



Annual Report 2021





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# **To Our Shareholders**

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Dear Shareholders.

### "Ready for a competitive and patient-oriented pharmaceutical market through Biosimilars"

As we look back upon fiscal year 2021, we have chosen this as the title of our report to you. It was a year that began with our submission of approval applications to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for our Lucentis®\* biosimilar candidate FYB201, laying the foundation to create competition and improve patient access to vital treatments in the field of ophthalmology. We look forward with great optimism to these expected approvals of our first biosimilar this year, followed closely by anticipated market launches through our strong commercialization partners, notably Coherus BioSciences, Inc. in the United States and Teva Pharmaceutical Industries Ltd. in Europe and other territories. Together with these and other partners, we are ready to make a sustainable contribution so that more patients around the world will be able to benefit from high-quality, affordable biopharmaceuticals, while at the same time helping to relieve the cost burden on the world's healthcare systems.

The European biosimilars market, which with total 2021 sales revenue of some EUR 8.8 billion<sup>1</sup> accounts for roughly half of the global market by value,<sup>2</sup> testifies to the fact that biosimilars – just 15 years after the introduction of the first drug of this kind – are now firmly established, and demand is rising rapidly. With seven biosimilar products newly approved in Europe during 2021, the range of these new competing medicines is likewise expanding steadily.

Within Germany, legal protection periods for more than 40 originator biopharmaceuticals representing total annual sales of over EUR 3 billion will expire by 2025.<sup>3</sup> Within this one country alone, more than EUR 1.5 billion was saved during 2021 through the use of biosimilars.<sup>4</sup> Looking ahead, biosimilars represent a large and critically important segment of the world's pharmaceutical market in which FORMYCON has been working hard to establish a strong and enduring position. Our recently announced strategic partnership with ATHOS KG will help FORMYCON to achieve its goal of expanding into a fully integrated pharmaceutical company with global reach in the rapidly growing biosimilars market. Through this transaction with a total purchase

From left to right: Dr. Carsten Brockmeyer, CEO Dr. Stefan Glombitza, COO Dr. Nicolas Combé, CFO

IQVIA, "The Impact of Biosimilar Competition in Europe", December 2021

- McKinsey & Company, "An inflection point for biosimilars"
- Ärzteblatt, Umsatz mit Biopharmazeutika seit 2006 verfünffacht
- 4 Pro Biosimilars, "Grafik des Monats März 2022"

value of some EUR 650 million, FORMYCON will reacquire a 50 percent interest in our previously out-licensed candidate biosimilar to Lucentis® (FYB201) and full rights to our previously out licensed candidate biosimilar to Stelara®\*\* (FYB202), resulting in a significant increase of our participation in potential future sales revenues from these two new drugs. We will, moreover, be able to invest the expected cash inflows into the accelerated expansion of our development pipeline and into our company so that we will have the scope of resources to independently develop and commercialize our future biosimilar candidates. The potential future revenues from such new drugs will, in turn, sustainably increase our value creation and raise the growth trajectory of our company.

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A retrospective of 2021 can hardly ignore the unending coronavirus pandemic. Scientists around the world are now operating on the assumption that humanity will have to live with the novel SARS-CoV-2 virus, and the COVID-19 illness which it causes, for decades to come. While vaccination campaigns have been progressing in Europe and the United States, large parts of the world's population do not have access to COVID-19 vaccines - and for this reason, the risk of SARS-CoV-2 escape mutations remains high. During the second half of 2021, the course of the COVID-19 pandemic was marked by the emergence of the aggressive SARS-CoV-2 delta variant, followed by the highly infectious SARS-CoV-2 omicron variant, which spread even more rapidly in the first quarter of 2022. Both of these are considered "variants of concern", meaning in particular concerns about the efficacy of existing approved COVID-19 vaccines and therapeutic antibodies. Although the omicron variant appears clinically less worrisome than the delta variant, the high number of omicron infections has nevertheless resulted in a heavy burden to health systems and the patients they serve. Looking ahead to the next fall and winter, seasonal recurrence of new and aggressive SARS-CoV-2 variants must also be considered. Finally, special needs for effective COVID-19 therapies are presented by the large number of immunocompromised people whose immune systems are severely weakened due to serious illnesses, transplants or advanced age. For this patient segment, which is gaining increased attention, there remains an urgent need for a drug treatment which can effectively neutralize all SARS-CoV-2 variants, is resistant to mutations, and can even be administered prophylactically.

Through our innovative FYB207 drug development project, we are pursuing the goal of a long-acting drug which will be broadly effective against all coronaviruses that use ACE2 as an entry point for cell infection. Laboratory studies have shown that FYB207, in contrast to COVID-19 vaccines and SARS-CoV-2 neutralizing antibodies, retains its full effectiveness even against the newer SARS-CoV-2 variants of concern. As public recognition of its promise as a treatment and of the innovation which it represents, FORMYCON'S FYB207 received the Pharma Trend Image & Innovation Award

and Energy.

In all of our development projects, and from our earliest days, FORMYCON has steadfastly pursued a rigorously scientific approach: "Science First". Thus, in our development work for FYB207 at the end of 2021, we decided to conduct additional preclinical studies in order to determine which of our particular drug candidates is most effective and, on this basis, to proceed with this best candidate to clinicals trials as quickly as possible. Our experts are working with full commitment and in the confidence of creating a new drug that will make a long-term and sustained contribution to fighting the COVID-19 pandemic.

We are immensely proud of our outstanding team of highly qualified and committed scientists and professionals from a total of 24 different countries who are working hard not only on our exciting biosimilar development projects but also on this novel biopharmaceutical to help overcome the pandemic. On this subject, we are aware of the difficulties and hardships that the ongoing pandemic have presented to our entire team. We would therefore like to take this opportunity to once again express our gratitude to the entire FORMYCON family for their great commitment, their determination and their perseverance.

We extend our heartfelt thanks to our staff, to our partners for their continued excellent cooperation, and to you, our valued FORMYCON shareholders, for the confidence you have placed in our efforts.

Stay healthy.

Martinsried/Planegg, May 2022

Dr. Carsten Brockmeyer

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Dr. Nicolas Combé

2021 within the Leap Innovations category, along with grant funding of up to EUR 12.7 million from the Bavarian State Ministry of Economic Affairs, Regional Development

Dr. Stefan Glombitza

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

<sup>\*\*</sup> Stelara® ist eine eingetragene Marke von Johnson & Johnson

# **Report of the Supervisory Board**



Chairman of Supervisory Board

Dr. Olaf Stiller

Dear Shareholders,

FORMYCON is able to look back upon an eventful and successful year. In my capacity as Chairman of the Supervisory Board of FORMYCON AG, I am pleased to provide you with this overview of the Supervisory Board and its work during fiscal year 2021.

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

Members of Supervisory Board

		In office since	Elected until
Dr. Olaf Stiller	Chairman of Supervisory Board	2010	2025
Peter Wendeln	Deputy Chairman of Supervisory Board	2010	2025
Klaus Röhrig	Member of Supervisory Board	2020	2025

The composition of the Supervisory Board during 2021 was changed compared to the prior fiscal year. The Deputy Chairman of the Supervisory Board, Hermann Vogt, resigned from his position with effect from December 10, 2020. During the proceedings of the virtual Annual General Meeting on December 10, 2020, Klaus Röhrig was elected as a new member of the Supervisory Board.

#### Cooperation between Executive Board and Supervisory Board

Throughout the entire fiscal year, the Supervisory Board, under my chairmanship, duly performed the tasks and duties incumbent on it under German law and under the Company's Articles of Association. The Board intensively considered the operational and strategic development of FORMYCON AG, regularly advising the Executive Board as to its management of the Company and continuously monitoring this management. The Supervisory Board was directly involved in all decisions of fundamental importance. In my capacity as Chairman of the Supervisory Board, I was available to answer questions arising from investor discussions pertaining to the Supervisory Board and its activities.

The Supervisory Board received regular reports from the Executive Board in accordance with its informational obligations in both written and oral form, providing comprehensive and timely information about all business developments and events of substantive importance. These reports fully met the requirements established by the Supervisory Board in terms of both content and scope. On the basis of these reports, the current development status of the Company's biosimilar candidates and COVID-19 drug, the Company's financial position and organizational alignment, and business events of key importance were discussed. Furthermore, regular consultations were held with the Executive Board on matters of the Company's strategy,

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

business and financial planning, and business performance. The Supervisory Board also closely examined the Company's risk situation and risk management and its compliance with legal requirements and ethical norms.

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

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

#### Supervisory Board meetings and main topics of discussion

With regard to the ongoing COVID-19 pandemic, the Executive Board fully met its responsibilities to safeguard staff by promptly implementing all possible protective measures that enable them to continue their work safely under the prevailing pandemic conditions. This included, above all, the establishment of a detailed company policy on coronavirus from the start of the crisis, the decentralization of the organization by offering remote working arrangements, the offering of COVID-19 rapid tests to staff as part of a company-wide testing concept, and the offering of in house COVID-19 vaccinations by a company doctor. Since the earliest days of the pandemic, the members of the Executive Board have kept the Supervisory Board informed about current developments and precautions put in place.

In the course of the four regular quarterly board meetings during the fiscal year, all business matters and pending decisions requiring concurrence of the Supervisory Board under governing law or under the Company's Articles of Association were discussed in depth before being voted upon. All members of the Supervisory Board were in attendance at the meetings during which they held office, some of which took place by way of video or telephone conferences in lieu of presence meetings in compliance with government hygiene regulations and restrictions on personal contacts to prevent the spread of COVID-19. The Executive Board was also present at, or otherwise participated in, these meetings in order to discuss issues and answer questions.

Attendance at regular quarterly meetings of the Supervisory Board: Feb. 9. 2021 Apr. 27. 2021 Sep. 22. 2021 Dec. 9. 2021 virtual format virtual format presence format virtual format  $\checkmark$ 1 1 Dr. Olaf Stiller 1  $\checkmark$  $\checkmark$ √ (virtual)  $\checkmark$ Peter Wendeln Klaus Röhrig  $\checkmark$  $\checkmark$  $\checkmark$  $\checkmark$ 

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

- development projects
- financial resources
- Human resources and key staff

Other central core themes of the meetings involved ways to ensure and strengthen the Company's competitiveness and strategic concepts for its future growth as well as review and discussion of the Company's systems for risk management and compliance. There were, in addition, discussions of particular topics such as the design and review of the goals defined and agreed in writing (Zielvereinbarung) with the Executive Board and the approval of the agenda for the Annual General Meeting. In conjunction with the approval of the annual financial statements, discussions specifically focused on key details of accounting valuations and the resulting consequences for the Company's capital structure.

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

#### Supervisory Board committees

On the basis of the German Financial Market Integrity Strengthening Act (Finanzmarktintegritätsstärkungsgesetz, FISG) and the recast of section 107 (4) of the German Stock Corporation Act (Aktiengesetz) resulting therefrom, the supervisory board of a public interest company is obligated to establish an audit committee. As stipulated in the Company's prevailing Articles of Association, the Supervisory Board of FORMYCON AG currently consists of three members. Under the second sentence of section 107 (4) of the Stock Corporation Act in the version in force since July 1, 2021, a supervisory board consisting of only three members shall also correspond to the audit committee thereof. The role of the audit committee is to examine the company's annual financial statements, consolidated financial statements and unified management report of the company and consolidated group on behalf of the supervisory board and to review and discuss in detail the auditor's report, including also the auditor's verbal report on the main results of the audit. The Supervisory Board of FORMYCON AG duly established such an audit committee under the chairmanship of Klaus Röhrig (the "Audit Committee"), which accordingly carried out these duties for the Company's annual financial statements and consolidated financial statements for fiscal year 2021.

Progress reports on the Company's biosimilar and COVID-19 drug

Corporate planning, financial performance and adequacy of the Company's

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

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

The annual financial statements and consolidated financial statements as of December 31, 2021, including the unified management report, were properly examined by the Munich office of PanTaxAudit GmbH, the audit and tax firm appointed by the Annual General Meeting for fiscal year 2021, which has provided its unqualified audit opinion. Furthermore, the audit firm determined that the Executive Board has enacted measures, as required under sec. 91 para. 2 of the German Stock Corporation Act, to establish a risk monitoring system in appropriate form. The system has been adapted in line with the Company's growth and is suitable for recognizing, at an early stage, any developments which might endanger the Company's continued existence.

In its meeting of April 26, 2022 to review the financial statements of FORMYCON AG and consolidated financial statements of FORMYCON Group for fiscal year 2021, the Audit Committee specifically discussed the Company's accounting policies and procedures as well as the respective audit examinations carried out by PanTaxAudit GmbH for fiscal year 2021. A representative of the audit firm attended this meeting, reporting in considerable depth on the primary results of the audit and answering questions of the Audit Committee relating thereto. Advance copies of the audit reports and other documents relating to the annual financial statements and consolidated financial statements were provided to the Audit Committee to facilitate comprehensive review and discussion.

In addition, the Audit Committee asserted its right to inspect the accounts and papers of the Company, in particular by requesting presentation of certain legal agreements it deemed important, including documents not specifically requiring its concurrence. All transactions requiring concurrence of the Supervisory Board under governing law or under the Company's articles of incorporation were examined by the Audit Committee on its behalf before reaching a decision on such concurrence.

Based upon its own examining review, the Audit Committee found no cause to raise any objections to the financial statement documents which it reviewed, including also the concluding statement of the Executive Board. Upon recommendation of the Audit Committee, the Supervisory Board approved the unconsolidated and consolidated financial statements for fiscal year 2021 as presented to it. The annual financial statements of FORMYCON AG have been adopted accordingly.

#### **Corporate Governance**

FORMYCON shares trade within Germany's Open Market segment (formerly Freiverkehr) and, as such, are not legally considered to be listed on an organized market within the meaning of the German Securities Trading Act (Wertpapierhandelsgesetz). The German Corporate Governance Code is therefore not mandatory. Nevertheless, FORMYCON has already voluntarily implemented certain of the corporate governance principles embodied by the Code. Under the Code's basic principle requiring transparency of communication with investors, FORMYCON'S Executive Board and Supervisory Board of FORMYCON began planning in 2021 to implement the principles, recommendations and suggestions anchored in the Code to the greatest extent possible, with the aim over the course of the coming fiscal years of ultimately including a voluntary declaration of compliance in the Company's annual financial statements as well as a voluntary report on corporate governance. In doing so, we strive to further strengthen the bond of trust with our investors, our workforce and the public in our management and supervision of the Company and to further raise the level of transparency regarding our decisions and actions.

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

During fiscal year 2021, no conflicts of interest were reported involving Supervisory Board or Executive Board members.

We would like to thank the members of the Executive Board for the excellent cooperation and successful management of the company through a challenging fiscal year. We would also like to express our gratitude and appreciation to all FORMYCON staff members for their extraordinary commitment and performance under the continued difficult pandemic conditions over the past year. Finally, we would like to once again extend our special thanks to our partners, who have likewise made significant contributions to the success of our company.

Munich, April 2022

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Dr. Olaf Stiller Chairman of the Supervisory Board



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#### Unified Management Report for FORMYCON AG and FORMYCON Group for the period from January 1 to December 31, 2021

#### Basic information about the Group and FORMYCON AG

#### **Business model**

**Business objective** 

and strategy

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 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 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.

As key development milestones are reached, FORMYCON strives to transfer its biosimilar candidates into partnerships for advanced development and commercialization, while remaining closely involved in the project, whether as project partner or as provider to an out-licensed project. The responsibility for the subsequent production and marketing of the products generally lies with the selected partner, with FORMYCON participating in the sales proceeds following market launch. This preferred arrangement provides FORMYCON and its shareholders with significant growth potential while also reinforcing its leading global position in the rapidly developing biosimilars market.



Figure 1: FORMYCON AG – Vision and Concept

Scope of business activity

FORMYCON positions itself as a highly specialized expert in biosimilar drug development and is, with its current resources, able to develop up to five projects in parallel. Looking forward, our strategy for continued growth is based on the gradual and carefully considered expansion of our project pipeline through the targeted selection of additional biosimilar candidates, their early-stage development, and their transfer to advanced development and commercialization partnerships. With the help of our biosimilars, ever more patients around the globe will have access to high-quality, competitively priced 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 drugs.

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 contrast to our biosimilar development projects, where we focus on our long-term position and strive to independently bring our projects to a relatively advanced stage using our own in-house resources and expertise, our intention in the case of the COVID-19 project is to transfer it into a strategic partnership for development and commercialization at an earlier stage.

These two business and development areas differ significantly in their risk profile. 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 COVID-19 project is an innovative originator biopharmaceutical, which entails an exploratory approach and thus a higher level of development risk.



Figure 2: Risk profile for innovative biopharmaceutical development vs. biosimilar development

As of December 31, 2021, FORMYCON was working on the following development projects within its principal business of biosimilars:



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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. This blockbuster drug generated full-year 2021 sales revenue of USD 3.6 billion, which in turn represents the target market size for FYB201. During the past fiscal year, the particular focus of our activities was on resubmission of the biologics license application (BLA) for regulatory approval by the U.S. Food and Drug Administration (FDA) in parallel with submission of the marketing authorization application (MAA) for regulatory approval by the European Medicines Agency (EMA). Upon successful regulatory approval, FYB201 will be commercialized by Coherus Bio-Sciences, Inc. in the United States, by Teva Pharmaceutical Industries Ltd. in Europe and other territories, and by MS Pharma in North Africa and the Middle East.

FYB

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. Our activities during 2021 focused on recruitment of patients into the phase III clinical trials which began in November 2020, making FORMYCON one of the world's first companies to reach this milestone for a Stelara® biosimilar.

**FYB** 

FYB203 is a biosimilar candidate for Eylea®\*\*\* (aflibercept). Similarly to Lucentis®, Eylea® is used to treat neovascular age-related macular degeneration (nAMD) and other serious eye diseases, with 2021 global sales revenue of USD 9.0 billion. Phase III clinical trials of FYB203 commenced in August of 2020 with the administration of the first patient dosage.

Lucentis® is a registered trademark of Genentech Inc.

Stelara® is a registered trademark of Johnson & Johnson.

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<sup>\*\*\*</sup> Eylea $^{\otimes}$  is a registered trademark of Regeneron Pharmaceuticals Inc.

With FYB201, FYB202 and FYB203, FORMYCON has three biosimilar candidates in advanced stages of development for which regulatory approval is anticipated in the United States, the European Union and other highly regulated markets between 2022 and 2025, upon expiry of the statutory protection periods for the respective reference products.



FORMYCON is progressing with an additional biosimilar candidate project, FYB206, which is currently in preclinical development. The rights to this project are entirely held by FORMYCON, and relevant intellectual property (IP) protections are already in place.

FORMYCON is actively evaluating several other potential biosimilar candidates within the context of the Company's growth strategy.



As of December 31, 2021, FORMYCON was working on the following development projects involving 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 and delta). 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. An important aspect of our ongoing preclinical studies is the selection of the best of several FYB207 drug candidate versions, thereby raising the probability of success in subsequent clinical trials.

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 (angiotensinconverting 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 3).



Figure 3: SARS-CoV-2 infection pathway

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 4), 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 5). In addition, FYB207 can potentially be used to defend against any other coronavirus which exploits ACE2 as an entry point for cell infection.

 Sars-CoV-2
 Spike Protein
 ACE2

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

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

In vitro studies have specifically shown that our engineered ACE2-IgG-Fc fusion proteins are able to neutralize not only the original SARS-CoV virus and the pandemic (January and April 2020) SARS-CoV-2 variants but also the highly contagious alpha, beta and delta variants. Importantly, this neutralizing effect remains even when the SARS-CoV-2 delta variant is at picomolar concentrations, indicating that FYB207, our lead candidate ACE2-IgG4 Fc fusion protein, in contrast to vaccines and neutralizing antibodies, retains its full antiviral potential even with the more recent and worrying SARS-CoV-2 variants which have been circulating around the globe. A high degree of efficacy is likewise expected against the omicron variant.



Figure 4: Composition of the FYB207 fusion protein

A study in which we participated, entitled "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), based on previously published data (BioRxiv preprint: https://doi.org/ 10.1101/2020.12.06.413443), and published following peer review in the journal Antiviral Research, describes how these optimized ACE2-IgG4-Fc fusion constructs have a broad neutralizing effect against SARS CoV 2 viruses, preserve the desired ACE2 enzymatic activity, and show promising pharmaceutical properties.

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



Figure 5: FYB207's mechanism of action

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. Moreover, FYB207 could potentially be used for any other coronavirus which exploits ACE2 as an entry point, thus offering hope that it might be used to prevent similar future coronavirus pandemics.

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.



<sup>&</sup>lt;sup>1</sup> For the SARS-CoV-2 delta variant, the FYB207 concentration required for 50 % in vitro inhibition (IC50 value) was found to be in the picomolar range.

#### Structure of FORMYCON Group

FORMYCON Group consists of the parent entity, FORMYCON AG, along with two 100%-owned subsidiaries, FORMYCON Project 201 GmbH and FORMYCON Project 203 GmbH, and a 24.9% ownership participation in FYB 202 GmbH & Co. KG. The registered office of FORMYCON AG and the two subsidiaries is in the town of Planegg, a suburb of Munich. FYB 202 GmbH & Co. KG is registered in Berlin.

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, of which there are currently three, are appointed and monitored by the Supervisory Board (Aufsichtsrat). The members of the Supervisory Board of FORMYCON AG, of which there are likewise currently three, are elected by shareholders through the Annual General Meeting.

The corporate structure of FORMYCON Group thus corresponds to the Company's business model. The actual research and development work is performed by FORMYCON AG, which conducts these activities not only for its own projects and on behalf of its subsidiaries, such as FORMYCON Project 201 GmbH and FORMYCON Project 203 GmbH, but also for associated companies in which FORMYCON holds a minority investment participation, such as FYB 202 GmbH & Co. KG. This arrangement also has the effect of generating reported revenue, since FORMYCON continues to provide development work for the biosimilar candidates which is paid for by the licensing or cooperation partners even after the projects have been transferred to the partnership ventures. Once the already out-licensed biosimilar candidates FYB201 and FYB203 enter the marketing phase, FORMYCON will participate in future sales revenue in the form of royalties, thereby directly participating in the ultimate market success of its out-licensed projects.

FORMYCON Project 201 GmbH 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 to facilitate an out-licensing deal. It remains a 100%-owned subsidiary of FORMYCON AG. FORMYCON'S license partner for FYB201 is Bioeq AG, a 50/50 joint venture between Polpharma Biologics Group, Poland's largest pharmaceutical company, and Santo Holding (Deutschland) GmbH, a holding company owned by the Strüngmann family.

A similar arrangement is in place with FORMYCON Project 203 GmbH, which is likewise a 100%-owned subsidiary of FORMYCON AG. FORMYCON AG originally signed an exclusive worldwide out-licensing agreement for FYB203 in 2015 with Santo Holding (Deutschland) GmbH. The worldwide marketing rights have since been internally shifted within the Santo Group to another Santo entity, Klinge Biopharma GmbH.

In the case of the third project vehicle, FYB 202 GmbH & Co. KG, FORMYCON AG holds an investment participation. The company was founded in 2017 as a joint venture between FORMYCON AG, which owns a 24.9% share, and Aristo Pharma GmbH, which owns the remaining 75.1% and is likewise part of Strüngmann Group. FYB 202 GmbH & Co. KG, in turn, owns 100% of another project-specific subsidiary company, FYB 202 Project GmbH, into which FORMYCON contributed the project rights for its FYB202 biosimilar candidate. Following the successful completion of the pilot phase at the start of the second quarter of 2019, the terms of the joint venture agreement stipulated that already incurred and future development costs of both FORMYCON and Aristo Pharma GmbH, as well as future sales proceeds, be shared pro rata according to shareholding.



Figure 6: The structure of FORMYCON Group

With FYB206, an as yet unannounced biosimilar candidate in preclinical development for which the Company owns all rights in their entirety, FORMYCON plans to take the next step in its growth strategy. Our aim is to further maximize value creation through transfer to a future development and commercialization partnership in which FORMYCON which retain a greater ownership stake.

In the case of FYB207, our COVID-19 drug development project, rights within the world's highly regulated markets remain entirely owned by FORMYCON AG. A cooperation and out-licensing agreement for the development, manufacturing and commercialization of FYB207 in the Asia-Pacific (APAC) region (excluding Japan) has been signed with SCG Cell Therapy Pte Ltd ("SCG"), a biotechnology company headguartered in Singapore with a strong presence and scientific network in Singapore, China and Germany. In order to accelerate further development and clinical studies, FORMYCON is considering further options for financial and strategic partnerships in highly regulated markets such as the United States and Europe.



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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.

FORMYCON AG Annual Report 2021

#### Ш Report on business performance

General economic conditions

Over the past fiscal year, the pandemic and its consequences continued to impact Germany's economy. Beyond the direct effects of these COVID-19 infections, supply chains were increasingly disrupted worldwide, putting a further damper on economic growth. In particular, production suffered from bottlenecks in the procurement of materials and components, thus also hindering the economic recovery. Added to this were the burdens of higher procurement costs and sharply increased prices in the energy sector.

Despite this unfavorable environment, the German economy was able to grow during 2021, with full-year price-adjusted GDP increasing by 2.7%. Thus, Germany's output was significantly higher than in the previous year, during which the economy contracted by -4.6 %, but still below the pre-crisis year 2019. According to the German Federal Statistical Office (Destatis), this rise in economic activity was seen across almost all sections.

#### Real German GDP growth from 2009 through 2021

Price-adjusted gross domestic product, change from prior year in %



Figure 7: Price-adjusted gross domestic product, change from prior year in %

Only in the construction industry, a sector only minimally affected by the pandemic in the previous year, did price-adjusted economic output decline slightly by 0.4 % (prior year: +3.8%). Germany's manufacturing sector, in contrast, was able to post a substantial gain, with price-adjusted gross value added rising by 4.4 %, reversing the previous year's sharp decline of 10.0 %.

On the demand side, government consumption spending once again provided a boost, increasing by 3.4 % in real terms (previous year: +3.5 %) primarily because of outlays for COVID 19 quick tests, vaccines and vaccination centers. Capital investment also posted a rise of 3.2 %, thus partly recovering from the sharp slump during the pandemic's first year (prior year: -11.2 %).<sup>2</sup> Private consumer spending, on the other hand, remained subdued during 2021 at roughly the prior year's level and thus still below the pre-crisis level of 2019. As to Germany's foreign trade, both exports and imports almost completely recovered from the previous year's abrupt drops; on a price-adjusted basis, exports rose by 9.4% (prior year: -9.3 %) and imports by 8.6 % (prior year: -8.6 %).

During the second half of the year, inflation became increasingly apparent in the monthly figures, leading to a noticeable increase in year-on-year inflation during 2021. The monthly inflation rate ended the year at 5.3 % in December, and inflation for the year as a whole was 3.1 %.<sup>3</sup> In addition to price increases resulting from the strained procurement situation, this inflation was, in particular, attributable to the 10.4% rise in energy costs. In comparing to the 2021 inflation rate to the prior year's figure of 0.5%, it should be noted the German VAT rate was temporarily reduced from 19% to 16% during the second have of 2020, with a corresponding effect on end prices.

During the fiscal year, Germany's labor market was stable, with an average overall employment level of 44.9 million people, roughly the same as in the previous year. There were, however, noticeable shifts within individual economic sectors. For example, 1.3 % fewer people were employed in manufacturing, while the number employed in construction increased by 1.2 %.4

#### General industry conditions

As with the German economy as a whole, the country's chemical-pharmaceutical industry was also materially impacted by supply chain disruptions. According to a survey conducted by the German Chemical Industry Association (VCI) at the end of 2021, some 35% of its member companies were forced to halt production while another 10% were affected by temporary shutdowns. Because of these problems, many member companies were unable to fulfill existing orders on time or in full. Nevertheless, the industry grew significantly during the year under review, with the total value of sales according to VCI figures increasing to approx. € 220 billion (prior year: € 186.4 billion). <sup>5</sup>

German Federal Ministry for Economic Affairs, "The economic situation in Germany in January 2021".

German Federal Statistical Office (Destatis) "Gross domestic product up 2.7% in 2021"

German Federal Statistical Office (Destatis), "Inflation rate in 2021: +3.1% on a year earlier"

<sup>4</sup> German Federal Statistical Office (Destatis), "Employment in 2021 at the same level as in 2020"



Number of drugs with new active agents (excluding biosimilars) 1993 - 2021



Figure 8: Overall biosimilars market

Industry employment increased slightly during 2021 to 466,500,<sup>1</sup> an increase of some 2,000 employees over the prior year.

Specifically as to the pharmaceutical market in Germany, the industry generated full-year sales revenue of € 53.6 billion, marking an increase of 7.3% over the prior year (€49.5 billion). Thus, the country's pharmaceutical industry grew, in both the clinical and pharmacy segments, at a significantly faster rate than the overall economy. As in the previous year, pharmaceutical sales trends were influenced by the ongoing COVID-19 pandemic. In particular, the months of March and October 2021 saw sales increases of up to 15%;<sup>2</sup> it is no coincidence that these months marked the beginnings of the third and fourth COVID-19 waves. In terms of its innovative power, Germany's pharmaceutical industry clearly did not suffer because of the crisis: Some 46 drugs with new active ingredients were brought to market during 2021, which is 14 more than in the previous year and 21 more than in the pre-crisis year 2019.<sup>3</sup> As to areas of application, cancer treatment drugs came in first, followed by anti-infectives and drugs for treatment of cardiovascular disease.



Figure 9: Number of drugs with new active agents (excluding biosimilars) 1993 – 2021

As in other sectors, the tense procurement situation for raw materials and preliminary products underscored the pharmaceutical sector's dependence upon and vulnerability to global supply chains. Because of these issues, new calls have been increasingly heard to increase production of pharmaceutical raw materials and medicines within Germany or elsewhere in Europe. For example, the German Pharmaceutical Industry Association (BPI) once again emphasized the need for a secure supply of medicines through in-country production. In its pharmaceutical strategy for Europe presented at the end of 2020, the European Commission takes the same position.

#### Developments in the biosimilar market

During 2021, some 86 % of all pharmaceutical sales within the German were by way of the pharmacy segment. Among specific drug segments, biosimilars recorded by far the strongest growth, with annual sales for biosimilars (across all disease seqments) increasing by 23.6 % to  $\in$  1.96 billion, thus approaching the two-billion mark for the first time. Biosimilars likewise posted a significant rise in terms of sales volume, growing 17.3 % over the prior year.<sup>4</sup> Among all segments within Germany's pharmaceutical industry, biosimilars was the only segment to post a double-digit growth rate in sales volume.

German Chemical Industry Association (VCI), "Heftigem Gegenwind erfolgreich standgehalten"

<sup>&</sup>lt;sup>2</sup> IQVIA, "IQVIA MARKTBERICHT CLASSIC, Entwicklung des deutschen Pharmamarktes im Kalenderjahr 2021, 2022"

<sup>3</sup> German Association of Research-Based Pharmaceutical Companies (vfa), "Innovationsbilanz: Die neuen Medikamente und Anwendungsgebiete des Jahres 2021"

<sup>4</sup> IQVIA, "IQVIA MARKTBERICHT CLASSIC, Entwicklung des deutschen Pharmamarktes im Kalenderjahr 2021, 2022"

The European biosimilars market, which accounts for roughly half of the global market by value,<sup>1</sup> generated sales revenue of  $\in$  8.8 billion during the year under review.<sup>2</sup> The size of the market, just 15 years after the first such drug was introduced into the EU market, is a clear indication of how firmly established this new drug category already is, as demand continues to grow. The range of available biosimilars also further increased during 2021 with the regulatory approval of seven new products.

Against the background of progress made in coping with the pandemic through mass vaccination campaigns, the focus of healthcare systems in Germany and elsewhere over the past year was again turned toward financial stabilization. The cost burden of the COVID-19 has intensified the urgency of this theme. According to IQVIA, a leading information platform for human data science, global spending on corona vaccines alone will likely reach USD 157 billion by 2025.<sup>3</sup> In addition, healthcare systems are having to deal with ongoing cost burdens relating to long-term consequences of COVID-19 as well as the cost impact of catching up with procedures and treatments which had been postponed during pandemic waves.

As a safe and cost-effective alternative to originator biopharmaceuticals, biosimilars open up new potential for significant savings. With healthcare systems around the globe struggling to keep their relentless rising outlays under control, biosimilars are becoming increasingly attractive, a key reason why market experts are confident in predicting their growing adoption. The Association for Accessible Medicines (AAM) estimates that, in the United States alone, biosimilars will save healthcare providers a total of USD 133 billion over the period from 2020 to 2025.<sup>4</sup>

According to IQVIA forecasts, the global pharmaceutical market will increase to  $\in$  1.6 trillion by 2026. Alone in Europe, an increase of  $\in$  45 billion is anticipated<sup>5</sup> – and biosimilars and generic drugs are expected to be the strongest drivers of this growth. McKinsey, in turn, predicts that the global biosimilars market will continue its doubledigit growth, doubling in size to more than USD 30 billion over the period from 2020 to 2025 and reaching USD 60 billion annually by the end of the decade.<sup>6</sup> IQVIA is likewise unreservedly positive about the future of biosimilars and expects cumulative global sales revenue to reach USD 215 billion by the year 2026.<sup>7</sup>

<sup>4</sup> Association for Accessible Medicines (AAM), "The U.S. Generic & Biosimilar Medicines Savings Report 2021", October 2021

<sup>6</sup> McKinsey & Company, "An inflection point for biosimilars"

JAN





FEB

Presentation of the COVID-19 drug FYB207 at the international "Keystone Symposia – Antibodies and Vaccines as Drugs for COVID-19." Pre-approval by the Paul Ehrlich Institute for the proposed development concept of the innovative SARS-CoV-2 blocker FYB207.



### MÄR



FORMYCON and Leukocare AG announce a collaboration to jointly develop highquality biopharmaceuticals – especially in the area of formulation development.

#### APR



FORMYCON receives advance agreement so that government-funded measures for the development of our COVID-19 drug (FYB207) may begin, ahead of original schedule.

McKinsey & Company, "An inflection point for biosimilars"

<sup>&</sup>lt;sup>2</sup> IQVIA, "The Impact of Biosimilar Competition in Europe", December 2021

<sup>&</sup>lt;sup>3</sup> IQVIA, "Fokus Biosimilars", October 2021

<sup>&</sup>lt;sup>5</sup> IQVIA, "IQVIA Flashlight 89", January 2022

<sup>7</sup> IQVIA, "IQVIA Flashlight 89", January 2022

JUL

### MAI



Publication of the 2020 Annual Report.

### JUN



Teva Pharmaceutical Industries Ltd. will be responsible for commercializing FYB201, FORMYCON'S candidate biosimilar to Lucentis®, in Europe and other territories.



FORMYCON receives final funding approval from the Bavarian State Ministry of Economic Affairs, Regional Development and Energy in the amount of up to € 12.7 million for its continuing development of its FYB207 COVID-19 drug.

AUG

Submission to the U.S. Food and Drug Administration (FDA) of a biologics license application (BLA) for FYB201. The submission to the European Medicines Agency (EMA) was already made in June 2021.

SEP

FORMYCON'S COVID-19 drug FYB207 wins Pharma Trend Image & Innovation Award within the Leap Innovations category.

OKT



The U.S. Food and Drug Administration (FDA) accepted nine-month results. the submission of a biologics license application for FYB201 and assigned a target action date for the application of early August 2022.



#### NOV



Reporting on the

#### DEZ



Publication of new in vitro data of the COVID-19 drug FYB207 in the journal Antiviral Research.

MS Pharma becomes exclusive commercialization partner for FYB201 in the Middle East and North Africa.

#### ALL EVENTS OF THE YEAR 2021 IN CHRONOLOGICAL REVIEW

#### Business development during the fiscal year

Business performance during fiscal year 2021 was satisfactory, for both FORMYCON Group and FORMYCON AG. The Group ended the period with a consolidated annual net loss of  $\in$  -13,476K on consolidated full-year revenue of  $\in$  36,965K. For the parent company only, the net loss was  $\in$  -13,283K on revenue of  $\in$  26,546K. Neither FORMYCON AG nor FORMYCON Group has any financial debt.

#### Chronological review of key developments during fiscal year 2021:

#### JANUARY

In January, FORMYCON'S academic partners at the Technical University of Munich presented the **published results of testing** on FORMYCON'S **COVID-19 drug (FYB207)** at the **Keystone Symposia** international e conference on **"Antibodies and Vaccines as Drugs for COVID-19"**. A link to the poster presentation, entitled "Highly efficient inhibition of SARS-CoV-2 entry by a biologically unique ACE2-IgG4-Fc fusion protein with a stabilized hinge region", may be found on the FORMYCON website at https://www.formycon.com/en/pipeline/fyb207/.

#### FEBRUARY

In February, the Paul Ehrlich Institute (PEI), an agency of the German Federal Ministry of Health, granted pre-approval under its scientific advice procedure for the proposed development concept for FORMYCON'S innovative SARS-CoV-2 blocker FYB207, thus establishing official support for the project from Germany's National Institute for Vaccines and Biomedical Medicines. The consultation with PEI specifically included analysis, process development, production (particularly the chemistry, manufacturing and control, or "CMC", components), preclinical development and the design of phase I and II clinical trials, including the associated bioanalytical strategy. The review of subsequent applications for clinical testing is to be carried out under an accelerated procedure. In addition, FORMYCON has already secured GMP<sup>1</sup>-compliant production capacity for FYB207 from an experienced German biopharmaceutical manufacturer.

MARCH

In March, following a pre-BLA consultation with the U.S. Food and Drug Administration (FDA), FORMYCON and its license partner Bioeq AG confirmed the planned timeline for the resubmission of their biologics license application (BLA) for the regulatory approval of Lucentis® biosimilar candidate FYB201. As announced at the end of 2020, the original submission strategy was modified to simplify the approval process. Through optimization of the commercial supply chain, moreover, FYB201 can now be directly approved for large-scale commercial production. During the consultation with the FDA, the data requested by the authorities were reviewed and further procedures agreed.

Likewise in March, FORMYCON and Leukocare AG announced a collaboration to jointly develop high-quality biopharmaceuticals. Under the terms of the agreement, Leukocare will use its formulation development technologies, which combine state-of-the-art protein analysis, bioinformatics and artificial intelligence, to design stable drug formulations for several potential candidates in FORMYCON's product pipeline. The first project, involving the development of a formulation for a candidate biosimilar to a blockbuster therapeutic antibody, has already commenced. By bringing together the formulation and bioinformatics expertise of Leukocare with the comprehensive biopharmaceutical development abilities of FORMYCON, the partners strive to achieve better stability profiles for these drug candidates, thereby boosting the development projects' value creation potential.

In the same month, FORMYCON and its academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, announced new results on the in vitro neutralization action of FORMYCON'S COVID-19 drug FYB207 on SARS-CoV-2 variants. The results demonstrate that FYB207 has an even more potent effect against the B.1.1.7 mutation (the particularly contagious "alpha" variant) than against previous variants.

APRIL

In April, FORMYCON received advance agreement from the agency responsible for the oversight of our grant from the Bavarian State Ministry of Economic Affairs, Regional Development and Energy so that government-funded measures for the development of our COVID-19 drug (FYB207) may begin, ahead of original schedule. The government grant is intended to support the further development of FYB207 through to the end of phase IIa clinical trials and was applied for in the total amount of € 11 million. The early start of government-funded development is making it possible for FORMYCON to carry out preclinical development activities in accordance with the submitted plan and to manufacture the test product under GMP conditions even before the final approval notice is issued. Through the special "BayTherapie 2020" grant program, the German state of Bavaria aims to foster development and innovation projects with a total of up to €50 million of government funding with the goal of creating new therapeutic options to combat the COVID-19 pandemic and to treat serious COVID-19 sickness.

MAY

In May, FORMYCON released its audited financial results for fiscal year 2020. For the year ending December 31, 2020, total consolidated sales revenue was  $\in$  34.2 million. With EBITDA of negative  $\in$ 4.8 million, an operating loss (EBIT) of  $\in$  5.7 million, and a consolidated annual net loss of  $\in$ 5.9 million, compared to a net loss of  $\in$  2.3 million in the prior fiscal year, the full-year figures were closely in line with expectations. As of December 31, 2020, FORMYCON Group held cash and liquid resources, including short-term trade receivables and other assets, of  $\in$  49.3 million.

JUNE

As the first half of the year drew to a close, FORMYCON announced a strategic partnership between Bioeq AG and **Teva Pharmaceutical Industries Ltd.** ("Teva"). Under the **exclusive marketing agreement**, Teva will be responsible for **commercializing FYB201**, FORMYCON'S candidate biosimilar to Lucentis®, in **Europe** and other agreed territories. With a portfolio of over 3,500 products spanning virtually every therapeutic area, Teva Pharmaceutical Industries Ltd. is among the world's leading providers of generic and specialty drugs. At the end of 2019, Bioeq AG had already signed a license and development agreement with **U.S. biosimilar specialist Coherus BioSciences**, **Inc.**, which will distribute FYB201 exclusively in the United States of America.

The very next day, FORMYCON and Bioeq announced the **formal submission** of their marketing authorization application (MAA) to the **European Medicines Agency** (EMA) for the **regulatory approval of FYB201**, FORMYCON's candidate biosimilar to Lucentis<sup>®</sup>.

In its reporting of financial results for the first quarter, FORMYCON AG announced consolidated sales revenue and other income of  $\in$  9.4 million for the three months ending March 31, 2021. EBITDA was negative  $\in$  1.7 million, while the operating loss (EBIT) and net loss after tax for the period were each approx.  $\in$  2.0 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  $\in$  46.0 million.

JULY

In July FORMYCON received final funding approval from the Bavarian State Ministry of Economic Affairs, Regional Development and Energy in the amount of € 12.7 million for its continuing development of its FYB207 COVID-19 drug. The grant is intended to support the preclinical development, investigational product manufacture under GMP conditions and phase I/IIa clinical trials of FYB207.

AUGUST

In early August, FORMYCON AG and its license partner Bioeq AG announced the submission to the U.S. Food and Drug Administration (FDA) of a biologics license application (BLA) for FYB201, FORMYCON'S candidate biosimilar to Lucentis<sup>®</sup>.

In the same month, FORMYCON announced the **results of in vitro studies on FYB207**, confirming the efficient neutralization of SARS-CoV-2 variants of concern – namely the **alpha (B.1.17)** and **beta (B.1.351)** variants – in the picomolar range. The study was conducted with two ACE2 fusion protein candidates, FYB207a and FYB207b, with subsequent investigations of FYB207a further showing that FORMYCON'S ACE2 fusion protein forms a **strong bond to the viral spike protein** of the **delta variant** (B.1.617.2). In parallel with these laboratory studies, FORMYCON, in cooperation with experienced European biopharmaceutical manufacturing partners, rapidly pushed forward with the development of the production process for FYB207, producing enough material already for preclinical in vivo studies on a pilot scale, along with the start of the larger-scale, GMP-compliant production scale-up needed to launch clinical trials on

human patients. Under the ongoing preclinical in vivo studies, data on the pharmacokinetics of FYB207a and FYB207b are being collected using two different models and data on the efficacy of both candidates using yet another model.

SEPTEMBER

In September, FORMYCON received the Pharma Trend Image & Innovation Award for Most Innovative Product<sup>®</sup> within the Leap Innovations category for its novel COVID-19 drug development project, FYB207. Winners of the Pharma Trend Image & Innovation Award, also known within the industry as the "Pharma Oscars", were honored in a festive presentation ceremony under the patronage of the Bavarian State Ministry of Health and Care, represented by Minister of State Klaus Holetschek.

In the publication of its half-year results, FORMYCON announced consolidated revenue of  $\in$  20.3 million for the six months ending June 30, 2021. EBITDA was negative  $\in$  9.7 million, while the Company's operating loss (negative EBIT) and net loss for the period were respectively around  $\in$  10.2 million, in line with expectations. The changes compared to the prior-year period are primarily due to non-capitalized investments into the Company's pipeline of owned development projects. The announced figures did not yet include the effect of the research funding grant of up to  $\in$  12.7 million awarded to FORMYCON by the Bavarian State Ministry of Economic Affairs, Regional Development and Energy, as the first tranche in the amount of  $\in$  1.5 million was received after the end of the period. As of June 30, 2021, FORMYCON Group held cash and liquid resources, including short-term trade receivables and other assets, of  $\in$  42.2 million.

The **Annual General Meeting** of FORMYCON AG was held on **September 27, 2021.** Because of the ongoing COVID 19 pandemic, and for the protection of all involved, the meeting was held **in virtual form**, with shareholders able to follow and participate in the **live proceedings**, including both **image and sound**, via the Company's AGM portal. Shareholders followed the recommendations of the Executive Board and Supervisory Board, **approving all resolutions proposed by management with large majorities**.

In **October**, FORMYCON and Bioeq announced that the U.S. Food and Drug Administration (FDA) accepted their August submission of a biologics license application (BLA) for FYB201 for review and assigned a target action date for the application of early August 2022.

Also in **October**, FORMYCON announced the signing of a **cooperation and licensing agreement** with **SCG Cell Therapy Pte Ltd** to develop and commercialize **FYB207**, FORMYCON'S COVID-19 drug. Under the terms of the agreement, SCG, a Singapore-based biotechnology company with a strong presence and scientific network spanning Singapore, China and Germany, is gaining access to FORMYCON'S ACE2 fusion protein technology and acquiring an **exclusive license to develop, manufac**-

OCTOBER

ture and commercialize FYB207 throughout the Asia Pacific (APAC) region excluding Japan. FORMYCON will be eligible for potential development, regulatory and sales-related milestone payments of up to € 63.5 million along with low doubledigit percentage royalties on future net sales.

#### NOVEMBER

In November, the Company announced its financial results for the nine months ending September 30, 2021, with consolidated sales and other income of € 29.1 million and a more specific full-year forecast raised to roughly  $\textcircled{\mbox{\sc e}}$  40 million. EBITDA for the period was negative € 10.0 million, while the operating loss (negative EBIT) was € 10.6 million and  $net \ loss \ \in \ 10.7 \ million$  , in line with expectations based upon non-capitalized investments into the development pipeline. As of the period close, FORMYCON Group's cash and liquid resources (including short-term trade receivables and other assets) totaled € 33.7 million.

#### DECEMBER

In December, FORMYCON AG announced the publication, together with its academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, of new, peer-reviewed in vitro data from the FYB207 COVID-19 drug development project in the journal Antiviral Research. The study describes how these optimized ACE2-IgG4-Fc fusion constructs have a broad neutralizing effect against SARS-CoV-2 viruses, preserve the desired ACE2 enzymatic activity, and show promising pharmaceutical properties, not only in fighting the original SARS-CoV virus and the pandemic (January and April 2020) SARS CoV 2 variants but also the highly contagious  ${\color{black}{alpha}}, {\color{black}{beta}}$  and delta variants.

Importantly, the neutralizing effect remains even at picomolar concentrations. Based on these findings, a similarly high level of efficacy is expected against the omicron variant. As part of ongoing preclinical in vivo studies, data on pharmacokinetics are being collected in two different models along with, in yet another model, data on the comparable efficacy of different variant candidates of the ACE2-Fc fusion protein so that we will be able to select the most suitable candidate for clinical testing.

In December, Bioeq AG, our license partner and exclusive holder of worldwide commercialization rights for FYB201, announced that it had entered into an exclusive partnership with MS Pharma for the commercialization of FYB201 in the Middle East and North Africa (MENA) region.

#### Shares and the capital markets

#### German and international stock market environment

2021 was a turbulent year on the stock market. Seemingly unfazed by the ongoing pandemic, inflationary fears, rising prices and supply bottlenecks, prices at times reached record levels. The German benchmark DAX equity index closed with a fullyear gain for the ninth time in ten years.

From January through April, the DAX reached one record high after another, and over first half of the year, share prices rose by an average of approx. 13%. In November of 2021, the DAX broke 16,000 for the first time, with the relentless market advances providing the rather misleading impression that the COVID 19 pandemic was no longer relevant. Late in the year, however, the omicron variant swept the globe, bringing some uncertainty back into international markets because of the as yet unpredictable extent and impact of the new virus variant (Figure 10). Although the brief correction put a damper on the markets, it did not prevent the DAX from further building on its annual gains above and beyond the first half of 2021. For the full year, the DAX posted a gain of some 16%, while the EuroStoxx and Dow Jones market indexes posted gains of roughly 20%. The NASDAQ 100 index returned an even stronger 27%.<sup>1</sup>



In addition, the German DAX index of blue chips was expanded as planned from 30 to 40 stocks, adding ten largely younger and more diverse companies to the benchmark. Even if the ten new names represent only 13% of the index (according to calculations by DZ Bank), the additions mark a very visible change to the sectoral mix with the addition of e-commerce and healthcare leaders.

2021 was also a boom year for IPOs, with new issuances globally climbing to a 20-year high. In total, 2,388 companies went public with a combined issuance value of USD 453 billion. China (including Hong Kong) was at the forefront with 593 transactions, despite the soft performance of the Chinese stock market over the past year. With a 7% decline in the CSI 300, China far underperformed Western market due to monetary policy effects, new government regulations and China's "zero COVID" strategy, along with reduced fiscal support. With 485 transactions, the European market ranked second in terms of new issues. Of these, 22 were in Germany, with a total placement value of approx. USD 10 billion. While the U.S. came in third in terms of number of IPO transactions (416), it ranked significantly higher by total issuance value (USD 156 billion).<sup>1</sup>

#### Performance of FORMYCON shares

FORMYCON shares opened the trading year 2021 with their market price holding steady at around  $\in$  60.00, then rose to  $\in$  68.80 due to the general positive mood among investors and a press release in early January regarding FORMYCON'S COVID-19 drug development project FYB207, then finally leveled off again to € 60.00 towards the end of January. At the beginning of February the share price caught a fresh wind and surged to  $\in$  78.60 in the middle of the month, thereby reaching an all-time high. Starting in mid-February, stock markets came under pressure again, with rising prices, fears of coming inflation, and the associated rise in bond yields creating competition with equities as an asset class.<sup>2</sup> Following the surge in the FORMYCON share price to its record high of  $\in$  78.60, there was also presumably a certain amount of profit taking. In late February, FORMYCON shares rose once again above the € 65.00 mark before falling back from the beginning of March through mid-April, trading in the range of  $\in$  59.00 to  $\in$  64.00. The general stock market environment during the second quarter of 2021 was more buoyant as investors began to bet on a rapid economic recovery following the subsiding coronavirus pandemic. This investor optimism was further boosted by strong company results, and German retail sales for the month of March were also significantly better than expected. The market seemed to take all of this together as a sign that the economic upturn was gaining momentum.<sup>3</sup> A further and particularly important trigger for the brightening mood on capital markets was the progress in vaccinations and the associated hopes of containing the pandemic.

In terms of relative performance, FORMYCON share trading outperformed relevant market benchmarks (Scale 30, TecDAX and NASDAQ Biotechnology), as shown in



Figure 11, but was unable to sustain this positive momentum into the third quarter. In the course of the summer months, the coronavirus pandemic temporarily receded into the background as new infections dropped and as ever more people in Germany and elsewhere received vaccinations. Despite positive news regarding the Company's biosimilar projects and COVID-19 drug project, FORMYCON shares came under selling pressure, falling below € 50 and marking a year-to-date drop of roughly 20%. Following a brief period of recovery and stabilization, FORMYCON share trading was again volatile in the fourth quarter. The shares fell further in early December, hitting a year low of  $\in$  43.95, then surged back up by some 34% to close the year at  $\in$  59.00 (Xetra). Thus, for 2021 as a whole, FORMYCON shares delivered a solid return of some 8%. Throughout the year, FORMYCON'S stock market performance was largely driven by the ups and downs of the coronavirus pandemic in conjunction with the Company's announced advances in the development of its new COVID-19 drug, although the Company was also able to make important announcements regarding its primary business of biosimilar development, notably including submissions to the FDA and EMA of applications for regulatory approval and the announcement of strong new marketing partners for FYB201, both of these being key milestones toward the successful market launch of FORMYCON'S first biosimilar product in 2022.

During fiscal year 2021, the total number of FORMYCON shares traded across all trading venues was 6,067,055, a drop of almost 23% compared to the previous year (2020: 7,834,601 shares), and corresponding to daily average trading liquidity of 23,790 shares (prior year: 30,845 shares). Alone in the first quarter of 2021, some 3.1 million shares changed hands, equal to more than half (52%) of the annual total. Of this annual total, approx. 49% of the shares were traded on the Xetra trading system, 6% on the Frankfurt Stock Exchange, and 45% on other stock exchanges (of which approx. 88% via Tradegate).

<sup>1</sup> Frankfurt Stock Exchange, "Jahresrückblick nicht nur Corona"

ntv, "Der Börsen-Tag: Dax testet Richtung 13.800 – und kämpft"

<sup>&</sup>lt;sup>3</sup> Finanzen.net, "Konjunkturoptimismus treibt Europas Börsen weiter an"





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Figure 12: Share price performance and trading volume of FORMYCON shares

#### FORMYCON shares: Basic information

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

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

In €	2021	2020
Opening price on Jan. 4, 2021/Jan. 2, 2020 (Xetra)	54.60	31.40
Closing price on Dec. 30, 2021/Dec. 30, 2020 (Xetra)	59.00	53.00
Average price (Xetra closing price)	57.85	28.57
Market capitalization as of Dec. 31 (in €)	652.820.250	583.000.000

#### In shares

Total shares traded (on all trading venues)	6.067.055	7.834.601
Daily average shares traded (on all trading venues)	23.790	30.845
Total shares issued as of Dec. 31	11.064.750	11.000.000

<sup>&</sup>lt;sup>1</sup> Onvista, historical share price data for Formycon AG (Xetra)

### 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", as these companies are not legally considered to be listed on an official exchange.

As of the period closing date of December 31, 2021, the Company had received no such notifications that any such voting rights thresholds had been exceeded. Nevertheless, as part of its targeted investor relations activities, FORMYCON strives to ascertain its shareholder structure to the greatest extent possible.

With some 35% of shares in the hands of family offices and another 15% held by institutional investors, the shareholder structure of FORMYCON AG remained stable. Founders and management held approx. 15% of shares, with the remaining 35% in free float. As of December 31, 2021, and on the basis of total registered capital (Grund-kapital) of  $\in$  11,064,750.00, divided into 11,064,750 no par value bearer shares with an imputed nominal value of  $\in$  1.00 per share, Peter Wendeln, anchor shareholder and long-time FORMYCON supervisory board member, held a total of 21.61% of the Company's outstanding shares by way of asset management company Wendeln & Cie. KG and other entities under the control of Mr. Wendeln. This holding is included within the aforementioned figure for family office holdings. Since October 22, 2020, the Active Ownership Group has held 1,000,000 shares, representing a 9.04% stake in FORMYCON AG as of December 31, 2021.



#### 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, 2021, the registered capital (Grundkapital) of FORMYCON AG was  $\in$  11,000,000.00, divided into 11,000,000 bearer shares without par value but with an imputed nominal value of  $\in$  1.00 per share. During the fiscal year, 64,750 new shares were issued from Conditional Capital 2015, as resolved on June 30, 2015 to facilitate the Company's Employee Stock Ownership Plan 2015. By the respective resolutions of the Supervisory Board on February 3, 2021 and November 8, 2021, Section 4 of the Company's Articles of Association (Satzung), governing the amount and division of registered capital conditional capital, was amended accordingly. The registered capital of FORMYCON AG thus amounted to a total of  $\in$  11,064,750.00 as of December 31, 2021. 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") or Notes to the Consolidated Financial Statements (section V: "Additional notes to the Consolidated Balance Sheet") included in this report.

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

During fiscal year 2021, members of the Executive Board or Supervisory Board conducted the following securities transactions subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR):

Executive or Supervisory Board Member	Position	Transaction Date	Type of Transaction	Average Price	Aggregate Value	Trading Venue
Dr. Carsten Brockmeyer	CEO	03.03.21	Sales of shares acquired under Employee Stock Ownership Plan 2015	64.90 €	486,750.00 €	Off exchange
Dr. Nicolas Combé	CFO	03.03.21	Sales of shares acquired under Employee Stock Ownership Plan 2015	64.90 €	973,500.00 €	Off exchange
Dr. Stefan Glombitza	соо	03.03.21	Sales of shares acquired under Employee Stock Ownership Plan 2015	64.90 €	973,500.00 €	Off exchange
Dr. Carsten Brockmeyer	CEO	03.02.21	Purchase of Shares under Employee Stock Ownership Plan 2015	20.70 €	155,250.00 €	Off exchange
Dr. Nicolas Combé	CFO	03.02.21	Purchase of Shares under Employee Stock Ownership Plan 2015	20.70€	310,500.00 €	Off exchange
Dr. Stefan Glombitza	соо	03.02.21	Purchase of Shares under Employee Stock Ownership Plan 2015	19.46 €	291,900.00 €	Off exchange

<sup>&</sup>lt;sup>1</sup> BaFin Bundesanstalt für Finanzdienstleistungsaufsicht: Allgemeine Grundsätze zur Abgabe von Mitteilungen nach §§33, 38 und 39 WpHG.

#### **Annual General Meeting**

Because of the ongoing COVID-19 pandemic, and for the protection of all involved, the Company's Annual General Meeting was held on September 27, 2021 in virtual format.

In this way, 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. Shareholders likewise ratified the actions of the members of the Executive and Supervisory Boards during the fiscal year with overwhelming voting majorities of over 98% for each such officer. During the proceedings, the Executive Board provided shareholders with a detailed informative presentative about the Company's current biosimilar and COVID-19 drug development projects and answered all of the questions submitted in advance of the meeting. 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. 6.1 million shares were voted, representing 55.36% 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. As a result of the ongoing coronavirus pandemic, most conferences and events during 2021 were held in virtual format. During the fiscal year, 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 Kepler Life Science Day, the Hauck & Aufhäuser Stockpicker Summit, and the Deutsche Börse Equity Capital Forum. Through such conferences as well as other outreach activities, notably including virtual non deal roadshows in Luxembourg, the UK and the USA, the Company has strived to maintain active contact with existing and potential investors and to increase its visibility on the capital markets. As of December 31, 2021, six analysts were regularly providing equity research coverage on FORMYCON AG.

## during fiscal year 2021:

#### Bank or research provider

3. Metzler seel. Sohn & Co. Ko
dison Investment Research L
irst Berlin Equity Research G
lauck & Aufhäuser Privatbanl
Cepler Cheuvreux
RH AlsterResearch AG

FORMYCON AG **Contact Person** 

Street address Phone Email Web

#### The following analysts published research studies on FORMYCON

Analyst
Tom Diedrich
Dr. John Savin
Simon Scholes
Alexander Galista
Damien Choplain
Oliver Drebing

More information about FORMYCON and its investor relations activities may be found in the "Investors" section of the Company'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 AG stands ready to respond to any questions or suggestions:

	Sabrina Müller
	Senior Manager Corporate Communications
	& Investor Relations
•••••	Fraunhoferstraße 15,
	82152 Martinsried/Planegg, Germany
•••••	+49 89 864 667 149
	ir@formycon.com
	https://www.formycon.com/en/investor-relations/shares

<sup>&</sup>lt;sup>1</sup> Deutsche Börse AG commissions research for all issuers in the Scale segment, with at least one research house preparing regular research reports for each company in the segment. The aim of this is to enhance financial transparency of companies in the Scale segment and to make them more directly comparable for investors.







FORMYCON AG Annual Report 2021



Staffing and

structure

organizational

As of December 31, 2021, a total of 171 persons (prior year: 131) were employed at FORMYCON'S offices and laboratories in Planegg on the outskirts of Munich. The average staffing during fiscal year 2021 compared to the prior fiscal year 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)

	2021	2020	% increase
Research & Development	117	89	31 %
Business Operations <sup>1</sup>	4	_	-
General & Administrative	16	12	67 % <sup>2</sup>
Total	137	101	36 %

Staff expenses during fiscal year 2021 were € 12,997K (prior year: € 10,032K), 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 (73%) work on a full-time basis. In addition to the Project Management and Clinical Development departments, scientific staff were added over the past year, particularly within the Protein Analytics & Process Sciences area, in order to have the necessary resources and expertise in place for FORMYCON'S growing portfolio of existing and new development projects. The Regulatory Affairs & Quality Management department was also expanded over the fiscal year to have the necessary staff in place to create highly complex regulatory approval documents and to interact as necessary with regulatory approval authorities in key international markets. On the general and administrative side of the organization, staffing was increased in particular in the Business Operations department, which is playing a key role in our further development of purchasing and digitization, as well as in the Corporate Communications department. These staffing additions ensure that FORMYCON is able to fully meet the needs of its growing business and organization and to face the challenges and opportunities which lie ahead.





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<sup>&</sup>lt;sup>1</sup> Beginning with fiscal year 2021, business operations, previously included under general and administrative, is shown separately.

<sup>&</sup>lt;sup>2</sup> For reasons of comparability, business operations is combined with general and administrative for purposes of calculating the percentage increase (i.e. calculated on the basis of 20 FTEs during 2021).



Responsibility – Our responsibilities to our staff and our company community

**Corporate Social** 

#### 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 24 different countries (Australia, Austria, Bosnia and Herzegovina, Brazil, China, Colombia, Croatia, Cyprus, France, Germany, Hungary, India, Iran, Italy, Japan, Macedonia, Montenegro, Nepal, Poland, Portugal, Romania, 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

In terms of education level, 83 % of the Company's total employees have a university degree, and 39 % specifically a doctorate. As to gender, 60 % are female and 40 % male. The average employee age as of December 31, 2021 was 39 years. The percentage of women within the second management level (Vice President, Senior Director, Director) was 30%. FORMYCON is proud of the stable organization and diverse workforce that it has built over the years, with employees from 24 different countries.

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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. In addition to offering such specific benefits as flexible working hours, a company pension scheme, health and wellness programs, and teambuilding events, FORMYCON places great importance on overall employee satisfaction, which is - along with technical excellence - essential to the Company's ultimate success. In order 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 present a risk to the Company. The survey thus includes specific questions not only about the employee's satisfaction with the Company but also about psychological stresses within the workplace. The company also offers individual health assessments to its employees, along with coaching on relevant health topics. Through all of these measures, the Company strives to achieve and maintain the highest possible levels of employee satisfaction and loyalty.

In order to enable our employees to better reconcile their work with the demands of their private lives, we have developed a new concept for FORMYCON as a modern and forward-looking workplace, including work hours, working locations and working methods, not only during but also beyond the COVID-19 pandemic.

#### 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.

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 fiscal year, 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.

#### Biopharmaceuticals to meet the needs of patients

Corporate Social Responsibility – Our responsibilities to patients, to our investors and to the world at large

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 60

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.

During 2021, FORMYCON focused its efforts on adopting and integrating the first two of these Ten Principles, which call for support and respect for the protection of internationally proclaimed human rights. Beyond respecting human rights in our own business activities, this also means that we must ensure that human rights are likewise respected through the business relationships we have in our value chain as well as in our supply chain. The Company, with its headquarters and laboratories in Germany, 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 recast by the Government Commission on the German Corporate Governance Code (Regierungskommission Deutscher Corporate Governance Kodex) at the end of 2019, which entered into legal force upon publication in the Federal Gazette on March 20, 2020.

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 (as described above), 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.<sup>2</sup> 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 with our investors, the Executive Board and Supervisory Board of FORMYCON began in 2021 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.

Government Commission on the German Corporate Governance Code.

Research and development

As in previous fiscal years, the Group's activities during the period ending December 31, 2021, were primarily in the area of research and development.

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

	Fiscal year
Cost of raw materials, consumables and supplies	€ 2,689K
Third-party services	€ 33,633K
Staff expenses	€ 12,997K
Depreciation and amortization	€ 943K
Other	€ 5,122K
	€ 55,384K

As of December 31, 2021, 117 staff members (FTE) worked in research and development (prior year: 89). Expenditures during the period totaled  $\in$  55,384K, and these were all were charged as current expense. No research and development expenditures were capitalized, although certain expenses for the FYB206 project, such as reference material, were capitalized. In the area of patent protection, the Group continued to push forward with the international phase of its pending patent applications. 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, 2021 to December 31, 2021. 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 reporting period, **FORMYCON Group** generated consolidated revenue of € 36,965K, compared to € 34,227K in the prior fiscal year, resulting in an annual consolidated net loss of € 13,476K (prior year: net loss of € 5,926K). Cost of materials for the year was € 36,321K (prior year: € 26,050K), yielding consolidated gross profit from € 5,729K (prior year: € 9,171K).

During fiscal year 2021, **FORMYCON AG** continued to drive forward with the development of its four 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. Under the terms of these deals, FORMYCON AG received ongoing payments for its product development services provided on behalf of the licensee As part of the creation of a new joint venture with Aristo Pharma GmbH in 2017, FORMYCON transferred the intellectual property rights in its FYB202 biosimilar project to the joint venture entities, FYB 202 GmbH & Co. KG and FYB 202 Project GmbH. FORMYCON holds a 24.9 % stake in the joint venture with Aristo Pharma GmbH and bears a pro rata share of accumulated project investments and further development costs. FORMYCON AG also receives ongoing remuneration for the development services which it provides to the joint venture. The full-year net loss for FORMYCON AG (parent company only) was thus  $\in$  13,283K on revenue of  $\in$  26,546K.

#### b. Financial position

The financial position of both FORMYCON AG and FORMYCON Group remains stable, with key liquidity ratios significantly above average, as in prior years. Current assets totaled  $\in$  37,992K, compared to total current liabilities of  $\in$  5,594K. The Company did not have any bank loans or long-term loans during the period.

As of the period closing date, consolidated cash and equivalents amounted to € 25,029K, while marketable securities, also included in cash and liquid resources in the following Statements of Cash Flows, totaled € 150K. Return on sales (annual net income/loss divided by sales revenue) for the period was - 36.5 %, while EBIT (operating profit/loss) was - € 13,333K and EBITDA (operating profit/loss plus depreciation and amortization) was - € 12,389K.

The Company did not have any financial debts. Its cash flows during the period are summarized in the following Consolidated Statement of Cash Flows:

#### **Consolidated Statement of Cash Flows:**

#### per German Accounting Standard (DRS) 21

		2021	2020	Delta	
		in € K	in € K	in € K	in %
	Net income/loss	- 13,476	-5,926	-7,550	127
+/-	Depreciation, amortization, writedowns (impairments) and				
	write-ups of fixed assets	943	915	28	3
+/-	Additions to/subtractions from provisions and reserves	2,149	269	1,880	699
+/-	Other non-cash expenses/income	0	30	-30	- 100
-/+	Gain/loss resulting from disposals of fixed assets	175	37	138	373
-/+	Changes to inventories and trade receivables, as well as other assets not included among investing and financing activities	-4,683	-2,483	- 2,200	89
+/-	Changes to trade payables, as well as other liabilities not included among investing and financing activities	550	1.950	- 1.400	-72
+/-	Interest expense/interest income	164	104	60	58
=	Cash flow from operating activities	- 14,178	-5,104	-9,074	178
-	Payments for investments in intangible assets	-547	-92	-455	495
-	Payments for investments in property, plant and equipment	-704	-558	- 146	26
-	Payments for investments in financial assets	-2,988	0	-2,988	
+	Interest received	2	2	0	0
=	Cash flow from investing activities	- 4,237	- 648	- 3,589	554
+	Proceeds from shareholders for additions to equity capital	1,512	25,750	- 24,238	- 94
-	Interest paid	- 166	- 106	- 60	57
=	Cash flow from financing activities	1,346	25,644	- 24,298	- 95
	Total changes in cash and liquid resources from cash flows	- 17,069	19,893	- 36,962	- 186
+	Cash and liquid resources at the beginning of the period	42,247	22,354	19,893	89
	Cash and liquid resources at the end of the period*	25,178	42,247	- 17,069	- 40

\* Cash and liquid resources includes cash and cash equivalents as well as short-term marketable securities available for sale.

### Statement of Cash Flows (parent company only)

per German Accounting Standard (DRS) 21

	Net income/loss
+/-	Depreciation, amortization, writedowns (impairments) and write-ups of fixed assets
+/-	Additions to/subtractions from provisions and reserves
+/-	Other non-cash expenses/income
-/+	Gain/loss resulting from disposals of fixed assets
-/+	Changes to inventories and trade receivables, as well as other ass not included among investing and financing activities
+/-	Changes to trade payables, as well as other liabilities not included among investing and financing activities
+/-	Interest expense/interest income
=	Cash flow from operating activities
-	Payments for investments in intangible assets
-	Payments for investments in property, plant and equipment
-	Payments for investments in financial assets
+	Interest received
=	Cash flow from investing activities
+	Proceeds from shareholders for additions to equity capital
-	Interest paid
=	Cash flow from financing activities
	Total changes in cash and liquid resources from cash flows
+	Cash and liquid resources at the beginning of the period
=	Cash and liquid resources at the end of the period*

\* Cash and liquid resources includes cash and cash equivalents as well as short-term marketable securities available for sale.

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	2021	2020
	in € K	in€K
	- 13,283	-5,733
	943	915
	2,058	-348
	0	30
	175	37
sets		
	-6,290	-244
1		
	1,942	767
	64	41
	- 14,389	-4,535
	-547	-92
	-704	-558
	-2,988	-423
	84	57
	-4,154	- 1,016
	1,512	25,750
	- 149	-98
	1,363	25,652
	- 17,181	20,101
	39,428	19,327
	22,248	39,428

# c. Net assets

As of the close of the fiscal year, the Group's equity capital ratio was 84.5% which, although slightly lower than in the prior year (90.0%), remained relatively high. Non-current assets, which rose as a result of investing activities, continued to be completely covered by equity capital, suggesting a healthy balance sheet structure.

The Group's current assets consist almost completely of cash and marketable, highly liquid securities and thus involve negligible risks.

Financial and nonfinancial 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.

Cash flow from operating activities was -  $\in$  14,178K (prior year: -  $\in$  5,104K), in line with expectations. Cash flow from investing activities was -  $\in$  4,237K (prior year: -  $\in$  648K) As expected, return on equity (annual net income(loss)/average equity) and total return on capital (annual net income(loss)/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.



#### 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). In addition to these existing pipeline projects, FORMYCON is working hard to steadily expand its future development pipeline. With the anticipated market launch of its first product in 2022, FORMYCON is drawing closer to its next phase as a company, whereby it will be able to finance new growth opportunities from existing cash flows. In this way, marketing revenues already being brought in by late-stage biosimilar candidates will enable the Company to financing its own development pipeline from its own resources through to a more advanced stage, making it possible to delay out-licensing or joint venture deals until this later stage, meaning that FORMYCON will be in a position to retain a substantially greater share in the projects, thus reaping far more of their potential for value creation. Independently of this, FORMYCON will work to further strengthen the administration and management of its maturing organization and, in parallel with the Company's existing German statutory (HGB) financial accounts, will also being preparing its annual financial statements, including retroactively to fiscal year 2020, 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 will be able to consider an uplisting to a more highly regulated stock market segment and/or an international listing such as on the Nasdag Stock Market in order to reach a broader base of potential investors.

#### FYB201 - candidate biosimilar to Lucentis®

FYB201, FORMYCON'S candidate biosimilar to ophthalmic blockbuster drug ranibizumab (reference product: Lucentis®), is the furthest advanced development project within the product pipeline. Together with our license partner Bioeq AG, we are working hand in hand towards the successful market launch of our first product. Due to the ongoing COVID-19 pandemic, which again had the effect over the past year of restricting 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. With the marketing authorization application (MAA) for FYB201 submitted by our licensing partner Bioeq to the European Medicines Agency (EMA) in June 2021 and the corresponding biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) shortly thereafter, Formycon now anticipates these respective regulatory approvals during the third quarter of 2022. Alongside U.S. biosimilar specialist Coherus BioSciences, Inc., the exclusive distributor of our Lucentis® biosimilar FYB201 in the United States, our partner Teva Pharmaceutical Industries Ltd., a leading global provider of generic and specialty drugs, will be responsible for the market launch of FYB201 in Europe as well as certain other territories. MS Pharma, a leading pharmaceutical company specializing in the distribution of biotechnology products and generics in the MENA region, is our third announced FYB201 distribution partner, with responsibility for the Middle East and North Africa. In addition to regulatory approval in the United States and in the countries of the European Union, FORMYCON and Bioeq are pursuing regulatory approval in further markets, particularly in highly regulated countries.

#### 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. With the transfer of the FYB202 project into a joint venture (24.9% participation) with Aristo Pharma GmbH, FORMYCON created a strong basis to drive forward with the remaining development work. Thus far, FORMYCON has invested approx. € 23.7 million into the FYB202 project. The manufacturing process for the active ingredient has already now been scaled up to a commercial production level. The start of phase I clinical trials was announced in October of 2019. Phase III clinical trials (the VESPUCCI study) were launched in November 2020, marking the third FORMYCON biosimilar candidate to be successfully moved into phase III clinical trials, with the aim here of demonstrating the comparability of FYB202 to reference product Stelara® in patients with moderate to severe psoriasis vulgaris (plaque psoriasis) in terms of efficacy, safety and immunogenicity. Results from the VESPUCCI study, initiated by FORMYCON and its license partner Bioeq as one of the world's first phase III trials of a Stelara® biosimilar, are expected during 2022. As to the overall market for Stelara®, the growth dynamics are likewise extremely encouraging: According to the manufacturer, full-year 2021 sales revenue grew by 18% over the prior year to approx. USD 9.1 billion, with this growth partly fueled by the regulatory approval during 2019 of ulcerative colitis as an additional treatment indication.

#### 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. In 2015, FORMYCON signed a deal to license out FYB203 to cooperation partner Santo Holding (Deutschland) GmbH. In this drug development project as well, the manufacturing process for FYB203's active ingredient has already been scaled up to a commercial production level. In August of 2020, FORMYCON AG and Bioeq GmbH, sponsor of the phase III clinical study, announced the kick-off of phase III trials for FYB203 (the MAGELLAN-AMD study). These randomized, double-blind, multi-center phase III trials are examining the comparability of FORMYCON's biosimilar candidate FYB203 to reference


product Eylea® in terms of efficacy, safety and immunogenicity in patients with nAMD. Results from the MAGELLAN-AMD study are expected in 2023. 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 worldwide marketing rights were more recently shifted internally within our partner, the Santo Group, to another Santo entity, Klinge Biopharma GmbH. With full-year global revenue of some USD 9.0 billion, the manufacturer of reference drug Eylea® announced 12.5% growth over the prior year.

# FYB206 – biosimilar candidate not yet announced

Details of FYB206, another project in the Company's development pipeline, have not yet been publicly announced. Development efforts for the biosimilar drug candidate are currently in the pre-clinical phase, and intellectual property (IP) rights specific to the project have been established.

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

Building upon on its extensive and clinically validated experience with antibodies and antibody fusion proteins, the Company launched development of an innovative COVID-19 drug (FYB207) in March 2020, promptly following the outbreak of the COVID-19 pandemic in Europe. In addition to vaccines, as well as conventional pharmaceuticals produced through chemical synthesis, SARS CoV 2 blocking antiviral biopharmaceuticals will also play a critical role in the fight to contain COVID-19 and treat infected patients. With its FYB207 project, FORMYCON is, together with its renowned academic partners at the Technical University of Munich, Prof. Dr. Ulrike Protzer, Chair of Virology, and Prof. Dr. Johannes Buchner, Chair of Biotechnology, working to develop an efficient, broad-spectrum antiviral SARS-CoV-2 blocker based on a long-acting ACE2-immunoglobulin fusion protein which has been shown in vitro to completely prevent the infection of cells. Through its scientific advice procedure, the Paul Ehrlich Institute (PEI), an agency of the German Federal Ministry of Health, granted pre-approval to FORMYCON in February 2021 for the Company's proposed development concept, thus marking official support of the country's Federal Institute for Vaccines and Biomedicines for FORMYCON'S planned development of FYB207. Review of FORMYCON'S applications for clinical trials will be carried out under an accelerated procedure. Through preclinical in vivo studies, which are already in progress, data will be simultaneously collected under two different models – firstly, on pharmacokinetics, and secondly, on the efficacy of different candidate variants of the ACE2-Fc fusion proteins, in order to select the most suitable candidate for subsequent clinical trials, which are expected to begin as soon as possible.

Funding for the basic research work under this project has been provided to FORMYCON and its academic research partners by the Bavarian Research Foundation (Bayerische Forschungsstiftung). Further funding in the amount of  $\in$  12.7 million has been granted by the Bavarian State Ministry for Economic Affairs, Regional Development and Energy to support the preclinical development, investigational product manufacture under GMP conditions and phase I/IIa clinical trials of FYB207.

A cooperation and out-licensing agreement was signed with SCG Cell Therapy Pte Ltd ("SCG") in October of 2021 with the aim of accelerating the development, manufacture and commercialization of FYB207 in the Asia-Pacific (APAC) region (excluding Japan). Under the deal, FORMYCON will be eligible to potential receive development, regulatory and sales-related milestone payments of up to  $\in$  63.5 million along with low double-digit percentage royalties on future net sales. The APAC region, which is home to some 60% of the world's population, constitutes the world's second largest healthcare market.

#### Summary and strategic focus

The development of biosimilars remains FORMYCON'S strategic focus and the basis for the Company's sustainable, long-term future growth. As in the past, FORMYCON will continue to invest a major part of its resources into its biosimilar project pipeline in order to maintain independent ownership of these projects through to the furthest possible stage of development. As certain development milestones are reached, FORMYCON aims to transfer these biosimilar candidates into advanced development and commercialization partnerships and to remain closely involved, whether as a direct participant or as provider to our out-licensing partner company. Under these partnership deals, subsequent production and marketing is generally the responsibility of the partner company, with FORMYCON then participating in future sales proceeds. These arrangements provide FORMYCON with significant growth potential and a leading position in the world's rapidly developing biosimilars market.

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. In contrast to our bio-similar development projects, in which our strategic aim is to pursue development independently for as long as possible with a long-term aim, and with future sales participation, our aim in the case of the FYB207 project is to completely transfer it to a strategic development and commercialization partnership once certain development milestones have been reached.

#### Financial profile and organization of FORMYCON Group

With its financial soundness and its strong portfolio of capabilities, FORMYCON Group is well positioned in the market. Provided that the development and regulatory approval of its current biosimilar candidates proceeds as planned, FORMYCON should enter the royalty phase starting from 2022. The resulting cash flows should serve to significantly change the Company's balance sheet structure and help to sustainably finance its long-term growth. Exchange rate or inflation risks are not currently viewed as relevant factors.

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).

Sales revenue for fiscal year 2021 was in line with forecast. EBIT and EBITDA were, as expected, negative for both FORMYCON Group and FORMYCON AG largely because of investments into the FYB206 and FYB207 development projects.

The anticipated market launch of FYB201 in Europe and the United States during the second half of 2022 should lead to the Company's first product revenue through its participation (as royalties) in the sales of FYB201. As a result, 2022 full-year revenue for FORMYCON Group is expected to exceed consolidated revenue for fiscal year 2021. Due to planned investments into the Company's existing owned development programs, including the COVID-19 project, as well as in new product development initiatives, the Company expects to once again report a full-year net loss, as it did in fiscal year 2021.

#### IV Report on opportunities and risks

#### **Opportunities**

Once again in 2021, the ongoing COVID-19 pandemic dominated political and social discussion as well as virtually every corner of the economy, even as newly available vaccines fueled hopes that the pandemic could soon be overcome, and associated health restrictions obviated, through national vaccination programs in Germany and elsewhere. No sooner had new coronavirus infection, hospitalization and death rates faded from the headlines during the summer months, did newly emerging and highly infection coronavirus variants, accompanied by skyrocketing infections in late autumn and resulting new government health restrictions, bring the surging pandemic back into the forefront of public awareness.

The offering of "booster" vaccinations starting in mid-2021, and the related discussions about the optimal combination of available vaccines, dashed hopes in early 2021 of a quick end to the pandemic. In fact, there is every reason to believe that, in the years to come, there will continue to be a pressing need not only for new vaccines but also for highly effective drugs to treat acute coronavirus illness; the ability of the virus to adapt through new variants, along with insufficient immunization particularly of immunocompromised population segments, suggests that COVID cannot be fully contained, and significant number of seriously ill patients avoided, solely with the vaccines approved so far. The FYB207 project, which FORMYCON initiated in the spring of 2020, aims to develop a long-acting and broad-spectrum drug for the treatment of acute coronavirus disease and, in the view of FORMYCON, has significant further potential to meet future healthcare challenges, particularly with respect to new and as yet unknown coronavirus variants which similarly exploit the ACE2 protein as a mechanism of cell entry.

FORMYCON'S core business, however, continues to be 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 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. Towards this end, individual risks are identified across all relevant business areas and projects and are categorized according to the probability of occurrence as well as to their potential harmfulness. Where changes in these individual risks occur, or structural changes, these are then reevaluated through periodic reviews. This process aims to ensure that the Company steers clear of such risks to the extent possible, or if they arise, that their consequences are managed as effectively and expeditiously as possible.

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#### 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 bio-similar 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. EUR 21.5 billion, so that – provided that their development reaches successful completion – the profitability of these projects, as they stand right now, seems assured.

Through its established out-licensing partnerships as well as its joint venture with Aristo Pharma GmbH, FORMYCON has the benefit of reliable partners with great expertise and with whom close partnerships have been in place for years. While the potential unplanned termination of such a partnership constitutes a significant strategic risk as a matter of principle, the likelihood of such event occurring is viewed as remote.

#### 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 30.7% of the total drug market in 2020, equal to  $\in$  14.6 billion in sales revenue<sup>1</sup> – 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 healthcare system costs. The political will to act as a result of these cost pressures could also, by increasing the pressure on biopharmaceutical prices, impact FORMYCON'S business environment

#### 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 consolidated financial statements and group 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.

## 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.

#### 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 the successful out-licensing deals and in the case of FYB202 through the establishment of a joint venture partnership. The Bavarian State Ministry of Economic Affairs, Regional Development and Energy has granted funding of up to € 12.7 million to FORMYCON in support of its FYB207 project to develop a COVID 19 drug. This funding is dependent upon the success

Statista, "Umsatz mit Biopharmazeutika in Deutschland im Vergleich zum gesamten deutschen Pharmamarkt in den Jahren 2007 bis 2020"

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of the development project in accordance with the submitted plan, and thus there is a risk that this government funding might not be disbursed in full. Furthermore, in the event of significant deviations from the development and project realization plan, the government has the right to revoke funding already granted or even to reclaim funding already paid out. In the case of the FYB207 project, additional options for development financing, beyond the existing partnership in Asia, are currently under examination.

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. In particular, it appears likely that the producer of the reference drug will pursue legal avenues available to it with regards to the regulatory approval of FYB201 in the United States in order to hinder or delay the market entry of competing products. While the possibility cannot be excluded that FORMYCON might be drawn into such a legal dispute, the Company is prepared for this contingency. At the present time, no other legal conflicts of material relevance are identifiable.

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.

## 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 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.

#### 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 2021, the continuing coronavirus crisis demanded that FORMYCON make significant changes to its organization and work processes, which the Company was 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 the coronavirus crisis, 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.

#### **Overall assessment**

Compared to the previous fiscal year, 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 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 the Company as a going concern. Martinsried/Planegg, March 15, 2022

Dr. Carsten Brockmeyer

Dr. Nicolas Combé

Dr. Stefan Glombitza

## VI Report on branches

The Company does not currently maintain any branches.



# **FORMYCON Group** Consolidated Financial Statements

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# **Consolidated Balance Sheet** Assets

#### as of December 31, 2021

εκ	Dec. 31, 2021	Dec. 31, 202	
Fixed assets			
I. Intangible assets			
<ol> <li>Purchased concessions, industrial property rights, and similar rights and assets,</li> </ol>			
as well as licenses for such rights and assets	590	2	
2. Goodwill		2	
3. Advance payments	81		
	789	4	
II. Property, plant and equipment			
1. Land and buildings, including property-like rights and buildings on third-party land	107	1	
2. Technical equipment and machinery	2,589	2,8	
3. Other plant, production equipment and office equipment	587	5	
4. Advance payments	60		
	3,343	3,5	
III. Financial assets			
1. Investment participations	23,661	20,6	
	23,661	20,6	
Current assets			
I. Inventories			
1. Raw materials, consumables and supplies	359	2	
2. Unfinished products and services	1,118	-	
3. Advance payments	378		
	1,855	1,:	
II. Receivables and other assets			
1. Trade accounts receivable	7,747	6,8	
2. Other assets	3,211		
	10,958	7,0	
III. Securities			
1. Other securities	150	:	
	150	:	
IV. Cash and cash equivalents	25,029	42,0	
Prepaid expenses and deferred items	238		
Deferred tax asset	310	:	
	66,333	75,5	

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# **Consolidated Balance Sheet** Liabilities and Equity

zur	n 31. Dezember 2021
ln €	εκ
A.	Equity
	I. Subscribed capital <sup>1</sup>
	II. Capital reserve III. Accumulated loss carryforward
в.	Provisions
	Tax provisions     Other provisions
<u>с</u> .	Liabilities
	1. Trade accounts payable
	of which due within one year: € 4,734K (prior year: € 4,484K) 2. Other liabilities
	of which due within one year: € 860K (prior year: € 535K)
	of which due in more than one year: € 372K (prior year: € 398K)
	of which from taxes: € 404K (prior year: € 165K)
	of which relating to social security: € 42K (prior year: € 0K)

<sup>1</sup> Conditional Capital 2020: € 724K Conditional Capital 2019: € 4,285K Conditional Capital 2015: € 311K

Dec. 31, 2020	Dec. 31, 2021
11,000	11,065
76,989	78,436
-19,954	- 33,430
68,035	56,071
0	0
2,147	4,296
2,147	4,296
4 40 4	
4,484	4,734
022	1 222
933	1,232
E 440	E 067
5,416	5,967
75,598	66,333

# **Consolidated Income Statement**

for the period from January 1, 2021 to December 31, 2021

εĸ		Fiscal year 2021	Prior yea
1.	Sales revenue	36,965	34,22
2.	Increase or decrease in inventories of finished and unfinished products	363	584
	Other operating income	4,722	410
	of which income attributable to foreign currency translation:		
	€ 36K (prior year: € 65K)		
4.	Cost of materials		
	a. Cost of raw materials, consumables and supplies	2,689	3,278
	b. Cost of purchased services	33,633	22,772
		36,321	26,050
5.	Staff expenses		
	a. Wages and salaries	10,974	8,555
	b. Social contributions and costs for retirement benefits and for support benefits	2,023	1,477
	of which for retirement benefits:		
	€ 144K (prior year: € 136K)		
		12,997	10,032
<b>3</b> .	Depreciation, amortization and writedowns		
	of intangible assets and on property plant and equipment	943	915
7.	Other operating expenses	5,122	3,951
	of which expense arising from foreign currency translation:		
	€ 70K (prior year: € 53K)		
8.	Other interest and similar income	2	2
Э.	Writedowns of financial assets and of securities held in current assets	3	3
Э.	Interest and similar expense	166	106
1.	Taxes on income	- 30	90
2.	Income after tax	- 13,470	- 5,923
3.	Other taxes	6	3
4.	Annual net loss	- 13,476	-5,926
5.	Loss carryforward from prior year	19,954	14,028
6.	Accumulated loss to balance sheet	- 33,430	- 19,954

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# Notes to the Consolidated Financial Statements for the fiscal year from January 1, 2021 to December 31, 2021

#### 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).

#### Ш General information about the content and structure of these Consolidated Financial Statements

The Consolidated Financial Statements and Unified Management Report for FORMYCON AG and FORMYCON Group, presented here in translation from the German original, have been prepared in accordance with the legal provisions of the Commercial Code as well as the applicable sections of the German Stock Corporation Act (Aktiengesetz, AktG).

Items in the Consolidated Balance Sheet and Consolidated Income Statement for which there is no reportable amount either in the current fiscal year or the prior year are omitted as provided under sec. 298 para. 1 and sec. 265 para. 8 of the German Commercial Code (Handelsgesetzbuch, HGB).

The Consolidated Financial Statements have been prepared in accordance with the principles of accounting and valuation prescribed for large corporations under the Commercial Code, in particular sections 297 and 298.

The Consolidated Balance Sheet uses the presentation structure required by sec. 298 para. 1 and sec. 266 para. 2 and 3 of the Commercial Code.

The Consolidated Income Statement retains the total expenditure format, as used in prior years. This format is appropriate to the Group's structure.

#### III Consolidation

Fiscal year and period of consolidation

These Consolidated Financial Statements have been prepared as of December 31, 2021, which is the balance sheet closing date for FORMYCON AG, the parent company.

These Consolidated Financial Statements are based upon the duly attested financial statements of the individual consolidated companies, the fiscal years of which likewise end on the same date.

#### Scope of consolidation

These Consolidated Financial Statements include, in addition to FORMYCON AG, two other companies in which FORMYCON AG has a direct or indirect controlling interest. Further information about shareholdings may be found in these Notes to the Consolidated Financial Statements, within the relevant table in section VII ("Other

Principles of consolidation

information"). For subsidiaries which are fully consolidated into the Consolidated Financial Statements (per sec. 301 of the Commercial Code), capital is consolidated in accordance with the revaluation method, under which assets and liabilities are stated at their full present value and the acquired cost of the shareholding offset against the owned percentage share of the present value of the subsidiary's equity at the time of its acquisition. Should this difference be positive, i.e. an asset, it is carried as goodwill. Should this difference be negative, i.e. a liability, it is shown as an excess resulting from capital consolidation. Such items were not required.

Sales revenue, expenses and earnings, as well as receivables and liabilities, between fully consolidated companies are eliminated in accordance with sec. 303 and sec. 305 of the Commercial Code.

The elimination of intermediate results in accordance with sec. 304 para. 2 of the Commercial Code was not necessary because the influence of intracompany sales of goods and services was of minimal importance for the presentation of a true and fair view of the Group's net assets, earnings and financial position.

In the procedures for consolidation, deferred tax items were taken into account in accordance with sec. 306 of the Commercial Code, with the resulting effect on reported net income, so long as the difference in tax expense is expected to be reversed in subsequent fiscal years.

#### Balance sheet presentation and valuation methods IV



Derivatives

In preparing these Consolidated Financial Statements, there were no consolidated

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

The Group did not hold any derivative financial instruments as of December 31, 2021.

Principles of balance sheet presentation and valuation

**Fixed assets** 

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.

Purchased intangible assets are capitalized at the 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.

#### **Current assets**

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 expenses and deferred items

Commercial Code.

Deferred taxes

partnerships, 15.8%.

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

	Difference in		
	taxable amount	Tax rate	Deferred taxes
	(in €K)	(in %)	(in €K)
Valuation of participation in FYB 202 GmbH & Co. KG	20,645	15.8	3,267
Deferred tax asset from loss carryforward		26.7	3.581
Deferred tax assets to balance sheet			313
Deferred tax assets to balance sheet			
(rounded)			310
Prior year			280
Addition to deferred tax assets			30

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.

Liabilities

Liabilities are stated at the amount required for their fulfillment.

Prepaid expenses and deferred items are posted in accordance with sec. 250 of the

The calculation of **deferred taxes**, 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 has now been recognized. The income tax rate used to calculate deferred taxes is 26.7%, or in the case of investment participations in

#### V Additional notes to the

#### **Consolidated Balance Sheet**

Fixed assets	A <b>Consolidated Schedule of Fixed Assets</b> , including depreciation and amortization taken in the current fiscal year, is provided in Attachment 1 to these Notes.
Receivables and other assets	The remaining term of receivables and other assets, and their relationship to other balance sheet items, is shown in the <b>Consolidated Schedule of Receivables</b> included as Attachment 2.
Equity capital	Changes to consolidated equity are presented in the <b>Consolidated Schedule of</b> <b>Changes in Equity</b> included as Attachment 6.

# Information required per sec. 160 of the **Stock Corporation Act**

#### Number of shares outstanding

The Company has registered capital (Grundkapital) of € 11,064,000, which is divided into 11,064,750 bearer shares without par value.

#### Approved capital

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  $\in$  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

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.

# **Conditional Capital 2019**

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

The Company's registered capital has been conditionally increased by a maximum of € 4,284,740, divided into a maximum of 4,284,740 no-par-value bearer shares (the "Conditional Capital 2019"). This capital increase is conditional upon the exercise of warrants or conversion rights by the holders of convertible bonds and/or bonds with attached warrants issued under the authority granted to the Executive Board by the resolution of the Annual General Meeting of June 27, 2019 and valid until June 26, 2024, or upon the triggering of obligations to issue shares arising from such warrants or convertible bonds. The newly issued shares shall participate in profits from the start of the fiscal year in which they arise due to such exercise, or due to the fulfillment of such obligations arising from such warrants or convertible bonds. 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.

The Supervisory Board is authorized to amend the Company's articles of incorporation to reflect the issuance of shares under these subscription rights, as well as to make other minor amendments thereto involving only wording. The same amendment authority applies if authorization to issue bonds with warrants or convertible bonds has not been utilized upon expiry of the authorization period or if the Conditional Capital 2019 has not been utilized upon the expiry of option or conversion rights and of the Company's conversion or option exercise obligations relating thereto.

- 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

#### **Conditional Capital 2015**

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

The Company's registered capital has been conditionally increased by a maximum of  $\in$  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.

During the fiscal year, 46,500 stock options were exercised under the agreed conditions on February 3, 2021, and a further 18,250 on December 1, 2021. As of the balance sheet closing date, a total of 311,250 stock options were therefore outstanding 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

	gent capital increase. In the case of such subsc granted to Executive Board members, the Superv The Supervisory Board is further authorized to incorporation to reflect such utilization of condition	isory Board is similar amend the Company	ly autho
	As of the balance sheet closing date, a total of a thereunder and not either expired or exercised.	19,000 stock options	s were is
Provisions	Other provisions are substantially comprised of th	e following:	
	In€K	2021 Fiscal year	Prio
	Unpaid invoices	2,863	
	Bonuses	908	
	Accrued vacation	217	
	Safekeeping obligations	147	
	Audit and advisory costs	80	
	Occupational cooperative and other social expenses	54	
	Miscellaneous staff provisions	28	
	Costs of litigation	0	
Liabilities	The remaining term of liabilities, along with th or similar rights and their relationship to other ba <b>Consolidated Schedule of Liabilities</b> included as	lance sheet items, is	shown i
Other financial obligations	The total amount of other financial obligations, within the meaning of sec. 314 para no. 2a of the Commercial Code, results from contractual obligations for ongoing p formance. For obligations up to one year, the total amount is $\in$ 951K, for obligation between one and five years $\in$ 4,053K, and for obligations beyond five years, $\in$		

determine further details regarding the specific implementation of any such contino In the of such subscription rights (stock options) bein

# VI Additional notes to the

**Consolidated Income Statement** 

Sales revenue of € 36,965K during the fiscal year was entirely attributable to development services.

Total research and development costs during the fiscal year were € 55,384K.

# VII Other information

Number of staff

Sec. 314 para. 1 no. 4 of the Commercial Code requires the following information regarding the average number of staff during the fiscal year:

Average number of staff	2021 Fiscal year
Administration	20
Research & development	140
Total company staff	160

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, CEO
- Dr. Nicolas Combé, residing in Munich, CFO
- Dr. Stefan Glombitza, residing in Holzkirchen, COO

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

- Dr. Olaf Stiller, residing in Marburg (Chairman) Member of the executive board of Paedi Protect AG
- Peter Wendeln, residing in Oldenburg (stellvertretender Vorsitzender) Managing partner of 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

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, NanoRepro AG Member of supervisory board, BioTec CCI AG

 Klaus Röhrig Member of board of directors, Agfa-Gevaert NV Chairman of supervisory board, Francotyp-Postalia Holding AG

Remuneration	neration of € 83K (prior Executive Board, within t €1,378K (prior year:€1,68 along with 22,500 stock
Information on share- holdings per sec. 313 para. 2 no. 1–8 of the Commercial Code	The following subsidiar Financial Statements in ad
	FORMYCON Project 201 GmbH Planegg/Martinsried FORMYCON Project 203 GmbH
	FYB 202 GmbH & Co. KG Berlin
Information on auditor fees per sec. 314 para. 1 no. 9 of the	In €K Audit services
Commercial Code	Tax advisory and other service: Gesamt
Number of subscription	As of the balance sheet c yet exercised.

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

FORMYCON AG Annual Report 2021

During the fiscal year, the members of the Supervisory Board received total remuyear: € 127K, while total remuneration to members of the the meaning of sec. 285 no. 9 of the Commercial Code, was 84K), of which € 461K (prior year: € 638K) was success-based, coptions with a current fair value of € 36K..

> ry companies were included within these Consolidated accordance with sec. 313 para. 2 no. 1 of the Commercial Code:

Share of capital (in %)	<b>Equity</b> (in €K)	Annual net income / loss (in €K)
100	196	72
100	-2,100	- 121
24.9	12.114	-26,054

	2021 Fiskal year	2020 Prior year
	95	82
25	8	4
	103	86

closing date, there were no subscription rights issued but not

Significant events subsequent to balance sheet closing date

There have been no events of material significance which occurred following the end of the financial year and are not reflected in the Consolidated 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 company's operational activities, particularly for development, has thus far been minimal.

On March 29, 2022, FORMYCON announced, by way of ad hoc announcement and press release, a significant transaction with ATHOS KG. Under the terms of the agreement, FORMYCON will reacquire full rights to FYB202, a candidate biosimilar to Stelara® (ustekinumab), and a 50% interest in FYB201, a candidate biosimilar to Lucentis® (ranibizumab). As a result of this transaction, FORMYCON will have a significantly higher share of future sales proceeds following anticipated market launch. The Company will be able to invest a major part of the cash inflows expected therefrom into the accelerated expansion of its drug development pipeline. The strategic intent thereby is to enable FORMYCON'S future biosimilar candidates to be developed on an independent basis, thereby making a sustained contribution to the Company's value creation and continued growth. The transaction thus helps to put the necessary foundation in place to further expand FORMYCON'S position as a global leader in the growing market for new biosimilar drugs. In addition, through the acquisition and integration of long-term partner Bioeq GmbH, FORMYCON will expand its in-house competencies in several areas which are critical to the development, approval and commercialization of biosimilars.

Assuming that regulatory approvals are obtained and that market launches or outlicensing deals of its biosimilar candidates proceed according to plan, FORMYCON anticipates EBITDA (calculated in accordance with the currently applicable accounting methods for financial reporting) in 2025 in the three-digit millions of euros. The transaction between FORMYCON and ATHOS was concluded at fair value conditions which were jointly determined and confirmed by an expert and based upon a FORMYCON valuation of € 83.41 per share. A part of the purchase price to ATHOS, valued at a total of approx. € 650 million, will be made in shares of FORMYCON AG issued as a non-cash capital increase under the Company's existing approved capital (consisting of registered capital of  $\in$  4,000,000, or equivalently 4,000,000 shares). Shares issued under this non-cash capital increase will be limited to ATHOS and subsidiaries thereof. In addition, ATHOS is to receive a revenue share (earn-out component) in future sales which FORMYCON achieves with FYB201 and FYB202, which is expected to amount to future income for ATHOS in the mid three-digit million range. Upon completion of the transaction, ATHOS will become FORMYCON'S largest shareholder, with a total stake (including indirect holdings) of some 26.6% of the Company's share capital. An investor consortium consisting of ATHOS and investment company Active Ownership, which specializes in healthcare investments, will also provide an available credit line of up to € 50 million. The transaction is subject to customary closing conditions, including certain regulatory approvals, with completion expected in the first half of 2022.

Appropriation of profit or loss

The Executive Board of FORMYCON AG proposes to carry forward the annual net loss to the next fiscal year.

Martinsried/Planegg, Germany March 30, 2022

Dr. Carsten Brockmeyer

Dr. Nicolas Combé

Dr. Stefan Glombitza

# **Consolidated Schedule of Fixed Assets**

## for the fiscal year from Jan. 1 to Dec 31, 2021

In € K		Changes in hi	storical cost of acc	quisition		Chan	ges in accumulated d	epreciation & amorti	zation	Cha	anges in net book va	lue
	Historical cost of acquisition or production			Historical cost	Historical cost of acquisition or production	Accumulated depreciation & amortization	Current-year depreciation &	Depreciation & write-downs on	Accumulated depreciation & amortization	Net book value	Net book value	Net book valu
	at Dec. 31, 2020	Additions	Rebookings	of disposals	at Dec. 31, 2021	at Dec. 31, 2020	amortization	disposals	at Dec. 31, 2021	at Dec. 31, 2020	of disposals	at Dec. 31, 202
Intangible assets												
Concessions, commercial property rights, and												
similar rights and assets, as well as licenses												
for such rights and assets	671	546	-80	0	1,137	447	100	0	547	223	0	59
Goodwill	1,576	0	0	0	1,576	1,300	158	0	1,458	276	0	11
Advance payments	0	1	80	0	81	0	0	0	0	0	0	8
Property, plant and equipment												
Land and buildings, including property-like												
rights and buildings on third-party land	613	0	0	0	613	461	45	0	506	152	0	10
Technical equipment and machinery	5,780	477	-60	433	5,764	2,962	471	257	3,176	2,818	175	2,58
Other plant, production equipment		•••••••••••••••••••••••••••••••••••••••	•••••••				••••••				•••••	• • • • • • • • • • • • • • • • • • • •
and office equipment	1,548	227	0	27	1,748	1,018	170	27	1,161	530	0	58
Advanced payments and construction in		•••••••••••••••••••••••••••••••••••••••	•••••••••••••••••••••••••••••••••••••••				••••••					
progress	0	0	60	0	60	0	0	0	0	0	0	6
Financial assets												
Investment participations	20.673	2.988	0	0	23,661	0	0	0	0	20,673	0	23,66
Total	30,862	4,239	0	459	34,641	6,188	943	284	6,848	24,673	175	27,79

# Consolidated Schedule of Receivables

Attachment 2

for the fiscal year from Jan. 1 to Dec 31, 2021		
In € K	Dec. 31, 2021	of which due in more than 1 year
Trade accounts receivable	7,747	0 (prior year: 0)
Other assets	3,211	0 (prior year: 0)
Total	10,958	0 (prior year: 0)

# **Consolidated Schedule of Liabilities**

for the fiscal year from Jan. 1 to Dec 31, 2021				
In € K	Dec. 31, 2021	of which due within 1 year	of which due in 1–5 years	of which due in more than 5 years
Trade accounts payable	4,734	4,734 (prior year: 4,484)	0 (prior year: 0)	0 (prior year: 0)
Other liabilities	1,232	860 (prior year: 398)	372 (prior year: 553)	0 (prior year: 0)
Total	5,967	5,594 (prior year: 4,882)	372 (prior year: 553)	0 (prior year: 0)

# Consolidated Schedule of Changes in Equity

## for the fiscal year from Jan. 1 to Dec 31, 2021

In € K	Subscribed capital	Capital reserves
as of Jan. 1, 2021	11,000	76,989
Capital increases and additions to capital reserves	65	1,447
Appropriation of prior-year profit	0	0
Annual net income (loss)	0	0
as of Dec. 31, 2021	11,065	78,436

Profit reserves	Loss carryforward	Consolidated annual net income (loss)	Consolidated equity
0	- 14,028	-5,926	68,045
0	0	0	1,512
0	-5,926	5,926	0
0	0	- 13,476	- 13,476
0	- 19,954	- 13,476	56,071

	of which pledged as security
0	0
Industry-customary	
conditional retention of title	372
72	372

Attachment 4

# **Consolidated Statement of Cash Flows**

per German Accounting Standard (DRS) 21

		2021	2020	Change	
		in€K	in € K	in € K	in %
	Net income/loss	- 13,476	-5,926	-7,550	127
+/-	Depreciation, amortization, writedowns (impairments) and		······		
	write-ups of fixed assets	943	915	28	3
+/-	Additions to/subtractions from provisions and reserves	2,149	269	1,880	-699
+/-	Other non-cash expenses/income	0	30	- 30	- 100
-/+	Gain/loss resulting from disposals of fixed assets	175	37	138	373
-/+	Changes to inventories and trade receivables, as well as other assets not included among investing and financing activities	-4,683	-2,483	-2,200	89
+/-	Changes to trade payables, as well as other liabilities not included among investing and financing activities	550	1.950	- 1,400	-72
+/-	Interest expense/interest income	164	104	60	58
=	Cash flow from operating activities	- 14,178	-5,104	-9,074	178
-	Payments for investments in intangible assets	-547	-92	-455	495
-	Payments for investments in property, plant and equipment	-704	-558	-146	26
-	Payments for investments in financial assets	- 2,988	0	-2,988	
+	Interest received	2	2	0	0
=	Cash flow from investing activities	- 4,237	-648	- 3,589	554
+	Proceeds from shareholders for additions to equity capital	1,512	25,750	-24,238	-94
-	Interest paid	- 166	- 106	-60	57
=	Cash flow from financing activities	1,346	25,644	-24,298	- 95
	Total changes in cash and liquid resources from cash flows	-17,069	19,893	-36,962	-186
+	Cash and liquid resources at the beginning of the period	42,247	22,354	19,893	89
=	Cash and liquid resources at the end of the period*	25,178	42,247	- 17,069	- 40

\* Cash and liquid resources includes cash and cash equivalents as well as short-term marketable securities available for sale.

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#### Report of independent auditor

#### To FORMYCON AG

#### Audit opinions

We have examined the consolidated annual financial statements of FORMYCON AG (the "Company") and its subsidiaries (together the "Group"), consisting of the consolidated balance sheet as of December 31, 2021, and the consolidated income statement, consolidated schedule of changes in equity, consolidated statement of cash flows and group segment report for the fiscal year from January 1 to December 31, 2021, along with the notes to the consolidated financial statements, including the presentation of the accounting policies employed. We have, in addition, examined the unified management report of FORMYCON Group for the fiscal year from January 1 to December 31, 2021.

In our opinion, on the basis of the findings of our audit examination,

- the accompanying consolidated financial statements comply, in all material respects, with the requirements of the German Commercial Code (Handelsgesetzbuch, HGB) and provide a true and fair view of the assets, liabilities and financial position of the Group as of December 31, 2021, and of its financial performance for the fiscal year from January 1, to December 31, 2021, in accordance with German principles of proper accounting, and
- the accompanying unified management report as a whole provides an accurate picture of the Group's position, is consistent in all material respects with the consolidated financial statements, complies with German legal requirements, and suitably presents the opportunities and risks relating to future development.

Pursuant to sec. 322 para. 3 sentence 1 of the Commercial Code, we declare that our audit examination has not led to any reservations relating to the compliance of the consolidated financial statements and unified management report with legal and accounting requirements.

#### Basis for our audit opinions

We conducted our audit examination of the consolidated financial statements and unified management report in accordance with sec. 317 of the Commercial Code and German generally accepted standards for the audit of financial statements promulgated by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer, IDW). Our responsibilities under these legal requirements and standards are further described in the section of this audit report entitled "Responsibility of the auditor in its audit examination of the consolidated financial statements and unified management report". We are, in accordance with the requirements of the Commercial Code as well as German laws and regulations governing public accountants, independent of the subject group companies and have fulfilled our other professional duties as German public accountants in accordance with these requirements. We believe that the evidence we have obtained through our audit examination provides a sufficient and suitable basis for our audit opinions regarding the consolidated financial statements and unified management report.

#### Other information

The Company's legal representatives [members of the Executive Board, per sec. 78 of the German Stock Corporation Act] are responsible for other information, including also statements and explanations provided to us prior to the date of this auditor's report pertaining to such other information in sections of the annual report other than the components of the annual financial statements and unified management report specifically audited by us, as well as this auditor's report and certain remaining final portions of this annual report expected to be made available to us after this date. In addition, such other information in the unified management report specifically includes statements on the Company's development projects (status, progress, forecast) and on its staffing policy.

Our audit opinions on the consolidated financial statements and unified management report do not extend to such other information, nor do we provide any other audit opinion or any other form of audit conclusion in respect thereof.

In connection with our audit, it is our responsibility to read this other information and, in doing so, to assess whether the other information

If, on the basis of the work we have carried out, we come to the conclusion that there has been a material misrepresentation of such other information, we are obliged to report this fact. In the present instance, we have nothing to report.

# Responsibility of the Company's legal representatives and supervisory board for the consolidated financial statements and unified management report

The Company's legal representatives are responsible for the preparation of the consolidated financial statements and for ensuring that these comply, in all material respects, with the Commercial Code and provide a true and fair view of the assets,

- contains material inconsistencies with the annual financial statements, the unified management report or our knowledge obtained during the audit, or

- appears to contain other materially incorrect representations.

liabilities, financial position and financial performance of the Group in accordance with German principles of proper accounting. In addition, the legal representatives are responsible for such internal controls as they deem necessary, in accordance with German principles of proper accounting, to facilitate the preparation of consolidated financial statements that are free from material misstatement, whether intentional or unintentional.

In preparing the consolidated financial statements, the Company's legal representatives are responsible for assessing the Group's continued viability as a going concern, as well as for disclosing, as applicable, any information relevant to the Group's continuance as a going concern. They are, in addition, responsible for maintaining financial accounts on the basis of the going concern principle, unless contrary to law or factual circumstances

Furthermore, the Company's legal representatives are responsible for the preparation of the unified management report which, as a whole, provides an accurate picture of the Group's position, is consistent in all material respects with the consolidated financial statements, complies with German legal requirements, and suitably presents the opportunities and risks relating to future development. The legal representatives are, in addition, responsible for such procedures and precautionary measures (systems) as they deem necessary to facilitate the preparation of the unified management report in accordance with the applicable German legal requirements, and to be able to provide appropriate and sufficient evidence for the assertions in the unified management report.

The Company's supervisory board is responsible for oversight of the accounting processes used by the Group in its preparation of the consolidated annual financial statements and unified management report.

# Responsibility of the auditor in its audit examination of the consolidated financial statements and unified management report

The objective of our audit examination is to obtain reasonable assurance as to whether the consolidated financial statements as a whole are free from material misstatement, whether intentional or unintentional, and as to whether the unified management report as a whole provides an accurate picture of the Group's position, is consistent in all material respects with the consolidated financial statements and the findings of our audit examination, complies with German legal requirements and suitably presents the opportunities and risks relating to future development, then to issue a report of our audit examination including our audit opinions regarding the consolidated financial statements and unified management report.

"Reasonable assurance" is a high level of assurance but is not a guarantee that an audit conducted in accordance with sec. 317 of the Commercial Code and with German

generally accepted standards for the audit of financial statements promulgated by the Institute of Public Auditors in Germany (IDW) will always detect a material misstatement. Misstatements may arise through error or through intentional act and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the business decisions of users of this information taken on the basis of these consolidated financial statements and unified management report.

During our audit examination, we exercise due professional discretion and maintain a critical stance. Furthermore, we:

- tions or the override of internal controls.
- effectiveness of these systems.
- estimates and related disclosures.

- identify and assess the risks of material misstatement, whether intentional or unintentional, in the consolidated financial statements and unified management report, plan and perform audit procedures responsive to such risks, and obtain audit evidence that is sufficient and appropriate to form a basis for our audit opinions. The risk of not detecting a material misstatement resulting from intentional act is higher than for one resulting from error, as intentional acts may involve fraudulent collusion, forgery of documents, intentional omissions, misrepresenta-

 gain an understanding of the internal control systems relevant to our audit examination of the consolidated financial statements, and of the Company's procedures and precautionary measures relevant to our audit examination of the unified management report, so that we are able to design audit methods appropriate to the circumstances, but not for the purpose of expressing an audit opinion on the

- assess the appropriateness of the accounting policies employed by the Company's legal representatives and the reasonableness of their accounting

- draw conclusions as to the suitability of the accounting policies employed by the legal representatives on the basis of the going concern principle and, on the basis of the audit evidence obtained, whether material uncertainty exists relating to events or circumstances which raise significant doubts regarding the Group's ability to continue as a going concern. If we conclude that such material uncertainty exists, we are required to draw attention in our audit report to the related disclosures in the consolidated financial statements and unified management report or, if these disclosures are inadequate, to modify our audit opinions accordingly. We draw our conclusions upon the basis of the audit evidence obtained up to the date of our audit opinion. Subsequent events or circumstances could. however, cause the Group to cease being able to continue as a going concern.

 assess the overall presentation, structure and content of the consolidated financial statements, including related disclosures, and determine whether the consolidated financial statements present the underlying transactions and events in such a way that the consolidated financial statements provide a true and fair view of the assets, liabilities, financial position and financial performance of the Group in accordance with German principles of proper accounting.

- obtain sufficient suitable audit evidence in support of the accounting information of the companies or business activities within the Group to form audit opinions on the consolidated financial statements and unified management report. We are responsible for the planning, supervision and execution of the audit examination of the consolidated financial statements. We bear sole responsibility for our audit opinions.
- assess the consistency of the unified management report with the consolidated financial statements, its conformity with German law, and the picture it conveys of the Group's position.
- conduct audit examinations of forward-looking statements made by the Company's legal representatives in the unified management report. On the basis of sufficient and suitable audit evidence, we validate, in particular, the significant assumptions used by the Company's legal representatives as a basis for forward-looking statements and determine whether these assumptions provide a reasonable basis for the forward-looking statements. We do not express any audit opinion specific to such forward-looking statements or to the underlying assumptions. There is a substantial and unavoidable risk that actual future circumstances may differ substantially from such forward-looking statements.

In our discussions with those responsible for the supervision of the Company, we determine the planned scope and timeframe of the audit examination. We then report significant audit findings, specifically including any deficiencies in internal control systems identified during our audit examination.

Munich, April 14, 2022

# PanTaxAudit GmbH Wirtschaftsprüfungsgesellschaft

Dr. Rudolf Schmitz

Wirtschaftsprüfer [German Public Accountant]

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Shirt

Kevin Lucien Schneider Wirtschaftsprüfer [German Public Accountant]

# Legal information

#### FORMYCON AG Company name: Legal form: German stock corporation (Aktiengesellschaft) **Registered location:** Martinsried/Planegg, Germany Street address: Fraunhoferstraße 15, 82152 Martinsried/Planegg, Germany Company founding and The Company was established through its articles of articles of incorporation: incorporation (Satzung) dated 5 May 2010, which were most recently amended on December 1, 2021. Subject of business: 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. Commercial register: The Company is entered into the commercial register (Handelsregister) of the District Court of Munich under number HRB 200801. Fiscal year: The Company's fiscal year runs from January 1 to December 31 of each year. **Registered capital:** 11,064,750 € Executive Board (Vorstand): Dr. Carsten Brockmeyer Dr. Nicolas Combé Dr. Stefan Glombitza Supervisory Board (Aufsichtsrat): Dr. Olaf Stiller, residing in Marburg, Chairman Peter Wendeln, residing in Oldenburg, Deputy Chairman Klaus Röhrig, residing in Vienna (Austria), Member

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# **FORMYCON AG** Financial Statements

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# **Balance Sheet**

Assets

#### as of December 31, 2021

ЕК	Dec. 31, 2021	Dec. 31, 202
Fixed assets		
I. Intangible assets		
1. Purchased concessions, industrial property rights, and similar rights and assets,		
as well as licenses for such rights and assets	590	2
2. Goodwill	118	2
3. Advance payments	81	
	788	49
II. Property, plant and equipment		
1. Land and buildings, including property-like rights and buildings on third-party land	107	1
2. Technical equipment and machinery	2,589	2,8
3. Other plant, production equipment and office equipment	587	5
4. Advance payments	60	
	3,344	3,5
III. Financial assets		
1. Shares in affiliated companies	50	
2. Loans to affiliated companies	2,000	2,0
3. Investment participations	23,661	20,6
	25,711	22,7
Current assets		
I. Inventories		
1. Raw materials, consumables and supplies	359	2
2. Unfinished products and services	334	
3. Advance payments	378	2
	1,071	5
II. Receivables and other assets		
1. Trade accounts receivable	3,186	2,0
2. Receivables from affiliated companies	7,235	5,8
3. Other assets	3,211	1
	13,632	8,0
III. Securities		
Other securities	150	2
	150	2
IV. Cash and cash equivalents		
	22,098	39,1
Prepaid expenses and deferred items	238	1
Deferred tax asset	310	2

# Balance Sheet Liabilities and Equity

ln €	εĸ	
Α.	Eq	uity
	١.	Subscribed capital <sup>1</sup>
	Ш.	Capital reserve
		Accumulated loss carryforward
в.	Pre	ovisions
	1.	Other provisions
	1.	Other provisions
	1.	Other provisions
		Other provisions
с.		
	Lia	
	Lia	bilities
	Lia	ibilities Trade accounts payable
 C.	Lia 1.	ibilities Trade accounts payable of which due within one year:
 C.	Lia 1.	ibilities Trade accounts payable of which due within one year: $\in$ 4,211K (prior year: $\in$ 2,566K)
 c.	Lia 1.	Ibilities Trade accounts payable of which due within one year: € 4,211K (prior year: € 2,566K) Other liabilities
	Lia 1.	bilities Trade accounts payable of which due within one year: € 4,211K (prior year: € 2,566K) Other liabilities of which from taxes:
 c.	Lia 1.	bilities Trade accounts payable of which due within one year: € 4,211K (prior year: € 2,566K) Other liabilities of which from taxes: € 404K (prior year: € 165K)
 c.	Lia 1.	<b>bilities</b> Trade accounts payable         of which due within one year: $\notin$ 4,211K (prior year: $\notin$ 2,566K)         Other liabilities         of which from taxes: $\notin$ 404K (prior year: $\notin$ 165K)         of which relating to social security:
 c.	Lia 1. 3.	<b>bilities</b> Trade accounts payable         of which due within one year: $\notin$ 4,211K (prior year: $\notin$ 2,566K)         Other liabilities         of which from taxes: $\notin$ 404K (prior year: $\notin$ 165K)         of which relating to social security: $\notin$ 42K (prior year: $\notin$ 0K)
C.	Lia 1. 3.	<b>bilities</b> Trade accounts payable         of which due within one year: $\notin$ 4,211K (prior year: $\notin$ 2,566K)         Other liabilities         of which from taxes: $\notin$ 404K (prior year: $\notin$ 165K)         of which relating to social security: $\notin$ 42K (prior year: $\notin$ 0K)         of which due within one year:

<sup>1</sup> Conditional Capital 2020: € 724K Conditional Capital 2019: € 4,285K Conditional Capital 2015: € 311K

Dec. 31, 2021	Dec. 31, 2020
 11,065	11,000
 78,436	76,989
 - 31,084	- 17,801
 58,416	70,188
 3,458	1,426
 3,458	1,426
 4,211	2,566
 1,230	933
 5,441	3,499
67,342	75,113

### Income Statement

for the period from January 1, 2021 to December 31, 2021

l€k		Fiscal year 2021	Prior year
1.	Sales revenue	26,546	25,097
2.	Increase or decrease in inventories of finished and unfinished products	- 282	
3.	Other operating income	4,696	402
	of which income attributable to foreign currency translation:		
	€ 12K (prior year: € 57K)		
4.	Cost of materials		
	a. Cost of raw materials, consumables and supplies	2,689	3,278
	b. Cost of purchased services	23,088	12,926
		25,777	16,204
5.	Staff expenses		
	a. Wages and salaries	10,974	8,555
	b. Social contributions and costs for retirement benefits		
	and for support benefits	2,023	1,477
		12,997	10,032
	of which for retirement benefits:		
	€ 144K (prior year: € 136K)		
6.	Depreciation, amortization and writedowns		
	of intangible assets and on property plant and equipment	943	915
7.	Other operating expenses	5,047	3,912
	of which expense arising from foreign currency translation: € 26K (prior year: € 44K)		
8.	Other interest and similar income	84	57
	of which from affiliated companies		
	€ 82K (prior year: € 55K)		
9.	Writedowns of financial assets and of securities held in current assets	3	3
10.	Interest and similar expense	149	98
11.	Taxes on income	- 27	90
12.	Income after tax	- 13,280	-5,731
13.	Other taxes	3	3
14.	Annual net loss	13,283	5,733
15.	Loss carryforward from prior year	17,801	12,068
16.	Accumulated loss to balance sheet	31,084	17,801

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# Notes to the Financial Statements for the fiscal year from January 1, 2021 to December 31, 2021

#### 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).

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

These Financial Statements, presented here in translation from the German original, have been prepared 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. the German Stock Corporation Act (Aktiengesetz, AktG).

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.

The Company's fiscal year corresponds to the calendar year.

#### Balance sheet presentation and valuation methods Ш

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 Section 266 of the German Commercial Code and Section 152 of the German Stock Corporation Act, organized into fixed assets, current assets, equity, liabilities, and deferred and prepaid items.

ment 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.

Derivates

Principles of balance sheet presentation and valuation

Fixed assets

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.

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.

The accounting and valuation methods applied to balance sheet and income state-

The Company did not hold any derivative financial instruments as of December 31, 2021.

Current assets	Raw materials, consumables and supplies as well as purchased goods in <b>inventories</b> 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.
	<b>Receivables and other assets</b> 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.
	<b>Securities</b> 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 expenses and deferred items	<b>Prepaid expenses and deferred items</b> are posted in accordance with sec. 250 of the Commercial Code.
Deferred taxes	The calculation of <b>deferred taxes</b> , 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 has now been recognized. The income tax rate used to calculate deferred taxes is 26.7%, or in the case of investment participations in partnerships, 15.8%.

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

	Difference in				
	taxable amount (in €K)	Tax rate (in %)	Deferred taxes (in €K)		
	(III EK)	(111 /0)	(III EK)		
Valuation of participation in FYB 202 GmbH & Co. KG	20,645	15.8	3,267		
Deferred tax asset from loss carryforward		26.7	3,581		
Deferred tax assets to balance sheet			313		
Deferred tax assets to balance sheet (rounded)			310		
Prior year			280		
Addition to deferred tax assets			30		

Provisions

Liabilities

**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.

Liabilities are stated at the amount required for their fulfillment.

#### Additional notes to the Balance Sheet IV

A Schedule of Fixed Assets, including depreciation and amortization taken in the Fixed assets current fiscal year, is provided in Attachment 1 to these Notes. The remaining term of receivables and other assets, and their relationship to other bal-**Receivables and other** ance sheet items, is shown in the Schedule of Receivables included as Attachment 2. assets Changes to equity are presented in the Schedule of Changes in Equity included as Attachment 4. Equity capital

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

#### Number of shares outstanding

The Company has registered capital (Grundkapital) of € 11,064,750, which is divided into 11,064,750 bearer shares without par value.

#### Approved capital

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

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.

2020.

# **Conditional Capital 2019**

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

The Company's registered capital has been conditionally increased by a maximum of € 4,284,740, divided into a maximum of 4,284,740 no-par-value bearer shares (the "Conditional Capital 2019"). This capital increase is conditional upon the exercise of warrants or conversion rights by the holders of convertible bonds and/or bonds with attached warrants issued under the authority granted to the Executive Board by the resolution of the Annual General Meeting of June 27, 2019 and valid until June 26, 2024, or upon the triggering of obligations to issue shares arising from such warrants or convertible bonds. The newly issued shares shall participate in profits from the start of the fiscal year in which they arise due to such exercise, or due to the fulfillment of such obligations arising from such warrants or convertible bonds. 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.

The Supervisory Board is authorized to amend the Company's articles of incorporation to reflect the issuance of shares under these subscription rights, as well as to make other minor amendments thereto involving only wording. The same amendment authority applies if authorization to issue bonds with warrants or convertible bonds has not been utilized upon expiry of the authorization period or if the Conditional Capital 2019 has not been utilized upon the expiry of option or conversion rights and of the Company's conversion or option exercise obligations relating thereto.

- 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

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

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.

During the fiscal year, 46,500 stock options were exercised under the agreed conditions on February 3, 2021, and a further 18,250 on December 1, 2021. As of the balance sheet closing date, a total of 311,250 stock options were therefore outstanding 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.

	gent capital increase. In the case of such subscr granted to Executive Board members, the Superv The Supervisory Board is further authorized to incorporation to reflect such utilization of condition	isory Board is similar amend the Compan	ly authorized
	As of the balance sheet closing date, a total of 4 thereunder and not either expired or exercised.	ł9,000 stock options	s were issuec
Provisions	Other provisions are comprised of the following:		
	In € K	2021 Fiscal year	2020 Prior year
	Unpaid invoices	2,078	74
	Bonuses	908	981
	Accrued vacation	217	181
	Safekeeping obligations	146	135
	Audit and advisory costs	54	44
	Occupational cooperative and other social expenses	54	6
	Miscellaneous staff provisions	28	5
Liabilities	<ul> <li>The remaining term of liabilities, along with their similar rights and their relationship to other bala Schedule of Liabilities included as Attachment 3 t</li> <li>The Company has issued a letter of comfort (Pa subsidiaries FORMYCON Project 201 GmbH and FO best of our knowledge, the respective companies their underlying obligations. Claims thereunder are</li> </ul>	ance sheet items, is o these Notes. tronatserklärung) in RMYCON Project 203 s will be able, in all o	shown in the support of its GmbH. To the cases, to fulfil
Other financial obligations	The total amount of other financial obligations, within 1 no. 3a of the Commercial Code, results from c performance. For obligations up to one year, the tot between one and five years € 4,053K, and for oblig	ontractual obligation tal amount is € 951K, †	s for ongoing for obligations
Additional notes to the Income Statement	Total research and development costs during the	fiscal year were € 44	,763K.

The Executive Board is authorized, subject to approval of the Supervisory Board, to determine further details regarding the specific implementation of any such continNumber of staff

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

Average number of staff	20 Fiskal y	
Administration	20	
Research & development	140	
Total company staff	160	

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, CEO
- Dr. Nicolas Combé, residing in Munich, CFO
- Dr. Stefan Glombitza, residing in Holzkirchen, COO

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

- Dr. Olaf Stiller, residing in Marburg (Chairman)
   Member of the executive board of Paedi Protect AG
- Peter Wendeln, residing in Oldenburg (stellvertretender Vorsitzender)
   Managing partner of 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

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, NanoRepro AG
 Member of supervisory board, BioTec CCI AG

Klaus Röhrig
 Member of board of directors, Agfa-Gevaert NV
 Chairman of supervisory board, Francotyp-Postalia
 Holding AG

# Remuneration

During the fiscal year, the members of the Supervisory Board received total remuneration of  $\in$  83K (prior year:  $\in$  127K, while total remuneration to members of the Executive Board, within the meaning of sec. 285 no. 9 of the Commercial Code, was  $\in$  1,378K (prior year:  $\in$  1,684K), of which  $\in$  461K (prior year:  $\in$  638K) was success-based, along with 22,500 stock options with a current fair value of  $\in$  36K.

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

FORMYCON Project 201 GmbH Planegg/Martinsried

FORMYCON Project 203 GmbH Planegg/Martinsried

FYB 202 GmbH & Co. KG Berlin

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

# In € K Audit services Tax advisory and other services

Total

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

Significant events subsequent to balance sheet closing date yet exercised.

There have been no events of material significance which occurred following the end of the financial year and are not reflected in the 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 company's operational activities, particularly for development, has thus far been minimal.

On March 29, 2022, FORMYCON announced, by way of ad hoc announcement and press release, a significant transaction with ATHOS KG. Under the terms of the agreement, FORMYCON will reacquire full rights to FYB202, a candidate biosimilar to

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Share of capitalEquity(in %)(in € K)	Annual net incom/loss (in € K)
100 - 196	- 72
100 -2.100	- 121
24,9 12.114	-26.054

	2021 Fiscal year	2020 Prior year
	69	55
S	8	1
	77	56

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

Stelara® (ustekinumab), and a 50% interest in FYB201, a candidate biosimilar to Lucentis® (ranibizumab). As a result of this transaction, FORMYCON will have a significantly higher share of future sales proceeds following anticipated market launch. The Company will be able to invest a major part of the cash inflows expected therefrom into the accelerated expansion of its drug development pipeline. The strategic intent thereby is to enable FORMYCON'S future biosimilar candidates to be developed on an independent basis, thereby making a sustained contribution to the Company's value creation and continued growth. The transaction thus helps to put the necessary foundation in place to further expand FORMYCON'S position as a global leader in the growing market for new biosimilar drugs. In addition, through the acquisition and integration of long-term partner Bioeq GmbH, FORMYCON will expand its in-house competencies in several areas which are critical to the development, approval and commercialization of biosimilars.

Assuming that regulatory approvals are obtained and that market launches or out-licensing deals of its biosimilar candidates proceed according to plan, FORMYCON anticipates EBITDA (calculated in accordance with the currently applicable accounting methods for financial reporting) in 2025 in the three-digit millions of euros. The transaction between FORMYCON and ATHOS was concluded at fair value conditions which were jointly determined and confirmed by an expert and based upon a FORMYCON valuation of € 83.41 per share. A part of the purchase price to ATHOS, valued at a total of approx. € 650 million, will be made in shares of FORMYCON AG issued as a non-cash capital increase under the Company's existing approved capital (consisting of registered capital of € 4,000,000, or equivalently 4,000,000 shares). Shares issued under this non-cash capital increase will be limited to ATHOS and subsidiaries thereof. In addition, ATHOS is to receive a revenue share (earn-out component) in future sales which FORMYCON achieves with FYB201 and FYB202, which is expected to amount to future income for ATHOS in the mid three-digit million range. Upon completion of the transaction, ATHOS will become FORMYCON'S largest shareholder, with a total stake (including indirect holdings) of some 26.6% of the Company's share capital. An investor consortium consisting of ATHOS and investment company Active Ownership, which specializes in healthcare investments, will also provide an available credit line of up to € 50 million. The transaction is subject to customary closing conditions, including certain regulatory approvals, with completion expected in the first half of 2022.

Martinsried/Planegg, Germany, March 30, 2022

Dr. Carsten Brockmeyer

Dr. Nicolas Combé

Dr. Stefan Glombitza

Appropriation of profit or loss

The Executive Board proposes to carry forward the annual net loss to the next fiscal year.



# Schedule of Fixed Assets

## for the fiscal year from Jan. 1 to Dec 31, 2021

In € K		Changes in h	istorical cost of ac	quisition		Changes in accumulated depreciation & amortization Changes in net book val			ue			
	Historical cost of acquisition or production at Dec. 31, 2020	Additions	Rebookings	Historical cost of disposals	Historical cost of acquisition or production at Dec. 31, 2021	Accumulated depreciation & amortization at Dec. 31, 2020	Current-year depreciation & amortization	Depreciation & write-downs on disposals	Accumulated depreciation & amortization at Dec. 31, 2021	Net book value at Dec. 31, 2020	Net book value of disposals	Net book value at Dec. 31, 2021
Intangible assets												
Concessions, commercial property rights, and similar rights and assets, as well as licenses												
for such rights and assets	671	546	- 80	0	1,137	447	100	0	547	223	0	590
Godwill	1,576	0	0	0	1,576	1,300	158	0	1,458	276	0	118
Advance payments	0	1	80	0	81	0	0	0	0	0	0	81
Property, plant and equipment												
Land and buildings, including property-like	· ······											
rights and buildings on third-party land	613	0	0	0	613	461	45	0	506	152	0	107
Technical equipment and machinery	5,780	477	- 60	433	5,764	2,962	471	257	3,176	2,818	175	2,589
Other plant, production equipment and office equipment	1,548	227	0	27	1,748	1,018	170	27	1,161	530	0	587
Advanced payments and construction in	· ······											
progress	0	0	60	0	60	0	0	0	0	0	0	60
Financial assets												
Shares in affiliated companies	50	0	0	0	50	0	0	0	0	50	0	50
Loans to affiliated companies	2,000	0	0	0	2,000	0	0	0	0	2,000	0	2,000
Investment participations	20,673	2,988	0	0		0	0	0	0	20,673	0	23,661
Total	32,912	4,239	0	459	36,691	6,188	943	284	6,848	26,723	175	29,843

# Schedule of Receivables

#### Attachment 2

for the fiscal year from Jan. 1 to Dec 31, 2021		of which due in	of which due
In € K	Dec. 31, 2021	more than 1 year	within 1 year
Trade accounts receivable	3,186	0 (prior year: 0)	3,186 (prior year: 2,002)
Receivables from affiliated companies	7,235	0 (prior year: 0)	7,235 (prior year: 5,878)
Other assets	3,211	0 (prior year: 0)	3,211 (prior year: 130)
Total	13,632	0 (prior year: 0)	13,632 (prior year: 8,010)

Attachment 1

# Schedule of Liabilities

for the fiscal year from Jan. 1 to Dec 31, 2021				
In € K	Dec. 31, 2021	of which due within 1 year	of which du in 1–5 year	
Trade accounts payable	4,211	4,211 (prior year: 2,566)	0 (prior year:	0) 0 (prior year: 0)
Other liabilities	1,230	858 (prior year: 398)	372 (prior year: 53)	5) 0 (prior year: 0)
Total	5,441	5,069 (prior year: 2,964)	372 (prior year: 53	5) 0 (prior year: 0)

# Schedule of Changes in Equity

#### for the fiscal year from Jan. 1 to Dec. 31, 2021

In € K	Subscribed capital	Capital reserves	Profit reserves	Loss carryforward	Annual net income (loss)	Equ
as of Jan. 1, 2021	11,000	76,989	0	- 12,068	-5,733	70,18
Capital increases	65	0	0	0	0	6
Additions to capital reserves	0	1,447	0	0	0	1.44
Appropriation of prior-year profit	0	0	0	-5,733	5,733	
Annual net income (loss)	0	0	0	0	- 13,283	- 13,28
as of Dec. 31, 2021	11,065	78,436	0	- 17,801	- 13,283	58,4 <sup>-</sup>

#### Attachment 3

-	of which pledged as security
0	0
Industry-customary	
372 conditional retention of title	372
372	372

#### Attachment 4

#### To FORMYCON AG

#### Audit opinions

We have examined the annual financial statements of FORMYCON AG (the "Company"), consisting of the balance sheet as of December 31, 2021, and the income statement, schedule of changes in equity and statement of cash flows for the fiscal year from January 1 to December 31, 2021, along with the notes to the financial statements, including the presentation of the accounting policies employed. We have, in addition, examined the unified management report of FORMYCON AG for the fiscal year from January 1 to December 31, 2021.

In our opinion, on the basis of the findings of our audit examination,

- the accompanying financial statements comply, in all material respects, with the requirements of the German Commercial Code (Handelsgesetzbuch, HGB) and provide a true and fair view of the assets, liabilities and financial position of the Company as of December 31, 2021, and of its financial performance for the fiscal year from January 1, to December 31, 2021, in accordance with German principles of proper accounting, and
- the accompanying unified management report as a whole provides an accurate picture of the Company's position, is consistent in all material respects with the financial statements, complies with German legal requirements, and suitably presents the opportunities and risks relating to future development.

Pursuant to sec. 322 para. 3 sentence 1 of the Commercial Code, we declare that our audit examination has not led to any reservations relating to the compliance of the financial statements and unified management report with legal and accounting requirements

#### Basis for our audit opinions

We conducted our audit examination of the annual financial statements and unified management report in accordance with sec. 317 of the Commercial Code and German generally accepted standards for the audit of financial statements promulgated by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer, IDW). Our responsibilities under these legal requirements and standards are further described in the section of this audit report entitled "Responsibility of the auditor in its audit examination of the financial statements and unified management report". We are, in accordance with the requirements of the Commercial Code as well as German laws and regulations governing public accountants, independent of the Company and have fulfilled our other professional duties as German public accountants in accordance with these requirements. We believe that the evidence we have obtained through our audit examination provides a sufficient and suitable basis for our audit opinions regarding the financial statements and unified management report.

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#### Other information

The Company's legal representatives [members of the Executive Board, per sec. 78 of the German Stock Corporation Act] are responsible for other information, including also statements and explanations provided to us prior to the date of this auditor's report pertaining to such other information in sections of the annual report other than the components of the annual financial statements and unified management report specifically audited by us, as well as this auditor's report and certain remaining final portions of this annual report expected to be made available to us after this date. In addition, such other information in the unified management report specifically includes statements on the Company's development projects (status, progress, forecast) and on its staffing policy.

Our audit opinions on the annual financial statements and unified management report do not extend to such other information, nor do we provide any other audit opinion or any other form of audit conclusion in respect thereof.

If, on the basis of the work we have carried out, we come to the conclusion that there has been a material misrepresentation of such other information, we are obliged to report this fact. In the present instance, we have nothing to report.

# Responsibility of the Company's legal representatives and supervisory board for the financial statements and unified management report

The Company's legal representatives are responsible for the preparation of the annual financial statements and for ensuring that these comply, in all material respects, with the Commercial Code and provide a true and fair view of the assets, liabilities, financial position and financial performance of the Company in accordance with German principles of proper accounting. In addition, the legal representatives are responsible for such internal controls as they deem necessary, in accordance with German principles of proper accounting, to facilitate the preparation of financial statements that are free from material misstatement, whether intentional or unintentional.

In preparing the financial statements, the Company's legal representatives are responsible for assessing the Company's continued viability as a going concern, as well as for disclosing, as applicable, any information relevant to the Company's continuance

In connection with our audit, it is our responsibility to read the other information described above and, in doing so, to assess whether the other information

- contains material inconsistencies with the annual financial statements, the management report or our knowledge obtained during the audit, or

appears to contain other materially incorrect representations.

as a going concern. They are, in addition, responsible for maintaining financial accounts on the basis of the going concern principle, unless contrary to law or factual circumstances.

Furthermore, the Company's legal representatives are responsible for the preparation of the unified management report which, as a whole, provides an accurate picture of the Company's position, is consistent in all material respects with the financial statements, complies with German legal requirements, and suitably presents the opportunities and risks relating to future development. The legal representatives are, in addition, responsible for such procedures and precautionary measures (systems) as they deem necessary to facilitate the preparation of the unified management report in accordance with the applicable German legal requirements, and to be able to provide appropriate and sufficient evidence for the assertions in the unified management report.

The Company's supervisory board is responsible for oversight of the accounting processes used by the Company in its preparation of the annual financial statements and unified management report.

# Responsibility of the auditor in its audit examination of the annual financial statements and unified management report

The objective of our audit examination is to obtain reasonable assurance as to whether the annual financial statements as a whole are free from material misstatement, whether intentional or unintentional, and as to whether the unified management report as a whole provides an accurate picture of the Company's position, is consistent in all material respects with the financial statements and the findings of our audit examination, complies with German legal requirements and suitably presents the opportunities and risks relating to future development, then to issue a report of our audit examination including our audit opinions regarding the annual financial statements and unified management report.

"Reasonable assurance" is a high level of assurance but is not a guarantee that an audit conducted in accordance with sec. 317 of the Commercial Code and with German generally accepted standards for the audit of financial statements promulgated by the Institute of Public Auditors in Germany (IDW) will always detect a material misstatement. Misstatements may arise through error or through intentional act and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the business decisions of users of this information taken on the basis of these financial statements and unified management report.

critical stance. Furthermore, we:

- override of internal controls.
- ness of these systems.
- related disclosures.
- principles of proper accounting.

During our audit examination, we exercise due professional discretion and maintain a

 identify and assess the risks of material misstatement, whether intentional or unintentional, in the annual financial statements and unified management report, plan and perform audit procedures responsive to such risks, and obtain audit evidence that is sufficient and appropriate to form a basis for our audit opinions. The risk of not detecting a material misstatement resulting from intentional act is higher than for one resulting from error, as intentional acts may involve fraudulent collusion, forgery of documents, intentional omissions, misrepresentations or the

 gain an understanding of the internal control systems relevant to our audit examination of the financial statements, and of the Company's procedures and precautionary measures relevant to our audit examination of the unified management report, so that we are able to design audit methods appropriate to the circumstances, but not for the purpose of expressing an audit opinion on the effective-

 assess the appropriateness of the accounting policies employed by the Company's legal representatives and the reasonableness of their accounting estimates and

- draw conclusions as to the suitability of the accounting policies employed by the legal representatives on the basis of the going concern principle and, on the basis of the audit evidence obtained, whether material uncertainty exists relating to events or circumstances which raise significant doubts regarding the Company's ability to continue as a going concern. If we conclude that such material uncertainty exists, we are required to draw attention in our audit report to the related disclosures in the annual financial statements and unified management report or, if these disclosures are inadequate, to modify our audit opinions accordingly. We draw our conclusions upon the basis of the audit evidence obtained up to the date of our audit opinion. Subsequent events or circumstances could, however, cause the Company to cease being able to continue as a going concern.

 assess the overall presentation, structure and content of the annual financial statements, including related disclosures, and determine whether the financial statements present the underlying transactions and events in such a way that the financial statements provide a true and fair view of the assets, liabilities, financial position and financial performance of the Company in accordance with German

- assess the consistency of the unified management report with the annual financial statements, its conformity with German law, and the picture it conveys of the Company's position.
- conduct audit examinations of forward-looking statements made by the Company's legal representatives in the unified management report. On the basis of sufficient and suitable audit evidence, we validate, in particular, the significant assumptions used by the Company's legal representatives as a basis for forward-looking statements and determine whether these assumptions provide a reasonable basis for the forward-looking statements. We do not express any audit opinion specific to such forward-looking statements or to the underlying assumptions. There is a substantial and unavoidable risk that actual future circumstances may differ substantially from such forward-looking statements.

In our discussions with those responsible for the supervision of the Company, we determine the planned scope and timeframe of the audit examination. We then report significant audit findings, specifically including any deficiencies in internal control systems identified during our audit examination.

Munich, April 14, 2022

# PanTaxAudit GmbH

Wirtschaftsprüfungsgesellschaft

Dr. Rudolf Schmitz Wirtschaftsprüfer [German Public Accountant]

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1/1. Shirt

Kevin Lucien Schneider Wirtschaftsprüfer [German Public Accountant]

# Legal information

#### FORMYCON AG Company name: Legal form: German stock corporation (Aktiengesellschaft) **Registered location:** Martinsried/Planegg, Germany Street address: Fraunhoferstraße 15, 82152 Martinsried/Planegg, Germany The Company was established through its articles of Company founding and articles of incorporation: incorporation (Satzung) dated 5 May 2010, which were most recently amended on December 1, 2021. Subject of business: 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. Commercial register: The Company is entered into the commercial register (Handelsregister) of the District Court of Munich under number HRB 200801. Fiscal year: The Company's fiscal year runs from January 1 to December 31 of each year. **Registered capital:** 11,064,750 € Executive Board (Vorstand): Dr. Carsten Brockmeyer Dr. Nicolas Combé Dr. Stefan Glombitza Supervisory Board (Aufsichtsrat): Dr. Olaf Stiller, residing in Marburg, Chairman Peter Wendeln, residing in Oldenburg, Deputy Chairman Klaus Röhrig, residing in Vienna (Austria), Member

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