

Half-Year Report 2020



# **To Our Shareholders**

"We also use our experience with therapeutic antibody-based pharmaceuticals for the development of a COVID-19 drug."

Dr. Carsten Brockmeyer

Dr. Carsten Broc

## Dear shareholders,

the world is holding its breath as the global SARS-CoV-2 pandemic continues unabated, and with the relentlessly increasing number of infections, the current situation remains fragile. In a crisis situation like this, what matters most is having strong and capable healthcare systems.

FORMYCON is playing an important role in the development of high quality and affordable biopharmaceutical drugs, with the aim of making a contribution to the cost-effective supply of important medications to patients around the world. Our company employs a staff of committed scientists with unique expertise at the cutting edge of medical research. Beyond our own team of scientific experts, we also rely upon our extensive network within both academia and industry. For all of these reasons, we as a company made the decision earlier this year to help respond to the current pandemic by applying our experience with therapeutic antibody-based pharmaceuticals to the development of a drug for the treatment of COVID-19, alongside and in addition to our ongoing biosimilar projects. For us as a German company, our decision is also founded upon the premise that our country, as one of the great scientific leaders, should not rely solely upon other countries like the USA and China - which are funding the efforts of their own biotech companies to develop COVID-19 drugs - to ensure that Germany has the necessary quantities of life-saving drugs to provide for its own population. Throughout the current ongoing situation, we will also not lose sight of our company's already established mission, which is to develop biosimilar drugs for the treatment of serious diseases, thereby providing patients with better access to vital medications.

During the first half of 2020, we made further significant strides forward with the development of our biosimilar candidates. Of particular significance to our company's future prospects was a major step forward with our FYB203 project (candidate biosimilar to Eylea®1): The preparatory work for the start of phase III clinical trials was completed according to plan, so that we and our development partners were able to announce the commencement in August 2020 of our global clinical trials (MAGELLAN-AMD). We see our attainment of this critical milestone in our second project specifically within the field of ophthalmology as confirmation of our company's leading position in the development of ophthalmic biosimilars. Also due to the extensive experience gained from our FYB201 project, we are highly confident that we will, with FYB203, succeed in developing and making available to our partners a cost-effective biosimilar product of the highest quality. In the case of FYB202, our candidate biosimilar to Stelara®2being developed in a joint venture with Aristo Pharma GmbH, our advances during the first half of 2020 included the successful recruitment of test subjects for phase I clinical trials, for which Bioeg GmbH is responsible as sponsor, as well as the concurrent preparatory work for phase III clinical trials, which will commence shortly. Last but not least, there is FYB201, the furthest advanced development project in our product pipeline and a candidate biosimilar to blockbuster ophthalmic drug Lucentis®3 (Ranibizumab). Upon the submission by our license partner Bioeq AG of our approval application to the U.S. Food and Drug Administration, the FDA, following its preliminary review, requested additional data for the following reason: Pursuant to an order from the national health authority of a European country, the contract manufacturing organization (CMO) responsible for the manufacture of the FY201 active ingredient had moved part of the process equipment specifically used for its manufacture to another area within the company site after the batches for FYB201 process qualification had already been produced. The official order for this relocation was unrelated to the production of the FYB201 active ingredient. We are confident that FYB201 will be successfully approved and that we will, together with our partners, be able to subsequently bring to market a cost-effective product of excellent quality.

As to our FYB206 pipeline project, no details have yet been announced. This fourth biosimilar candidate is currently in the preclinical phase, with relevant intellectual property (IP) rights already established. FORMYCON has, over the past years, been one of the true pioneers in biosimilar drug development, and we are thus highly optimistic that we have, in our selection of further drug development candidates beyond these, made the right decisions.

Against the backdrop of the corona pandemic, we promptly took extensive measures to protect our staff from infection to the maximum possible extent and to maintain continued operations. At a very early stage, and even before the COVID-19 crisis fully reached Germany, we took proactive measures by decentralizing our organization.



# " With our development programs we create sustainable values."

Dr. Nicolas Combé CFO



By responding with maximum flexibility, and by adjusting working hours and models around the needs of staff, we have been able to meet the requirements of the extraordinary situation while ensuring operational continuity. As to the closely related subject of workplace digitalization, we have put numerous immediate measures into place and initiated other more far-reaching projects in order to be prepared not only for present but also potential future circumstances, as well as to further develop the organization's broader digital capabilities to adapt to changing needs. Needless to say, our entire workforce has also been equipped with vital equipment such as protective masks and disinfectant. We would like to take this opportunity to thank the entire FORMYCON team for their excellent cooperation throughout this ongoing public health crisis.

and outlook.

Stay healthy.

FORMYCON Management September 2020

Finally, we would like to thank our partners for their partnership in the truest sense of the word and our shareholders for their continued confidence in our achievements

<sup>&</sup>lt;sup>1</sup> Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.

<sup>&</sup>lt;sup>2</sup> Stelara<sup>®</sup> is a registered trademark of Johnson & Johnson

<sup>&</sup>lt;sup>3</sup> Lucentis<sup>®</sup> is a registered trademark of Genentech Inc.



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#### Basic Information About the Group and FORMYCON AG

**Business model** 

FORMYCON develops biosimilars, meaning follow-on products to biopharmaceuticals already on the market. The Company seeks to license out its biosimilar candidates to cooperation partners once certain defined development milestones have been attained and to further develop these through to regulatory approval together with the respective partner company. In doing so, FORMYCON 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. Through these in-house capabilities, FORMYCON is also in a position, following such an out-licensing deal or partnership arrangement, to undertake the remaining development work. The partner company generally assumes responsibility for subsequent production and product marketing. In addition, FORMYCON is drawing upon its extensive expertise in biopharmaceutical development to pursue new and innovative antibody-based treatments for COVID-19.

As of June 30, 2020, FORMYCON was working on the following biosimilar projects:

- 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. Phase III clinical trials were successfully completed in June 2018. During the first half of 2020, a particular focus of activity was responding to the request of the U.S. Food and Drug Administration (FDA) that additional data be collected in the drug's relocated production environment. The additionally generated data will likewise be incorporated as we prepare drug approval documents for the European Medicines Agency (EMA).
- FYB202 is a biosimilar candidate for Stelara<sup>®\*\*</sup> (ustekinumab), a biopharmaceutical used in the treatment of various serious inflammatory diseases, such as moderate to severe psoriasis, Crohn's disease, and ulcerative colitis. The start of phase I clinical trials for FYB202 was announced in October 2019. Preparations for the launch of phase III clinical trials, anticipated in the third guarter of 2020, are proceeding according to plan.
- 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. Through the completion of preclinical studies in mid-2019, it was successfully demonstrated that FYB203, in its alternative formulation, exhibits comparable pharmacokinetics to Eylea®, the reference drug. Activities during the first half of 2020 have particularly centered around preparatory work for the planned phase III clinical trials, which has been started in August 2020.

Drawing upon the Company's extensive experience in biopharmaceuticals development, FORMYCON has also launched efforts to develop new and innovative antibody-based drugs for the treatment of COVID-19:

the drug suitable for prophylactic use.

The corporate structure of FORMYCON Group corresponds to this 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 generates reported sales revenue, since FORMYCON continues to provide development work for the biosimilar candidates which is paid for by the licensing partners even after the projects have been licensed out. 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 the Polpharma SA, Poland's largest pharmaceutical company, and Santo Holding (Deutschland) GmbH, a holding company owned by the Strüngmann family.

- FYB20X: FORMYCON is actively working on other pipeline projects, which include further biosimilar drug candidates currently under evaluation. For example, development work on FORMYCON's biosimilar candidate FYB206 is currently in the preclinical phase, with relevant intellectual property (IP) rights already in place. The rights to these projects remain with FORMYCON.

- Under the new FYB207 project, FORMYCON is developing antibody-based COV-ID-19 agents based upon the Company's clinically validated technology platform for antibody-based protein drugs. The development process is using computer-aided structural protein design in conjunction with a series of physiochemical, functional and biological tests to screen antibody-based active substances which are able to block the SARS-CoV-2 virus. FORMYCON is using sophisticated computer modeling to efficiently develop these antibody-based COVID-19 agents with the specific desired functional action, and thereby attaining the required efficacy and safety. Large molecules have certain important advantages over small molecule antiviral drugs, such as significantly longer half-life, which might also make

<sup>\*</sup> Lucentis® is a registered trademark of Genentech Inc.

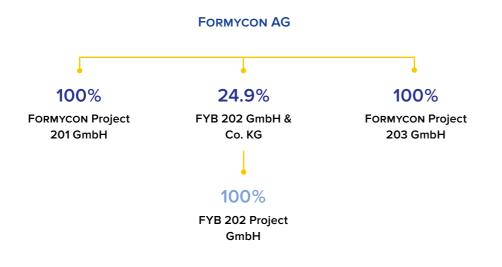
<sup>\*</sup> Stelara® is a registered trademark of Johnson & Johnson \*\*\* Evlea® is a registered trademark of Regeneron Pharmaceuticals Inc.

#### **Report on Business Performance** Ш

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 the 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.

#### The structure of FORMYCON Group may thus be summarized as follows:



The current focus of FORMYCON Group is on research and development activities for its own biosimilar projects, as well as in the development of novel antibody-based COVID-19 treatments. 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 product candidates is the global pharmaceutical market. Healthcare policy and regulation should therefore be recognized as an important external influence factor.

# General economic conditions

During the first half of 2020, the escalation of the coronavirus pandemic abruptly pushed the German economy into a sharp recession. The slump in economic output starting from the middle of March was already so severe in its first weeks that German GDP for the first guarter as a whole fell by 2.2% compared to the same guarter in the prior year. Under the rapidly passed German federal emergency law to contain the spread of the virus (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite), a strict national lockdown was imposed starting from the end of March, suspending many service-based businesses and significantly constraining retail consumption channels. The resulting collapse in domestic and foreign demand and interruptions to supply chains, as well as the precipitous drop in exports and capital equipment orders, acted as additional multipliers. The recession in Germany reached its bottom with the collective halt of production throughout the entire German automotive industry, even as construction investment and government consumption were beginning to expand. Although a weak and barely perceptible economic recovery was set in motion by the gradual easing of lockdown restrictions starting from the beginning of May, a high degree of uncertainty continued to prevail, along with the recognition that, given the ongoing world coronavirus pandemic, any return to normal would be a long time coming. At the same time, it became increasingly clear that economic output in the second guarter would once again fall well below that of the first guarter and that this would have far-reaching effects on employment. While Germany's actions to ease the legal conditions for special government subsidies to avoid outright layoffs (Kurzarbeit) made it possible to avoid even more extensive job losses, the number of people with jobs nonetheless fell sharply, and the unemployment rate increased. Starting from May, the gradual easing of coronavirus-related restrictions heralded economic recovery, which was initially quite significant on a month-to-month basis because of the drastic production cuts and even production shutdowns in April.<sup>1</sup> The economic indicators were at this point sending two essentially positive signals: firstly, that the catch-up process within the German economy had begun, even as production capacity was still heavily underutilized, and secondly, that the relaxation of the infection control measures was causing both demand and supply to rise again. As a result, German industry reported a production increase of 10.3 percent for May compared to the previous month, with particularly striking recovery of the production index within Germany's vitally important automotive and auto parts sector, with further increases in June compared to May in both new vehicle registrations (+18 percent) and production (+84 percent). The current outlook suggests further improvement. The ifo Institute's business climate index, considered the country's most important economic barometer, the purchasing managers' index (PMI) and new orders are all pointing to a continued upward trend. Recovery can also be seen in much of the retail trade and service sectors. For this economic recovery trend to continue, overall demand for German goods will be decisive; although (nominal) goods exports rose sharply by 11.6 percent in May, exports to important trading partners that have been particularly hard hit by the epidemic (such as the United States and the United Kingdom) have been notably softer than exports to, for example, China. The situation is similar with industrial orders from abroad; while orders from other Eurozone countries have been showing improvement, the recovery

<sup>1</sup> cf. German Federal Ministry for Economic Affairs, "The economic situation in Germany in May 2020", https://www.bmwi.de/ Redaktion/EN/Pressemitteilungen/Wirtschaftliche-Lage/2020/20200515-the-economic-situation-in-germany-in-may-2020.html

in orders from outside the Eurozone has so far been weak, underscoring the continued risks to the German economy and its outlook for recovery.<sup>2</sup> Whatever the immediate economic impact, the epidemiological risks persist, and both society and businesses will continue to have to adapt their behaviors according to the prevailing risk situation.

## Developments in the global biosimilars market

For the past several years, the global biosimilars market has been growing rapidly. Worldwide sales totaled USD 12.3 billion in 2019, a 67-percent increase over the prior year. With a market share of 59 percent, the European sector continues to play a major and leading role in the development of biosimilars, which has from the beginning been largely driven by the fact that biosimilars have been available in the European market for more than ten years.<sup>3</sup> Already in 2005, the EU established a legal framework for the regulatory approval of biosimilar drugs, placing the European Medicines Agency (EMA) at the global forefront in pioneering a new approval process for biosimilars. In 2006, the first biosimilar was approved in Europe: Omnitrope<sup>®4</sup>, a biosimilar to the reference drug somatropin, a growth hormone.<sup>5</sup> Since then, 11 more biosimilars to 11 other reference drugs have established themselves in the European market and have since been playing a vital role in the treatment of autoimmune diseases of varying degrees of severity, cancer and diabetes. The U.S. Affordable Care Act ("Obamacare") passed by Congress in 2010 also included a regulatory approval route for biosimilars, and the first biosimilar was subsequently approved in the United States.

Two years later, market access for biosimilars was accelerated by a change in law, and in July 2018 the establishment of the American biosimilars market was given a further boost by the publication by the U.S. Food and Drug Administration (FDA) of its Biosimilars Action Plan (BAP). U.S. sales of biosimilars almost doubled in the following year, compared to the same 12-month period in 2018, with the U.S. share of the world's biosimilar market rising last year to 36 percent (see Figure 1).

As a result of this rapid market development, biosimilars have become a key element in the more cost-effective use of biopharmaceutical-based treatments, benefiting not only patients but also the healthcare systems of entire countries shifting to less expensive biosimilars. Germany, with an 11-percent share of the world's biosimilar market and total sales of approximately  $\in$  1.5 billion, holds second place among the world's largest markets for biosimilar drugs; first place is now held by the United States.<sup>6</sup> This overall market growth has been particularly influenced by the approvals of biosimilars to infliximab, rituximab, trastuzumab and adalimumab antibodies. The German biosimilars market exceeded the billion-euro mark for the first time in 2019, with an increase

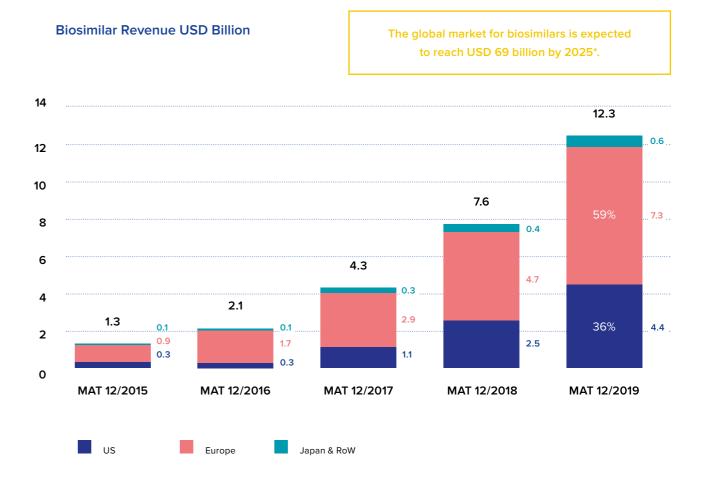


Figure 1: Based on IQVIA European Thought Leadership, IQVIA" MIDAS® 12/2019; Global Growth / Year in LCUS\$ (Local Currency US\$) without taking exchange rate fluctuations into account, https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/fokus-biosmilars/newsletter-fokus-biosmilars-07.pdf?la=de-de&hash=47556A108E4F783339E883AF85A BB969& =1595406121172

\* Biosimilars Market Analysis – Global Share Outlook Report 2019 – 2025, Global Market Insights: GMI3328

of 63 percent over the prior year (see Figure 2).<sup>7</sup>

The AOK Research Institute (Wissenschaftliches Institut der AOK ), under the aegis of Germany's largest statutory health insurer, states in its Statutory Health Insurer Pharmaceutical Market Report 2020 that, by purchasing cheaper biosimilars instead of reference drugs, savings of  $\in$  460 million were realized during 2019 – and of this total amount, € 205 million was saved just by substituting blockbuster drug Humira® with the now available adalimumab biosimilar. In fact, if biosimilars had been systematically preferred over more expensive reference drugs for all such prescriptions in Germany during 2019, the total savings to the health care system would have been approx.  $\in$  792 million. This illustrates the vast sums of money which health insurers can save

<sup>&</sup>lt;sup>2</sup> cf. German Federal Ministry for Economic Affairs, "The economic situation in Germany in July 2020", https://www.bmwi.de/ Redaktion/EN/Pressemitteilungen/Wirtschaftliche-Lage/2020/20200713-the-economic-situation-in-germany-in-july-2020.html

<sup>&</sup>lt;sup>3</sup> cf. IQVIA, "Fokus Biosimilars Mai 2020" (German only), https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/fokusbiosmilars/newsletter-fokus-biosimilars-07.pdf?la=de-de&hash=47556A108E4F783339E883AF85ABB969&\_=1595406121171 Omnitrope® is a registered trademark of Sandoz GmbH

<sup>&</sup>lt;sup>5</sup> cf. Pro Generika e.V. / Arbeitsgemeinschaft Pro Biosimilars: Handbuch Biosimilars 2019: https://probiosimilars.de/img\_ upload/2019/10/Handbuch-Biosimilars\_Oktober-2019-1.pdf?ddl=1

<sup>&</sup>lt;sup>6</sup> cf. IQVIA, "Fokus Biosimilars Mai 2020" (German only), https://www.iqvia.com/-/media/iqvia/pdfs/germany/publications/fokusbiosmilars/newsletter-fokus-biosimilars-07.pdf?la=de-de&hash=47556A108E4F783339E883AF85ABB969&\_=1595406121171

<sup>7</sup> cf. Boston Consulting Group & German Association of Research-Based Pharmaceutical Companies (vfa), "Medizinische Biotechnologie in Deutschland 2020" (German only), http://www.yfa-bio.de/download/bcg-yfa-bio-biotech-report-2020.pdf



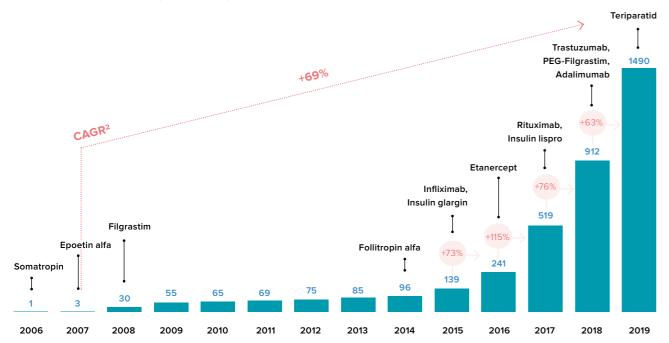


Figure 2: IMS AMV®: Overall market consisting of clinical market (sales in EUR at assessed clinic prices) plus pharmacy market (sales in EUR at the producer's listed selling price without consideration of discounts or savings from discount agreements); data excludes low-molecular-weight heparins, CAGR = compound (average) annual growth rate Source: IQVIA Commercial GmbH & Co. OHG; BCG analysis

> through biosimilar drugs, the potential of which is, at present, far from exhausted.<sup>8</sup> The future outlook is even more promising as patent protection for more and more biologics expires over the coming years, meaning that more and more biosimilars may be expected to enter the market. According to the Generics and Biosimilar Initiative Journal, European Union patent protection for 23 proprietary biopharmaceuticals is set to expire over the next five years.

**Business development** during the period

Business performance during the first six months of 2020 was satisfactory, for both FORMYCON Group and FORMYCON AG. The Group ended the period with a consolidated net loss of € 1,382K on consolidated half-year revenue of € 16,510K. For the parent company only, the period net loss was € 1,328K on revenue of € 11,968K. Neither FOR-MYCON AG nor FORMYCON Group has any financial debt.

## During the first half of 2020, FORMYCON was able to achieve the following corpo-

- In February 2020, FORMYCON and its license partner Bioeq AG announced that the U.S. Food and Drug Administration (FDA) had requested additional data for FYB201, the candidate biosimilar to Lucentis®, as part of the FDA's review of the biologics license application (BLA) submitted by Bioeq in December 2019. Pursuant to an order from the national health authority of a European country, the contract manufacturer responsible for production of the FY201 active ingredient had moved part of the process equipment specifically used for its manufacture to another area within the company site after the batches for FYB201 process qualification had already been produced. The FDA thus requested, under its review procedure, additional data in the new production environment following the move. FORMYCON and Bioeq estimate that it will take approximately four months to collect this data. In view of the situation, Bioeg decided to withdraw the initial approval application for the Lucentis® biosimilar candidate and to resubmit the BLA after incorporating the additional data, which could lead to a corresponding delay in regulatory approval. It should be underscored that these procedural delays are not related to any guality deficiencies of the active ingredient or other drug characteristics.

 In April, FORMYCON announced the launch of accelerated development efforts for new and innovative antibody-based treatments for COVID-19 using FORMYCON's clinically validated technology platforms for antibody-based protein drugs. For the development of these potential COVID-19 biologics, FORMYCON is using sophisticated computer-aided structural protein design as well as a series of physiochemical, functional and biological tests to efficiently screen for antibody-based active substances which can block the SARS-CoV-2 virus. In addition to its decades of combined organizational experience in protein chemistry, analytics and immunology, FORMYCON also has many years of experience with the successful transfer of antibodies and antibody-based therapies into clinical development and testing. FORMYCON expects to have the results of its preclinical development work in the fourth quarter of 2020. Depending on the outcome of the preclinical phase, clinical trials could be initiated as soon as the third guarter of 2021.

- In view of the ongoing coronavirus pandemic, and in the interests of protecting shareholders, FORMYCON staff and all others involved with the event, FORMYCON announced in May that the Annual General Meeting originally planned for June 30, 2020 would be postponed to December 10, 2020. FORMYCON's decision was in line with the decree imposed by the German federal government in mid-April 2020 banning all major public events through August 31, 2020, and in accordance with the law passed by the German legislature to mitigate the consequences of the COVID-19 pandemic, which allows annual general meetings to be held beyond the usual eight-month period (per section 175 para. 1 sentence 2 of the German Stock

Vol. Wissenschaftliches Institut der AOK (WidQ): Der GKV-Arzneimittelmarkt – Bericht 2020: https://www.wido.de/fileadmin/ Dateien/Dokumente/Forschung Projekte/Arzneimittel/wido arz gky-arzneimittelmarkt 2020.pdf

Corporation Act, Aktiengesetz). Through this action, FORMYCON hopes to provide its shareholders with the opportunity to fully participate in a face-to-face event, provided that the prevailing coronavirus situation in December allows such an event.

- During the month of May, FORMYCON also issued an update on its biosimilar development projects, noting that through prompt and proactive measures including organizational decentralization, the effects of the pandemic on the Company's operational development activities had so far been minimal. Together with license partner Bioeg AG and the relevant contract manufacturer, FORMYCON is working intensively on the revised approval documents for FYB201, the candidate biosimilar to Lucentis® (ranibizumab). It was further announced that phase I clinical trials for FYB202, the candidate biosimilar to Stelara® (ustekinumab), which have been underway since October 2019, are well advanced and that preparations for phase III clinical trials, expected to begin in the third quarter of 2020, are proceeding as planned. As to the launch of phase III clinical trials for FYB203, FORMYCON's candidate biosimilar to Eylea® (aflibercept), the preparatory work is likewise proceeding according to plan, and thus phase III clinical trials should likewise be in a position to begin in mid-2020. It was also noted that the worldwide marketing rights for FYB203 have now been internally shifted within the Santo Group from Santo Holding (Deutschland) GmbH to another Santo entity, Klinge Biopharma GmbH. FORMYCON continues to build and expand its biosimilar project pipeline. As to other announced biosimilar candidates, FYB206 is currently in the preclinical phase, with relevant intellectual property (IP) rights already established. Finally, the May announcement stated that no details had yet been publicly announced as to further pipeline candidates (FYB20x).
- Also in May, FORMYCON released its financial results for fiscal year 2019. For the year ending December 31, 2019, total consolidated sales revenue was € 33.2 million. With EBITDA of -€1.2 million and an annual net loss of €2.3 million, the fullyear figures were in line with expectations. FORMYCON Group closed the year with cash and liquid resources of € 22.4 million and an equity ratio in excess of 90 percent, which is well above average.
- Following closely thereafter in June, FORMYCON announced its results for the first guarter of 2020, pointing to a strong start for the new fiscal year. Thanks to its rapid reaction and aggressive implementation of appropriate measures to protect staff amid the COVID-19 pandemic, FORMYCON announced that had so far been able to adapt well to the prevailing situation, so that the Company's operational development activities were continuing in line with plan. For the quarter ending March 31, 2020, consolidated revenue (including other income) was € 7.2 million, with EBITDA of  $\in$  0.4 million and first-quarter net income of  $\in$  0.2 million. For the year as a whole, FORMYCON Group anticipates consolidated revenue in the range of € 35 to 40 million.

FORMYCON continues to strategically position itself as a leading and independent developer of biosimilar drugs. As a pioneer in the creation and engineering of these follow-on biopharmaceuticals, particularly within the rapidly growing therapeutic areas such as ophthalmology and inflammatory skin and intestinal diseases, the Company is now focused on achieving regulatory approval in the highly regulated markets of the European Union, the United States, Japan, Canada and Australia and on positioning itself as a potential partner for major pharmaceutical corporations and generic drug producers. In this way, FORMY-CON is making a significant contribution to providing patients throughout the world with access to vital and affordable biopharmaceuticals, to providing urgently needed cost savings to healthcare systems, and thus to making highly effective healthcare more sustainable.

# Shares and the capital

markets

Shares of FORMYCON AG began 2020 within a narrow trading range between € 30.10 and € 32.50 before dropping significantly upon the Company's ad hoc announcement on February 4, 2020 regarding the FYB201 approval process. As part of a preliminary review of the biologics license application (BLA) submitted by Bioeq in December 2019 for FYB201, the candidate biosimilar to Lucentis®, the U.S. Food and Drug Administration (FDA) requested additional data. The stock price reacted signifi-

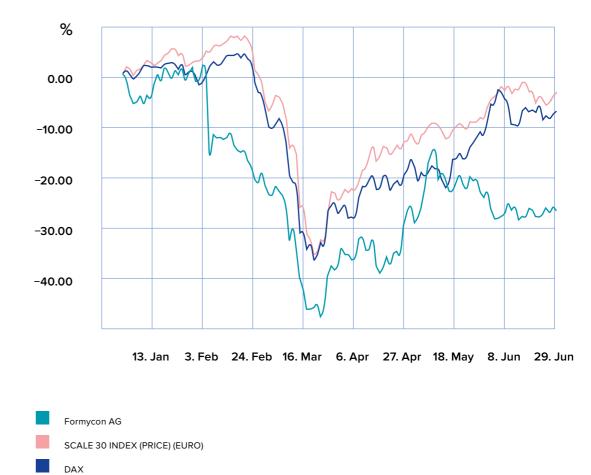


Figure 3: https://www.onvista.de/aktien/chart/FORMYCON-AG-Aktie-DE000A1EWVY8?notation=41353628&activeType=line&activeTab=T5&displayVolume=true&min=159488076600 0&max=1595514602000&zoom=false&scaling=linear&assetName=EORMYCON%20AG&isPopup=false

#### General stock market conditions and performance of FORMYCON shares

cantly, recording a drop of some 24 percent for the month of February. Moreover, with the emergence of the coronavirus pandemic and the associated financial uncertainties which broadly dragged down world markets, shares of FORMYCON were further negatively impacted by the general panic-like investor behavior during the month of March, suffering a further drop of an additional 18 percent.

On March 20, the day upon which Germany's first hard lockdown restrictions were announced in the state of Bavaria, FORMYCON shares reached a low with a XETRA day closing price of € 16.90.<sup>9</sup> During the first half of 2020, the total number of FORMYCON shares traded across all trading venues was 1,764,467, almost 67% more than during the comparable prior-year period (1,058,396 shares), and corresponding to a daily average trading volume of 14,116 shares (prior year: 8,536 shares). Of this total, approx. 63% of the shares were traded on the Xetra trading system, 7% on the Frankfurt Stock Exchange, and 30% on other stock exchanges.

Up until this point, no event had ever before impacted the equity markets with quite such speed as the coronavirus pandemic. Within a span of just 28 days, the DAX German stock market index lost a full 40 percentage points, marking this plunge as the most rapid and abrupt stock market crash in Germany's history to the present date. The market crash of 1987 was of a similar order of magnitude but took more than three times as long: Only after 102 days had the DAX dropped by more than 37 percent, finally reaching its low-water mark of minus 44.5 percent only after 207 days.<sup>10</sup> Even as it became increasingly clear that the coronavirus crisis would drag on longer than initially believed, despite the lockdown measures, the sky cleared again within the financial markets, and by the end of April the German benchmark index had regained some 30 percentage points. The presumed reasons for this market recovery were the billions in economic support pumped in by central banks and governments around the globe, news updates about the receding tide of the pandemic, and the gradual lifting of lockdown restrictions. Recovery from the economic damage is, however, expected to take considerable time, and thus market experts continue to expect significant volatility in the equity markets.<sup>11</sup>

#### **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 Sponsors	Wolfgang Steubing AG / mwb faitrade Wertpapierhandelsbank AG

#### In €

Opening price on Jan. 2, 2020 Closing price on June 30, 2020 Six-month average price (XETR

#### Stück

Total shares traded (on all tradin Daily average shares traded (or Total shares issued as of June

#### Shareholder structure

If certain voting rights thresholds are exceeded, the relevant shareholders are reguired, under German law, to file a notification thereof with the respective issuing company as well as with the German Federal Financial Services 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.<sup>13</sup> 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 June 30, 2020, 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 June 30, 2020, Peter Wendeln, anchor shareholder and long-time FORMYCON supervisory board member, held a total of 23.91% 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.

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#### FORMYCON shares: Performance information<sup>12</sup>

	1H 2020	1H 2019
/ Jan. 2, 2019 (XETRA)	31.60	26.25
0 / June 28, 2019 (XETRA)	23.10	31.70
RA closing prices)	24.87	30.81
ing venues)	1,764,467	1,058,396
n all trading venues)	14,116	8,536
30	10,000,000	10,000,000

<sup>9</sup> cf. Frankfurter Allgemeine Zeitung (FAZ), "Wer ist schuld am Börsencrash" (German only), https://www.faz.net/aktuell/finanzen/ meine-finanzen/krise-erfasst-deutsche-boerse-dax-auf-niedrigstand-14068614.html

<sup>&</sup>lt;sup>10</sup> cf. Spiegel, "Der schnellste Börsencrash der Geschichte" (German only), https://www.spiegel.de/wirtschaft/unternehmen/coronakrise-der-schnellste-boersencrash-aller-zeiten-a-2b6cde01-966d-4aa4-b7b9-90f2c4886415

<sup>&</sup>lt;sup>1</sup> cf. ZDF, "Sind die Börsen über den Berg" (German only), https://www.zdf.de/nachrichten/wirtschaft/coronavirus-geld-anlegenboerse-100.html

<sup>&</sup>lt;sup>12</sup> cf. Onvista, https://www.onvista.de/onvista/times+sales/popup/historische-kurse/?notationId=41353628&dateStart=01.01.2019&i nterval=Y3&assetName=FORMYCON AG&exchange=Xetra

<sup>&</sup>lt;sup>13</sup> cf. German Federal Financial Supervisory Authority (BaFin), "General principles for filing notifications under sections 33, 38 and 39 of the WbHG". https://www.bafin.de/EN/Aufsicht/BoersenMaerkte/Emittentenleitfaden/Modul2/Kapitel1\_2/Kapitel1\_2/Kapitel1\_2\_2/ kapitel1\_2\_2\_node\_en.html;jsessionid=5F92791D547EE0101FDA99B0D2C1DDDC.1\_cid393

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

During the first half of 2020, no members of the Executive Board or Supervisory Board conducted any securities transactions subject to reporting requirements under article 19 of the Market Abuse Regulation (MAR).

#### Scale (Open Market) market segment

The Company's shares have, since March 1, 2017, been listed in the Frankfurt Stock Exchange's "Scale" segment for small- to medium-sized companies. The initial listing requirements and ongoing obligations of this Open Market (unofficial regulated) seqment 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 quarterly adjusted market capitalization. The Scale 30 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. The Scale 30 Index serves as a complement to Deutsche Börse's "Scale All Share Index", which tracks the entirety of stocks in the Scale segment.

Finally, 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

FORMYCON AG has registered capital (*Grundkapital*) of  $\in$  10,000,000, which is divided into 10,000,000 bearer shares without par value but with an imputed nominal value of  $\in$  1.00 per share.

#### Annual General Meeting

In May of this year, the Executive and Supervisory Boards of FORMYCON AG resolved to postpone the Annual General Meeting, originally planned for June 30, 2020, until December 10, 2020. This decision was made under careful consideration of the ongoing coronavirus pandemic and with the aim of protecting shareholders, FORMYCON staff and the various service providers involved in this large event. Through this action, FORMYCON is acting in line with the decree imposed by the German federal government in mid-April 2020 banning all major public events through August 31, 2020, and in accordance with the law passed by the German legislature to mitigate the consequences of the COVID-19 pandemic, which allows annual general meetings to be held beyond the usual eight-month period (per section 175 para. 1 sentence 2 of the German Stock Corporation Act, Aktiengesetz). Through this postponement of the Annual General Meeting to the end of the year, FORMYCON hopes to provide its shareholders with the opportunity to fully participate in a face-to-face event in Munich, provided that the prevailing coronavirus situation allows such an event at that time. The formal announcement to convene the Annual General Meeting on the new date will be made in accordance with the usual statutory requirements.

#### Investor relations

Professional dialogue with investors and with the international capital markets forms an important component of FORMYCON's corporate strategy. As a result of the ongoing coronavirus pandemic, a number of planned conferences and events have been cancelled over recent months, while others have been held in virtual form. During the first half of 2020, FORMYCON's senior management presented the Company at selected investor conferences, such as the Kepler Life Science Day. Through such conferences as well as other outreach activities, the Company has strived to maintain active contact with existing and potential investors and to increase its visibility on the capital markets. As of June 30, 2020, five analysts were regularly providing equity research coverage on FORMYCON AG

The following analysts pu of 2020:

## Equity research provider

B. Metzler seel. Sohn & Co. KGa Edison Investment Research Lin First Berlin Equity Research Gm Kepler Cheuvreux SRH AlsterResearch AG

The following analysts published research studies on FORMYCON during the first half

	Analyst
aA	Tom Diedrich
mited	Dr. John Savin
nbH	Simon Scholes
	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 (formycon.com/en/investor-relations/ shares/). FORMYCON believes in open dialogue with its investors and with the capital markets, as an integral part of its corporate philosophy. In this spirit, the Investor Relations department of FORMYCON AG stands ready to respond to any questions or suggestions:

# FORMYCON AG Contact Person Sabrina Müller Corporate Communications & Investor Relations Street Address Fraunhoferstr. 15, 82152 Martinsried/Planegg, Germany Phone +49 89 864 667 149 Email ir@formycon.com Web https://www.formycon.com/en/investor-relations/shares/

# Staffing and organizational structure

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. 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.

As of June 30, 2020, FORMYCON had a total of 119 employees (June 30, 2019: 103). The average staffing during the six-month current-year and prior-year periods is shown below, divided by functional area, and expressed in terms of full-time equivalents (FTEs) to more meaningfully reflect part-time staff:

Average staffing during the period by function

(in FTE, rounded, excluding Executive Board members)

	1H 2020	1H 2019	Change
Research & development	86	76	13 %
General & administrative	12	10	20 %
Total	98	86	14 %

The analytics area was, in particular, strengthened over the period in order to have the resources in place needed for the extensive work efforts entailed in the Company's existing and new biosimilar projects. The Company's regulatory affairs department was also further expanded in order to have sufficient expertise and capacity to produce regulatory approval documents of the highest quality standards and to interface with regulatory approval authorities internationally.

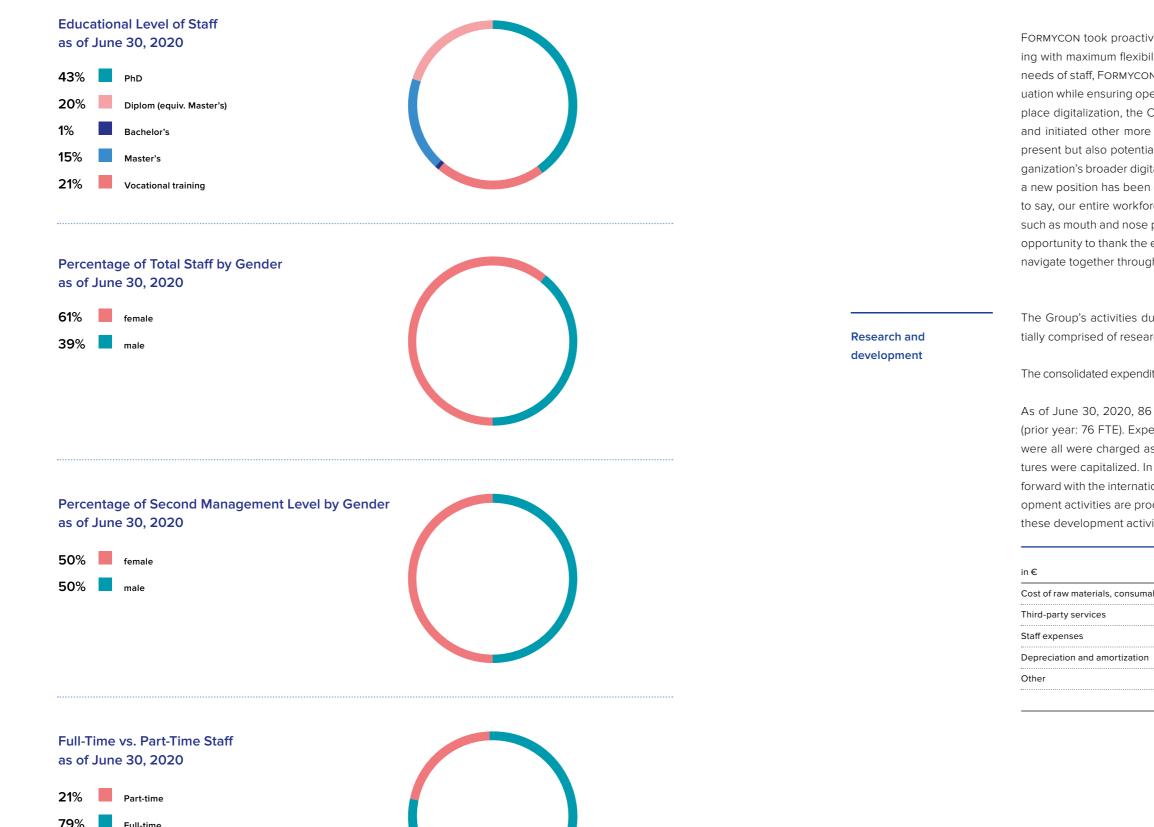
Staff expenses during the first six months of 2020 were  $\in$  4,893,881 (1H 2019:  $\in$  3,952,709), due primarily to the increase in the average number of employees between the respective periods.

Among FORMYCON's key success factors is the recruiting and retention of highly educated and skilled employees with superb abilities. 79% of the Company's total employees have a university degree, and 43% a doctorate. In terms of gender, 61% are female and 39% male. The average employee age as of the end of the period was 39 years. The percentage of women within the second management level (director level) is 50%. FORMYCON is proud of the stable organization and diverse workforce that it has built over the years, with employees from 11 different countries (Austria, China, Croatia, Cyprus, Germany, India, Italy, Montenegro, Romania, UK, USA).

FORMYCON operates in a global and highly dynamic environment and hires the best possible employees, without regard to gender, nationality or age. To further these 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. In order to achieve 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, as well as a "scientific career path" for its research staff, 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 generally 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.

Against the backdrop of the ongoing corona 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. As to the closely related subject of workplace digitalization, the Company has put numerous immediate measures into place and initiated other more far-reaching projects in order to be prepared not only for present but also potential future circumstances, as well as to further develop the organization's broader digital capabilities to adapt to changing needs. Towards this end, a new position has been created in the area of digitalization management. Needless to say, our entire workforce has also been equipped with vital protective equipment such as mouth and nose protection as well as disinfectants. We would like to take this opportunity to thank the entire FORMYCON team for their excellent cooperation as we navigate together through this public health crisis.

The Group's activities during the first half of 2020 were, as in prior years, substantially comprised of research and development activities at the parent company level.

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

As of June 30, 2020, 86 staff members (FTE) worked in research and development (prior year: 76 FTE). Expenditures during the period totaled  $\in$  17,902,925, and these were all were charged as current expense. No research and development expenditures 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.

	1,394,788
ables and supplies	9,382,154
	4,893,881
	448,310
	1,783,792
	17,902,925
	17.902.925

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

#### Financial performance

The financial results herein are reported for the six-month period from January 1, 2020 to June 30, 2020. 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 € 16,509K, compared to € 17,228K in the prior-year period, resulting in an consolidated period net loss of € 1,382K (1H 2019: net loss of € 695K). Cost of materials was € 10,777K (prior year: € 11,428K), yielding consolidated gross profit for the six-month period of € 5,774K (1H 2019: € 5,757K).

During the first half of 2020, 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 FYB 201 signed in late 2013 and for FYB 203 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 its intellectual property rights in its FYB202 biosimilar project to the joint venture entities, FYB 202 GmbH & Co. KG and its subsidiary FYB 202 Project GmbH. FORMYCON holds a 24.9% stake in the joint venture with Aristo Pharma GmbH and, following the completion of the pilot phase, will bear a pro rata share of accumulated project investments and other development costs. Including this non-recurring item, the six-month net loss for FORMYCON AG (parent company only) was € 1,328K on revenue of € 11,968K.

#### 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 € 26,679K, compared to total current liabilities of € 5,351K. 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  $\in$ 19,999K, while marketable securities, also included in cash and liquid resources in the following Statements of Cash Flows, totaled € 235K. Return on sales (net income/ loss divided by sales revenue) for the period was -8.4%, while EBIT (operating profit/ loss) was –€ 1,392K and EBITDA (operating profit/loss plus depreciation and amortization) was –€ 943K.

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

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

in €K

# Net income/loss +/- Depreciation, amortization, writedowns (impairments) and writeups of fixed assets -/+ Gain/loss resulting from disposals of fixed assets = Gross cash flow before change in working capital +/- Additions to/subtractions from medium- and short-term reserves -/+ Changes to inventories and trade receivables, as well as other assets 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 +/- Expense for taxes on income -/+ Payment (reimbursement) of taxes on 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 of the parent company 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

	Change	FY 2019	1H 2020
%	€K	€K	€K
>100.0	-1,379.8	-2,293.29	-1,382.1
-50.8	-463.6	911.9	448.3
>100.0	25.4	7.7	33.1
-34.4	473.0	-1,373.7	-900.7
-5.2	36.4	-704.2	-667.7
<-100.0	-1,776.9	907.0	-869.9
<-100.0	1,009.7	-335.3	674.5
9.5	2.4	25.6	28.0
-100.0	-8.6	8.6	0.0
-100.0	8.6	-8.6	0.0
17.2	-255.3	-1,480.5	-1,735.9
-94.4	84.8	-89.8	-5.0
	······		
-61.9	571.4	-922.6	-351.2
-100.0 -75.2	4,700.0	-4,700.0	0.0
-93.8	5,354.2	-5,709.7	-355.5
	······	······	
-100.0	-17,264.2	17,264.2	0.0
1.5	-0.4	-28.3	-28.7
<-100.0	-17,264.6	17,235.9	-28.7
<-100.0	-12,165.7	10,045.6	-2,120.1
81.6	10,045.6	12,308.5	22,354.1
	-2,120.1	22,354.1	20,234.0

## III Report on Subsequent Events

c. Net assets

Over the reporting period, the Group's equity capital ratio declined slightly to 89.7% (Dec. 31, 2019: 90.0%), thereby remaining at its above-average level. 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 Company'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.

Consolidated working capital, measured as the difference between current assets and current liabilities, amounted to € 21,876K as of the period closing date. Cash flow from operating activities was -€ 1,736K, in line with forecast, while cash flow from investing activities was -€ 356K.

As expected, return on equity (net income(loss)/average equity) and total return on capital (net income(loss)/average total capital) were both negative for the six-month period. 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.

Since the end of the reporting period, there have been no subsequent events at FORMYCON of accounting significance.

#### IV Report on Outlook

Over the past several years, FORMYCON has successfully gone through various phases of its development as a vibrant and rapidly growing organization, with the capitalization of the Company and the launch of multiple biosimilar development projects marking the emergence of FORMYCON into a more mature phase of its corporate development, where the Company stands now. The current focus is on continued execution of this strategy and, particularly during 2020, continued progress with the project development of the current biosimilar candidates; on the further expansion of FORMYCON's project pipeline; and on additional partnering deals to license out these biosimilar candidates or shift them into joint ventures. In addition, FORMYCON is pushing forward with further efforts to digitalize its business processes to bring greater efficiency and effectiveness to its management and organization.

## FYB201 – candidate biosimilar to Lucentis®

FYB201, FORMYCON's candidate biosimilar to ophthalmic blockbuster drug Lucentis® (ranibizumab), is the furthest advanced development project within the product pipeline. Together with licensing partner Bioeq AG, the combined team is working hand in hand towards the successful launch of the Company's first commercial product. In addition to the attractive growth of the overall market for Lucentis®, which according to the manufacturer grew by some 8% during 2019 to just short of USD 4 billion, the selection of biosimilar specialist Coherus BioSciences Inc. as the U.S. marketing partner further boosts FORMYCON's confidence as it looks toward the future. The Company's FYB201 development activities during the second half of 2020 will focus, in particular, on preparations on the submission of approval documents to the European Medicines Agency (EMA) and on the preparations of the re-submission by Bioeg AG to the U.S. Food and Drug Administration (FDA).

#### FYB202 – candidate biosimilar to Stelara®

FYB202, FORMYCON's candidate biosimilar drug 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 with Aristo Pharma GmbH, FORMYCON has created a strong basis to drive forward with the remaining development work. Thus far, FORMYCON has invested some € 21 million into the FYB202 project. Under current planning, FORMYCON will be able to fund its remaining pro rata obligations to the joint venture from its available liquidity resources. The manufacturing process for the active ingredient has already been scaled up to a com-

mercial production level. In October of 2019, the start of the phase I clinical trials was announced, with the aim of demonstrating that the pharmacokinetics, safety and tolerability of FYB202 are comparable to those of reference drug Stelara<sup>®</sup>. Preparations for phase III clinical trials, scheduled to begin in the third quarter of 2020, are proceeding according to plan. As part of this comprehensive clinical evaluation, FYB202 will then be tested on a larger patient population and at several study sites. Bioeq GmbH is the sponsor of the clinical trials, with responsibility for their design as well as their operational implementation. Advance coordination with the relevant approval authorities – the FDA in the U.S. and the EMA in Europe – has already been successfully completed through scientific advice procedures. As to the overall market for Stelara<sup>®</sup>, the growth dynamics are very encouraging: According to the manufacturer, full-year 2019 sales grew by 21% over the prior year to approx. USD 6.3 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. FORMYCON signed a deal in 2015 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 level. The preclinical study was successfully completed last year, demonstrating comparable intraocular pharmacokinetics of our alternative formulation to reference product Eylea®. The launch of the randomized, double-blind, multi-center phase III study for FYB203 has been published in August 2020. The MAGELLAN-AMD study examines the comparability of FYB203 and the reference product Eylea® in terms of efficacy, safety and immunogenicity in patients with neovascular age-related macular degeneration (nAMD). Advance coordination with the relevant approval authorities - the FDA in the U.S., the EMA in Europe, and the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan - has already been successfully completed through scientific advice procedures. The worldwide marketing rights were recently shifted internally within the Santo Group to another Santo entity, Klinge Biopharma GmbH. As with the reference drugs to our first two biosimilar candidates, Eylea® posted a significant rise in sales during 2019: With full-year revenue of some USD 7.5 billion, the manufacturer announced 12% growth over the prior year.

#### FYB20x - biosimilar candidates not yet announced

Details of other FORMYCON pipeline projects (FYB20x) have not yet been publicly announced. Specific development efforts for several biosimilar candidates, however, are currently in the analytical phase, and important intellectual property (IP) rights have been established. Beyond these, further potential biosimilar candidates are under active evaluation. As a general matter, FORMYCON wishes to develop and eventually commercialize each of its projects together with a partner, thereby maximizing the value of a significant retained equity interest.

## FYB207 – antibody-based drug candidate for the treatment of COVID-19

Against the backdrop of the ongoing global coronavirus pandemic, FORMYCON is using its scientific and business expertise in antibody development to seek new and highly effective biopharmaceuticals for the treatment of COVID-19. In addition to vaccines and drugs based on conventional chemical synthesis, antibody-based biologics which are able to effectively block the SARS-CoV-2 virus will play an equally important role in the fight against the novel coronavirus. Due to their larger molecules, these biologics have a longer half-life in the body, which will make them particularly suitable for prophylaxis so that, for example, doctors and nursing staff can be protected in the event of an acute outbreak. In the innovative and accelerated approach to development which it is taking, FORMYCON is working closely together with academic and industry partners. Preclinical development results are expected in the fourth quarter of 2020.

With its financial soundness and its strong portfolio of capabilities, FORMYCON Group is well positioned in the market. As in the past, FORMYCON will continue to invest a large part of these resources into the development of new biosimilars. Based upon the two projects already licensed out, FYB201 and FYB203, and the development fees resulting from these, as well as the provision of development services for FYB202, the company expects 2020 sales revenue in the range of  $\in$  35 to  $\in$  40 million. No significant changes in the Company's balance sheet structure are anticipated. Provided that the development of its current biosimilar candidates proceeds as planned, FORMYCON could enter the royalty phase starting from 2022. Exchange rate or inflation risks are not currently viewed as relevant factors.

FORMYCON has, to date, 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 (V. Report on opportunities and risks).

Based upon the further moderate increase in staffing planned for 2020, the Company expects a corresponding increase in its cost structure over the course of the year.

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#### **Report on Opportunities and Risks** V

This staff increase along with investments into new development programs are expected to result in a net loss for fiscal year 2020.

All of us at FORMYCON feel a great responsibility for the work we are doing. Through our biosimilars, we are making a significant contribution to broadening access to vital medications so that as many patients as possible may receive effective treatment. Beyond this sense of responsibility to help patients, FORMYCON also believes in social responsibility. FORMYCON has been a member of the UN Global Compact Network Germany since 2019. The UN Global Compact, one of the world's largest and most important initiatives for responsible corporate governance, has set itself the goal of an inclusive and sustainable global economy, supporting companies in aligning their strategies and activities with social and sustainability goals. In addition to the protection of human rights, these also include the elimination of all forms of forced labor, the abolition of child labor, the elimination of discrimination in hiring and employment, and protection of the environment, with a focus on a precautionary approach, the promotion of environmental awareness, and the development and diffusion of environmentally friendly technologies. FORMYCON stands firmly for global action with responsibility and will maintain this principled commitment long into the future. On a final note, the "Social Day" which had been planned for 2020, and through which FORMYCON and its staff will have the opportunity to further demonstrate their social commitment through various environmental and societal initiatives, has regrettably been postponed to 2021 due to the prevailing coronavirus pandemic.

**Opportunities** 

FORMYCON continues to hold a positive view as to future growth in the healthcare sector, which is decisively important to the Company, for the following reasons:

- continue in the coming years.

- over the coming years.

Opportunities for further growth lie in the expansion of the product portfolio, in the out-licensing of product candidates, and in strategic collaborations to jointly develop biosimilar projects or further expand the Company's value creation chain.

In positioning itself against competitors, FORMYCON continues to rely upon the experience and expertise of its staff, the innovations which they are able to achieve, the reliability of the scientific procedures which it uses in its development work, its stringent selection of reliable partners, and the high standards of quality and scientific expertise in the selection of its service providers and consultants.

Biosimilars 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. 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. Because the similarity and comparability

- Advances in medical technology, in particular using powerful biopharmaceuticals, have enabled the treatment of diseases that were considered untreatable or only poorly treatable even just ten to twenty years ago. Because of the intensity of medical research, notably in the field of genetic technology, these rapid advances should

- Because of demographic trends, there is an ever increasing number of seniors who require extensive medical care. Moreover, the life expectancy of the population as a whole is increasing, so that their medical treatment, in particular with pharmaceuticals, is often possible or necessary over a significantly longer period of time.

- 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.

 Anticipated regulatory changes in the two markets currently most important in terms of sales revenue, the United States and Europe, suggest that environmental conditions for both the development and marketing of biosimilars will further improve

Risks

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.

In addition to taking share in existing markets where their reference products are already being sold, biosimilars may, because of their lower price, be able to reach new markets where the more expensive reference products are not currently available.

#### Principles

FORMYCON, one of the few independent developers of biosimilars, 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.

#### 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 drug costs 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 early-stage development projects have not yet been announced.

The future size and growth trajectory of these markets may be derived from existing sales statistics for the respective reference products. Declining sales of a reference product could, however, result in a potential future market size for a biosimilar under development by FORMYCON which is significantly smaller than originally assumed. This could, in the worst case, lead to future product sales inadequate to make the biosimilar development effort profitable. At present, FORMYCON is developing biosimilars to compete with three of the world's best-selling biopharmaceuticals set to lose their patent protection following the year 2020, so that – provided that their development reaches successful completion - the profitability of the projects would seem 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, who have already been working closely with FORMYCON 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 minimal.

## 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 28.7 percent of the total drug market in 2019, equal to € 12.7 billion in sales revenue<sup>14</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 up to € 100,000 per patient per year, or even 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

<sup>14</sup> cf. BCG & German Association of Research-Based Pharmaceutical Companies (vfa), "Biotech Report: Medizinische Biotechnologie

report. In this, FORMYCON relies upon the standards established by the Institute of Public Auditors in Germany (*Institut der Wirtschaftsprüfer*, IDW) for accounting-related internal control systems and risk management systems.

#### Environmental, health 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.

#### Special risks relating to the coronavirus pandemic

FORMYCON recognized the potential danger which the novel coronavirus presented to its staff and business operations at an early stage. The Executive Board promptly and proactively established an emergency task force, with close and direct Executive Board involvement. Appropriate measures were immediately put into place to protect employees from infection to the maximum possible extent and to ensure the best possible continuity of business operations, even in the event of an actual or suspected infection within the workforce. FORMYCON has acted to implement all applicable government and occupational emergency health orders in a timely manner.

Wherever possible depending on the specific work activities involved, our workforce has been working decentrally. The Company promptly introduced comprehensive hygiene and social distancing policies to protect against coronavirus infections. Further organizational measures aim to ensure traceability of the chain of infection in the event of an infected person on premises. The task force has been reviewing and adapting these measures on a weekly basis and promptly informing staff of any significant changes.

Nevertheless, it cannot be ruled out that an infection, or even just a suspected infection, might occur within the workforce which could lead to an official quarantine order, which could potentially impact business operations and thus the ongoing projects and their timelines. Moreover, despite all of these measures taken by FORMYCON itself, there is also the potential for the coronavirus crisis to affect the work processes of FORMYCON's partners and suppliers, which could indirectly impact FORMYCON.

## Financing and liquidity risks

FORMYCON's liquidity situation and equity capitalization is 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 possibility cannot be 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 drug 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, for example as the result of the ongoing coronavirus pandemic, could have an impact on these trials and thus also adversely affect the timeline and/or profitability of a drug development project or even 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. 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. 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 the permitted choice of prescription drug, the eligibility of biosimilars for reimbursement, and/or their interchangeability with the originator drug 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 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.

It is currently not known whether the regulatory authorities are prioritizing approval procedures for vaccines or therapeutics to combat the novel coronavirus, and/or whether present circumstances which might more generally lead to delays in the drug approval process, an eventuality that in the present situation cannot be ruled out.

#### 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 patent expiry, 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

Even if the risks involved for FORMYCON are less than those in the development of original biotechnology-based drugs, there are, in the biosimilars development business, the same fundamental risks that one or several projects could fail, either partially or completely, for a range of different scientific, technical, regulatory, economic and other reasons.

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 requlatory 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.

## VI Report on Risks Relating to the Use of Financial Instruments

The ongoing coronavirus crisis has demanded, and continues to demand, that FORMYCON make rapid and significant changes to its organization and work processes, which the Company has able to successfully achieve – thanks in no small part to the excellent co-operation and support from its staff. Up until the present, there has been no indication of any circumstances arising as a result of the novel coronavirus, neither within the organization nor externally, which would significantly impair the Company's business activities. However, the possibility cannot be ruled out that the infection statistics in Germany might rise, and/or measures be imposed in other areas, in such a way as to significantly and adversely impact work activities at FORMYCON.

#### **Overall assessment**

Compared to the previous year, there has been no fundamental change in the risks facing the Company as these relate to its biosimilar development business activities. 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.

The measures made necessary by the coronavirus crisis have, of course, affected the organizational functioning and day-to-day activities at FORMYCON, and great care has been taken to put these changes into place within the respective organizational areas in the best way possible. That being said, it must be recognized that the risks presented by the coronavirus pandemic can only be countered under the prevailing medical guidance and government emergency measures, as well as to the best of our ability and current understanding. As the same time, this crisis – like every crisis – also presents opportunities, which specifically now include not only vaccines and treatments for COVID-19, as FORMYCON is currently pursuing with its newly announced FYB207 project, but also fundamental advances in digitalization and rethinking of the workplace and key business activities.

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 manage 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.

## VII Report on Branches

The Company does not currently maintain any branches.

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FORMYCON's risk management policy is fundamentally to protect against financial risks

Martinsried/Planegg, Germany, July 16, 2020

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Dr. Carsten Brockmeyer

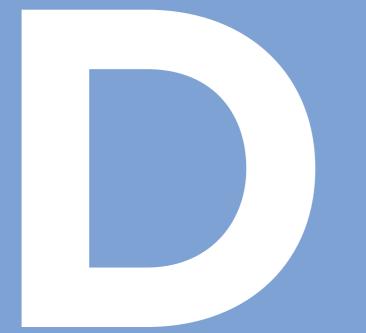
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Dr. Nicolas Combé

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Dr. Stefan Glombitza

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# **FORMYCON Group Consolidated Interim** Financial Statements

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# Consolidated Interim Balance Sheet – Assets

as of June 30, 2020

n€	June 30, 2020	Dec. 31, 2019
Fixed assets		
I. Intangible assets		
<ol> <li>Purchased concessions, industrial property rights, and similar rights</li> </ol>		
as well as licenses for such rights and assets	170,627.03	198,217.1
2. Goodwill	354,645.00	433,455.0
	525,272.03	631,672.1
II. Property, plant and equipment		
1. Land and buildings, including property-like rights		
and buildings on third-party land	115,793.16	74,685.5
2. Technical equipment and machinery	3,008,102.25	3,233,310.2
3. Other plant, production equipment and office equipment	546,580.94	392,873.6
4. Advance payments and plant under construction	11,611.75	0.0
	3,682,088.10	3,700,869.4
III. Financial assets		
Investment participations	20,673,249.00	20,673,249.0
	20,673,249.00	20,673,249.0
Current assets		
I. Inventories		
1. Raw materials, consumables and supplies	194,390.46	199,374.8
2. Unfinished products and services	239,309.00	171,182.0
3. Advance payments	0.00	36,131.3
	433,699.46	406,688.2
II. Receivables and other assets		
1. Trade accounts receivable	5,864,935.24	4,920,107.6
2. Other assets	146,774.03	379,224.8
	6,011,709.27	5,299,332.4
III. Securities		
Other securities	235,470.00	238,250.0
	235,470.00	238,250.0
IV. Cash and cash equivalents	19,998,535.86	22,115,843.9
Prepaid expenses	249,895.68	119,418.6
Deferred tax asset	370,000.00	370,000.0

# Consolidated Interim Balance Sheet – Liabilities and Equity

as (	of June 30, 2020
n €	3
۹.	Equity
	I. Subscribed capital <sup>1</sup>
	II. Capital reserve
	III. Loss carryforward
3.	Provisions
	1. Tax provisions
	2. Other provisions
2.	Liabilities
	1. Trade accounts payable
	of which due within one year
	€ 2,920,651.10 (prior year: € 2,211,539.47)
	2. Other liabilities
	of which due within one year:
	€ 674,195.41 (prior year: € 553,542.44)
	of which due in more than one year: € 546,367.10 (prior year: € 701,673.69)
	of which from taxes:
	€ 288,694.74 (prior year: € 162,140.83)
	of which relating to social security:
	€ 1,193.46 (prior year: € 2,977.46)

1 Conditional Capital 2015: 624,260 € Conditional Capital 2019: 4.284,740 €

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	June 30, 2020	Dec. 31, 2019
	10,000,000.00	10,000,000.00
	52,238,527.64	52,238,527.64
	-15,409,931.85	-14,027,807.15
	46,828,595.79	48,210,720.49
	0.00	519,700.00
	1,210,110.00	1,358,147.80
	1,210,110.00	1,550,147.00
	1,210,110.00	1,877,847.80
······		
	2,920,651.10	2,211,539.47
	1,220,562.51	1,255,216.43
······		
	4,141,213.61	3,466,755.60
	52,179,919.40	53,555,323.89

# **Consolidated Interim Income Statement**

for the period from January 1, 2020 to June 30, 2020

€		June 30, 2020	June 30, 201
1.	Sales revenue	16,509,407.92	17,228,361.6
2.	Increase or decrease in inventories of finished and unfinished products	427.00	-730,450.0
	Total revenue	16,509,834.92	16,497,911.6
3.	Staff expenses	41,906.01	687,806.6
	of which income attributable to foreign currency translation: € 17,464.26 (prior year: € 36,554.70)		
4.	Cost of materials		
	a. Cost of raw materials, consumables and supplies and of purchased goods	1,394,788.54	1,256,932.9
	b. Cost of purchased services	9,382,154.21	10,171,331.8
		10,776,942.75	11,428,264.7
	Gross profit	5,774,798.18	5,757,453.5
5.	Staff expenses		
	a. Wages and salaries	4,157,187.12	3,351,321.5
	b. Social contributions and costs for retirement benefits and for support benefits	736,693.47	601,387.5
	of which for retirement benefits: € 58,342.44 (prior year: € 59,107.85)		
		4,893,880.59	3,952,709.0
6.	Depreciation, amortization and writedowns of intangible assets and on property plant and equipment	448,310.15	448,718.9
7.	Other operating expenses	1,783,792.30	2,037,670.0
	of which expense arising from foreign currency translation: € 34,037.20 (prior year: € 26,708.81)		
	Operating income	-1,351,184.86	-681,644.5
8.	Other interest and similar income	662.82	710.6
9.	Writedowns of financial assets and securities held in current assets	2,780.00	0.3
0.	Interest and similar expense	28,665.07	13,932.1
1.	Taxes on income	-395.41	0.0
2.	Income after tax	-1,381,571.70	-694,866.2
3.	Other taxes	553.00	156.0
4.	Period net loss	1,382,124.70	695,022.2
5.	Loss carryforward from prior year	14,027,807.15	11,039,497.1
	Accumulated loss to balance sheet	15,409,931.85	11,734,519.4

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## Notes to the Consolidated Interim Financial Statements for the Period From January 1, 2020 to June 30, 2020

#### **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).

#### General Information About the Content and Structure of These Consolidated Interim Ш **Financial Statements**

The Consolidated Interim Financial Statements and Interim Management Report, 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 or prior period are omitted as provided under sec. 298 para. 1 and sec. 265 para. 8 of the German Commercial Code (Handelsgesetzbuch, HGB).

The Consolidated Interim 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

Scope of consolidation

These Consolidated Interim Financial Statements have been prepared as of June 30, 2020, which is the balance sheet closing date for FORMYCON AG, the parent company.

the same date.

These Consolidated Interim 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 the section "Other informa-

**Principles of** consolidation tion".

For subsidiaries which are fully consolidated into the Consolidated Interim 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.

These Consolidated Financial Statements are based upon the financial statements of the individual consolidated companies, the first-half periods of which likewise end on

#### **Balance Sheet Presentation and Valuation Methods** IV

Foreign currency translation	In preparing these Consolidated Financial Statements, there were no consolidated companies with accounts in other currencies. 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.
Derivatives	The Group did not hold any derivative financial instruments as of June 30, 2020.
Principles of balance sheet presentation and valuation	The Balance Sheet includes all assets, all liabilities and all prepaid and deferred items. Assets and liabilities are valued individually. The valuation of assets and liabilities takes all risks into account which are identifiable based on the principles of prudent business judgment.
Fixed assets	Purchased <b>intangible assets</b> 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.
	<b>Goodwill</b> derived from acquisitions is amortized on a linear pro rata basis over a busi- ness-customary useful life of ten years. The long useful life (extending until Septem- ber 30, 2022) was chosen because this goodwill represents, among other factors, li- censing opportunities over long periods.
	<b>Property, plant and equipment</b> 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.
	<b>Financial assets</b> are stated at their cost of acquisition, or should there be an impair- ment 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 <b>inventories</b> are valued at their average cost of acquisition, insofar as a write-down to a lower val- ue as of the balance sheet closing date is not required. Finished and unfinished prod- ucts are valued at their cost of production in accordance with sec. 255 para. 2 sen-

tence 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.

cial Code.

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 29.83%, or in the case of investment participations in partnerships, 15.83%.

Provisions

Prepaid and deferred

**Deferred taxes** 

items

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.

Liabilities

FORMYCON AG Half-Year Report 2020

Cash and cash equivalents are stated at their nominal value.

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

#### 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 period, is provided in Attachment 1 to these Notes.
Equity capital	Changes to consolidated equity are presented in the <b>Consolidated Schedule of</b> <b>Changes in Equity</b> included as Attachment 3.
Information required per	Number of shares outstanding
sec. 160 of the Stock Corporation Act	The Company has registered capital ( <i>Grundkapital</i> ) of € 10,000,000, which is divided into 10,000,000 bearer shares without par value.

#### Approved Capital 2019

By resolution of the Annual General Meeting of June 27, 2019, the Executive Board is authorized, subject to the approval of the Supervisory Board, to increase the Company's registered capital one or more times at any time until June 26, 2024, and by no more than a total of  $\in$  5,000,000, through the issuance of up to 5,000,000 new nopar-value 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 June 27, 2019 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 June 27, 2019, likewise in accordance with sec. 186 para. 3 sentence 4 of the Stock Corporation Act; and

 in the case of capital increases against non-cash contributions for the granting of companies, parts of companies, or equity interests in companies (including increases of existing equity investments), or in satisfaction of financial obligations of the Company.

This action was entered into the Company's commercial register on July 2, 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  $\in$  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 of the Supervisory Board, to determine further details regarding the specific implementation of any such contingent capital increase.

### 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 € 715,260 for the issuance of a maximum of 715,260 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 the conditional capital. As of the reporting date, a total of 376,000 stock options were issued.

## VII Other Information

Number of staff

Provisions

Other provisions are substantially comprised of the following:

in €	1H 2020
Bonuses	377,400
Unpaid invoices	306,300
Accrued vacation	350,420
Safekeeping obligations	115,300
Audit and advisory costs	21,650
Costs of litigation	25,000
Occupational cooperative and other social expenses	12,240
Miscellaneous staff provisions	1,800

Liabilities

The remaining term of liabilities, along with their collateralization through liens or similar rights and their relationship to other balance sheet items, is shown in the Consolidated Schedule of Liabilities included as Attachment 2 to these Notes.

Other financial obligations

The total amount of other financial obligations, within the meaning of sec. 314 para. 2 no. 2a of the Commercial Code, results from contractual obligations for ongoing performance. For obligations up to one year, the total amount is € 731,340, for obligations between one and five years  $\in$  1,375,450, and for obligations beyond five years,  $\in$  0.

Average number of staff Administration Research & development

Total company staff:

Information on the Executive Board and Supervisory Board

mercial Code:

Commercial Code:

- Peter Wendeln, residing in Oldenburg (member) Managing partner of Wendeln & Cie. Asset Management GmbH

boards:

Dr. Olaf Stiller:

Hermann Vogt:

During the period, the members of the Supervisory Board received total remuneration of  $\in$  41,500, while total remuneration to members of the Executive Board, within the meaning of sec. 314 para. 1 no. 6 of the Commercial Code, was € 607,061.34 (of which € 212,500 was success-based).

Remuneration

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

1H 2020
13.00
 100.00
113.00

Information on members of the Executive Board per sec. 314 para. 1 no. 6 of the Com-

- Dr. Carsten Brockmeyer, residing in Marzling, Chief Executive Officer - Dr. Nicolas Combé, residing in Munich, Chief Financial Officer - Dr. Stefan Glombitza, residing in Holzkirchen, Chief Operating Officer

Information on members of the Supervisory Board per sec. 314 para. 1 no. 6 of the

- Dr. Olaf Stiller, residing in Marburg (Chairman)
  - Member of the executive board of Paedi Protect AG
- Hermann Vogt, residing in Dieburg (Deputy Chairman)
  - Independent management advisor and financial advisor

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

Member of supervisory board, Bodenwert Immobilien AG Chairman of supervisory board, Nano Repro AG Member of supervisory board, Cumerius AG

Information on shareholdings per sec. 313 para. 2 no. 1-8 of the Commercial Code

The following subsidiary companies were included within these Consolidated Financial Statements in accordance with sec. 313 para. 2 no. 1 of the Commercial Code:

Company name	Share of capital (in %)	Equity (in €K)
FORMYCON PROJECT 201 GmbH		
Planegg/Martinsried	100.0	-56
FORMYCON PROJECT 203 GmbH		
Planegg/Martinsried	100.0	-1,907
FYB 202 GmbH & Co. KG*		Interim results not
Berlin	24.9	available

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

Significant events subsequent to balance sheet closing date

As of the balance sheet closing date, the total number of subscription rights (stock options) granted to staff and members of the Executive Board and Company employees but not yet exercised was 376,000.

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.

Martinsried/Planegg, Germany, July 16, 2020

Dr. Carsten Brockmeyer

Dr. Nicolas Combé

Dr. Stefan Glombitza

# Consolidated Schedule of Fixed Assets

in€	Cha	nges in historical	cost of acquisitior	1	Chang	es in accumulated de	preciation & amortiz	zation	Chan	iges in net book va	lue
	Historical cost			Historical cost	Accumulated			Accumulated			
	of acquisition or			of acquisition or	depreciation &	Current-year		depreciation &			
	production at		Historical cost	production at	amortization at	depreciation &	Write-downs	amortization at	Net book value at	Disposals at	
	Jan. 1st, 2020	Additions	of disposals	June 30, 2020	Jan. 1st, 2020	amortization	on disposals	June 30, 2020	June 30, 2020	book value	Dec. 31, 2019
Intangible assets	2,155,326	4,996	0	2,160,322	1,523,654	111,396	0	1,635,050	525,272	0	631,672
Purchased concessions, industrial property rights, and similar											
rights and assets, as well as licenses for such rights and assets	579,126	4,996	0	584,122	380,909	32,586	0	413,495	170,627	0	198,217
Goodwill	1,576,200	0	0	1,576,200	1,142,745	78,810	0	1,221,555	354,645	0	433,455
Property, plant and equipment	7,743,109	351,213	272,354	7,821,968	4,042,239	336,915	239,274	4,139,880	3,682,088	33,079	3,700,869
Land and buildings, including property-like rights											
and buildings on third-party land	504,047	51,576	0	555,622	429,361	10,468	0	439,829	115,793	0	74,686
Technical equipment and machinery	5,999,475	49,389	272,354	5,776,510	2,766,165	241,517	239,274	2,768,408	3,008,102	33,079	3,233,310
Other plant, production equipment and office equipment	1,239,587	238,637	0	1,478,224	846,713	84,930	0	931,643	546,581	0	392,874
Advance payments and plant under construction	0	11,612	0	11,612	0	0	0	0	11,612	0	0
Financial assets	20,673,249	0	0	20,673,249	0	0	0	0	20,673,249	0	20,673,249
Investment participations	20,673,249	0	0	20,673,249	0	0	0	0	20,673,249	0	20,673,249
Total	30,571,684	356,208	272,354	30,655,538	5,565,893	448,310	239,274	5,774,929	24,880,609	33,079	25,005,791

# **Consolidated Schedule of Liabilities**

in €	June 30, 2020	of which due within 1 year	of which due in 1–5 years	of which due in more than 5 years
Trade accounts payable	2,920,651.10	2,920,651.10	0.00	0.00
Other liabilities	1,220,562.51	674,195.41	546,367.10	0.00
Total	4,141,213.61	3,594,846.51	546,367.10	0.0

Liabilities may, in addition, be secured by industry-customary conditional retentions of title.

Attachment 2

Type and form of security interest	of which collateralized
	0.00
Conveyance of title	1,030,156.00
	1,030,156.00

# Consolidated Schedule of Changes in Equity

in€	Subscribed capital	Capital reserves	Loss carryforward	Consolidated net income (loss)
as of Jan. 1, 2020	10,000,000.00	52,238,527.64	-11,734,519.47	-2,293,287.68
Capital increases	0.00	0.00	0.00	0.00
Additions to capital reserves	0.00	0.00	0.00	0.00
Carryforward of prior-year loss	0.00	0.00	-2,293,287.68	2,293,287.68
Period consolidated net income (loss)	0.00	0.00		-1,382,124.70
as of June 30, 2020	10,000,000.00	52,238,527.64	-14,027,807.15	-1,382,124.70

 Equity
48,210,720.49
0.00
 0.00
 0.00
 -1,382,124.70
46,828,595.79

#### **Review Report of Independent Auditor**

#### To FORMYCON AG:

We have reviewed the accompanying consolidated interim financial statements as of June 30, 2020, consisting of the consolidated balance sheet, consolidated income statement, notes to the consolidated financial statements, consolidated statement of cash flows and consolidated schedule of changes in equity, as well as the interim group management report for the period from January 1, 2020 to June 30, 2020.

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

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

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

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

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

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

Munich, Germany, August 5, 2020

#### SRS Audit GmbH Wirtschaftsprüfungsgesellschaft Steuerberatungsgesellschaft

Doris Wolff Wirtschaftsprüferin [German Public Accountant]

The above report is a company translation from the original German. Only the original German text is signed and authoritative.

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



#### Legal Information

#### Company name FORMYCON AG Legal form German stock corporation (Aktiengesellschaft) Munich, Germany **Registered offices** Street address Fraunhoferstr. 15 82152 Martinsried/Planegg, Germany Articles of incorporation The Company was founded through its articles of incorporation (Satzung) of May 5, 2010, which were most recently amended as of July 2, 2019. 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. The Company's fiscal year runs from January 1 to Fiscal year December 31 of each year. Subscribed capital The Company's registered capital (Grundkapital) is € 10,000,000.00 Executive Board Dr. Carsten Brockmeyer, Member of Executive Board Dr. Nicolas Combé, Member of Executive Board Dr. Stefan Glombitza, Member of Executive Board Supervisory Board Dr. Olaf Stiller, residing in Marburg, Chairman Hermann Vogt, residing in Dieburg, Deputy Chairman Peter Wendeln, residing in Oldenburg

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# **Formycon AG** Interim Financial Statements

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#### Interim Balance Sheet – Assets

## Interim Balance Sheet – Liabilities and Equity

3	June 30, 2020	Dec. 31, 2019	in€
			<u> </u>
Fixed assets			A. Equity
I. Intangible assets			I. Subscribed capital <sup>1</sup>
1. Purchased concessions, industrial property rights, and similar rights and assets,			II. Capital reserve
as well as licenses for such rights and assets	170,627.03	198,217.10	III. Loss carryforward
2. Goodwill	354,645.00	433,455.00	
	525,272.03	631,672.10	
II. Property, plant and equipment			B. Provisions
<ol> <li>Land and buildings, including property-like rights and buildings on third-party land</li> </ol>	115,793.16	74,685.53	1. Tax provisions
2. Technical equipment and machinery	3,008,102.25	3,233,310.27	2. Other provisions
3. Other plant, production equipment and office equipment	546,580.94	392,873.64	
4. Advance payments and plant under construction	11,611.75	0.00	
	3,682,088.10	3,700,869.44	C. Liabilities
III. Financial assets			1. Trade accounts payable
1. Shares in affiliated companies	50,000.00	50,000.00	of which due within one year:
2. Loans to affiliated companies	2,000,000.00	1,577,000.00	€ 2,335,378.54 (prior year: € 1,475,010.5
3. Investment participations	20,673,249.00	20,673,249.00	2. Liabilities toward affiliated companies
	22,723,249.00	22,300,249.00	of which due within one year: € 0.00 (prior year: € 5.88)
• • •			3. Other liabilities
Current assets			of which due within one year:
I. Inventories			€ 673,010.31 (prior year: € 553,373.37)
1. Raw materials, consumables and supplies	194,390.46	199,374.83	of which due in more than one year:
2. Unfinished products and services	231,509.00	85,382.00	€ 546,367.10 (prior year: € 701,673.69)
3. Advance payments	0.00	36,131.37	of which from taxes:
	425,899.46	320,888.20	€ 288,694.74 (prior year: € 162,140.83)
II. Receivables and other assets			of which relating to social security: € 1,193.46 (prior year: € 2,977.46)
1. Trade accounts receivable	1,119,182.63	1,218,073.53	
2. Receivables from affiliated companies	6,157,030.11	6,310,210.28	
3. Other assets	146,730.33	377,985.99	
	7,422,943.07	7,906,269.80	
III. Securities			<sup>1</sup> Conditional Capital 2015: 624.260 € Conditional Capital 2019: 4.384.740 €
Other securities	235,470.00	238,250.00	Conditional Capital 2019: 4.284.740 €
	235,470.00	238,250.00	
IV. Cash and cash equivalents	17,953,031.13	19,087,955.25	
Prepaid expenses	249,895.68	119,418.68	
Deferred tax asset	370,000.00	370,000.00	

June 30, 2020	Dec. 31, 2019
10,000,000.00	10,000,000.00
 52,238,527.64	52,238,527.64
 -13,396,045.12	-12,067,516.44
48,842,482.52	50,171,011.20
0.00	519,700.00
 1,190,610.00	1,254,797.80
 1,190,610.00	1,774,497.80
2,335,378.54	1,475,010.53
 2,555,576.54	1,475,010.55
0.00	5.88
 1,219,377.41	1,255,047.06
3,554,755.95	2,730,063.47
E3 E07 040 47	E4 67E E70 47
 53,587,848.47	54,675,572.47

#### Interim Income Statement

for the period from January 1, 2020 to June 30, 2020

€		June 30, 2020	June 30, 2019
1.	Sales revenue	11,968,529.08	11,332,759.88
2.	Increase or decrease in inventories of finished and unfinished products	146,127.00	-103,550.00
	Total revenue	12,114,656.08	11,229,209.8
3.	Other operating income	41,232.99	73,973.8
0.	of which income attributable to foreign currency translation: € 16,984.61 (prior year: € 4,766.73)		
4.	Cost of materials		
	a. Cost of raw materials, consumables and supplies and of purchased goods	1,394,788.54	1,256,932.90
	b. Cost of purchased services	4,981,201.74	4,279,313.2
		6,375,990.28	5,536,246.1
	Gross profit	5,779,898.79	5,766,937.66
5.	Staff expenses		
	a. Wages and salaries	4,157,187.12	3,351,321.50
	b. Social contributions and costs for retirement benefits and for support benefits	736,693.47	601,387.58
	of which for retirement benefits: € 58,342.44 (prior year: € 59,107.85)		
		4,893,880.59	3,952,709.08
6.	Depreciation, amortization and writedowns of intangible assets and on property plant and equipment	448,310.15	448,718.96
7.	Other operating expenses	1,764,251.94	2,013,009.98
	of which expense arising from foreign currency translation:		
	€ 26,549.92 (prior year: € 15,082.94)		
	Operating income	-1,326,543.89	-647,500.36
8.	Other interest and similar income	28,221.92	619.13
	of which from affiliated companies:		
9.	€ 27,582.03 (prior year: € 0.00) Writedowns of financial assets and securities held in current assets	2,780.00	0.00
	Interest and similar expense	27,269.12	13,909.83
	Taxes on income	-395.41	0.00
2.	Income after tax	-1,327,975.68	-660,791.00
3.	Other taxes	553.00	156.00
4.	Period net loss	1,328,528.68	660,947.06
	Loss carryforward from prior year	12,067,516.44	9,209,331.86
15.			

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#### Notes to the Interim Financial Statements for the Period From January 1, 2020 to June 30, 2020

#### **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).

#### General Information About the Content and Structure of These Interim Financial Statements Ш

These Interim Financial Statements, presented here in translation from the German original, have been prepared in euros (€) in accordance with sections 242 et seq. of the German Commercial Code (Handelsgesetzbuch, HGB) under observance of the supplementary provisions of sections 264 et seq. of the Commercial Code applicable to medium-sized corporations as well as sections 150 et seq. of the German Stock Corporation Act (Aktiengesetz, 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 111

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.

	Assets and liabilities denom
Foreign currency	average spot exchange rate
translation	rates between then and the
	sets or write-ups of liabilitie
	to the extent necessary so
	es. Items due within a perio
	exchange rate as of the dat
	pense arising from currency
	under other operating incor
Derivatives	The Company did not hold a
Derivatives	
	The Balance Sheet includes
Principles of balance	Assets and liabilities are va
sheet presentation and	takes all risks into account
valuation	business judgment.
	Purchased intangible asset
Fixed assets	cost of acquisition and amo
	No use has been made of th
	Contrate and the line of the second

prepaid items.

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.

#### FORMYCON AG Half-Year Report 2020

## Foreign cu translatio

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

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

> ninated in foreign currency are translated into euros at the e on the day of their original posting. Changes in exchange he balance sheet date are reflected by write-downs of asies only for amounts due in more than one year and only that valuation on the balance sheet date is without lossod of less than one year are translated at the average spot ate of the financial statements. The resulting income or excy translation is shown separately in the Income Statement ome or expenses.

any derivative financial instruments as of June 30, 2020.

es all assets, all liabilities and all prepaid and deferred items. valued individually. The valuation of assets and liabilities which are identifiable based on the principles of prudent

ets (including software and licenses) are capitalized at their ortized based upon expected useful life.

he elective right under sec. 248 para. 2 of the Commercial Code to capitalize self-produced intangible assets.

#### IV Additional Notes to the Balance Sheet

	written down to the lower fair value.
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 and deferred items	<b>Prepaid and deferred items</b> are posted in accordance with sec. 250 of the Commer- cial 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 29.83%, or in the case of investment participations in partnerships, 15.83%.
Provisions	<b>Tax provisions</b> and <b>other provisions</b> 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 fulfill- ment at the average market interest rate over the past seven fiscal years.

Financial assets are stated at their cost of acquisition, or should there be an impair-

ment in value, regardless of whether it is expected to be permanent or temporary,

Liabilities are stated at the amount required for their fulfillment.

#### Liabilities

rent period, is provided in Attachment 1 to these Notes. Changes to equity are presented in the Schedule of Changes in Equity included as Attachment 3.

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

**Fixed assets** 

Equity capital

The Company has registered capital (Grundkapital) of € 10,000,000.00, which is divided into 10,000,000 bearer shares without par value.

#### Approved capital 2019

By resolution of the Annual General Meeting of June 27, 2019, the Executive Board is authorized, subject to the approval of the Supervisory Board, to increase the Company's registered capital one or more times at any time until June 26, 2024, and by no more than a total of  $\in$  5,000,000.00, through the issuance of up to 5,000,000 new no-par-value 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,

A Schedule of Fixed Assets, including depreciation and amortization taken in the cur-

#### Number of shares outstanding

- 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 June 27, 2019 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 June 27, 2019, likewise in accordance with sec. 186 para. 3 sentence 4 of the Stock Corporation Act; and

- in the case of capital increases against non-cash contributions for the granting of companies, parts of companies, or equity interests in companies (including increases of existing equity investments), or in satisfaction of financial obligations of the Company.

This action was entered into the Company's commercial register on July 2, 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 € 4,284,740.00, 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.

#### 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 € 715,260.00 for the issuance of a maximum of 715,260 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 the conditional capital. As of the reporting date, a total of 376,000 stock options were issued.

	Other provisions are substantially comprised of the following	ıg:
Provisions		
	in €	1H 2020
	Bonuses	377,400
	Accrued vacation	350,420
	Unpaid invoices	298,500
	Safekeeping obligations	114,500
	Costs of litigation	25,000
	Occupational cooperative and other social expenses	12,240
	Audit and advisory costs	10,750
	Miscellaneous staff provisions	1,800
Liabilities	lar rights and their relationship to other balance sheet items of Liabilities included as Attachment 2 to these Notes.	, is shown in the <b>Schedule</b>
Contingent liabilities	The Company has issued a letter of comfort ( <i>Patronatserklä</i> sidiaries FORMYCON Project 201 GmbH and FORMYCON P best of our knowledge, the respective companies will be	Project 203 GmbH. To the able, in all cases, to fulfill
Other financial obligations	their underlying obligations. Claims thereunder are thus no The total amount of other financial obligations, within the tence 1 no. 3a of the Commercial Code, results from contra- ing performance. For obligations up to one year, the total a	meaning of sec. 285 sen- ctual obligations for ongo-
	obligations between one and five years € 1,375,450.02, a	

five years,  $\in 0.00$ .

#### V Other Information

Number of staff

Information on the

Supervisory Board

**Executive Board and** 

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

Average number of staff	1H 2020
Administration	13
Research & development	100
Total company staff	113

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

- Dr. Carsten Brockmeyer, residing in Marzling, Chief Executive Officer

- Dr. Nicolas Combé, residing in Munich, Chief Financial Officer
- Dr. Stefan Glombitza, residing in Holzkirchen, Chief Operating Officer

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
- Hermann Vogt, residing in Dieburg (Deputy Chairman)
   Independent management advisor and financial advisor
- Peter Wendeln, residing in Oldenburg (member)
   Managing partner of Wendeln & Cie. Asset Management GmbH

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

- Dr. Olaf Stiller: Member of supervisory board, Bodenwert Immobilien AG Chairman of supervisory board, Nano Repro AG
- Hermann Vogt: Member of supervisory board, Cumerius AG

Remuneration

During the period, the members of the Supervisory Board received total remuneration of  $\in$  41,500.00, while total remuneration to members of the Executive Board, within the meaning of sec. 285 no. 9 of the Commercial Code, was  $\in$  607,061.34 (of which  $\in$  212,500.00 was success-based).

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

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

Significant events subsequent to balance sheet closing date

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

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	Share of capital (in %)	<b>Equity</b> (in €K)	Period net income/loss (in €K)
H	100,0	-56	8
Н	100,0	-1.907	-62
	24,9	Interim results not available	Interim results not available

As of the balance sheet closing date, the total number of subscription rights (stock options) granted to staff and members of the Executive Board and Company employees but not yet exercised was 376,000.

There have been no events of material significance which occurred following the end of the period and are not reflected in these Financial Statements. Martinsried/Planegg, Germany, July 16, 2020

w  $\mathcal{O}$ 

Dr. Carsten Brockmeyer

U

Dr. Nicolas Combé

le

Dr. Stefan Glombitza

#### Schedule of Fixed Assets

in€	Cha	nges in historica	cost of acquisition	n	Change	Changes in accumulated depreciation & amortization			
	Historical cost			Historical cost	Accumulated			Accum	
	of acquisition or			of acquisition or	depreciation &	Current-year		deprecia	
	production at		Historical cost	production at	amortization at	depreciation &	Write-downs	amortiza	
	Jan. 1st, 2020	Additions	of disposals	June 30, 2020	Jan. 1st, 2020	amortization	on disposals	June 30	
Intangible assets	2,155,326	4,996	0	2,160,322	1,523,654	111,396	0	1,63	
Purchased concessions, industrial property rights, and similar rights						••••			
and assets, as well as licenses for such rights and assets	579,126	4,996	0	584,122	380,909	32,586	0	4	
Goodwill	1,576,200	0	0	1,576,200	1,142,745	78,810	0	1,22	
Property, plant and equipment	7,743,109	351,213	272,354	7,821,968	4,042,239	336,915	239,274	4,13	
Land and buildings, including property-like rights									
and buildings on third-party land	504,047	51,576	0	555,622	429,361	10,468	0	43	
Technical equipment and machinery	5,999,475	49,389	272,354	5,776,510	2,766,165	241,517	239,274	2,76	
Other plant, production equipment and office equipment	1,239,587	238,637	0	1,478,224	846,713	84,930	0	9:	
Advance payments and plant under construction	0	11,612	0	11,612	0	0	0		
Financial assets	22,300,249	423,000	0	22,723,249	0	0	0		
Shares in affiliated companies	50,000	0	0	50,000	0	0	0		
Loans to affiliated companies	1,577,000	423,000	0	2,000,000	0	0	0		
Investment participations	20,673,249	0	0	20,673,249	0	0	0		
Total	32,198,684	779,208	272,354	32,705,538	5,565,893	448,310	239,274	5,77	

#### Schedule of Liabilities

in€	June 30, 2020	of which due within 1 year	of which due in 1–5 years	
Trade accounts payable	2,335,378.54	2,335,378.54	0.00	0.00
Other liabilities	1,219,377.41	673,010.31	546,367.10	0.00
Total	3,554,755.95	3,008,388.85	546,367.10	0.00

Liabilities may, in addition, be secured by industry-customary conditional retentions of title.

Accumulated depreciation &			
amortization at	Net book value at	Disposals at	Net book value at
June 30, 2020	June 30, 2020	book value	Dec. 31, 2019
June 30, 2020			
1,635,050	525,272	0	631,672
413,495	170,627	0	198,217
1,221,555	354,645	0	433,455
4,139,880	3,682,088	33,079	3,700,869
439,829	115,793	0	74,686
2,768,408	3,008,102	33,079	3,233,310
931,643	546,581	0	392,874
0	11,612	0	0
0	22,723,249	0	22,300,249
0	50,000	0	50,000
0	2,000,000	0	1,577,000
0	20,673,249	0	20,673,249
5,774,929	26,930,609	33,079	26,632,791

#### Changes in net book value

Attachment 2

Type and form of security interest	of which collateralized
	0.00
Conveyance of title	1,030,156.00
	1,030,156.00

## Schedule of Changes in Equity

in€	Subscribed capital	Capital reserves	Loss carryforward	Net income (loss)	Equity
as of Jan. 1st, 2020	10,000,000.00	52,238,527.64	-9,870,278.92	-2,197,237.52	50,171,011.20
Capital increases	0.00	0.00	0.00	0.00	0.00
Additions to capital reserves	0.00	0.00	0.00	0.00	0.00
Carryforward of prior-year loss	0.00	0.00	-2,197,237.52	2,197,237.52	0.00
Period net income (loss)	0.00	0.00	0.00	-1,328,528.68	-1,328,528.68
as of June 30, 2020	10,000,000.00	52,238,527.64	-12,067,516.44	-1,328,528.68	48,842,482.52

#### **Review Report of Independent Auditor**

#### To FORMYCON AG:

We have reviewed the accompanying interim financial statements as of June 30, 2020, consisting of the balance sheet, income statement, notes to the financial statements and schedule of changes in equity as well as the interim management report for the period from January 1, 2020 to June 30, 2020.

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

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

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

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

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

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

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

Munich, Germany, August 5, 2020

#### SRS Audit GmbH

Wirtschaftsprüfungsgesellschaft Steuerberatungsgesellschaft

Doris Wolff Wirtschaftsprüferin [German Public Accountant]

The above report is a company translation from the original German. Only the original German text is signed and authoritative.



## Legal Information

## Company name Legal form Registered offices Street address

Articles of incorporation

#### Subject of business

**Commercial register** 

Fiscal year

Subscribed capital

Executive Board

Supervisory Board

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FORMYCON AG
German stock corporation (Aktiengesellschaft)
Munich, Germany
Fraunhoferstr. 15 82152 Martinsried/Planegg, Germany
The Company was founded through its articles of incorporation ( <i>Satzung</i> ) of May 5, 2010, which were most recently amended as of July 2, 2019.
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.
The Company is entered into the commercial register ( <i>Handelsregister</i> ) of the District Court of Munich under number HR B 200801.
The Company's fiscal year runs from January 1 to December 31 of each year
The Company's registered capital (Grundkapital) is € 10,000,000.00
Dr. Carsten Brockmeyer, Member of Executive Board
Dr. Nicolas Combé, Member of Executive Board
 Dr. Stefan Glombitza, Member of Executive Board
Dr. Olaf Stiller, residing in Marburg, Chairman
 Hermann Vogt, residing in Dieburg, Deputy Chairman
 Peter Wendeln, residing in Oldenburg

#### Imprint

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#### **Concept and Realisation**

klargedacht, Berlin

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