	Remaining until vesting	Expiry date
2015	1	JULY 16, 2015	July 16, 2019	0.00	July 15, 2025
2015	2	June 28, 2016	June 28, 2020	0.00	June 27, 2026
2015	3	Oct. 4, 2016	Oct. 4, 2020	0.00	Oct. 3, 2026
2015 (amended)	4	July 3, 2017	July 3, 2021	0.00	July 2, 2027
2015 (amended)	5	Feb. 28, 2018	Feb. 28, 2022	0.00	Feb. 27, 2028
2015 (amended)	6	Apr. 1, 2018	Apr. 1, 2022	0.00	Mar. 31, 2028
2015 (amended)	7	July 1, 2018	July 1, 2022	0.00	June 30, 2028
2015 (amended)	8	July 10, 2019	July 10, 2023	1.03	July 9, 2029
2020	1	Dec. 16, 2020	Dec. 16, 2024	2.47	Dec. 15, 2030
2020	2	Oct. 19, 2021	Oct. 19, 2025	3.31	Oct. 18, 2031
2020	3	Dec. 9, 2021	Dec. 9, 2025	3.45	Dec. 8, 2031

Expected exercise date	Expected term	Market price at grant date in €	Strike price in €	Share price floor (hurdle) in €	Market value of options in €
Nov. 15, 2020	5.34	27.10	30.98	29.36	8.4058
Oct. 29, 2021	5.34	17.51	22.77	22.70	4.7053
Feb. 4, 2022	5.34	19.90	19.46	21.42	7.0826
Nov. 3, 2022	5.34	34.32	36.62	36.16	11.1178
July 1, 2023	5.34	33.10	31.73	34.95	11.1551
Aug. 2, 2023	5.34	32.20	31.74	35.04	10.6511
Nov. 1, 2023	5.34	35.00	36.07	39.33	10.3722
Nov. 9, 2024	5.34	30.40	32.83	36.04	8.0761
Apr. 18, 2026	5.34	58.40	47.57	38.32	22.2827
Feb. 19, 2027	5.34	53.30	51.72	57.71	18.1448
Apr. 11, 2027	5.34	53.60	49.78	55.00	18.9723

### XIII Income tax expense

#### Components of income tax expense

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

in €K	Jan. 1 – June 30, 2022	Jan. 1 – June 30, 2021
Current tax expense	15	3
<b>Deferred tax expense</b>		
from at equity measurement	-3,551	-
from measurement of non-current assets	2	1
from capitalization of certain leases as right-of-use (ROU) assets net of corresponding lease liabilities	-33	-
from capitalization of certain internally generated intangible assets	544	-
from deferred taxes on tax loss carryforwards	-	-
from valuation adjustments to deferred tax assets	3,039	-1
<b>Total tax expense</b>	<b>15</b>	<b>3</b>

As of the reporting date, deferred tax assets and deferred tax liabilities consisted of the following items:

in T€	June 30, 2022		Dec. 31, 2021	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
At Equity measurement	296	-	-	3,255
Measurement of non-current assets	-	601	-	55
Right-of-use (ROU) assets and corresponding leasing obligations	38	-	5	-
Arising from purchase price allocation to capitalized assets	-	94,888	-	-
Tax loss carryforwards - Formycon AG corporate tax (Körperschaftsteuer)	7,742	-	7,742	-
Tax loss carryforwards - Formycon AG trade tax (Gewerbesteuer)	3,655	-	3,655	-
Offset (netting) of deferred tax assets and liabilities	-601	-601	-3,310	-3,310
Valuation adjustment to deferred tax assets	-11,131	-	-8,093	-
<b>Total</b>	<b>-</b>	<b>94,888</b>	<b>-</b>	<b>-</b>

In accordance with IAS 34 ("Interim Financial Reporting"), income taxes for these Financial Statements have been determined based on the average annual tax rate expected for the full fiscal year. For both the reporting period and prior-year comparable period, the effective tax rate was 0%.

### XIV Earnings before interest, tax, depreciation and amortization (EBITDA)

The Executive Board additionally presents earnings before interest, taxes, depreciation and amortization (EBITDA) in this section of the Financial Statements because it relies upon consolidated EBITDA as a key performance measure in managing the Group and believes that this measure is relevant to an understanding of the Group's financial performance. EBITDA is derived and calculated from reported operating profit (EBIT). While EBITDA is not a defined performance measure under the IFRS cost of sales method, the Group's definition of EBITDA is consistent with usual definitions.

EBITDA for the reporting period is derived and calculated as follows:

in €K	Jan. 1 – June 30, 2022	Jan. 1 – June 30, 2021
Operating income (EBIT)	-8,515	-10,485
Depreciation of property, plant and equipment	354	318
Depreciation of right-of-use (ROU) assets	505	431
Amortization of intangible assets	75	40
<b>EBITDA</b>	<b>-7,581</b>	<b>-9,696</b>

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

### Reconciliation of book value

in €K	Right-of-use (ROU) assets	Property, plant and equipment	Leasehold improvements	Technical equipment and machinery	Other equipment and furnishings
Cost as of Jan. 1, 2022	7,651	6,659	613	4,082	1,963
Additions due to business combinations	-	50	-	-	50
Additions	4,170	169	31	114	25
Disposals	-	-120	-	-108	-12
Cost as of June 30, 2022	11,821	6,757	644	4,087	2,026
Accumulated depreciation as of Jan. 1, 2022	-1,914	-3,964	-368	-2,493	-1,103
Additions	-505	-354	-28	-206	-121
Disposals	-	107	-	102	5
Accumulated depreciation as of June 30, 2022	-2,419	-4,212	-396	-2,597	-1,219
Net book value as of Jan. 1, 2022	5,737	2,694	246	1,589	860
Net book value as of June 30, 2022	9,402	2,545	248	1,490	807

#### 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 vehicles leased for employee use. During the reporting period, 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).

## XVI Goodwill and other intangible assets

### Reconciliation of book value

in €K	Licenses and similar rights	Software	Prepayments for intangible assets	Total
Cost as of Jan. 1, 2022	324	813	81	1,218
Additions due to business combinations	460,882	1	-	460,883
Additions	2,053	103	-	2,156
Rebookings	-	18	-18	-
Disposals	-	-	-	-
Cost as of June 30, 2022	463,259	935	62	464,257
Accumulated amortization as of Jan. 1, 2022	-47	-444	-	-490
Additions	-17	-57	-	-75
Disposals	-	-	-	-
Accumulated amortization as of June 30, 2022	-64	-501	-	-565
Net book value as of Jan. 1, 2022	277	370	81	727
Net book value as of June 30, 2022	463,195	434	62	463,692

For more detailed information on the relevant acquisitions, see Note 8 ("Acquisition of Subsidiaries").

## XVII Financial assets

### Reconciliation of book value

in €K	Investment participation FYB 202 GmbH & Co. KG	Investment participation Bioeq AG	Loan to associate Bioeq AG	Total
Cost as of Jan. 1, 2022	23,615	-	-	<b>23,615</b>
Additions due to business combinations	-	-	-	-
Additions	1,419	199,339	85,500	<b>286,258</b>
Rebookings	-	-	-	-
Disposals	-25,035	-1,108	-	<b>-26,143</b>
Cost as of June 30, 2022	-	198,230	85,500	<b>283,730</b>
Accumulated amortization as of Jan. 1, 2022	-	-	-	-
Additions	-	-	-	-
Disposals	-	-	-	-
Accumulated amortization as of June 30, 2022	-	-	-	-
Net book value as of Jan. 1, 2022	23,615	-	-	<b>23,615</b>
Net book value as of June 30, 2022	-	198,230	85,500	<b>283,730</b>

### Shareholdings in associated companies

During the reporting period, the Group ceased to be a shareholder in its heretofore associate FYB 202 GmbH & Co. KG. The gain from the ensuing distribution of assets is recognized in period finance income. Reference is further made to the other relevant explanatory notes.

As a component of the transaction described in the above Note 8 ("Acquisition of Subsidiaries"), the Group became a 50% shareholder and joint venture partner of Bioeq AG (Zug, Switzerland). For details of the valuation at the time of acquisition, reference is made to the explanation in Note 8.

### Loans to associated companies

Together with the acquisition of the shares in Bioeq AG, the Group acquired a loan receivable from Bioeq AG in the amount of € 82,000K. By the end of the period on June 30, 2022, the loan had been increased by a further € 3,500K to € 85,500K within the contractual loan framework amount of € 99,000K through a further loan drawdown. 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.

## XVIII Shareholders equity

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

### Number of shares outstanding

The Company has subscribed capital of € 15,064,750.00, which is divided into 15,064,750 bearer shares without par value.

### Approved Capital 2019

By resolution of the Annual General Meeting of June 27, 2019, the Executive 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 June 26, 2024, and by no more than a total of € 4,000,000, through the issuance of up to 4,000,000 new no-par-value common bearer shares, against contributions in cash and/or in kind (the "Approved Capital 2019"). 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 Company's shareholders shall, in general, be granted subscription rights. The shares may, however, also be assumed by one or more banks subject to the obligation that they offer these to the Company's shareholders for subscription (indirect subscription rights). Notwithstanding the foregoing, the Executive Board is authorized, subject to the approval of the Supervisory Board, to 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 that the capital increase is made against cash contributions and the issue price of the new shares is not significantly lower than the stock exchange price and the new shares issued under exclusion of subscription rights do not exceed 10% of the share capital, either at the time this authorization takes effect or at the time this authorization is exercised, whereby this 10% limit is to be calculated based on the proportion of share capital attributable to new shares issued, or repurchased treasury shares sold, subsequent to December 10, 2020 under a simplified exclusion of subscription rights pursuant to or in accordance with sec. 186 para. 3 sentence 4 of the German Stock Corporation Act, as well as calculated based on the proportion of share capital relating to stock options and/or conversion rights or obligations arising from bonds issued subsequent to December 10, 2020, likewise in accordance with sec. 186 para. 3 sentence 4 of the Stock Corporation Act.
- In the case of capital increases against non-cash contributions for the granting of shares for the purchase of companies, parts of companies, or equity interests in companies (including increases of existing equity investments), or in satisfaction of financial obligations of the Company.



The Executive Board is authorized, subject to approval of the Supervisory Board, to determine further details regarding the specific implementation of any such capital increase from Approved Capital 2019. The Supervisory Board is further authorized to amend the Company's articles of incorporation (Satzung) to reflect the increase in registered capital and corresponding decrease in Approved Capital 2019 in the event of any such full or partial utilization of the Approved Capital 2019, or in the event of its expiry.

This action was entered into the Company's commercial register on October 22, 2020.

With increase in the Company's registered capital increased by € 4,000,000.00 through the issue of 4,000,000 new shares during the first half of 2022, the Approved Capital 2019 has now been fully utilized.

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#### Approved Capital 2022

By resolution of the Annual General Meeting of June 30, 2022, the Executive 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 June 29, 2027, and by no more than a total of € 7,532,375.00, through the issuance of up to 7,532,375 new no-par-value common bearer shares, against contributions in cash and/or in kind (the "Approved Capital 2022"). The Company's shareholders shall, in general, 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 Executive 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 approved capital.

The Executive 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 Approved Capital 2022 in the event of any such full or partial utilization of the Approved Capital 2022 or in the event of its expiry.

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#### Conditional Capital 2019

By resolution of the Annual General Meeting of June 30, 2022, the Conditional Capital 2019 has been revoked.

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#### 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 for the issuance of a maximum of 6,497,125.00 new no-par-value bearer shares (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 financial 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 Executive Board is authorized, subject to the approval of the Supervisory Board, to determine further details regarding the specific implementation of any capital increases hereunder.

#### 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 Executive 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 Executive 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 Executive 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.

As of the period closing date, a total of 311,250 stock options remained issued under the Conditional Capital 2015 and not either expired or exercised.

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

#### 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 Executive 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 Executive 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 Executive 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.

As of the period closing date, a total of 101,500 stock options were issued thereunder and not either expired or exercised.

### XIX Other non-current liabilities

Other non-current liabilities include the conditional purchase price payments relating to the acquisition of subsidiaries, as described in the above Note 8 ("Acquisition of subsidiaries"), in the amount of € 291,502K (previous year: € 0K) and loans from shareholders in the amount of € 10,000K.

As part of the described strategic transaction, the Group was granted a credit line in the amount of € 50,000K by its shareholders (or associated companies thereof), with loans thereunder bearing interest at a market (arm's length) rate. As of the reporting date, € 10,000K of this credit line was drawn by the Group and outstanding.

## XX Transactions with related parties

### Members of management in key positions and members of Supervisory Board

Apart from regular remuneration, there were no transactions with members of management or members of the Supervisory Board during either the reporting period or the prior-year period.

### Related companies

Prior to the completion of the transaction summarized in the above Note 8 "Acquisition of subsidiaries", the Group had not entered into any transactions with related companies. Due to the acquisition of the 26.55% shareholding in Formycon AG, ATHOS Group member companies may, with effect from May 1, 2022, be regarded as related companies. Klinge Biopharma GmbH, as development partner for the FYB203 project, may likewise be regarded as a related company with effect from May 1, 2022.

Also with effect from May 1, 2022, the Group became a shareholder in Bioeq AG, development partner for the FYB201 project, which is thereby an associated company.

Subsequent to May 1, 2022 and during the reporting period, sales revenue of € 4,428K was recognized with related companies and trade receivables of € 4,652K recognized in the balance sheet. All transactions with related companies are carried out under usual market (arm's length) conditions.

In addition to the development partnerships and the resulting sale revenue and trade receivables, the Group has received loans from shareholders (see "19. Other non-current liabilities").

## XXI Events subsequent to end of reporting period

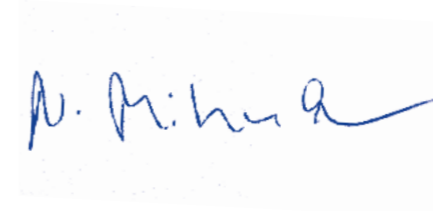
There have been no events of material significance which occurred following the end of the reporting period and are not reflected in these Financial Statements.

With regard to the ongoing COVID 19 pandemic, Formycon has been able to adapt well to the prevailing situation by reacting promptly and by implementing appropriate measures to decentralize organizational functions, so that the impact of the pandemic on the Group's operational activities, particularly for development, has thus far been minimal.

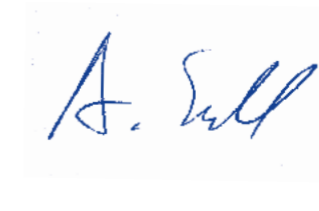
Martinsried/Planegg, Germany, July 31, 2022



Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

## Legal information

<b>Company name:</b>	Formycon AG
<b>Legal form:</b>	German stock corporation (Aktiengesellschaft)
<b>Registered location:</b>	Martinsried/Planegg, Germany
<b>Street address:</b>	Fraunhoferstr. 15, 82152 Martinsried/Planegg, Germany
<b>Company founding and articles of incorporation:</b>	The Company was established through its articles of incorporation (Satzung) dated 5 May 2010, which were most recently amended on December 1, 2021.
<b>Subject of business:</b>	The subject of the Company's business is the development of pharmaceutical and biopharmaceutical products, the development of drug delivery systems, the provision of diagnostic laboratory services and works for third parties, and the carrying out of diagnostic laboratory services.
<b>Commercial register:</b>	The Company is entered into the commercial register (Handelsregister) of the District Court of Munich under number HRB 200801.
<b>Fiscal year:</b>	The Company's fiscal year runs from January 1 to December 31 of each year.
<b>Registered capital:</b>	15.064.750 €
<b>Executive Board (Vorstand):</b>	Dr. Stefan Glombitza Nicola Mikulcik Dr. Andreas Seidl
<b>Supervisory Board (Aufsichtsrat):</b>	Dr. Olaf Stiller, residing in Marburg, Chairman Peter Wendeln, residing in Oldenburg, Deputy Chairman Klaus Röhrig, residing in Vienna (Austria), Member Dr. Thomas Strüngmann, residing in Pinneberg, Member (with effect from July 1, 2022)





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## Interim Management Report for Formycon AG

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Interim Management Report for Formycon AG for the period from January 1 to June 30, 2022

I Basic information about Formycon AG

Business model

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

Formycon AG (hereinafter the “Company”) 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.

Following the successful approval of FYB201, a biosimilar to Lucentis® , our development pipeline now includes five further biosimilar projects and an innovative COVID 19 drug. Of these, two biosimilar projects are in advanced (phase III) stages of clinical development, while the remaining three as yet unannounced biosimilar candidates are in preclinical development.

Formycon’s preferred path is to independently develop its biosimilar drug candidates through to final development stages and then, as they approach market readiness, to transfer them completely or partially to commercialization partnerships for global marketing. The cash flows generated from the sale of these approved and commercialized biosimilar products then provide Formycon with the financial means to further expand its development pipeline. Formycon thus has a promising position and significant growth potential in the rapidly expanding market for biosimilars.

Business objective and strategy

Formycon is positioned as a highly specialized expert in biosimilar drug development and able, with its current resources, to carry out multiple biopharmaceutical projects in parallel. Our strategy for long-term growth is based upon the step-by-step expansion of our project pipeline through the targeted selection of additional biosimilar candidates, their laboratory and clinical development, and their eventual commercialization, preferably through commercialization partnerships.

Scope of business activity

With the help of our biosimilars, ever more patients around the globe will have access to high-quality, important biopharmaceuticals for the treatment of serious diseases. Through our work, we aim not only to improve care for patients worldwide but also to contribute to relieving the financial burden on healthcare systems.

Formycon’s current business activities may be summarized as follows

- The Company’s primary and core business, and the center of its strategy for sustainable long-term growth, is the development of biosimilar medicines.
- At the start of the coronavirus crisis, Formycon initiated development of an innovative COVID 19 fusion protein based upon its extensive experience in the development of biopharmaceuticals and as a contribution to the global fight against the pandemic. In order to maximize the potential and speed of our product development approach, our plan for the innovative COVID 19 project is to transfer it into a strategic global partnership for development and commercialization at an early stage.

These two product development areas are fundamentally different in terms of their respective risk profiles. While biosimilar drug development takes a confirmatory approach, whereby the biosimilar candidate is designed from the start to be comparable to the reference drug and is accordingly managed over the entire development period of typically six to eight years, the research and development process for an innovative originator biopharmaceutical entails an exploratory approach and thus a significantly higher level of development risk.

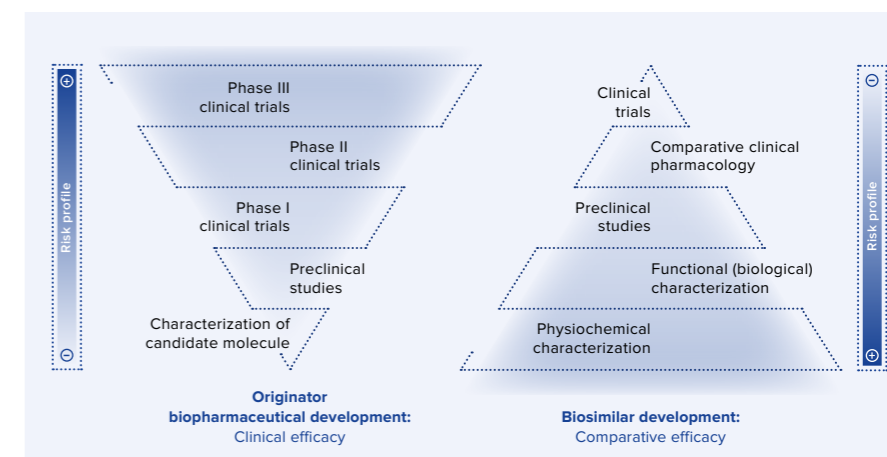


Figure 1: Risk profile for innovative biopharmaceutical development vs. biosimilar development

<sup>1</sup> Lucentis® is a registered trademark of Genentech, Inc.

**As of June 30, 2022, Formycon was working on the following development projects within its principal business of biosimilars:**



FYB201 is a candidate biosimilar to Lucentis® (ranibizumab), an ophthalmic drug used in the treatment of neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases such as diabetic macular edema (DME), diabetic retinopathy (DR), macular edema secondary to retinal vein occlusion (RVO) and myopic choroidal neovascularization (mCNV).

During the first half of 2022, the focus of the Company’s activities was on the respective pending approval processes at the U.S. Food and Drug Administration (FDA), at the European Medicines Agency (EMA) and in the United Kingdom, where FYB201 received final approval from the Medicines and Healthcare products Regulatory Agency (MHRA) in May 2022. A positive opinion was received from the EMA’s Committee for Medicinal Products for Human Use (CHMP) in June, marking an important step towards final approval in the European Union. FYB201 will be marketed in the UK and Europe by Teva Pharmaceutical Industries Ltd. and in the United States by Coherus BioSciences, Inc.



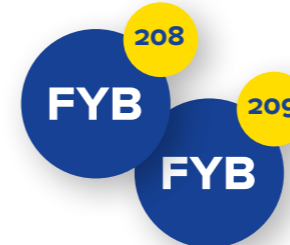
FYB202 is a candidate biosimilar to Stelara® (ustekinumab), a biopharmaceutical used in the treatment of various serious inflammatory diseases, such as moderate to severe psoriasis, Crohn’s disease, and ulcerative colitis. Over the past full year, Stelara® generated global sales revenue of USD 9.1 billion. In addition to completion of treatment of all patients in the phase III clinical trials (“last patient out”), our activities during the first half of 2022 focused on the evaluation of the resulting phase III data regarding the primary efficacy endpoint and on the initiation of an additional phase I comparative pharmacokinetics study.



FYB203 is a biosimilar candidate for Eylea® (aflibercept). Similarly to Lucentis®, Eylea® is used to treat neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases, with 2021 global sales revenue of USD 9.0 billion. April 2022 marked an important development milestone, namely the completion of patient recruitment for phase III clinical trials (“last patient in”).



FYB206 is a Formycon-initiated biosimilar candidate in the advanced preclinical stage for which the project rights are 100% owned by Formycon.



FYB208 and FYB209, which commenced during the first half of 2022, are Formycon’s two newest biosimilar development initiatives. Formycon holds 100% of the project rights to both.

<sup>1</sup> Lucentis® ist eine eingetragene Marke von Genentech Inc.

<sup>2</sup> Stelara® ist eine eingetragene Marke von Johnson & Johnson.

<sup>3</sup> Eylea® ist eine eingetragene Marke von Regeneron Pharmaceuticals Inc.

As of June 30, 2022, Formycon was working on the following development project within the area of COVID 19 drug development:



Upon the initial outbreak of the coronavirus pandemic in Europe, and drawing upon Formycon's extensive and clinically validated experience with antibodies and antibody fusion proteins, the Company launched a new project, FYB207, to develop an innovative COVID 19 fusion protein.

For its FYB207 project, Formycon has been working closely with two renowned academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, to develop an efficient antiviral and broad-spectrum SARS CoV 2 blocker on the basis of a long-acting ACE2-immunoglobulin fusion protein. Through an *in vitro* study, Formycon has already been able to demonstrate that FYB207 completely inhibits the infection of cells while preserving natural enzyme activity and, moreover, that it is able to effectively neutralize all SARS CoV 2 virus variants tested to date (**alpha, beta, delta and omicron**). Compared to vaccines and neutralizing antibodies, FYB207's active ingredient offers, through its particular biological mechanisms, a maximum of protection against virus breach through mutation.

Formycon holds 100% of the rights to the FYB207 innovative COVID 19 drug development project.

#### A brief explanation of how the COVID-19 fusion protein works

#### SARS-CoV-2 infection pathway

SARS-CoV-2 and other coronaviruses exploit the ACE2 protein (angiotensin-converting enzyme 2) on the surface of human cells as an entry point to infect the respiratory tract. The virus achieves this by using its spike 1 protein to bind to ACE2 on the surface of target cells. After docking, the virus is then absorbed into the cell (Figure 2).

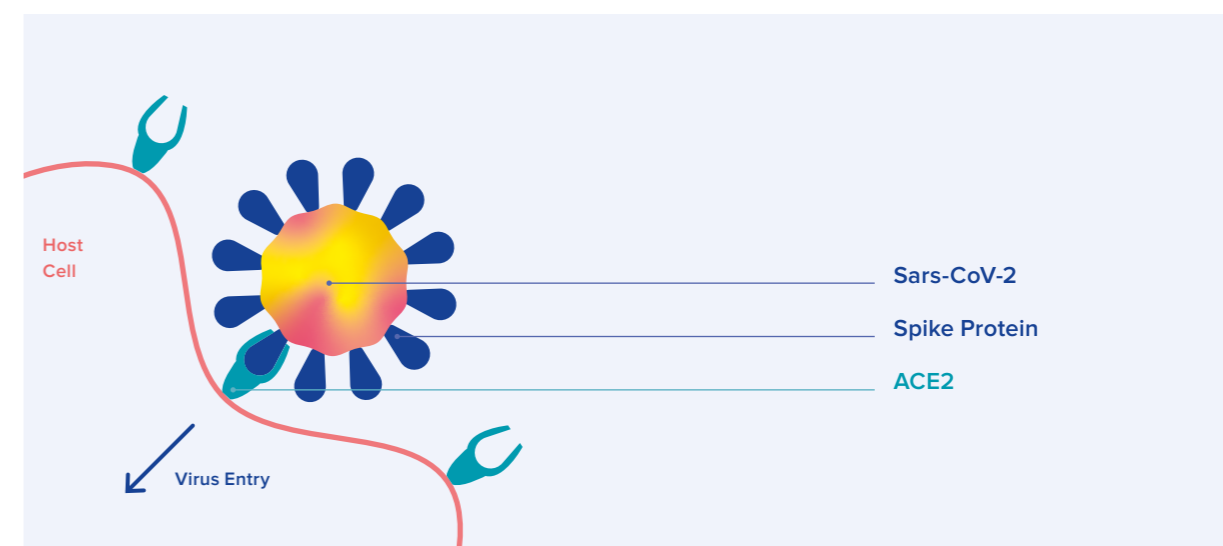


Figure 2 : SARS-CoV-2 infection pathway

#### The FYB207 fusion protein and its unique mechanism of action

Laboratory studies have shown that the introduction of a soluble form of ACE2 blocks the SARS-CoV-2 and earlier SARS-CoV coronaviruses, thereby preventing cells from becoming infected. Formycon has built on this scientific knowledge by linking the human ACE2 protein with the constant portion of the human immunoglobulin G (IgG) protein using computer-aided structural design techniques (Figure 2), thereby creating a highly effective SARS CoV 2 blocker (FYB207). Formycon has demonstrated, through *in vitro* testing, that FYB207 completely prevents the infection of cells. Because ACE2 is the human receptor for the spike protein used by the SARS-CoV-2 virus to gain entry, FYB207 provides maximal protection even against attempts by the virus to evade the block through mutation (Figure 3). In addition, FYB207 can potentially be used to defend against any other coronaviruses or variants which exploit ACE2 as an entry point for cell infection.

Based on the findings of preclinical studies carried out in 2021, Formycon has been able to make defined proprietary modifications to the FYB207 molecular structure, resulting in a significant improvement in bioavailability.



**Activity of FYB207 in known SARS-CoV-2 variants**

Previously published laboratory studies<sup>1</sup> have shown that FYB207 retains its full anti-viral potential even against the SARS-CoV-2 alpha, beta and delta variants. New laboratory data now further show that the improved drug molecule, in contrast to vaccines and therapeutic antibodies, likewise neutralizes the currently predominant omicron variant with a high level of efficacy.

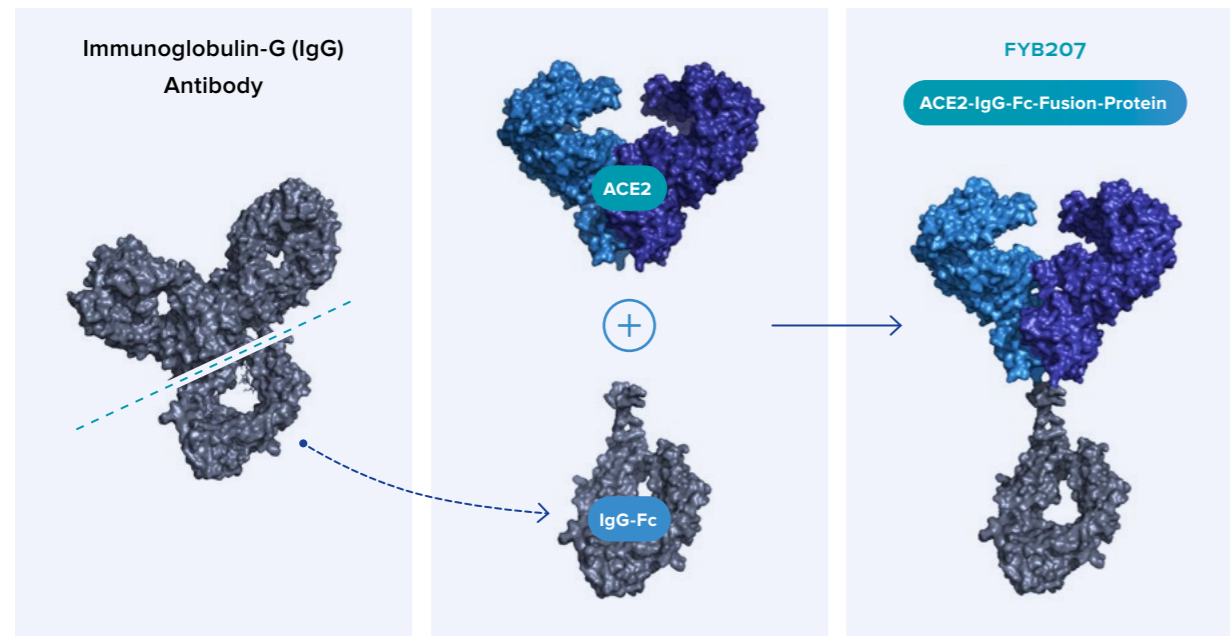


Figure 3: Composition of the FYB207 fusion protein

<sup>1</sup> „Picomolar inhibition of SARS-CoV-2 variants of concern by an engineered ACE2-IgG4-Fc fusion protein“ (<https://doi.org/10.1016/j.antiviral.2021.105197>)

With FYB207, Formycon is thus developing a novel anti-COVID-19 drug which promises to be both effective and long-lasting.

Possible future indications for FYB207 include hospitalized COVID-19 patients, newly infected but asymptomatic COVID-19 patients, and preventive use in risk situations such as care facilities.

Large molecules have specific advantages over small-molecule antiviral drugs, in particular their significantly longer half-life, thus making them potentially suitable for prophylactic use.

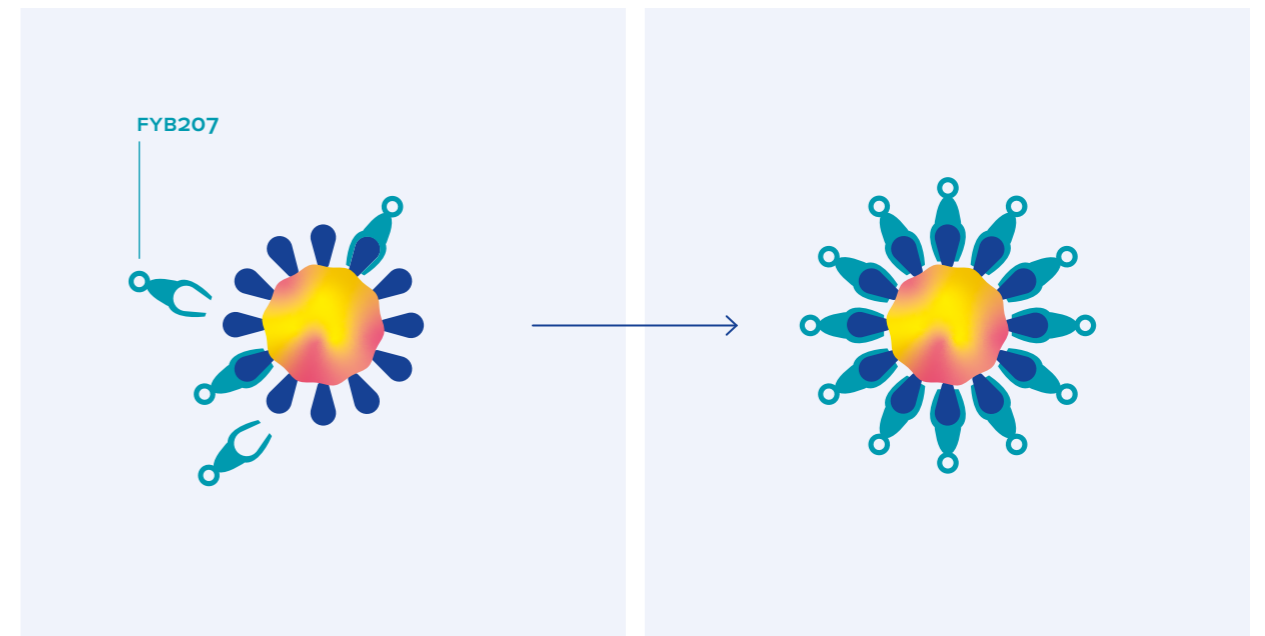


Figure 4: FYB207's mechanism of action

The natural enzyme activity of ACE2 may possibly serve to protect vital organs such as the lungs, and thus another potential indication for FYB207 might be in the treatment of acute respiratory distress syndrome (ARDS) of various etiologies.

**Structure of Formycon Group**

As a result of the strategic transaction concluded during the first half of 2022 with the family office of the Strüngmann family (ATHOS KG), the structure of Formycon Group has undergone changes. Under the transaction, Formycon acquired full rights to FYB202, a candidate biosimilar to Stelara®, and a 50% interest in FYB201, a candidate biosimilar to Lucentis®. In addition, through the acquisition and integration of long-term partner Bioeq GmbH, Formycon has been able to expand its resources and expertise in several areas important for the development, approval and commercialization of biosimilars.

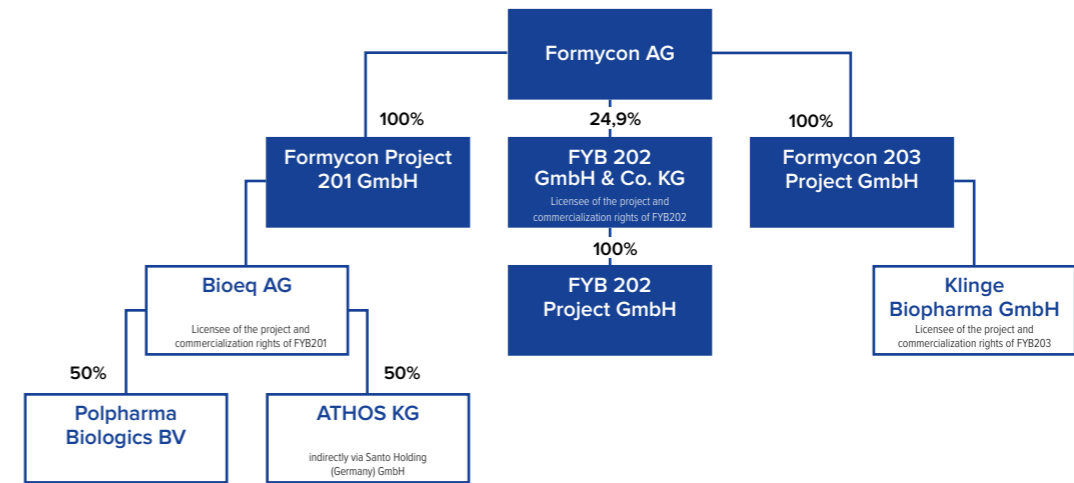
Formycon Group thus now consists of the **parent entity, Formycon AG**, along with its **100%-owned subsidiaries Formycon Project 201 GmbH, FYB202 Project GmbH, Formycon Project 203 GmbH and Bioeq GmbH**. In addition, Formycon owns **50%** of the shares of **Bioeq AG**, a joint venture between **Formycon** and **Polpharma Biologics BV**, which holds the project and commercialization rights to FYB201.

Formycon AG, the parent entity, is a German stock corporation (Aktiengesellschaft) listed on the Frankfurt Stock Exchange within the Scale (Open Market) segment for growth companies. Like all companies governed by the German Stock Corporation Act (Aktiengesetz), the company has a dual board structure with the Executive Board (Vorstand) as the managing body. The members of the Executive Board are appointed and monitored by the Supervisory Board (Aufsichtsrat). The members of the Supervisory Board of Formycon AG, of which there were three as of June 30, 2022, are elected by shareholders through the Annual General Meeting.

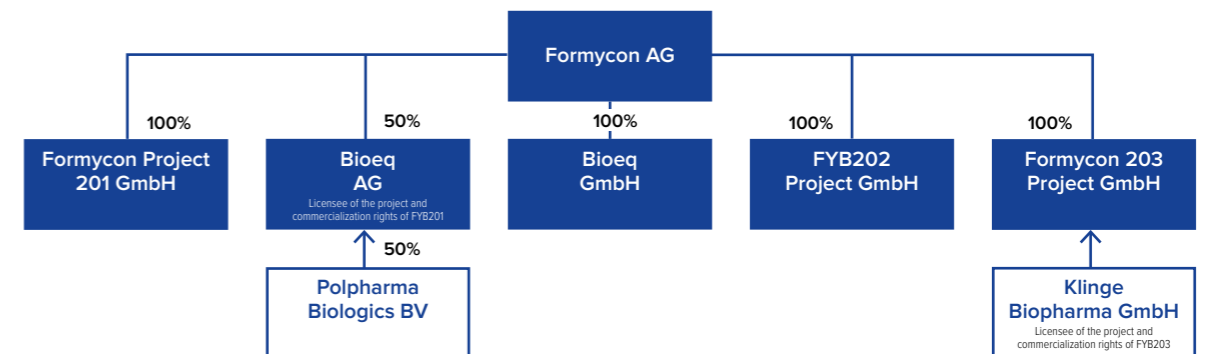
The **corporate structure of Formycon Group** reflects the establishment of dedicated legal entities for certain individual biosimilar projects, particularly in advanced stages of development. Formycon AG performs research and development activities not only for its own projects but also on behalf of its affiliated companies (subsidiaries) and development partners. Reported sales revenue has until now been substantially the result of such development activities whereby Formycon is remunerated by the license or cooperation partners subsequent to transfer of projects into development partnerships.

**Formycon Project 201 GmbH**, a 100%-owned subsidiary of Formycon AG, was the first project to be spun off into a separate subsidiary, during fiscal year 2014, and into which all project activities for biosimilar candidate FYB201 were transferred. Formycon's license partner for FYB201 is Bioeq AG, a 50/50 joint venture between Polpharma Biologics BV and Formycon AG. As the holder of the exclusive product and commercialization rights for FYB201, Bioeq AG has, in turn, commercialization partnerships with Coherus BioSciences, Inc. for the United States, with Teva Pharmaceutical Industries Ltd. for Europe and certain other territories, and with MS Pharma for the Middle East and North Africa (MENA) region. Following the relevant regulatory approvals, these companies will be able to market FYB201 in their respective territories. As part of the strategic transaction with ATHOS KG during the first half of 2022,

Structure of Formycon Group *before* transaction with ATHOS KG:



Structure of Formycon Group *after* transaction with ATHOS KG:



Formycon acquired 50% of the shares of Bioeq AG, which were previously held indirectly by ATHOS KG by way of Santo Holding (Deutschland) GmbH. As consideration for these shares, Santo Holding (Deutschland) GmbH received shares of Formycon AG newly issued from the approved capital against contributions in kind along with a share of future proceeds from the sale of FYB201.

**FYB202 Project GmbH**, likewise a 100% subsidiary of Formycon AG, owns the project and commercialization rights to biosimilar candidate FYB202. Prior to the strategic transaction with ATHOS KG, **FYB 202 GmbH & Co. KG**, founded in 2017, was an affiliate of Formycon AG, operating as a joint venture between Formycon AG (with a 24.9% ownership share) and Aristo Pharma GmbH (75.1%), a Strüngmann Group company. FYB 202 GmbH & Co. KG, in turn, owned 100% of FYB 202 Project GmbH until Formycon's acquisition of 100% ownership thereof through the transaction with ATHOS KG. As consideration for the transfer of Aristo's 75.1% ownership share in FYB202 Project GmbH, Aristo Pharma GmbH received shares in Formycon AG newly issued from approved capital against contributions in kind along with a share of future proceeds from the sale of FYB202. Formycon AG no longer has any ownership share in FYB 202 GmbH & Co. KG.

**Formycon Project 203 GmbH** is also a 100%-owned subsidiary of Formycon AG. In 2015, Formycon signed an exclusive worldwide out-licensing agreement for FYB203 with Santo Holding (Deutschland) GmbH. The worldwide marketing rights were subsequently internally shifted within the Santo Group to another Santo entity, Klinge Biopharma GmbH. Formycon will participate in any future proceeds from the sale of FYB203 in the form of royalties.

**Bioeq GmbH** has, as a result of the strategic transaction ATHOS KG, now been fully acquired as a 100% subsidiary of Formycon AG and is being organizationally integrated into Formycon Group. As consideration for the transfer of its ownership share in Bioeq GmbH, the former shareholder, Klinge Biopharma GmbH, received Formycon shares newly issued from approved capital against contributions in kind. With the takeover of Bioeq GmbH, Formycon has been able to broaden and strengthen its existing organization with complementary experience and expertise in the areas of clinical development, regulatory affairs, business development, commercial affairs, intellectual property and project management. The long-standing partnership between the two companies in ongoing biosimilar projects is expected to facilitate the rapid leveraging of synergies and efficient expansion of the development pipeline. In addition, Bioeq has an established international network for the commercialization of biosimilars.

As to the three biosimilar candidates **FYB206**, **FYB208** and **FYB209** in preclinical development and not yet publicly announced, and to which the Company owns all rights, Formycon plans to move forward with these as part of its broader growth strategy following the transaction with ATHOS KG and to independently develop each of these projects through to a very advanced stage.

Formycon AG continues to hold full rights to the **FYB207** project for development of an innovative COVID-19 drug and is actively considering further options for financial and global strategic partnerships.

The current focus of Formycon Group is on research and development activities for its own biosimilar projects, as well as on the development of its COVID-19 drug candidate (FYB207). To the extent that it engages in other business activities, these are primarily in support of these research and development activities.

The future market for Formycon's biosimilar and COVID-19 product candidates is the global pharmaceutical market. Healthcare policy and regulation should therefore be recognized as an important external influence factor.

## II Report on business performance

### General economic conditions

During the first half of 2022, the German economy faced an increasingly difficult environment. In addition to continuing issues resulting from the pandemic, especially disruptions to supply chains, the Ukraine war created new economic burdens. Specifically, the German economy has been significantly impacted by disruption of business activities within the crisis regions, dramatically higher procurement prices, and risks to the country's energy supply.

Already in the first quarter, it became evident that the hoped-for strong economic recovery would likely not materialize in 2022. From January to March, German economic output grew by just 0.2% over the final quarter of 2021. Investment spending, which rose by 4.6% in the construction sector and by 2.5% in the equipment sector, served as the main stabilizing component.<sup>1</sup> As to foreign trade, a divergence was seen, with exports falling by 2.1% compared to the previous quarter while imports rose slightly by 0.9%.<sup>2</sup>

In the months that followed, intensified supply bottlenecks and upward pressure on prices have been creating further uncertainties. In addition, there have been growing concerns about the continuity of Germany's supply of Russian natural gas. Preliminary data from the German Federal Statistical Office (Destatis) suggest that the German economy did not grow at all in the second quarter. According to the figures published in July by the German Federal Ministry for Economic Affairs and Climate Action, some of which are still provisional, incoming orders in the manufacturing sector were 5.3% below the prior-year month in April and 3.1% below in May. Industrial production fell by 3.0% in April and by 1.5% in May versus the respective prior-year months.<sup>3</sup> Growth in exports and imports, on the other hand, exceeded the prior-year months. However, in terms of the value of goods, Germany – which relies heavily on exports – posted a net trade deficit of € 1 billion for the month of May.<sup>4</sup> This was substantially attributable to higher import prices, which were 30.6% higher than in the previous year, with energy imports alone increasing in price by 143.8%.<sup>5</sup>

The inflation rate rose from 4.9% in January to 7.6% in June.<sup>6</sup> These price increases also adversely impacted private consumer spending. Germany's labor market, on the other hand, showed some positive trends, with 2,362,888 people registered as unemployed at the end of June, 250,937 fewer than one year earlier.<sup>7</sup> It should be noted, however, that official unemployment figures have more recently been rising again, due largely to the first-time inclusion of Ukrainian refugees.

<sup>1</sup> German Federal Ministry for Economic Affairs and Climate Action (BMWK), "Ausgewählte Daten zur wirtschaftlichen Lage", July 2022, [https://www.bmwk.de/Redaktion/DE/Downloads/W/wirtschaftliche-lage-in-deutschland-im-juli-2022.pdf?\\_\\_blob=publicationFile&v=4](https://www.bmwk.de/Redaktion/DE/Downloads/W/wirtschaftliche-lage-in-deutschland-im-juli-2022.pdf?__blob=publicationFile&v=4)

<sup>2</sup> German Federal Statistical Office (Destatis), "Gross domestic product: detailed results on the economic performance in the 1st quarter of 2022", press release dated May 25, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/05/PD22\\_215\\_811.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/05/PD22_215_811.html)

<sup>4</sup> German Federal Statistical Office (Destatis), "Exports in May 2022: -0.5% on April 2022", press release dated July 4, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22\\_279\\_51.html;jsessionid=BF6000FC819E656E8F81BE45D76B3793.live742](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_279_51.html;jsessionid=BF6000FC819E656E8F81BE45D76B3793.live742)

<sup>5</sup> German Federal Statistical Office (Destatis), "Import prices in May 2022: +30.6% on May 2021", press release dated June 30, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/06/PD22\\_274\\_614.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/06/PD22_274_614.html)

<sup>6</sup> German Federal Statistical Office (Destatis), "Inflation rate at +4.9% in January 2022", press release dated February 11, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/02/PD22\\_057\\_611.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/02/PD22_057_611.html)

<sup>7</sup> German Federal Statistical Office (Destatis), "Inflation rate slightly down to +7.6% in June 2022", press release dated July 13, 2022, [https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22\\_296\\_611.html](https://www.destatis.de/DE/Presse/Pressemitteilungen/2022/07/PD22_296_611.html)

<sup>8</sup> German Federal Employment Agency (Bundesagentur für Arbeit), "Monatsbericht zum Arbeits- und Ausbildungsmarkt", June 2022, [https://www.arbeitsagentur.de/datei/arbeitsmarktbericht-juni-2022\\_ba147522.pdf](https://www.arbeitsagentur.de/datei/arbeitsmarktbericht-juni-2022_ba147522.pdf)

### General industry conditions

The German Chemical Industry Association (VCI) reported that the country's chemical-pharmaceutical industry expanded its production by 0.5% in the first half of the year, while industry-wide sale revenue within Germany's third largest industrial sector increased by 22% due largely to higher producer prices. This strong performance was due in no small part to the pharmaceutical sector, which continues to benefit from the pandemic-related industry upswing and has remained unaffected by export restrictions to Russia because of its exemption from sanctions. Excluding pharmaceuticals, production in German's chemical-pharmaceutical industry for the first half of 2022 would have fallen by 3%.<sup>9</sup>

According to a recent market report from IQVIA, a leading information platform for human data science, pharmaceutical revenue to the country's hospital and pharmacy sector was € 13.6 billion during the first three months of 2022, 6.2% above the prior-year quarter. Specifically within the pharmacy sub-sector, which is the larger part by volume, sales increased by 7.1%, a sign that despite the continuing pandemic, visits to doctors and filling of prescriptions at pharmacies have been returning to normal levels. Aggregate sales of biosimilars through pharmacies grew at an even faster rate, rising by 10.7% in the first quarter by sales revenue – and measured in terms of number of package units, the increase over the prior-year quarter was an even more impressive 20.8%.<sup>10</sup>

Since 2012, the number of biosimilar approvals in Europe has increased approximately sixfold. In the past year alone, the European regulator granted nine new approvals. The circumstances arising from the pandemic and from the disruption of global supply chains, which continue to be fragile, have underscored the existential importance of proximal supply of pharmaceuticals to Germany's people, without excessive international dependencies. In the agreement of Germany's new governing coalition published at the end of 2021, the federal government explicitly committed itself to promoting domestic pharmaceutical production, for example by removing bureaucratic hurdles.

With regard to the market opportunity for newly introduced biosimilars, the prospects continue to be promising. According to calculations by IQVIA, patent protection in Germany for seven biopharmaceuticals, representing combined market revenue of € 584 million to pharmacies in Germany alone, will expire this year. By 2025, another 32 biopharmaceuticals will be added with total German pharmacy sales of more than € 2 billion.<sup>11</sup> Newly introduced biosimilars are, upon their regulatory approval and market introduction, expected to gain a large part of this market space. According to the

<sup>9</sup> German Chemical Industry Association (VCI), "Halbjahresbilanz der chemisch-pharmazeutischen Industrie 2022", July 6, 2022, <https://www.vci.de/ergaenzende-downloads/pm-standort-deutschland-bekommt-zunehmend-wettbewerbsproblem.pdf>

<sup>10</sup> IQVIA, "Marktbericht classic, Entwicklung des deutschen Pharmamarktes im ersten Quartal 2022", [https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/publications/iqvia-pharma-marktbericht-classic-q1-2022.pdf?\\_=1659001096958](https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/publications/iqvia-pharma-marktbericht-classic-q1-2022.pdf?_=1659001096958)

<sup>11</sup> IQVIA, "Biosimilars - Marktpräsenz und -entwicklung, 06/2021", <https://www.iqvia.com/-/media/iqvia/pdfs/germany/library/infographic/biosimilars--marktpraesenz-und--entwicklung.pdf>



German Association of Research-Based Pharmaceutical Companies (vfa), biosimilars have been gaining market shares of up to 80% in Germany in the first year after their market launch.<sup>1</sup>

**Developments in the global biosimilar market**

In considering the future potential of the global biosimilars market, the fundamental drivers continue to be the growing world population and the increasing number of patients requiring treatment as people live longer. Both of these trends demand urgent solutions to keep healthcare costs in check while maintaining standards of medical care. In addition, international healthcare systems have been and will continue to be burdened by additional expenses resulting from the COVID-19 pandemic, thereby increasing the urgency of cost containment. Given these budgetary pressures, biosimilars offer ideal opportunities for achieving significant cost efficiencies without compromising the quality of care. In Germany alone, for example, biosimilars are estimated to have saved a total of € 4.19 billion since 2011.<sup>2</sup>

Oncology, a field of medicine in which some 19.3 million new cases are registered every year, currently dominates the areas of application for biosimilars worldwide.<sup>3</sup> Overall, however, the number of disease areas in which biosimilars are available and in active use is steadily increasing. The trend of new and expected biosimilar approvals is, in particular, towards indications in immunology and ophthalmology.

According to expert forecasts, the robust growth within the global biosimilars market will continue into the future. International studies published in the summer of 2022 predict average annual growth rates (CAGR) for the global biosimilars market in excess of 20% over the next four to five years. It should be noted that these research institutions acknowledge the possibility of approval delays resulting from the pandemic as well as obstacles that could arise due to supply chain disruptions and exacerbation of raw material procurement difficulties.

**Sales revenue for biosimilars in Germany in € billion**

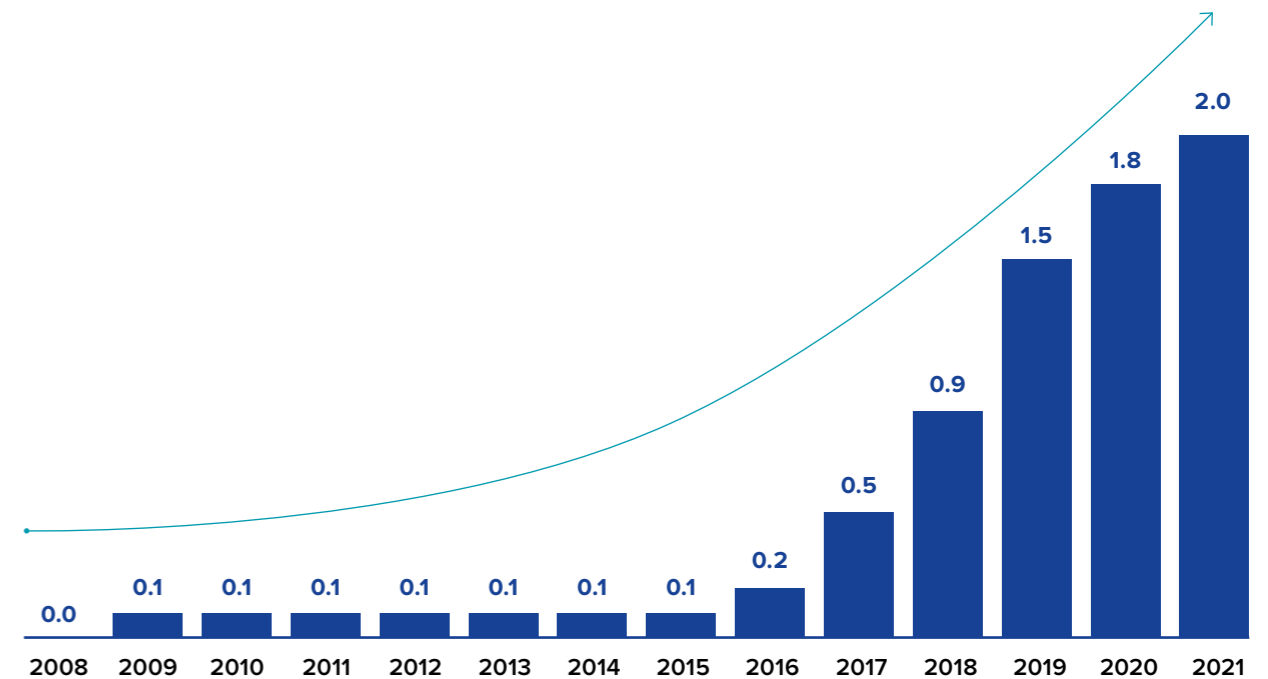


Figure 5: Sales revenue for biosimilars in Germany in € billion

<sup>1</sup> German Association of Research-Based Pharmaceutical Companies (vfa), "Biosimilars: der Wettbewerb funktioniert", press release dated July 7, 2022, <https://www.vfa.de/de/presse/pressemitteilungen/pm-018-2022-biosimilars-der-wettbewerb-funktioniert.html>  
<sup>2</sup> AG Pro Biosimilars, Grafik des Monats März 2022, 28.03.22, <https://probiosimilars.de/grafik-des-monats/maerz-2022/>  
<sup>3</sup> International Agency for Research of Cancer, Fact Sheet World, <https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf>



## Chronological review of key developments during the first half of 2022:

### March

In **March**, Formycon AG announced the **transaction** with **ATHOS KG**, through which Formycon has now acquired **full rights to FYB202**, a candidate biosimilar to Stelara® (ustekinumab), and a **50% interest in FYB201**, a candidate biosimilar to Lucentis® (ranibizumab). Moreover, through the acquisition and ongoing **integration** of its long-term partner **Bioeq GmbH**, Formycon AG has been able to expand its in house expertise and resources in a number of areas important for the development, approval and commercialization of biosimilars.

The transaction between Formycon AG and ATHOS KG took place at **fair value conditions** jointly determined and **confirmed by independent experts** and based on a valuation of **€ 83.41 per Formycon share**. Payment to ATHOS KG of consideration for the assets acquired (FYB201, FYB202 and Bioeq GmbH) with a total combined transaction value of approx. **€ 650 million** was made in part through the issuance and granting of **shares in Formycon AG** under a non-cash capital increase against contributions in kind, thereby fully utilizing the Company's existing Approved Capital 2019 in the amount of € 4,000,000.00. In addition, ATHOS KG will receive a **revenue share** (earn-out component) in future product sales of **FYB201 and FYB202** generated by Formycon, through which ATHOS is expected to earn a total participation estimated in the mid three-digit million range.

### May

In **May**, upon fulfilment of conditions precedent, receipt of required official approvals, and entry of the non-cash capital increase into the commercial register, Formycon AG and ATHOS KG announced the **completion of Formycon's acquisition** of biosimilar assets FYB201 and FYB202 as well as of Bioeq GmbH. Upon completion of this transaction, ATHOS KG became the **largest shareholder** of Formycon AG, with an ownership stake of approx. **26.6%**.

Also in May, Formycon AG and its license partner Bioeq AG announced that the **UK Medicines and Healthcare products Regulatory Agency (MHRA)** had granted **UK approval** for FYB201, a biosimilar to Lucentis® (ranibizumab). **Teva Pharmaceutical Industries Ltd.** will be the exclusive **commercialization partner** to market the biosimilar within the UK under the trade name **ONGAVIA®**.

In the middle of May, Formycon released its **audited financial results for fiscal year 2021**. For the year ending December 31, 2021, **total consolidated sales revenue was € 41.7 million**. With **EBITDA of negative € 12.4 million**, an **operating loss (EBIT) of € 13.3 million**, and a **consolidated annual net loss of € 13.5 million**, compared to a net loss of € 5.7 million in the prior fiscal year, the full-year figures were closely in line with expectations. Formycon Group held **cash and liquid resources**, including short-term receivables and other assets, of **€ 36.1 million**.

In this same month, Formycon AG announced **important changes to its Executive Board**. Firstly, the Supervisory Board appointed **Dr. Stefan Glombitza**, who has been serving as Chief Operating Officer since 2016, as **Chief Executive Officer** with effect from July 1, 2022, thereby assuming the role held until now by Dr. Carsten Brockmeyer, whose term of office as Chief Executive Officer and Executive Board member ended on June 30, 2022. In his new role as Chief Executive Officer, Dr. Glombitza will shape Formycon's strategic direction in an increasingly commercial phase of its corporate development and, together with his team of experts, drive forward with a continuously expanding portfolio of products and development projects. While Dr. Brockmeyer is stepping down from the Executive Board as planned, he will continue to support and guide the company as scientific advisor and help to ensure the success of the Company's biosimilar candidates and COVID-19 drug project. Secondly, in addition to Dr. Glombitza, **two more experienced pharmaceutical executives** were newly appointed to the Executive Board. The Supervisory Board of Formycon appointed **Nicola Mikulcik** to the Executive Board with effect from June 1, 2022 in the position of **Chief Business Officer (CBO)** and, with effect from July 1, 2022, Dr. Andreas Seidl in the position of **Chief Scientific Officer (CSO)**, each for a term of office of five years.



## June

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In June, Formycon AG released a **comprehensive development update** spanning all of its projects. In the case of the **FYB201** project, it was announced that the new drug is, upon approval by the UK Medicines and Healthcare products Regulatory Agency (MHRA), is expected to be the first biosimilar to Lucentis® to be marketed anywhere in Europe. It was also announced that the pending approval processes with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are proceeding according to plan.

In the case of the **FYB202** project, the treatment of the last remaining patient in the **phase III clinical trials** (VESPUCI study) was successfully completed (“**last patient out**”) and publication of the **primary efficacy endpoint** results announced. In addition, following advance discussion and agreement with both the FDA and the EMA, an additional **comparative phase I pharmacokinetic study** of FYB202 against reference product Stelara® was initiated. Submissions for regulatory approval of FYB202 in Europe and the U.S. are planned for the third quarter 2023, upon availability of these additional pharmacokinetic data.

In the case of the **FYB203** project, the final patient was recruited into the ongoing **phase III clinical trials** (MAGELAN-AMD study) in April (“**last patient in**”). Data on the **primary efficacy endpoint** are expected by the end of the year.

The **FYB206** biosimilar project is advancing according to plan. With convincing results from extensive analytical characterization of the developed molecule, along with significant progress in the development of a manufacturing process, a comprehensive data package is currently being compiled in order to closely coordinate next steps during the second half of the year with both the EMA and the FDA through the scientific advice procedure.

In the case of **FYB207**, Formycon's innovative COVID-19 drug under development, **new laboratory data** showed that the currently dominant **omicron variant** is likewise **neutralized** with a similarly high degree of efficacy. Defined **modifications to FYB207's proprietary molecular structure** were also undertaken within the scope of pending **preclinical studies**, leading to significant **improvements in half-life and efficacy**. In the course of 2022, the preclinical studies should be completed, the manufacturing process adapted to the optimized molecule, and test material produced for stability studies and **clinical trials**. It is currently anticipated that clinical trials will commence in **2023**.

In its reporting of **financial results for the first quarter**, Formycon AG announced consolidated **sales revenue and other income of € 8.2 million** for the three months ending March 31, 2022. **EBITDA was negative € 4.0 million**, while the **operating loss (EBIT)** and **net loss after tax** for the period were each approx. **€ 4.3 million**, in line with expectations. As of the reporting date, Formycon held **cash and liquid resources**, including short-term trade receivables and other assets, of **€ 24.5 million**. In addition, the start of two further new biosimilar projects was announced as part of the quarterly re-

porting. For FYB208 and FYB209, the reference molecules were identified and the first development activities initiated.

In June, the **EMA's Committee for Medicinal Products for Human Use (CHMP)** issued a **positive opinion** with respect to **FYB201**, thereby recommending the biosimilar to Lucentis® for **approval in the European Union** for treatment of patients with neovascular (“wet”) age-related macular degeneration (nAMD) and other serious eye diseases. The **CHMP's scientific assessment report** forms the **decision-making basis** for the European Commission's granting of **central regulatory approval**.

The **Annual General Meeting** of Formycon AG was held on **June 30, 2022 in virtual form**. Shareholders approved all resolutions with large majorities and received an interesting update from the Executive Board on Formycon's various ongoing development projects.

Shares and the capital markets

German and international stock market environment

During the first half of 2022, equity markets in Germany and around the world were adversely affected by multiple factors. The market downturn started in January with the announcement by the U.S. Federal Reserve of its decision to raise interest rates during 2022, thus bringing an end to its long-standing low-rate policy. The Russian attack on Ukraine followed in February, along with the resulting economic consequences. Other factors weighing on the world's stock markets were high inflation figures, concerns about the economy, China's zero-COVID strategy and production bottlenecks resulting from supply chain disruptions.

The unfavorable environment affected benchmark indexes across virtually all key markets. In the first six months of the year, the MSCI World index lost some 21% of its value.<sup>1</sup> The NASDAQ 100 was hit even harder, losing 30% over the same period.<sup>2</sup> Specifically within the German market, the DAX equity index ended at 12,783.77 points on June 30, 2022, thus ending the first half with a loss of 3,101 points, or almost 20%, compared to the close of 2021.<sup>3</sup> The performance of German blue-chip stocks was thus, on average, almost exactly matched eurozone blue chips more broadly, with the broad EURO STOXX 50 index likewise losing some 20% between January and June.<sup>4</sup>

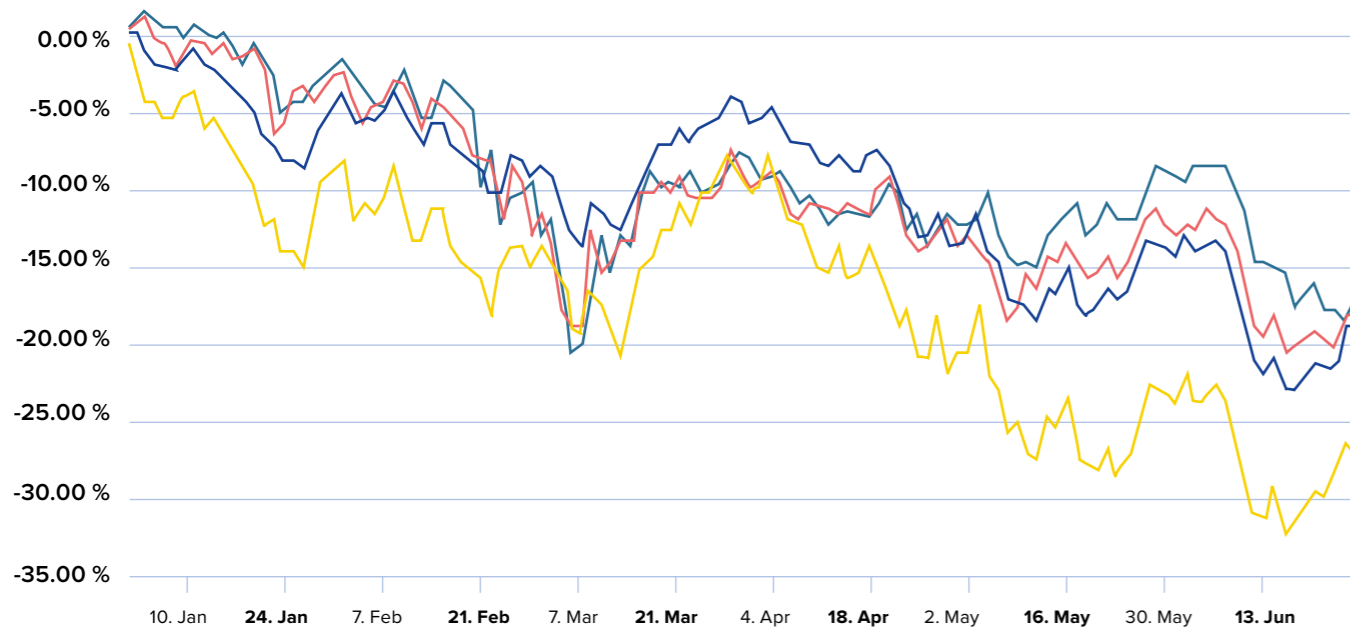


Figure 6: International market environment during the first half of 2022

■ DAX ■ EURO STOXX 50  
 ■ MSCI WORLD ■ NASDAQ 100

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

In view of the tense situation on the world's stock exchanges, the number of IPOs fell significantly. According to Ernst & Young's global IPO Barometer, a total of 626 companies<sup>5</sup> went public in the first half of 2022, 354 fewer<sup>6</sup> than in the prior-year period. In terms of global issuance, the total value during the first six months was USD 95 billion<sup>7</sup> (1H 2021: USD 198 billion<sup>8</sup>).

Performance of Formycon shares

The performance of Formycon shares during the first half of 2022 was remarkably positive, with a six-month gain of 30% for period ending June 30, 2022. This rise stands in stark contrast to the generally declining stock market environment. Sector benchmarks more closely aligned to Formycon likewise performed poorly during the reporting period, with the Deutsche Börse's Scale 30 Index of the 30 most actively traded shares within Formycon's Scale market segment down 24% from the 2021 close<sup>9</sup> and the biopharmaceutical-dominated NASDAQ Biotechnology Index down 21%<sup>10</sup>.

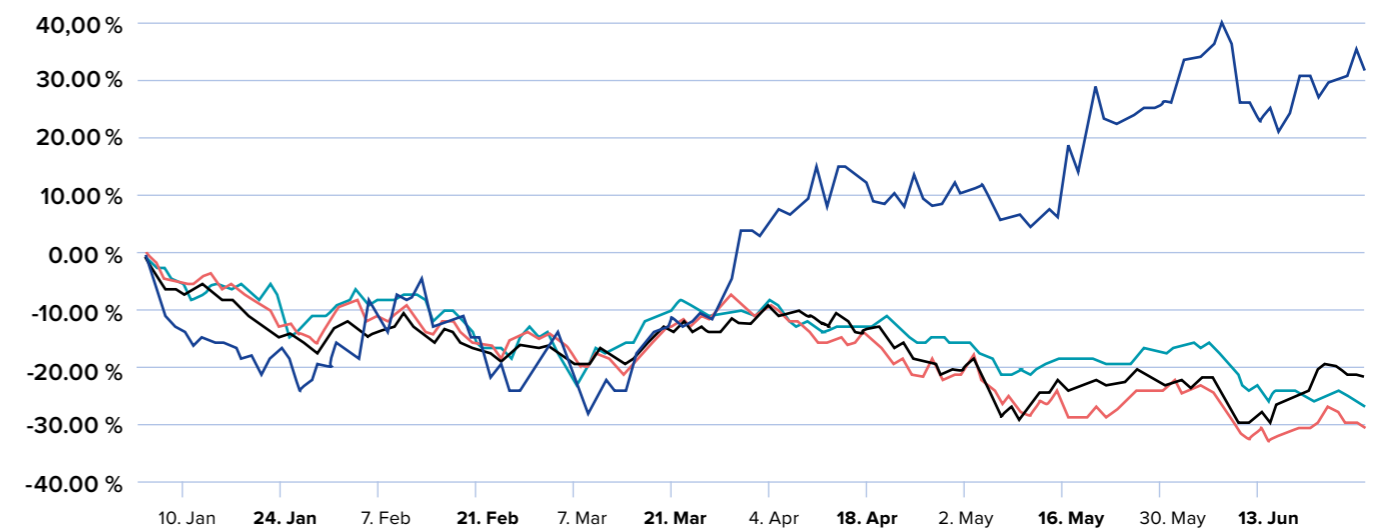


Figure 7: Trading performance of Formycon shares compared to key market benchmarks

■ FORMYCON AG ■ NASDAQ 100  
 ■ SCALE 30 INDEX ■ NASDAQ BIOTECHNOLOGY INDEX

<sup>5</sup> Ernst & Young, EY Global IPO Update Q1/2022, 28.03.22, [https://www.ey.com/de\\_at/news/2022/03/ey-global-ipo-update-q1-2022](https://www.ey.com/de_at/news/2022/03/ey-global-ipo-update-q1-2022), Ernst & Young, EY Global IPO Update Q2/2022, 30.06.22, [https://www.ey.com/de\\_at/news/2022/06/ey-global-ipo-update-q2-2022](https://www.ey.com/de_at/news/2022/06/ey-global-ipo-update-q2-2022)  
<sup>6</sup> Ernst & Young, EY Global IPO Update Q1/2021, 29.03.21, [https://www.ey.com/de\\_at/news/2021/03/ey-global-ipo-update-q1-2021](https://www.ey.com/de_at/news/2021/03/ey-global-ipo-update-q1-2021), Ernst & Young, EY Global IPO Update Q2/2021, 30.06.21, [https://www.ey.com/de\\_at/news/2021/06/ey-global-ipo-update-q2-2021](https://www.ey.com/de_at/news/2021/06/ey-global-ipo-update-q2-2021)  
<sup>7</sup> Ernst & Young, EY Global IPO Update Q1/2022, 28.03.22, [https://www.ey.com/de\\_at/news/2022/03/ey-global-ipo-update-q1-2022](https://www.ey.com/de_at/news/2022/03/ey-global-ipo-update-q1-2022), Ernst & Young, EY Global IPO Update Q2/2022, 30.06.22, [https://www.ey.com/de\\_at/news/2022/06/ey-global-ipo-update-q2-2022](https://www.ey.com/de_at/news/2022/06/ey-global-ipo-update-q2-2022)  
<sup>8</sup> Ernst & Young, EY Global IPO Update Q1/2021, 29.03.21, [https://www.ey.com/de\\_at/news/2021/03/ey-global-ipo-update-q1-2021](https://www.ey.com/de_at/news/2021/03/ey-global-ipo-update-q1-2021), Ernst & Young, EY Global IPO Update Q2/2021, 30.06.21, [https://www.ey.com/de\\_at/news/2021/06/ey-global-ipo-update-q2-2021](https://www.ey.com/de_at/news/2021/06/ey-global-ipo-update-q2-2021)  
<sup>9</sup> [https://www.finanzen.net/index/scale\\_30/historisch](https://www.finanzen.net/index/scale_30/historisch)  
<sup>10</sup> [https://www.finanzen.net/index/nasdaq\\_biotechnology/historisch](https://www.finanzen.net/index/nasdaq_biotechnology/historisch)



This strong outperformance of Formycon shares was almost entirely during the second quarter of 2022 and largely reflects Formycon's reported progress in expanding its position in the rapidly growing global market for biosimilars. Of particular importance was Formycon's announcement in March, and successful conclusion in May, of the transaction with ATHOS KG. Also in May, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization for FYB201, our biosimilar to Lucentis®.

A more detailed examination versus key market benchmarks shows that, following a somewhat restrained start to the year, Formycon's share price during the reporting period initially moved in line with the broader market, particularly in the weeks between mid-February and early March, a period in which growing uncertainty about Ukraine weighed on the world's stock exchanges. On March 7, Formycon shares reached a first-half low of €43.95, marking the beginning of a subsequent price rally during which, over the following months, Formycon significantly outperformed the broader market. Already by March 30, Formycon's share price exceeded the € 60 mark. Barely three weeks later, it broke the € 70 mark, setting a new price floor for further highs towards the end of the six-month period, and on June 8, Formycon shares reached a new all-time high of € 82.20.

As of the close of first-half trading on June 30, the price of Formycon shares in Xetra trading was € 76.50. With a total of 15,064,750 shares outstanding, the Company's market capitalization as of June 30, 2022 was thus € 1.15 billion (June 30, 2021: € 697 million with 11,046,500 shares). The total number of shares traded during the first half of 2022 was 2,026,360 (1H 2021: 4,144,437). Some 56% of all shares were traded in the Xetra trading segment, 4% on the Frankfurt Stock Exchange and 40% on other stock exchanges. Across all trading platforms, the average trading volume of Formycon shares per trading day was 16,610 shares (1H 2021: 33,155 shares).

#### Formycon shares: Trading information

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

#### Formycon shares: Performance information<sup>1</sup>

In €	H1 2022	H1 2021
Opening price on Jan. 3, 2022/Jan. 4, 2021 (Xetra)	58.90	54.60
Closing price on Dec. 30, 2022/Dec. 30, 2021 (Xetra)	76.50	63.10
Average price (Xetra closing price)	60.35	62.82
Market capitalization as of June 30	1,152,453,375	697,034,150
In shares		
Total shares traded (on all trading venues)	2,026,360	4,144,437
Daily average shares traded (on all trading venues)	16,610	33,155
Total shares issued as of June 30	15,064,750	11,064,750

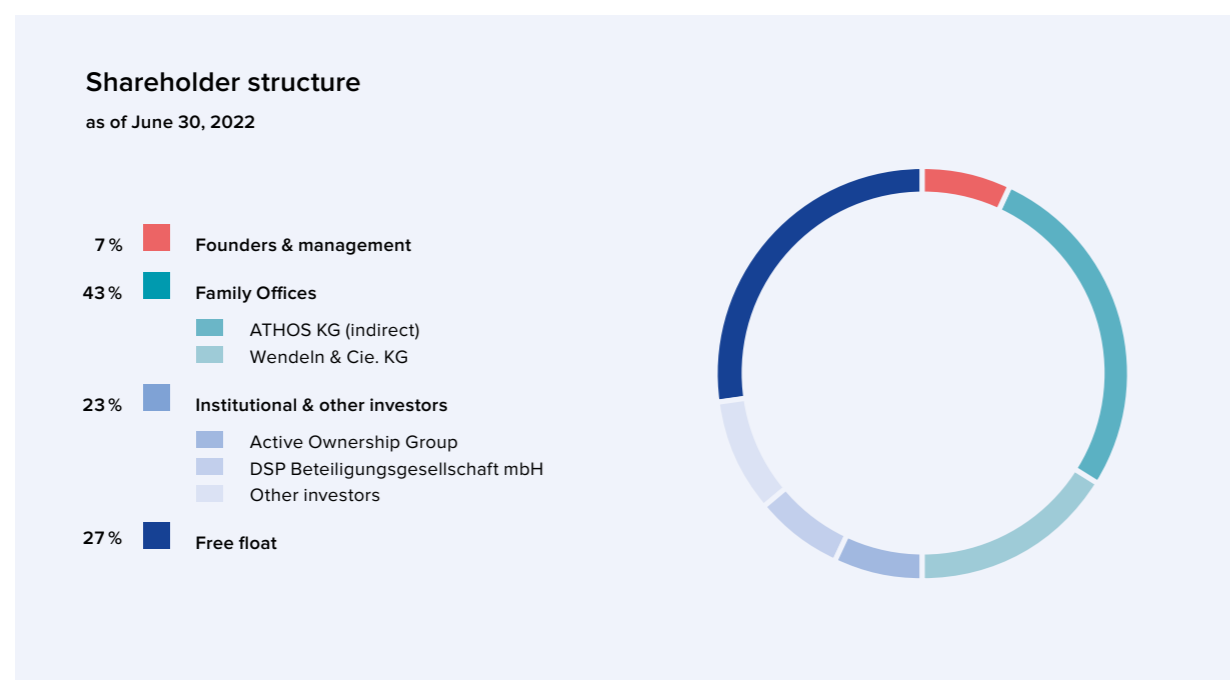


Figure 8: Overview of shareholder structure

### 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. Upon completion of the transaction, ATHOS KG became the largest shareholder in Formycon AG with an indirect shareholding of 26.6% of the Company's share capital. ATHOS KG and the relevant direct and indirect entities thereunder accordingly provided notification to Formycon and published an announcement in the Federal Gazette in accordance with sec. 20 para. 1 of the Stock Corporation Act.<sup>2</sup>

<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

<sup>3-4</sup> Percentages are approximate and rounded accordingly.

With this change, a total of some 43% of the Company's shares are now directly and/or indirectly held by two family offices (ATHOS KG, Wendeln & Cie. KG) with a further approx. 23% held by institutional and other investors<sup>3</sup> (of which the largest are Active Ownership Group and DSP Beteiligungsgesellschaft mbH), while an additional approx. 7% is held by founders and management. The overall shareholder structure of Formycon AG thus continues to be stable. The remaining approx. 27% of shares are in free float.<sup>4</sup>

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

During the first half of 2022, no members of the Executive Board or Supervisory Board conducted any securities transactions 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 has, since its introduction throughout the EU in July 2016, been subject to the requirements of the Market Abuse Regulation, replacing key parts of the German Securities Trading Act with the stated goal of promoting the integrity of the financial markets by improving transparency. Under the MAR, the Company is obligated to publicly release ad hoc announcements of information relevant to its share price, to report securities transactions by its executives (directors' dealings), and to maintain a registry of Company insiders. Formycon has implemented these requirements, integrating appropriate compliance processes into its existing risk management system as necessary.



### Subscribed capital

As of January 1, 2022, the registered capital (Grundkapital) of Formycon AG was € 11,064,750.00, divided into 11,064,750 bearer shares without par value but with an imputed nominal value of € 1.00 per share. Drawing upon the Approved Capital 2019/I resolved by the Annual General Meeting on June 27, 2019, the Company's share capital was increased by € 4,000,000 to a total of € 15,064,750.00 in conjunction with the transaction with ATHOS KG, with imputed registered capital of € 1.00 per share against contributions in kind.

By resolution of the Supervisory Board on April 26, 2022, Section 4 of the Company's Articles of Association (*Satzung*), governing the amount and division of registered capital conditional capital, was amended accordingly, then legally entered into the commercial register (*Handelsregister*) on May 6, 2022. The registered capital of Formycon thus amounted to a total of € 15,064,750.00 as of June 30, 2022. For detailed information on the Approved Capital and Conditional Capital of Formycon AG, please refer to the Notes to the Financial Statements of Formycon AG (section IV: "Additional notes to the Balance Sheet") included in this report.

### Annual General Meeting

The Annual General Meeting of Formycon AG was held on June 30, 2022 in virtual format. In the period subsequent to official publication of the meeting agenda in the Federal Gazette on May 20, 2022, agenda item 9 ("Election of new Supervisory Board member") was amended by resolution of the Supervisory Board of Formycon AG on June 27, 2022 and Dr. Thomas Strüngmann proposed for election as new member of the Supervisory Board.

Shareholders were able to follow the proceedings of the virtual AGM by way of live audio-visual streaming through a specially established AGM portal. 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 current biosimilar projects, the development of its new COVID 19 drug, and the transaction with ATHOS KG, answering all of the questions submitted in advance of the meeting.

In addition, shareholders were introduced to two members of the Executive Board newly appointed by the Supervisory Board: Nicola Mikulcik, serving as Chief Business

Officer (CBO) with effect from June 1, 2022, and Dr. Andreas Seidl, the Company's Chief Scientific Officer (CSO) with effect from July 1, 2022. The Annual General Meeting also approved the expansion of the Supervisory Board from three to four members by a large majority, and Dr. Thomas Strüngmann was elected as the new fourth member thereof with 99.99% of votes represented.

Shareholders were able to exercise their voting rights before or during the virtual AGM through postal voting or authorized proxy voting. A total of approx. 10.7 million shares were voted, representing 70.96% of the Company's share capital.

### Investor relations

Professional dialogue with investors and with the international capital markets forms an important component of Formycon's investor relations program. During the first six months of 2022, Formycon's senior management and investor relations department presented the Company at selected investor conferences, such as Metzler MicroCap Day, the Jefferies Pan-European Mid Cap Virtual Conference, the Deutsche Börse Equity Forum (spring conference), the Hauck & Aufhäuser Stockpicker Summit, and the Hamburg Investor Day. Through such conferences as well as other outreach activities, notably including non deal roadshows (both virtual and presence) in Milan, Luxembourg and Hamburg, the Company has strived to maintain active contact with existing and potential investors and to increase its visibility on the capital markets. As of June 30, 2022, five analysts were regularly providing equity research coverage on Formycon AG.



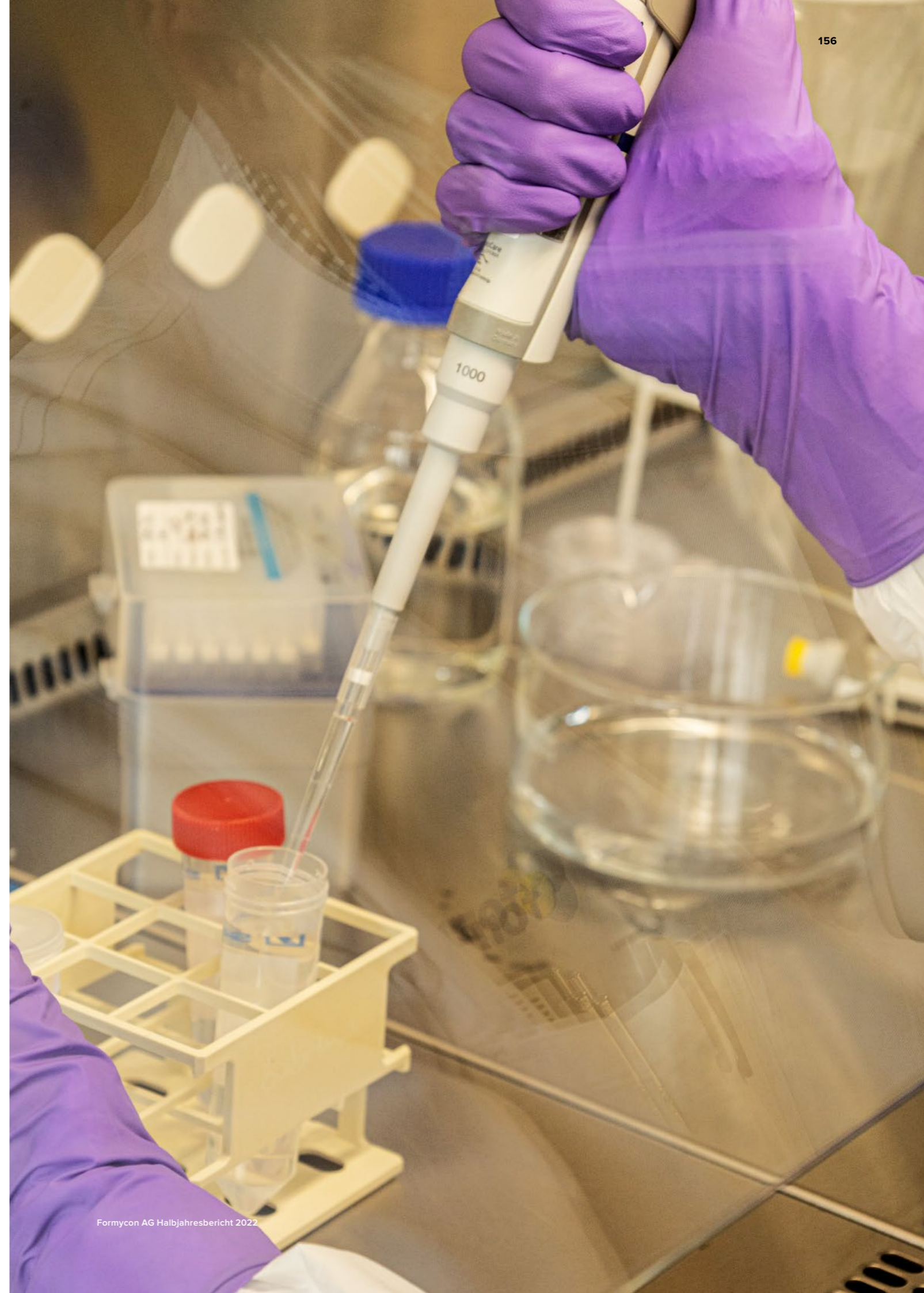
The following analysts published research studies on Formycon during the first half of 2022:

Bank or research provider	Analyst
B. Metzler seel. Sohn & Co. KGaA	Tom Diedrich
First Berlin Equity Research GmbH	Simon Scholes
Hauck & Aufhäuser Privatbankiers AG	Alexander Galista
Kepler Cheuvreux	Arsene Guekam
SRH AlsterResearch AG	Alexander Zienkowitz

Further information about Formycon Group and its investor relations activities may be found in the "Investors" section of Formycon's website  
<https://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 stands ready to respond to any questions or suggestions:

Formycon AG	
Contact Person	Sabrina Müller Senior Manager Corporate Communications & Investor Relations
Street address	Fraunhoferstr. 15, 82152 Martinsried/Planegg
Phone	+49 89 864 667 149
E-Mail	ir@formycon.com
Web	<a href="https://www.formycon.com/en/investor-relations/shares/">https://www.formycon.com/en/investor-relations/shares/</a>



**Staffing and organizational structure**

As of June 30, 2022, a total of 178 persons (prior year: 159) were employed at Formycon's offices and laboratories in Planegg on the outskirts of Munich. The average staffing during the six-month current-year and prior-year periods is shown below, divided by functional area, and expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff:

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

Persons	1H 2022	1H 2021	% increase
Research & development	129	123	+ 5 %
Business operations	7	3	+ 133 %
General & administrative	16	16	n/c
<b>Total</b>	<b>152</b>	<b>142</b>	<b>+ 7 %</b>

Staff expenses during the first half of 2022 were € 7,948K (1H 2021: € 6,234K), with the increase due primarily to the greater average number of employees.

Although part-time staff are important contributors to the Company, the great majority (75%) work on a full-time basis. New hires during the first half were made, in particular, within the areas of product development and scientific affairs in order to strengthen organizational resources and expertise for further expansion of the Company's development pipeline, which has since begun.

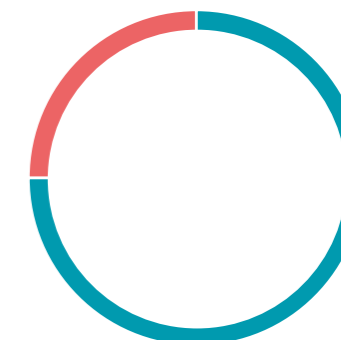
The Formycon organization is also being significantly strengthened through the pending integration of the 17 members of Bioeq staff who were acquired through the ATHOS transaction at the end of May, thereby adding product development resources and specialized expertise within the areas of clinical affairs, intellectual property, regulatory affairs and commercialization. Because these employees can only be formally counted as Formycon staff upon completion of the integration process in August/September, these individuals are not yet included in the above figures as of June 30, 2022.

In terms of education level, 83% of the Company's total employees have a university degree, and 38% specifically a doctorate. As to gender, 64% are female and 36% male. The average employee age as of June 30, 2022 was 39 years. The percentage of women within the second management level (Vice President, Senior Director, Director) was 33%. Formycon is proud of the stable organization and diverse workforce that it has built over the years, with employees from 22 different countries.

**Full-time vs. Part-time staff**

as of June 30, 2022

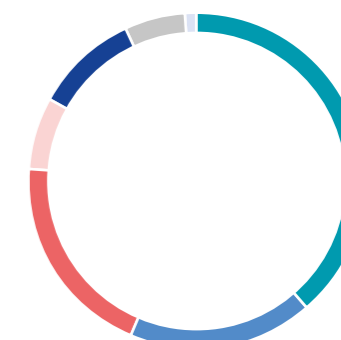
75 % Full-time  
25 % Part-time



**Educational level of staff**

as of June 30, 2022

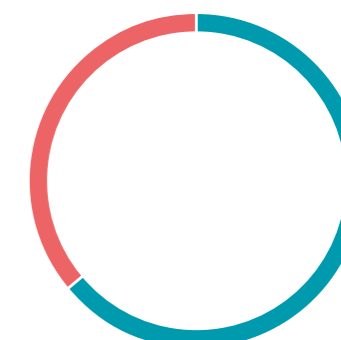
39 % Doctorate  
20 % Master's  
7 % Bachelor's  
18 % Diplom (equiv. master's)  
10 % Vocational training (technical)  
6 % Vocational training (administrative)  
1 % Degree or certification not yet completed



**Percentage of total staff by gender**

as of June 30, 2022

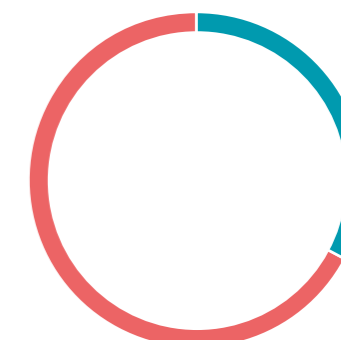
64 % female  
36 % male



**Percentage of second management level by gender**

as of June 30, 2022

33 % female  
67 % male





**Corporate Social  
Responsibility:  
Our responsibilities  
to our staff and our  
company community**

**Corporate culture and commitment to ethical behavior**

The business success of Formycon 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. This foundation is specifically defined through Formycon's 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 our Company's policy to properly investigate any instance in which non-compliance is suspected.

In its corporate and management culture, 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 and candid work environment as crucial for shared success. By participating in this open dialogue and actively participating in the company, each and every employee can make decisive contributions to the company's success.

**Staff recruitment, retention and satisfaction**

Among Formycon's key success factors is the recruiting and retention of highly educated and skilled employees with extraordinary abilities. Formycon recruits its staff without regard to gender, gender identity, sexual orientation, ethnicity, nationality, age, handicap or other such personal characteristics. Our corporate culture is characterized by an affirmative attitude towards integration, respect for diversity and equality of opportunity. Formycon is proud of the steadily growing organization and diverse workforce that it has built over the years, with employees from 22 different countries (Australia, Austria, Bosnia and Herzegovina, Brazil, China, Colombia, Croatia, France, Germany, Hungary, India, Iran, Italy, Japan, Macedonia, Montenegro, Nepal, Poland, Portugal, Tunisia, UK, USA). Despite the particular challenges created by the COVID 19 pandemic, Formycon has been able to recruit outstanding talent and to successfully integrate new staff into the organization.

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 upon general economic conditions, including but not limited to price and wage inflation, as part of the Company's regular annual salary review process. The Company has a stock option program for management and key staff under which options to buy shares are allocated annually according to set criteria as a long-term incentive component. To further our efforts to attract and

retain talent, the Company has implemented an employee referral program which offers incentives to staff who contribute to the recruitment process by recommending suitable candidates.

In order to maximize the attraction and retention of talent which is so vital to the Company, Formycon pursues a strategy of actively fostering long-term loyalty of its staff throughout the Company'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. The Company has, in addition, established a "scientific career path" for its research staff as well as a "managerial career path" program for staff in the regulatory affairs, quality management and project management areas, thereby fostering career planning within the Company.

Formycon places great importance on overall employee satisfaction, which is – along with technical excellence – essential to the Company's ultimate success. Opportunities for flexible work arrangements, company pension offerings, programs to promote general health, joint team-building events and various other employee benefits underscore the sincere regard the company has for its staff and contribute to high levels of employee loyalty and satisfaction.

To objectively measure the overall satisfaction of its workforce, Formycon regularly conducts anonymous surveys using an external service provider, focusing in particular on any psychological issues which might be adversely affecting its workforce. Although the overall feedback is invariably very positive, follow-up workshops are regularly conducted to identify specific opportunities for improvement, particularly with an eye to making Formycon the best possible place to work – now and long into the future.

**Workplace health and safety**

Against the backdrop of the ongoing COVID 19 pandemic, Formycon promptly took extensive measures to protect its staff from infection to the maximum possible extent. At a very early stage, and even before the COVID 19 crisis fully reached Germany, Formycon took proactive measures by decentralizing its organization. By responding with maximum flexibility, and by adjusting working hours and models around the needs of staff, Formycon was able to meet the requirements of the extraordinary situation while ensuring operational continuity. In addition, the entire Formycon workforce was also promptly equipped with vital protective equipment such as medical-grade mouth and nose protection as well as disinfectants. Finally, we made arrangements so that we were able to offer COVID 19 vaccinations to all employees starting from mid-June 2021 by way of our company doctor. Although the COVID-19 situation appeared to have generally relaxed overall as of early summer 2022, we will continue to closely monitor the ongoing situation so that appropriate measures may be promptly and proactively taken if and as necessary to protect our staff.

Because both productivity and quality depend crucially upon the health and motivation of the people who work in our Company, we believe that effective and efficiently orga-



nized 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. In 2021, Formycon once again received 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 includes rigorous assessments of a company's occupational health and safety management system as well as the effectiveness of its health management system. During the reporting period, Formycon recorded no workplace accidents or other reportable incidents (such as commuting accidents). Through our health and safety guidelines, our training courses and the regular medical check-ups which we offer, we pursue the goal of doing everything reasonably possible to prevent workplace accidents and to ensure the continued safety and well-being of our entire workforce.

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**Our responsibilities  
to patients, to our  
investors and to the  
world at large**

#### **Biopharmaceuticals to meet the needs of patients**

Through the biosimilar drugs which we are bringing to market, we aim to make an important contribution to world healthcare by providing patients with access to high-quality, competitively priced biopharmaceuticals to treat serious diseases. 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, even in the most developed countries. However, once the legal protection period for an originator biopharmaceutical reaches its end, biosimilars may be brought to market, providing a cheaper alternative for patient care. Thus, the reduced costs of effective treatment through new competition from biosimilars not only helps to relieve the burden on health providers such as statutory health insurers: They also make it possible to bring these powerful treatments to more patients.

#### **Our commitment to the United Nations Global Compact**

Formycon has since 2019 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, the Company already has a high consciousness with respect to human rights, and these standards are formally expressed in our Code of Conduct. Formycon and its business partners, as part of the biopharmaceutical development industry, operate in a highly regulated environment and are already accustomed to regular audits by supervisory authorities. By requiring our suppliers and cooperation partners to cooperate during 2022 with our initial risk assessment and review process for human rights compliance, we aim to ensure that we as a company are not complicit in any kind of human rights violations throughout our entire value chain.

Following these first steps, Formycon plans to successively increase its ongoing commitment to further sustainability goals and, above all, to continue to integrate the themes of environmental and social responsibility into our corporate management and culture.

#### **Corporate Governance**

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

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

Because Formycon shares trade within the "Open Market" segment,<sup>2</sup> it is not legally subject to the requirements for organized markets within the meaning of the German Securities Trading Act (Wertpapierhandelsgesetz) and it not legally considered to be listed. Although Formycon AG is therefore under no obligation to publish a corporate governance statement or declaration of compliance, we at Formycon have already implemented and embraced many of the corporate governance principles contained in the Code. In particular, as part of our commitment to transparent communication

<sup>1</sup> Regierungskommission Deutscher Corporate Governance Kodex

<sup>2</sup> Frankfurt Stock Exchange, Open Market

with our investors, the Executive Board and Supervisory Board of Formycon has taken initial steps to implement the principles, recommendations and suggestions anchored in the Code within our organization to the greatest extent possible with the aim of, in addition to this voluntary report on corporate governance, adding a declaration of compliance over the coming years – likewise on a voluntary basis – into this section of our future annual financial statements. Our aim in doing so is to strengthen the confidence of our investors, our employees and the public that we are a well-managed, properly supervised company that be counted on to do the right thing.

## Research and development

As in previous periods, the Company's activities during the half year ending June 30, 2022, were primarily in the area of research and development.

The consolidated expenditures for these activities may be broken down as follows:

Cost of raw materials, consumables and supplies	€ 1,498K
Third-party services	€ 10,427K
Staff expenses	€ 7,948K
Depreciation and amortization	€ 518K
Other	€ 3,627K
<b>Total</b>	<b>€ 24,018K</b>

As of June 30, 2022, 129 staff members (FTE) worked in research and development (1H 2021: 123). Expenditures during the period totaled € 24,018K, and these were all were charged as current expense. No research and development expenditures were capitalized. In the area of patent protection, the Company 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.

## Financial performance

The financial results herein are reported for the period from January 1, 2022 to June 30, 2022. Because of rounding errors, it is possible that the figures cited do not precisely add up to the stated total, or that percentages do not precisely correspond to the absolute figures.

## a) Results of operations

During the first half of 2022, Formycon AG generated revenue (before consolidation of subsidiaries) of € 12,469K, compared to € 12,364K in the prior-year period, resulting in six-month Company net income of € 82,574K (1H 2021: net loss of € 10,082K). Cost of materials for the period was € 11,925K (1H 2021: € 14,094K), yielding a six-month unconsolidated gross profit of € 544K (1H 2021: gross loss of - € 1,730K). In addition, the Company received government funding for the FYB207 project in the amount of € 3,894K (1H 2021: € 35K), which is included in net income.

As part of the transaction including acquisition of a 100% share of FYB202 Project GmbH, Formycon AG exited its holding in FYB 202 GmbH & Co. KG and is no longer a shareholder thereof. The division of assets through this departure from FYB 202 GmbH & Co. KG generated a book (non-cash) investment gain to the Company in the amount of € 89,730K.

During 2022, Formycon AG has continued to 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 sales revenue during the period. Under the terms of these deals, Formycon AG received ongoing payments for its product development services provided on behalf of the 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.<sup>1</sup> Formycon continued to hold a 24.9% stake in the joint venture with Aristo Pharma GmbH until April 30, 2022, bearing a pro rata share of accumulated project investments and development costs. With the acquisition of 100% ownership of FYB202 Project GmbH with effect from May 1, 2022, and the Company's simultaneous exit as a shareholder of FYB 202 GmbH & Co. KG, Formycon AG has, since this date, been bearing 100% of subsequent project and development costs incurred through its subsidiary FYB202 Project GmbH.

## b) Financial position

The financial position of Formycon AG remains stable, with key liquidity ratios significantly above average, as in prior years. Current assets totaled € 28,389K, compared to total current liabilities of € 13,264K. The Company did not have any bank loans during the period. To ensure the Company's financial resources, a credit line of € 50,000K was made available to Formycon AG during the reporting period by shareholders thereof, of which the Company had drawn € 10,000K as of the reporting date. At the same time, the Company was granted an intercompany loan by its subsidiary FYB202 Project GmbH in the amount of € 15,000K.



As of the period closing date, consolidated cash and equivalents amounted to € 12,963K, while marketable securities totaled an additional € 150K, as may be seen on the Statement of Cash Flows. Return on sales (net income/loss before inclusion of income from investment participations divided by sales revenue) for the period was - 57.4%, while the Company's operating loss (negative EBIT) was - € 7,113K and EBITDA (operating profit/loss plus depreciation and amortization) was - € 6,595K.

#### c) Net assets

As of the close of the period, the Company's equity capital ratio was 92.3%, thereby remaining at its above-average level. Non-current assets increased significantly during the period due to the transaction with ATHOS KG and the acquisitions thereunder of a 100% ownership share of FYB202 Project GmbH, a 100% share of Bioeq GmbH, and 50% of the shares of Bioeq AG. In addition, the Company assumed, as part of the transaction, a loan receivable from Bioeq AG in the nominal amount of € 82,000K. Non-current assets continue to be almost completely covered by equity capital, suggesting a healthy balance sheet structure. The Company's current assets consist almost completely of cash and marketable, highly liquid securities and thus involve negligible risks.

Because Formycon remains in the product development phase, the informative value of customary financial indicators is necessarily limited. The performance indicators of importance to the Company are those which measure its long-term, sustainable financial strength.

For the first six months of the year, net cash flow from operating activities was - € 9,971K (1H 2021: - € 7,621K), in line with expectations. Cash flow from investing activities was - € 24,113K (1H 2021: - € 1,863K), while cash flow from financing activities was € 24,949K (1H 2021: € 1,363K), reflecting the proceeds of loans from shareholders and from affiliated companies.

As expected, return on equity (annual net income(loss) before inclusion of income from investment participations / average equity) and total return on capital (annual net income(loss) before inclusion of income from investment participations / average total capital) were both negative for the fiscal year. As to non-financial performance indicators, please refer to the above "Research and development" section of this report. Formycon undertakes development for selected clients who see themselves as partners of Formycon and whose interests as to successful product development and subsequent market launch are fully aligned. The cooperative partnership arrangements and congruent objectives suggest a relatively low conflict potential. The Company's staff works primarily in research and development.

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#### Financial and non-financial performance indicators





### III Report on outlook

#### Company and development pipeline

Over the past years, Formycon has successfully gone through various phases of its development as a business and as an organization, culminating in the Company's significantly increased capitalization and initiation of multiple biosimilar drug development projects in recent years. The focus of fiscal year 2022 is on continuing to execute on the Company's defined strategy and, in particular, driving forward with the further development of its biosimilar candidates and COVID 19 drug (FYB207).

More broadly, Formycon is working to further strengthen the administration and management of its maturing organization and, in parallel with the Company's existing German statutory (HGB) financial accounts, has begun to prepare and publish its consolidated accounts in accordance with International Financial Reporting Standards (IFRS), thereby laying the groundwork for greater international transparency and comparability of financial statements as well as access to international capital markets. With IFRS reporting in place, Formycon is now working towards an uplisting to a more highly regulated stock market segment in order to reach a broader base of potential investors.



#### FYB201 – biosimilar to Lucentis®

FYB201 is Formycon's biosimilar to ophthalmic blockbuster drug ranibizumab (reference product: Lucentis®). Together with our license partner Bioeq AG, we have been working hand in hand towards the market success of our first approved product. Due to the ongoing COVID 19 pandemic, which again had the effect over the past year of impeding patient access and adversely affecting patient visits to ophthalmological practices, full-year 2021 sales of reference drug Lucentis® rose only slightly over the prior year, from USD 3.5 billion to 3.6 billion.

Following final approval by the UK Medicines and Healthcare products Regulatory Agency (MHRA) in May 2022, the U.S. Food and Drug Administration (FDA) on August 2, 2022 approved FYB201 for automatic substitution in the United States as the first biosimilar to Lucentis®. This makes FYB201 the first and, for a 12-month post-launch period, exclusive interchangeable biosimilar in the U.S. approved for all five Lucentis® indications, providing a new medical treatment option for patients with severe retinal disease. Following the positive opinion of the EMA's Committee for Medicinal Products for Human Use (CHMP) announced in June, the European Commission granted approval for FYB201 on August 26, 2022.

Further applications for the regulatory approval of FYB201 in other attractive markets are planned for submission in due course.

FYB201 was launched in the UK market by our partner Teva Pharmaceutical Industries Ltd. (Teva) in July under the name ONGAVIA®<sup>1</sup>. Within the 27 member states of the European Union as well as Iceland, Norway and Liechtenstein, the newly approved drug will be launched as soon as possible, likewise by Teva, under the name Ranivisio®<sup>2</sup>. The market launch in the U.S. by our partner Coherus BioSciences, Inc. is planned for October 2022 under the trade name CIMERLI™<sup>3</sup>.

In addition, upon regulatory approval, our partner MS Pharma will be responsible for commercializing FYB201 within the Middle East and North Africa (MENA) region (region) vermarkten.



#### FYB202 – candidate biosimilar to Stelara®

Der Biosimilar-Kandidat FYB202 referenziert auf das Arzneimittel Stelara® (Wirkstoff: Ustekinumab) und zielt auf mehrere Indikationen im entzündungshemmenden Bereich ab. Trotz des derzeit herausfordernden Umfelds bei der Durchführung klinischer Studien konnte die klinische Phase-III-Studie (VESPUCCI-Studie) im Juni erfolgreich abgeschlossen und mit dem Erreichen des primären Endpunkts die vergleichbare Wirksamkeit von FYB202 und dem Referenzarzneimittel Stelara® bei Patienten mit mittelschwerer bis schwerer Psoriasis vulgaris (Plaque-Psoriasis) belegt werden.

Der primäre Endpunkt misst die prozentuale Verbesserung des sogenannten Psoriasis Area and Severity Index (PASI) nach zwölf Wochen gegenüber dem Ausgangswert. Darüber hinaus verlief die Studie ohne klinisch relevante Unterschiede in Sicherheit und Immunogenität.

Eine im Rahmen von Scientific Advice Meetings mit der FDA und der EMA diskutierte erweiterte Phase-I-Studie konnte zwischenzeitlich gestartet werden. Nach Vorliegen dieser zusätzlichen pharmakokinetischen Daten ist die Einreichung der Zulassungsunterlagen für FYB202 in Europa und den USA für das dritte Quartal 2023 vorgesehen.

Durch die im ersten Halbjahr 2022 erfolgreich abgeschlossene Transaktion mit der ATHOS KG liegen die globalen Kommerzialisierungsrechte an FYB202 vollständig bei Formycon (vor der Transaktion 24,9 % Miteigentumsanteil).



#### FYB203 – candidate biosimilar to Eylea®

FYB203, a candidate biosimilar to Eylea® (active ingredient: aflibercept), is – like Lucentis® above – used in the treatment of neovascular age-related macular degeneration (nAMD) along with other serious eye diseases. Global reference drug sales in 2021 were up approximately 12.5% over the prior year, reflecting the increasing number of patients in the 55+ risk group.

As to the ongoing phase III clinical trials (MAGELLAN-AMD study), the final patient was recruited into the study ("last patient in") in April. The study was designed in consultation with the U.S. FDA, the European Medicines Agency (EMA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) with the aim of facilitating regulatory approval in each of these key regions.

<sup>1</sup> ONGAVIA® ist eine eingetragene Marke von Teva Pharmaceutical Industries Ltd.

<sup>2</sup> Ranivisio® ist eine eingetragene Marke der Bioeq AG.

<sup>3</sup> CIMERLI™ ist eine Marke von Coherus BioSciences, Inc.

The aim of these randomized, double-blind, multi-center phase III clinical trials is to demonstrate the comparability of FYB203 to the reference product Eylea® in terms of efficacy, safety and immunogenicity in patients with neovascular (wet) age-related macular degeneration. Primary efficacy endpoint data are expected by the end of this year.

FYB201 was out-licensed to our partner Santo Holding (Deutschland) GmbH under a deal signed in 2015. The worldwide marketing rights to the drug were subsequently shifted internally within Santo Group to another Santo entity, Klinge Biopharma GmbH.

Provided that clinical trials reach their successful conclusion and that respective regulatory approval is obtained, we should, by way of our respective commercialization partners, be able to launch FYB203 upon respective expiry of legal protection for the reference product first in the United States in 2024, then in Europe in 2025.



#### **FYB206 – biosimilar candidate not yet announced**

The FYB206 biosimilar project is advancing according to plan. With convincing results from extensive analytical characterization of the developed molecule, along with significant progress in the development of a manufacturing process, a comprehensive data package is currently being compiled in order to closely coordinate next steps during the second half of the year with both the EMA and the FDA through the scientific advice procedure. A scaling of the manufacturing process to commercial scale is planned for the end of 2022.



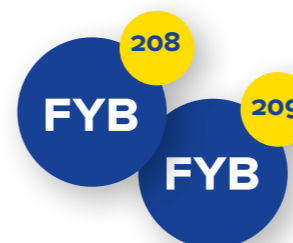
#### **FYB207 – development of an antibody-based COVID-19 drug**

FYB207 is a promising antiviral drug candidate against SARS CoV 2 and variants thereof. It is a fusion protein which links the ACE2 protein (angiotensin-converting enzyme 2) to the constant part of a natural human antibody. Because ACE2 is the entry point for cell infection, the virus is fundamentally unable to overcome an antiviral drug based specifically on this protein. Previously published laboratory studies have already demonstrated that FYB207 is able to retain its full antiviral potential even against the SARS CoV 2 alpha, beta and delta variants. New laboratory data now also show that the currently predominant omicron variant is likewise neutralized by FYB207 with a high level of efficacy.

Thanks to preclinical studies carried out during 2021, Formycon has been able to make modifications to the molecular structure leading to significant improvements in drug half-life and efficacy. The development strategy for an accelerated approval process was already coordinated during 2021 through the scientific advice procedure with both the Paul Ehrlich Institute (PEI) in Europe and with the U.S. FDA.

In a follow-on scientific advice consultation in May 2022, the PEI confirmed its full support for the accelerated development of the improved drug molecule. On this basis, preclinical studies are to be completed in 2022, the manufacturing process is to be adapted to the optimized molecule, and the production of test material for stability studies and clinical trials is to be carried out. Initiation of clinical trials is planned for 2023.

Formycon has extensive expertise and numerous patent applications in the field of fusion proteins against viral diseases, an increasingly important therapeutic area. Together with two renowned academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, Formycon has established a superb scientific reputation in this area, as reflected by the work on FYB207. The extraordinary promise of FYB207 is underscored not only by the extensive government funding received but also its recognition as Most Innovative Product® within the Pharma Trend Image & Innovation Award's "Leap Innovations". In view thereof, Formycon is currently evaluating various strategic options to maximally exploit the commercial potential of this platform technology. The exclusive license to develop, manufacture and market FYB207 for the Asia-Pacific region (excluding Japan) previously granted to SCG Cell Therapy Ltd. has, for this reason, been reclaimed. The intensive cooperation with our academic partners toward the ongoing development of FYB207, however, continues apace.



#### **FYB208 and FYB209 – biosimilar candidates not yet announced**

With the aim of continuously expanding its proprietary development pipeline, Formycon initiated two new biosimilar projects during the first half of 2022. The reference molecules for FYB208 and FYB209 were identified and preliminary development activities initiated.



### Summary and strategic focus

The development of biosimilars is Formycon's strategic focus and the basis for the Company's sustainable, long-term future growth.

With the market launch of its first biosimilar drug in 2022, Formycon is now entering a new phase of its corporate development in which resulting cash inflows are expected to open new growth opportunities for the Company. In addition, through the transaction with ATHOS KG and the associated acquisition by Formycon of a 50% stake in the FYB201 biosimilar candidate and 100% of FYB202, Formycon will enjoy a significantly higher share of future revenues upon approval and market launch. The Company plans to primarily invest the resulting cash inflows into the accelerated expansion of its product development pipeline. The resulting product portfolio will, in turn, create a strong and powerful basis to build the Company's position as a global competitor in the high-growth biosimilars market and to further develop Formycon's organization and resources as a fully integrated pharmaceutical company within this attractive market segment.

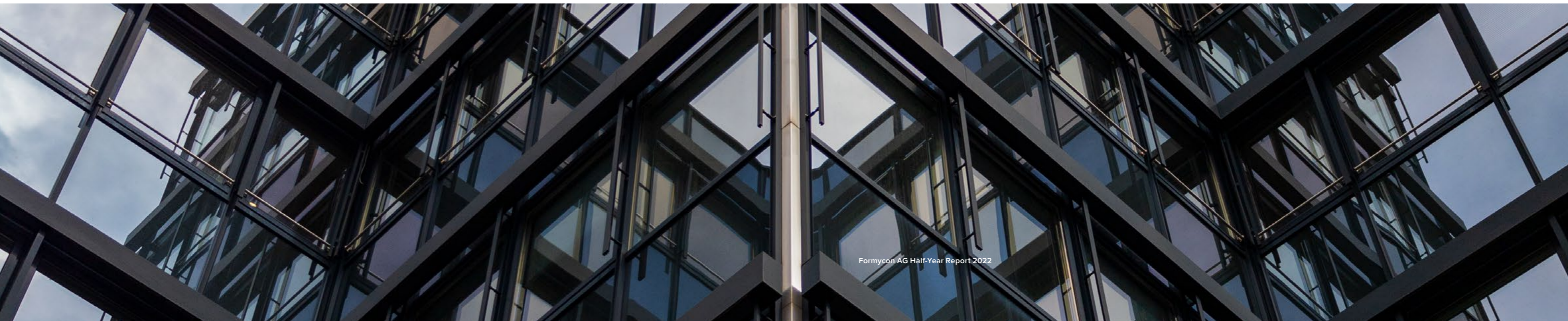
The development work on our innovative COVID 19 fusion protein was initiated to contribute to the global fight against COVID 19 by building upon our long and extensive experience in biopharmaceutical development. While the Company's strategic preference in the case of its biosimilar candidates is to develop these independently through to an advanced stage approaching commercialization, the intention in the case of Formycon's innovative COVID-19 drug project (FYB207) is, in contrast, to enter into a strategic global development and commercialization partnership at an earlier development phase because of the particular advantages of this alternative development approach.

### Financial profile and organization of Formycon

With its financial soundness and its strong portfolio of capabilities, Formycon is well positioned in the market. Through the market launches of FYB201 in the UK, the USA and Europe by the respective commercialization partners during 2022, both planned and already underway, Formycon expects to post its first-ever product sales revenue – and income resulting therefrom – in the second half of the fiscal year.

Formycon has been able to successfully cope with the coronavirus pandemic by taking prompt and proactive measures to protect its staff. The Company's emergency task force established for this purpose quickly worked to develop a comprehensive pandemic policy for the entire organization and remains in regular working contact with senior management as well as the relevant department heads to review the emergency measures taken so far and to improve and strengthen them as necessary. The early-stage decentralization of the Formycon organization by quickly putting into place a new work model focused on flexibility and mobility has proven to be extremely practical as well as effective in ensuring operational continuity. Nevertheless, it must be recognized that the risk of an infection spreading within or otherwise impacting the Company cannot be entirely eliminated and that such an event could have an impact on the Company's business operations, potentially hindering development activities of its biosimilar candidates. In order to counter this risk, the task force team is working on longer-term improvements to protect the health of our staff. For a further discussion of potential risks relating to the ongoing coronavirus pandemic, please refer to the following section (IV. Report on opportunities and risks).

Revenue for the first half of 2022 was in line with plan. Formycon's operating performance reflects non-capitalized investments into the Company's own FYB202, FYB206 and FYB207 projects as well as the expansion of its development pipeline to encompass the new FYB208 and FYB209 biosimilar projects.





## IV Report on opportunities and risks

### 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, for the most part, 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 the Company applies for its biosimilar development projects, the stringent selection of strong and reliable partners, and finally the quality and scientific expertise of the service providers and advisors on which Formycon additionally relies.

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

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

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

### Risks

#### Principles

Formycon, one of the few independent developers of biosimilar medicines, operates in a global market with many different participants and influencers. Business success is determined by the identification of profit opportunities, along with the best possible assessment of the many and varied risks associated with these. In order to ensure that this happens, the entire staff of Formycon, up to and including the Executive Board, must adhere to the Company's established risk management system, thereby aiming to ensure that these risks are handled optimally while at the same time providing the necessary entrepreneurial and operational flexibility. Regular reviews of this system further ensure that it is constantly improved and that, as circumstances change, changes are likewise made to the system promptly and in accordance with evolving needs.

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

In this way, all risks which are conceivable and significant, having first been broken down into the respective administrative and operational areas, are subjected to systematic ongoing monitoring and assessed as to their probability of occurrence and the severity of potential adverse consequences.

The Company's risk review process takes place every six months and is initiated and coordinated by the Legal & Compliance department. The results of the review, along with all relevant information, are presented to the Executive Board following each six-month period. The Executive Board may, if it deems appropriate, conduct its own independent assessment of risk management process and/or of specific key risks. The Executive Board also reports its findings to the Supervisory Board.

In parallel with these ongoing risk monitoring processes, the Company may also decide to assess and report on particular short-term risks that could require prompt action so that effective and timely countermeasures may be put in place as necessary.

The risk management system specifically encompasses the following risk areas, which are further described in the following sections: strategic risks; industry and market risks; controlling; environmental protection, health protection, and workplace safety; financing and liquidity risks; organizational risks; patent risks; staff risks; risks associated with product development; legal risks; regulatory and political risks; and competitive risks.

### Strategic risks

Compared to the development of an entirely new biopharmaceutical, the financial investment required for the development of a biosimilar drug is considerably less. Nevertheless, the development of a biosimilar may cost in the range of USD 100 to 200 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.

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. The intended therapeutic applications of the Company's other biosimilar development projects have not yet been announced.

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. With its advanced-stage biosimilar candidates, Formycon is focused on three of the world's best-selling biopharmaceuticals with combined 2021 global sales revenue of approx. € 21.5 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. Demographic trends around the globe are also playing a key role as populations continue to age and live longer. Older people require more extensive medical care, 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 31.3% of the total drug market in 2021, equal to € 16.1 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 cost € 100,000 per patient per year or more, is a major burden on health-care 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.

### Controlling

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

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

Workplace safety and health, as well as the protection of employees and the environment, is a top priority for Formycon. Formycon therefore places great importance not only on the fulfillment of statutory and regulatory requirements but also on the regular training and further qualification of all of its staff in the relevant aspects of workplace safety. In addition to our biological safety officer, our designated project manager as required under the German Genetic Engineering Act (Gentechnikgesetz) and our 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 and senior management 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 Company 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 Company's liquidity position is particularly strong for a company whose products are still in the development stage. Irrespective of this, conditions within the Company's operating business may change, giving rise to financial risks. As none of the Company's product candidates has 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 EUR 50 million by a consortium of two major company investors: ATHOS and the healthcare-focused investment group Active Ownership.

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 Company'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 starting from a certain product development stage.

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

With its strong financial footing, Formycon is well positioned to overcome future financial risks as these may arise. The Company's existing financial resources should be sufficient to cover its short- to medium-term capital needs. This, however, cannot be used to infer any sort of assurance as to the availability of long-term financial resources. There are, at present, no identifiable fundamental risks which would jeopardize the Company's continued existence.

#### **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 state-of-the-art security technology to eliminate or mitigate such risks – for example, relating to cyberattacks or data loss. The Company also regularly conducts maintenance and inspections of its critical equipment by trained personnel or specialized service providers, making changes to equipment as necessary to ensure that it remains at the state of the art.

#### **Patent risks**

The possibility of patent infringements, even if only alleged, is an inherent risk in biosimilar development because of the large number of potentially relevant patents which must be considered. Disputes with competitors or other patent owners, or defense against lawsuits claiming patent infringement, may pose a considerable financial burden. Particularly in the U.S., such legal actions generally involve very high costs. In the worst case, such a dispute could result in restrictions on, or even the prohibition of, the marketing of one or more products on one or more relevant markets, and/or the imposition of sizable fines. Such a legal action could also make it necessary to cease the development, launch, or ongoing marketing of one or more products.

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

#### **Staff risks**

The expertise and many years of experience of its employees are key pillars of Formycon's success. In particular, the development of a biosimilar drug, from early-stage analysis through to regulatory approval, requires highly qualified specialists. Over recent years, Formycon has been able to recruit numerous highly qualified scientists and managers. This demonstrates that the Company 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 would constitute a significant risk. To keep this risk as low as possible, the Company 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. The rate of sick leave at Formycon is, compared to other industries in Germany, very low. Formycon has, nevertheless, established a health management system to mitigate the impact of staff absences resulting from illness.

#### **Risks associated with product development**

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 Company'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 precise 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 Company'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. 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.

The above risks apply not only to the development of a biosimilar candidate but also, and to a very substantial degree, to the development of a new and innovative COVID 19 drug under the FYB207 development project. In the case of FYB207, there is the additional possibility that changes in the global pandemic and in the evolving situation might make it necessary to adjust basic assumptions underpinning the project and that circumstances could result that might lead to a reassessment of the profitability and financial viability of the overall project or could jeopardize the project in its entirety.

### Legal risks

Formycon does business in an 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, based upon patent law, competitive or antitrust law, tax law or environmental law, or arising from 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 Company's compliance obligations. Actions or inactions by the Company 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 Company has, in addition, introduced a compliance management system that takes into account applicable legal and regulatory requirements, which are also incorporated into the Company's Code of Conduct as well as other Company policies and standard operating procedures. The specific legal and regulatory requirements specifications are regularly reviewed and adjusted as necessary. The Company'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 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, upon expiry of patent protection on the reference product in the respective market. In each such market, Formycon must compete not only with the manufacturer of the reference drug, who might attempt to defend its market position and establish barriers to market entry (e.g. through life-cycle management), but also with other biosimilar producers. The competition situation in each specific case will depend upon the pricing of the reference drug as well as the pricing of any new competitors in the market. It is, in addition, entirely possible that the manufacturer of the originator product might reduce its pricing upon the market entry of new and competing biosimilars, or seek to enter into discount agreements with health insurers or other major buyers over extended contractually binding periods, in order to retain market share. This would improve its defensive competitive position against a new biosimilar entry and make it more difficult for the biosimilar to take share.

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

### Special risks relating to the Ukraine conflict

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 important to Formycon, as well as services, more expensive or potentially even scarce. Formycon strives to mitigate these risks through a long-term sourcing strategy based upon strategic partners and transparent pricing. However, the possibility cannot be ruled out that delays or interruptions in development projects could occur as a result of a potential scarcity of resources or rationing of energy, or that the development costs thereof could become significantly greater.

### Special risks relating to the COVID-19 pandemic

The proactive measures taken by Formycon in the very early stages of the COVID-19 pandemic to protect its workforce and avoid infection, and which have been continuously adjusted and consistently managed in the two years since, have proven their worth: Formycon's staff has been able to continue to work on a largely decentralized basis and with minimal disruption. A comprehensive hygiene concept was developed in cooperation with the company doctor and introduced as company policy, through

which Formycon also fully complies with applicable government regulations and occupational medical requirements. Where cases of suspected or potential COVID-19 infection have arisen, these have been promptly identified and tested, with no influence thus far on the course of business.

On this basis, and based upon present circumstances, it would thus seem unlikely that an infection outbreak within the Company's workforce – despite these far-reaching protective measures – would arise that would significantly impact business operations, projects and/or timelines. The possibility also continues to exist that, despite all these measures taken within Formycon, one of its partners or suppliers could be impacted by a COVID-19 outbreak, thereby indirectly impacting the Company.

### Summary assessment of risks

While there is always a possibility that one or more of Formycon's drug development projects could fail partially or completely for any of various scientific, technological, regulatory, economic or other reasons, this risk is inherently far lower than in the case of the development of an entirely new and innovative biopharmaceutical. The FYB207 project is, in contrast, an innovative project, and thus the associated risks are fundamentally those of any such innovative biopharmaceutical development project. In particular areas, Formycon must draw upon the services of outside partners and providers, which necessarily entails dependencies. Risks could thus potentially also arise within areas over which Formycon has no direct management control.

It must, moreover, be fundamentally recognized that the Company faces not only various known and identifiable risks but also unknown risks and uncertainties. These include, but are not limited to, risks associated with research and development, the regulatory approval process, the workings of regulatory and other authorities, the results of clinical trials, changes in laws and regulations, product quality, patient safety and patent disputes. With regards to projects in its pipeline, Formycon AG provides no representations, warranties or other guarantees that these will receive the regulatory or other related approvals required for market entry, or that these will be profitable and/or successful.

During 2022, the ongoing coronavirus situation has continued to demand that Formycon make significant changes to its organization and work processes, which the Company has been able to successfully achieve – thanks in no small part to the excellent cooperation and support from its staff. There has, however, been no indication to date of any circumstances arising as a result of COVID-19, neither within the organization nor externally, which would significantly impair the Company's business activities. That being said, the possibility can still not be entirely ruled out that the COVID situation in Germany might again worsen, and/or new restrictive measures be imposed, in such a way as to significantly and adversely impact work activities at Formycon.

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**Overall assessment**

Compared to the prior-year period, there has been no fundamental change in the risks facing the Company as these relate to its biosimilar development business activities. The risks with regard to FYB207 as an innovative project are comparable to those of any such innovative biopharmaceutical development project.

At present, no risks can be identified which might endanger the Company's continued existence. Through the use of internal control mechanisms, the Company is in a position to identify changes in its risk exposure at an early stage and to take appropriate action. Furthermore, in view of its financial stability, the Company is well equipped to deal with potential future risks.

Over the past year, the Company has continued to comply with requirements and carry out measures made necessary by the COVID-19 pandemic with minimal impact to its organizational function and business processes. As with so many other companies and industries, the coronavirus crisis has presented Formycon with an array of completely new challenges over the past two years. As a biotechnological company with extensive expertise in antibody development, Formycon has striven to turn these challenges into an opportunity by applying its scientific know-how and specialized resources to the FYB207 project, thus rising to the moment as it reaches beyond its core business of biosimilar development.

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

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

The Company'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 Company follows a conservative risk policy. To the extent that payment default or other credit risks are identifiable with regard to financial assets, these risks are reflected through value adjustments.

No risks are foreseen which might endanger Formycon AG as a going concern.

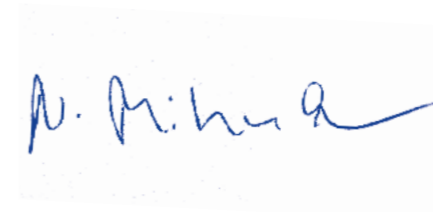
**VI Report on branches**

The Company does not currently maintain any branches.

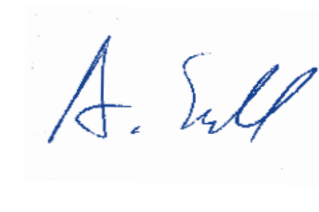
Martinsried/Planegg, Germany, July 31, 2022



**Dr. Stefan Glombitza**



**Nicola Mikulcik**



**Dr. Andreas Seidl**





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## Interim Balance Sheet Assets

as of June 30, 2022

In €K	June 30, 2022	Dec. 31, 2021
<b>A. Fixed assets</b>		
I. Intangible assets		
1. Purchased concessions, industrial property rights, and similar rights and assets, as well as licenses for such rights and assets	640	590
2. Goodwill	39	118
3. Advance payments	62	81
	<b>742</b>	<b>788</b>
II. Property, plant and equipment		
1. Land and buildings, including property-like rights and buildings on third-party land	114	107
2. Technical equipment and machinery	2,626	2,589
3. Other plant, production equipment and office equipment	583	587
4. Advance payments	0	60
	<b>3,323</b>	<b>3,344</b>
III. Financial assets		
1. Shares in affiliated companies	419,532	50
2. Loans to affiliated companies	2,000	2,000
3. Investment participations	23,661	23,661
4. Loans to associated companies	35,685	0
	<b>480,917</b>	<b>25,711</b>
<b>B. Current assets</b>		
I. Inventories		
1. Raw materials, consumables and supplies	152	359
2. Unfinished products and services	445	334
3. Advance payments	2,396	378
	<b>2,993</b>	<b>1,071</b>
II. Receivables and other assets		
1. Trade accounts receivable	0	3,186
2. Receivables from affiliated companies	6,485	7,235
3. Other assets	5,798	3,211
	<b>12,283</b>	<b>13,632</b>
III. Securities		
Other securities	150	150
	<b>150</b>	<b>150</b>
IV. Cash and cash equivalents	<b>12,963</b>	<b>22,098</b>
<b>C. Prepaid expenses</b>	<b>496</b>	<b>238</b>
<b>D. Deferred tax asset</b>	<b>310</b>	<b>310</b>
	<b>514,176</b>	<b>67,342</b>

## Interim Balance Sheet Liabilities and Equity

as of June 30, 2022

In €K	June 30, 2022	Dec. 31, 2021
<b>A. Equity</b>		
I. Subscribed capital <sup>1</sup>	15,065	11,065
II. Capital reserve	408,076	78,436
III. Retained Earnings	51,490	- 31,084
	<b>474,631</b>	<b>58,416</b>
<b>B. Provisions</b>		
1. Other provisions	2,939	3,458
	<b>2,939</b>	<b>3,458</b>
<b>C. Liabilities</b>		
1. Trade accounts payable	12,189	4,211
of which due within one year		
€ 12,189K (prior year: € 4,211K)		
2. Intercompany payables	12,838	0
3. Other liabilities	11,579	1,230
of which due within one year		
€ 11,170K (prior year: € 858K)		
of which due in more than one year:		
€ 409K (prior year: € 372K)		
of which from taxes		
€ 652K (prior year: € 404K)		
of which relating to social security		
€ 49K (prior year: € 42K)		
	<b>36,607</b>	<b>5,441</b>
	<b>514,176</b>	<b>67,342</b>

<sup>1</sup> Conditional Capital 2020: € 724K  
 Conditional Capital 2015: € 311K  
 Conditional Capital 2022: € 6,497K

## Interim Income Statement

for the period from January 1, 2022 to June 30, 2022

In T€	June 30, 2022	June 30, 2021
1. Sales revenue	12,469	12,364
2. Increase or decrease in inventories of finished and unfinished products	111	278
3. Other operating income	4,324	41
of which income attributable to foreign currency translation € 17K (prior year: € 5K)		
4. Cost of materials		
a. Cost of raw materials, consumables and supplies and of purchased goods	1,498	1,059
b. Cost of purchased services	10,427	13,035
	11,925	14,094
5. Staff expenses		
a. Wages and salaries	6,803	5,261
b. Social contributions and costs for retirement benefits and for support benefits	1,144	972
	7,948	6,234
of which for retirement benefits € 74K (prior year: € 69K)		
6. Depreciation, amortization and impairments of intangible assets and on property plant and equipment	518	455
7. Other operating expenses	3,627	2,025
of which expense arising from foreign currency translation € 20K (prior year: € 10K)		
8. Income from participations	89,730	0
of which from affiliated companies € 0K (prior year: € 0K)		
9. Other interest and similar income	33	42
of which from affiliated companies € 33K (prior year: € 41K)		
10. Impairments of financial assets and securities held in current assets	0	0
11. Interest and similar expense	75	75
12. Taxes on income	0	-77
<b>13. Income after tax</b>	<b>82,575</b>	<b>-10,081</b>
13. Other taxes	1	1
<b>14. Period net loss</b>	<b>82,574</b>	<b>-10,082</b>
15. Loss carryforward from prior year	31,084	17,801
<b>16. Accumulated loss to balance sheet</b>	<b>51,490</b>	<b>-27,883</b>



## Notes to the Interim Financial Statements of Formycon AG for the period from January 1, 2022 to June 30, 2022

### I I. General information about the Company

Formycon AG ("Formycon" or the "Company"), together with the subsidiary companies within its scope of consolidation (the "Group"), is a leading independent developer of high-quality biosimilar drugs, meaning follow-on products to biopharmaceuticals already on the market.

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).

### II General information about the content and structure of these Interim Financial Statements

These Interim Financial Statements, presented here in translation from the German original, have been prepared in euros (€) in accordance with sections 242 et seq. of the German Commercial Code (Handelsgesetzbuch, HGB) under observance of the supplementary provisions of sections 264 et seq. of the Commercial Code applicable to medium-sized corporations as well as sections 150 et seq. of the German Stock Corporation Act (Aktiengesetz).

The Company is a medium-sized corporation within the sense of sec. 267 of the Commercial Code and thus makes use of the simplified requirements depending upon company size as provided under sec. 266 para. 1, sec. 276 and sec. 288 of the Commercial Code.

The Income Statement has been prepared using the total expenditure format in accordance with sec. 275 para. 2 of the Commercial Code

### III Balance sheet presentation and valuation methods

#### General

The valuation methods used were selected in conformity with the general stipulations listed in sec. 252 of the Commercial Code and applied in observance of the principles of balance sheet continuity, going concern, individual valuation and prudent business judgment.

The Balance Sheet was structured in accordance with the provisions of sec. 266 of the German Commercial Code and sec. 152 of the German Stock Corporation Act, organized into fixed assets, current assets, equity, liabilities, and deferred and prepaid items.

The accounting and valuation methods applied to balance sheet and income statement items in the prior year were retained.

#### Foreign currency translation

Assets and liabilities denominated in foreign currency are translated into euros at the average spot exchange rate on the day of their original posting. Changes in exchange rates between then and the balance sheet date are reflected by write-downs of assets or write-ups of liabilities only for amounts due in more than one year and only to the extent necessary so that valuation on the balance sheet date is without losses. Items due within a period of less than one year are translated at the average spot exchange rate as of the date of the financial statements. The resulting income or expense arising from currency translation is shown separately in the Income Statement under other operating income or expenses.

#### Derivatives

The Company did not hold any derivative financial instruments as of June 30, 2022.

#### Principles of balance sheet presentation and valuation

The Balance Sheet includes all assets, all liabilities and all prepaid and deferred items. Assets and liabilities are valued individually. The valuation of assets and liabilities takes all risks into account which are identifiable based on the principles of prudent business judgment.

#### Fixed assets

Purchased **intangible assets** (including software and licenses) are capitalized at their cost of acquisition and amortized based upon expected useful life.

No use has been made of the elective right under sec. 248 para. 2 of the Commercial Code to capitalize self-produced intangible assets.

**Goodwill** derived from acquisitions is amortized on a linear pro rata basis over a business-customary useful life of ten years. The long useful life (extending until September 30, 2022) was chosen because this goodwill represents, among other factors, licensing opportunities over long periods.

**Property, plant and equipment** are valued at their cost of acquisition, less accumulated depreciation. The depreciation of all moveable assets is linear, with depreciation in the year of acquisition on a pro rata basis. In the event of any impairment in value which is expected to be permanent, the respective asset is written down to the lower fair value.

**Financial assets** are stated at their cost of acquisition, or should there be an impairment in value, regardless of whether it is expected to be permanent or temporary, written down to the lower fair value.

With effect from May 1, 2022, Formycon AG announced the acquisition of the biosimilar assets FYB201 and FYB202 as well as of Bioeq GmbH. This transaction specifically encompasses:

- the complete assumption of the biosimilar candidate FYB202 (ustekinumab) through the acquisition of 100% of the shares of FYB 202 Project GmbH, a Berlin-based company, and the acquisition of 50% of rights to biosimilar candidate FYB201 (ranibizumab) through the acquisition of 50% of the shares in Bioeq AG, based in Zug, Switzerland;
- the acquisition of 100% of the shares in Bioeq GmbH, the operational development unit based in the town of Holzkirchen on the southern outskirts of Munich; and
- a non-cash capital increase against contributions in kind to Formycon AG, making ATHOS KG the largest shareholder of Formycon AG with a total indirect shareholding of 26.6%.

At the time of closing, the valuation of the assets acquired under the transaction was approx. € 650 million, consisting of the following two components:

As a result of the related non-cash capital increase, the Company's registered capital (Grundkapital) increased from € 11,064,750.00 to € 15,064,750.00, thereby fully utilizing the Company's existing approved capital in the amount of € 4,000,000.00, through the issuance of 4,000,000 new bearer shares without par value but with an imputed nominal value of € 1.00 per share to the respective selling entities against contributions in kind. Based on a valuation of € 83.41 per Formycon share, jointly determined and confirmed by independent experts, the total value of this non-cash capital increase is approx. € 334 million. With the completion of the transaction, ATHOS is now the largest shareholder in Formycon AG with a total indirect shareholding of around 26.6% of Formycon's share capital. Of the total new shares issued, 55,000 shares are attributable to Bioeq GmbH, 670,000 to the 50% shareholding in Bioeq AG along with settlement of a shareholder loan in the nominal amount of € 82 million, which was also contributed under the transaction, and the remaining 3,275,000 shares to FYB202 Project GmbH.

In addition, ATHOS received a revenue share (earn-out component) in Formycon's future sales of FYB201 and FYB202, through which ATHOS is expected to earn a total participation estimated in the mid three-digit million range over an estimated period of 15 years. Under the terms of the transaction, Formycon has the option to satisfy the earn-out component at any time in advance, in full or in part. At the time of the capital contribution, the contributed loan receivable from Bioeq AG less the share of the earn-out component attributable thereto was valued at € 32.2 million.

## Umlaufvermögen

Raw materials, consumables and supplies as well as purchased goods in **inventories** are valued at their average cost of acquisition, insofar as a write-down to a lower value as of the balance sheet closing date is not required. Finished and unfinished products are valued at their cost of production in accordance with sec. 255 para. 2 sentence 2 of the Commercial Code.

**Receivables and other assets** are valued at the lower of nominal or fair value. In the case of doubtful receivables, bad debt allowances are made individually. There are no general provisions for bad debts.

**Securities** are stated at the lower of their cost of acquisition or fair (market) value as of the balance sheet closing date.

**Cash and cash equivalents** are stated at their nominal value.

## Prepaid and deferred items

**Prepaid and deferred items** are posted in accordance with sec. 250 of the Commercial Code.

## Deferred taxes

The calculation of **deferred taxes** as of December 31, 2021, in accordance with sec. 274 of the Commercial Code, is based upon timing differences between balance sheet items as these are stipulated under the Commercial Code and under German tax law. The resulting cumulative deferred tax relief (deferred tax asset) and cumulative deferred tax burden (deferred tax liability) are determined on a net basis in accordance with sec. 274 para. 1 sentence 3 of the Commercial Code. In addition, the deferred tax relief resulting from existing loss carryforwards is recognized. The income tax rate used to calculate deferred taxes is 26.68%, or in the case of investment participations in partnerships, 15.83%. With the exit of Formycon AG during the first half of 2022 as a shareholder of FYB202 GmbH & Co. KG, deferred tax assets now consist solely of tax loss carryforwards.

On this basis, the deferred tax amounts are calculated as follows:

	<b>Deferred taxes</b> (in €K)
Deferred tax asset from loss carryforward	5.292
Deferred tax assets to balance sheet	5.292
Impairment	-4.980
<b>Total</b>	<b>312</b>
<b>Prior year</b>	<b>310</b>
Addition to deferred tax assets as of June 30, 2022	0

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**Provisions**

**Tax provisions and other provisions** take into account all uncertain obligations and all identifiable risks. These are stated at the amount required for their fulfillment using prudent business judgment, including future increases in prices and costs. Provisions due after more than one year are discounted from the time of their expected fulfillment at the average market interest rate over the past seven fiscal years.

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**Liabilities**

**Liabilities** are stated at the amount required for their fulfillment.

#### IV Additional notes to the Balance Sheet

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**Fixed assets**

A **Schedule of Fixed Assets**, including depreciation and amortization taken in the current period, is provided in Attachment 1 to these Notes.

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**Receivables and other assets**

The remaining term of receivables and other assets, and their relationship to other balance sheet items, is shown in the **Schedule of Receivables** included as Attachment 2.

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**Equity capital**

Changes to equity are presented in the **Schedule of Changes in Equity** included as Attachment 4.

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**Information required per sec. 160 of the Stock Corporation Act**
**Number of shares outstanding**

The Company has registered capital (*Grundkapital*) of € 15,064,750.00, which is divided into 15,064,750 bearer shares without par value.

**Approved Capital 2019**

By resolution of the Annual General Meeting of June 27, 2019, the Executive 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 June 26, 2024, and by no more than a total of € 4,000,000, through the issuance of up to 4,000,000 new no-par-value common bearer shares, against contributions in cash and/or in kind (the "Approved Capital 2019"). 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 Company's shareholders shall, in general, be granted subscription rights. The shares may, however, also be assumed by one or more banks subject to the obligation that they offer these to the Company's shareholders for subscription (indirect subscription rights). Notwithstanding the foregoing, the Executive Board is authorized, subject to the approval of the Supervisory Board, to exclude the general statutory subscription rights of shareholders in the following specific cases:

- for fractional shares;
- in the case that the capital increase is made against cash contributions and the issue price of the new shares is not significantly lower than the stock exchange price and the new shares issued under exclusion of subscription rights do not exceed 10% of the share capital, either at the time this authorization takes effect or at the time this authorization is exercised, whereby this 10% limit is to be calculated based on the proportion of share capital attributable to new shares issued, or repurchased treasury shares sold, subsequent to December 10, 2020 under a simplified exclusion of subscription rights pursuant to or in accordance with sec. 186 para. 3 sentence 4 of the German Stock Corporation Act, as well as calculated based on the proportion of share capital relating to stock options and/or conversion rights or obligations arising from bonds issued subsequent to December 10, 2020, likewise in accordance with sec. 186 para. 3 sentence 4 of the Stock Corporation Act; and
- in the case of capital increases against non-cash contributions for the granting of shares for the purchase of companies, parts of companies, or equity interests in companies (including increases of existing equity investments), or in satisfaction of financial obligations of the Company.

The Executive Board is authorized, subject to approval of the Supervisory Board, to determine further details regarding the specific implementation of any such capital increase from Approved Capital 2019. The Supervisory Board is further authorized to amend the Company's articles of incorporation (Satzung) to reflect the increase in registered capital and corresponding decrease in Approved Capital 2019 in the event of any such full or partial utilization of the Approved Capital 2019, or in the event of its expiry.

This action was entered into the Company's commercial register on October 22, 2020.

With increase in the Company's registered capital increased by € 4,000,000.00 through the issue of 4,000,000 new shares during the first half of 2022, the Approved Capital 2019 has now been fully utilized.



### Approved Capital 2022

By resolution of the Annual General Meeting of June 30, 2022, the Executive 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 June 29, 2027, and by no more than a total of € 7,532,375.00, through the issuance of up to 7,532,375 new no-par-value common bearer shares, against contributions in cash and/or in kind (the "Approved Capital 2022"). The Company's shareholders shall, in general, 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 Executive 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.

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### Number of subscription rights per sec. § 192 para. 2 no. 1 of the Stock Corporation Act

- 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 approved capital.

The Executive 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 Approved Capital 2022 in the event of any such full or partial utilization of the Approved Capital 2022 or in the event of its expiry.

### Conditional Capital 2019

By resolution of the Annual General Meeting of June 30, 2022, the Conditional Capital 2019 has been revoked.

### 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 for the issuance of a maximum of 6,497,125 new no-par-value bearer shares (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 financial 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 Executive Board is authorized, subject to the approval of the Supervisory Board, to determine further details regarding the specific implementation of any capital increases hereunder.

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**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 Executive Board and Company employees, as well as executives and employees of Company subsidiaries and affiliates, 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 Executive 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 Executive 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.

As of the period closing date, a total of 311,250 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 Executive Board and Company employees, as well as executives and employees of Company subsidiaries and affiliates, 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 Executive 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 Executive 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.

As of the period closing date, a total of 49,000 stock options were issued thereunder and not either expired or exercised.

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#### Provisions

Other provisions are substantially comprised of the following:

In € K	June 30, 2022	Dec. 31, 2021
Bonuses	355	908
Accrued vacation	442	217
Safekeeping obligations	146	146
Accrued expenses	1.457	2.078
Audit and advisory costs	498	54
Litigation costs	0	0
Occupational cooperative and other social expenses	35	54
Miscellaneous staff provisions	7	28

**Liabilities**

The remaining term of liabilities, along with their collateralization through liens or similar rights and their relationship to other balance sheet items, is shown in the Schedule of Liabilities included as Attachment 3 to these Note.

**Contingent liabilities**

The Company has issued a letter of comfort (Patronatserklärung) in support of its subsidiaries Formycon Project 201 GmbH and Formycon Project 203 GmbH. To the best of our knowledge, the respective companies will be able, in all cases, to fulfill their underlying obligations. Claims thereunder are thus not anticipated.

**Other financial obligations**

The total amount of other financial obligations, within the meaning of sec. 285 sentence 1 no. 3a of the Commercial Code, results from contractual obligations for ongoing performance. For obligations up to one year, the total amount is € 843K, for obligations between one and five years € 3,958K, and for obligations beyond five years, € 0K.

**V. Additional notes to the Income Statement**

Total research and development costs during the reporting period were € 24,018K.

**VI Other information****Number of staff**

Sec. 285 no. 7 of the Commercial Code requires the following information regarding the average number of staff during the reporting period:

Average number of staff	1H 2022
Administration	30
Research & development	150
<b>Total company staff</b>	<b>180</b>

**Information on the Executive Board and Supervisory Board**

Information on members of the Executive Board per sec. 285 no. 10 of the Commercial Code:

- **Dr. Carsten Brockmeyer**, residing in Marzling, Chief Executive Officer (until June 30, 2022)
- **Dr. Stefan Glombitza**, residing in Holzkirchen, Chief Executive Officer (with effect from July 1, 2022)
- **Dr. Nicolas Combé**, residing in Munich, Chief Financial Officer (until June 30, 2022)
- **Dr. Stefan Glombitza**, residing in Holzkirchen, Chief Operating Officer (until June 30, 2022)
- **Nicola Mikulcik**, residing in Munich, Chief Business Officer (with effect from June 1, 2022)
- **Dr. Andreas Seidl**, residing in Oberhaching, Chief Scientific Officer (with effect from July 1, 2022)

Information on members of the Supervisory Board per sec. 285 no. 10 of the Commercial Code:

- **Dr. Olaf Stiller**, residing in Marburg (Chair)  
Member of the executive board of Paedi Protect AG  
Member of the executive board of Deutsche Kosmetikwerke AG
- **Peter Wendeln**, residing in Oldenburg (Deputy Chair)  
Managing partner, Wendeln & Cie. Asset Management GmbH
- **Klaus Röhrig**, residing in Vienna (member)  
Founding partner and managing director, Active Ownership Capital S.à r.l., Grevenmacher, Luxembourg
- **Dr. Thomas Strüngmann**, residing in Pinneberg (member)  
Principal, ATHOS KG



The following members of the Supervisory Board are members of other supervisory boards:

- **Dr. Olaf Stiller**      **Member of supervisory board,**  
Bodenwert Immobilien AG  
**Chairman of supervisory board,** Nano Repro AG  
**Member of supervisory board,**  
Deutsche Reinigungswerke AG
  
- **Klaus Röhrig**      **Member of board of directors,** Agfa-Gevaert NV  
**Member of supervisory board,** Francotyp-Postalia  
Holding AG
  
- **Dr. Thomas Strüngmann**      **Member of international oversight committee,**  
SiO2 Medical Products, Inc., Auburn, Alabama, USA

#### Remuneration

During the reporting period, the members of the Supervisory Board received total remuneration of € 42K (1H 2021: € 42K), while total remuneration to members of the Executive Board, within the meaning of sec. 285 no. 9 of the Commercial Code, was € 1,378K (1H 2021: € 676K), of which € 461K (1H 2021: € 213K) was success-based, and including 22,500 stock options with a current fair value of € 35,550.

As of the balance sheet closing date, there were no subscription rights issued but not yet exercised.

#### Information on shareholdings per sec. 285 no. 11 of the Commercial Code

	Share of capital (in %)	Equity (in €K)	Period net income/loss (in €K)
Formycon Project 201 GmbH (Planegg/Martinsried, Germany)	100	- 221	- 25
Formycon Project 203 GmbH (Planegg/Martinsried, Germany)	100	-2.121	-22
FYB202 Project GmbH (Planegg/Martinsried, Germany)	100	34.468	-2.029
Bioeq GmbH (Planegg/Martinsried, Germany)	100	4.244	366
Bioeq AG (Zug, Switzerland)	50	13.923*	-2.689*

\*in accordance with IFRS

#### Information on auditor fees per sec. 285 no. 17 of the Commercial Code

in € K	1H 2022	1H 2021
Audit services	489	10
Tax advisory and other services	30	2
<b>Total</b>	<b>519</b>	<b>12</b>

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

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

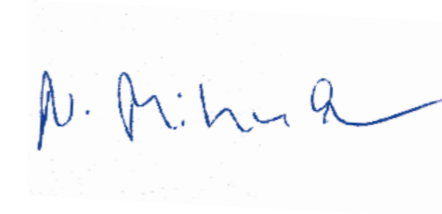
#### Significant events subsequent to balance sheet closing date

With regard to the ongoing COVID 19 pandemic, Formycon has been able to adapt well to the prevailing situation by reacting promptly and by implementing appropriate measures to decentralize organizational functions, so that the impact of the pandemic on the Company's operational activities, particularly for development, has thus far been minimal.

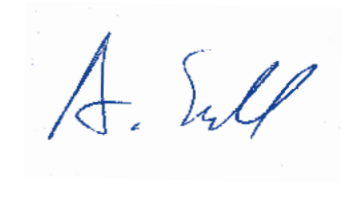
Martinsried/Planegg, Germany, July 31, 2022



Dr. Stefan Glombitza



Nicola Mikulcik



Dr. Andreas Seidl

## Schedule of Fixed Assets

Attachment 1

for the period from January 1, 2022 to June 30, 2022

In €K	Changes in historical cost of acquisition					Changes in accumulated depreciation & amortization				Changes in net book value		
	Historical cost of acquisition or production at Dec. 31, 2021	Additions	Rebookings	Historical cost of disposals	Historical cost of acquisition or production at June 30, 2022	Accumulated depreciation & amortization at Dec. 31, 2021	Current-year depreciation & amortization	Write-downs on disposals	Accumulated depreciation & amortization at June 30, 2022	Net book value at Dec. 31, 2021	Net book value of disposals	Net book value at June 30, 2022
<b>Intangible assets</b>												
Concessions, commercial property rights, and similar rights and assets, as well as licenses for such rights and assets	1,137	110	24	0	1,161	547	84	0	631	590	0	530
Godwill	1,576	0	0	0	1,576	1,458	79	0	1,537	118	0	39
Advance payments	81	6	- 24	0	62	0	0	0	0	81	0	62
<b>Property, plant and equipment</b>												
Land and buildings, including property-like rights and buildings on third-party land	613	31	0	0	644	506	25	0	530	107	0	114
Technical equipment and machinery	5,764	231	60	108	5,948	3,176	242	96	3,321	2,589	12	2,626
Other plant, production equipment and office equipment	1,748	85	0	4	1,829	1,161	89	4	1,246	587	0	583
Advanced payments and construction in progress	60	0	- 60	0	0	0	0	0	0	60	0	0
<b>Financial assets</b>												
Shares in affiliated companies	50	419,482	0	0	419,532	0	0	0	0	50	0	419,532
Loans to affiliated companies	2,000	0	0	0	2,000	0	0	0	0	2,000	0	2,000
Loans to associated companies	0	35,685	0	0	35,685	0	0	0	0	0	0	35,685
Investment in associates – private companies	23,661	1,419	0	25,081	0	0	0	0	23,661	25,081	0	0
Investment in associates – corporations	0	23,670	0	0	23,670	0	0	0	0	0	0	23,700
<b>Total</b>	<b>36,691</b>	<b>480,640</b>	<b>0</b>	<b>25,193</b>	<b>492,138</b>	<b>6,848</b>	<b>518</b>	<b>101</b>	<b>7,265</b>	<b>29,843</b>	<b>25,092</b>	<b>484,872</b>

## Schedule of Receivables

Attachment 2

for the period from January 1, 2022 to June 30, 2022

In €K	June 30, 2022	of which due in more than 1 year	of which due within 1 year
Trade accounts receivable	0	0 (prior year: 0)	0 (prior year: 3,186)
Receivables from affiliated companies	6,485	0 (prior year: 0)	6,485 (prior year: 7,235)
Receivables from associated companies	0	0 (prior year: 0)	0 (prior year: 0)
Other assets	5,798	0 (prior year: 0)	5,798 (prior year: 3,211)
<b>Total</b>	<b>12,283</b>	<b>0 (prior year: 0)</b>	<b>12,283 (prior year: 13,632)</b>

## Schedule of Liabilities

Attachment 3

for the period from January 1, 2022 to June 30, 2022

In €K	June 30, 2022	of which due within 1 year	of which due in 1 – 5 years	of which due in more than 5 years	of which pledged as security	Type and form of security
Trade accounts payable	12,189	12,189 (prior year: 4,211)	0 (prior year: 0)	0 (prior year: 0)	0	
Liabilities toward affiliated companies	12,838	12,838 (prior year: 0)	0 (prior year: 0)	0 (prior year: 0)	0	
Other liabilities	11,579	11,171 (prior year: 858)	409 (prior year: 372)	0 (prior year: 0)	409	Industry-customary conditional retention of title
<b>Total</b>	<b>36,607</b>	<b>36,198 (Vorjahr: 5,069)</b>	<b>409 (prior year: 372)</b>	<b>0 (prior year: 0)</b>	<b>409</b>	

## Schedule of Changes in Equity

Attachment 4

for the period from January 1, 2022 to June 30, 2022

In €K	Subscribed capital	Capital reserves	Profit reserves	Loss carryforward	Annual net income (loss)	Equity
<b>as of Dec. 31, 2021</b>	<b>11,065</b>	<b>78,436</b>	<b>0</b>	<b>- 17,801</b>	<b>- 13,283</b>	<b>58,416</b>
Capital increases	4,000	0	0	0	0	4,000
Additions to capital reserves	0	329,640	0	0	0	329,640
Appropriation of prior-year profit	0	0	0	- 13,283	13,283	0
Annual net income (loss)	0	0	0	0	<b>82,574</b>	<b>82,574</b>
<b>as of June 30, 2022</b>	<b>15,065</b>	<b>408,076</b>	<b>0</b>	<b>- 31,084</b>	<b>82,574</b>	<b>474,631</b>

## Review Report of Independent Auditor

To Formycon AG:

We have reviewed the accompanying interim financial statements as of June 30, 2022, consisting of the balance sheet, income statement, notes to the financial statements and schedule of changes in equity as well as the interim management report for the period from January 1, 2022 to June 30, 2022.

The preparation of the interim financial statements and interim management report in accordance with German commercial law, as well as supplementary provisions under the Company's articles of incorporation (Satzung), are the responsibility of the Company's management. Our responsibility is to issue a certified report, based on our review, on the interim financial statements and interim management report.

We have conducted our review of the interim financial statements and interim management report in accordance with German generally accepted standards for the review of financial statements as established by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer, IDW). These standards require that we plan and perform our review so as to exclude the possibility, with a reasonable degree of certainty in our critical appraisal, that the interim financial statements are not, in all material respects, in accordance with the requirements of German commercial law and supplementary provisions under the Company's articles of incorporation, or that the Company's net assets, financial position and profitability are not presented in accordance with [German] principles of proper accounting, or that the interim management report is not consistent with the interim financial statements, or as a whole does not provide a suitable view of the Company's position or does not suitably present the opportunities and risks of future developments.

A review, which consists primarily of asking questions of Company staff and of making analytical assessments, does not offer the degree of assurance which may be attained through an audit examination. Because we have not been commissioned to conduct an audit examination [of these interim financial statements], we cannot provide an audit opinion.

Based upon our review, nothing has come to our attention that causes us to believe the interim financial statements are not, in all material respects, in accordance with the requirements of German commercial law and supplementary provisions under the Company's articles of incorporation, or that the Company's net assets, financial position and profitability are not presented in accordance with [German] principles of proper accounting, or that the interim management report is not consistent with the interim financial statements, or as a whole does not provide a suitable view of the Company's position or does not suitably present the opportunities and risks of future developments.

This certified report is directed to the Company for informational purposes.

The mandate under which we have provided our services to Formycon AG as described above is subject to the General Terms of Engagement for German Public Auditors and Public Audit Firms of January 1, 2017. By acknowledging and using the information contained within this report, the recipient confirms acceptance of the terms and conditions therein (including the liability provision under item 9 of the General Terms of Engagement), specifically the applicability thereof in relation to us.

The publication or dissemination of the interim financial statements and interim management report in any form deviating from that which was the subject of our review shall, insofar as this report is quoted, or reference is made to our review, require our renewed review.

Munich, September 29, 2022



**PanTaxAudit GmbH**  
Wirtschaftsprüfungsgesellschaft

**Kevin Lucien Schneider**  
Wirtschaftsprüfer  
[German Public Accountant]



## Legal information

<b>Company name:</b>	Formycon AG
<b>Legal form:</b>	German stock corporation (Aktiengesellschaft)
<b>Registered location:</b>	Martinsried/Planegg, Germany
<b>Street address:</b>	Fraunhoferstr. 15, 82152 Martinsried/Planegg, Germany
<b>Company founding and articles of incorporation:</b>	The Company was established through its articles of incorporation (Satzung) dated 5 May 2010, which were most recently amended on December 1, 2021.
<b>Subject of business:</b>	The subject of the Company's business is the development of pharmaceutical and biopharmaceutical products, the development of drug delivery systems, the provision of diagnostic laboratory services and works for third parties, and the carrying out of diagnostic laboratory services.
<b>Commercial register:</b>	The Company is entered into the commercial register (Handelsregister) of the District Court of Munich under number HRB 200801.
<b>Fiscal year:</b>	The Company's fiscal year runs from January 1 to December 31 of each year.
<b>Registered capital:</b>	15.064.750 €
<b>Executive Board (Vorstand):</b>	Dr. Stefan Glombitza Nicola Mikulcik Dr. Andreas Seidl
<b>Supervisory Board (Aufsichtsrat):</b>	Dr. Olaf Stiller, residing in Marburg, Chairman Peter Wendeln, residing in Oldenburg, Deputy Chairman Klaus Röhrig, residing in Vienna (Austria), Member Dr. Thomas Strüngmann, residing in Pinneberg, Member (with effect from July 1, 2022)

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