Press Release // November 28, 2024

Formycon reports nine-month results for 2024 and continues growth trajectory with further operational success

- Excellent third quarter with product approvals for FYB202 in the key markets USA and Europe
- Keytruda® biosimilar candidate FYB206 starts clinical development program (phase I and phase III study)
- Development of FYB210 officially started as seventh pipeline project
- Successful business performance is reflected in the financial results and confirms the guidance
- Invitation to today's conference call at 3:00 p.m. (CET)

Planegg-Martinsried, Germany – Formycon AG (FSE: FYB, "Formycon") today reported on the financial results and business performance of the Formycon Group for the first nine months of fiscal year 2024.

"We can look back on an extremely successful business performance in the first nine months of fiscal year 2024 and have met all operational, clinical and regulatory targets. In the third quarter of 2024, we were able to announce the EMA and FDA approvals for FYB202/Otulfi®[1], which followed in quick succession. This also triggered two milestone payments from our partner Fresenius Kabi. We are equally pleased about the EMA's Committee for Medicinal Products for Human Use (CHMP) positive opinion for FYB203/AHZANTIVE®[2]/Baiama®[3], which once again underscores the excellent quality of our data, processes and products. Our biosimilar FYB201, approved in 2022, was able to further expand its strong market position in the key markets USA and UK during the course of this financial year, gaining impressive market shares. At the same time, we achieved a groundbreaking development milestone with our Keytruda®[4] biosimilar candidate by including the first patients in our clinical program for FYB206, thereby consolidating our position among the leading developers for this product. Thanks to our development expertise and agility, we are ideally placed to position Formycon AG as a leading independent provider of high-quality biosimilars in the market," says Dr. Stefan Glombitza, CEO of Formycon AG.

Enno Spillner, CFO of Formycon AG, adds: "After a great deal of intensive preparation, we completed the final step necessary for entry into the Prime Standard in the third quarter of 2024. This uplisting to the regulated market of the Frankfurt Stock Exchange in mid-November marks a significant chapter in our capital market strategy. It gives us access to a broader range of international and institutional investors. This increases our attractiveness to the capital market and strengthens our position in international competition."

Operational success and progress in the second half of the year underpin growth strategy

FYB201 Lucentis®[5] biosimilar

Formycon's FYB201 (ranibizumab), available in the United States under the tradename CIMERLI®[6], has captured a significant share of the overall U.S. Lucentis® market. Following the strategic realignment of Formycon's distribution partner Coherus BioSciences, Inc. (Coherus), the marketing rights for CIMERLI®, including the Coherus ophthalmology sales team, were transferred to Sandoz AG on March 1, 2024. According to market reports, CIMERLI®'s market share in the US ranibizumab market was over 40% in August. In the United Kingdom, FYB201/ONGAVIA®[7] has a market share of over 80% based on indication-based market volume and thus has a dominant market position. In addition, further markets such as Canada and Saudi Arabia have been tapped in the current fiscal year. FYB201 is now available in a total of 20 countries worldwide.

FYB202 Stelara®[8] biosimilar

At the end of September 2024, both the U.S. Food and Drug Administration (FDA) and the European Commission granted approval for FYB202/Otulfi®, Formycon's ustekinumab biosimilar, for the treatment of severe inflammatory diseases such as Crohn's disease, moderate to severe plaque psoriasis, and active psoriatic arthritis. A settlement agreement had already been concluded between Formycon, Fresenius Kabi and Johnson & Johnson, granting Formycon's marketing partner Fresenius Kabi the right to launch Otulfi® in the USA no later than February 22, 2025. A further agreement governs the launch of the biosimilar in Europe and Canada, the terms of which remain confidential. The European Commission's approval covers both subcutaneous and intravenous formulations and is valid in all countries of the European Economic Area (EEA), including the 27 EU member states, Iceland, Liechtenstein and Norway.

FYB203 Eylea®[9]-Biosimilar

On November 15, 2024 (after the reporting period), the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended the approval of FYB203, a biosimilar to Eylea® (aflibercept), under the brand names AHZANTIVE® and Baiama®. The recommendation includes the treatment of neovascular age-related macular degeneration (nAMD) as well as other serious eye diseases such as diabetic macular edema (DME), diabetic retinopathy (DR) and macular edema secondary to retinal vein occlusion (RVO). The final decision of the European Commission is expected in the second half of January 2025. The FDA had already approved FYB203/AHZANTIVE® in the US for the same indications on June 28, 2024. With these advances, Formycon is on track to make FYB203 available in both the US and Europe as a cost-effective treatment alternative for patients with severe retinal diseases.

FYB206 Keytruda® biosimilar candidate

Another important operational milestone was reached with the start of the clinical development program for FYB206, a biosimilar candidate for the immuno-oncology blockbuster drug Keytruda®. The first patient was enrolled in the phase I study to compare the pharmacokinetics (PK), safety and tolerability of FYB206 with the reference drug Keytruda® in patients with malignant melanoma (black skin cancer) in June 2024. The parallel phase III study comparing the safety and efficacy of FYB206 with Keytruda® in patients with non-small cell lung cancer (NSCLC) started at the end of July 2024. The scientific basis for the ongoing clinical trials is provided, among other things, by the results of an analytical study comparing FYB206 with Keytruda®, which were published in October 2024 in the peer-reviewed journal *Drugs in R&D*. The results confirmed a high degree of structural and functional similarity between FYB206 and the reference medicine. With the start of the study, Formycon is consolidating its excellent position in the leading group of developers of pembrolizumab biosimilars.

FYB208 / FYB209 – early biosimilar candidates and further development of the pipeline

Formycon is continuously investing in the expansion of its biosimilar platform and has further expanded its product pipeline with the two younger biosimilar candidates FYB208 and FYB209. For both candidates, cell lines with convincing stability, productivity and quality have been identified and transferred to manufacturing partners for further process development and scale-up.

FYB210 – a new biosimilar candidate in the pipeline in the field of immunology

Following a complex selection process, a further biosimilar candidate FYB210 was recently launched (after the reporting period). Following the official start of the development process, FYB210 is now the seventh biosimilar project in Formycon's development pipeline and is positioned in the immunology indication area. It addresses an attractive and strongly growing therapeutic area with the aim of commercialization after the loss of exclusivity rights after 2030.

Key personnel appointment and promotion to a higher stock exchange segment confirm strategic direction

Formycon has a highly experienced management team with many years of industry expertise. To ensure continuity in the company's successful management, the management contract of CEO Dr. Stefan Glombitza has been extended until December 2027 (after the reporting period).

In addition, on November 11 (after the reporting period), Formycon successfully completed its uplisting to the Prime Standard of the Frankfurt Stock Exchange, the segment with the highest transparency requirements on the Deutsche Börse. This step marks a significant milestone in the company's capital market strategy. The Prime Standard requires strict disclosure and reporting obligations and is an important prerequisite for investment decisions by institutional and international investors. This uplisting also lays the foundation for a potential inclusion in important indices, such as the SDax or TechDax; it strengthens the company's visibility and transparency in the global capital markets.

Formycon Group revenue and EBITDA remain in line with planning

The Formycon Group's revenue for the first nine months of 2024 was around €41.1 million (9M/2023: €60.2 million), in line with expectations. These revenues include both income from the marketing of FYB201 and revenues from development services for the partnered or out-licensed biosimilar candidates FYB201 and FYB203. In addition, milestone payments from the commercialization partnership for FYB202 with Fresenius Kabi AG (Fresenius Kabi) were recognized on a pro-rata basis, a portion of which had already been deferred in 2023.

The commercialization of the ranibizumab biosimilar FYB201, which was launched in further markets in the first nine months, is developing very positively in terms of sales figures. Revenues from the direct participation in the commercialization of this Lucentis® biosimilar increased to around €6.0 million (9M/2023: €2.3 million). The significant portion of the contribution of earnings from FYB201 is realized in the context of the 50% at-equity investment in Bioeq AG and is therefore not directly reflected in revenues, but below EBITDA (see below). As of the September 30, 2024 reporting date, it amounted to a total of €20.6 million and is reflected accordingly in the adjusted EBITDA.

Consolidated earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to around €-17.7 million in the first nine months (9M/2023: €5.2 million) and are in line with planning. This result was due to lower revenues, a planned and significant increase in research and development costs due to the rapid progress of FYB208 and FYB209, but also higher administrative costs due to the preparation and execution of the uplisting.

Adjusted group EBITDA reflects strong FYB201 performance

The adjusted Group EBITDA aims to present the total income from the FYB201 project, which is partially recognized as equity-accounted income below EBITDA due to the existing 50% stake in Bioeq AG, as regular operating income. It shows the direct financial contributions of FYB201 to the business success of the Formycon Group and the actual operating performance of the company.

Adjusted consolidated EBITDA for the first nine months of 2024 amounted to €2.9 million (9M/2023: €3.5 million). This is due in particular to the good performance of FYB201 and the resulting significant increase in the earnings contribution from Bioeq AG (at equity earnings) of €20.6 million (9M/2023: € -1.7 million).

Working capital increase due to higher cash and receivables

The net working capital of the Formycon Group amounted to €65.8 million as of September 30, 2024 (September 30, 2023: €41.3 million) and includes cash and cash equivalents of €33.8 million (September 30, 2023: €35.6 million). The working capital includes two milestone payments from Fresenius Kabi, which were recognized in receivables earlier than expected due to the already granted EU approval for FYB202 but are not due for payment until the fourth quarter.

The existing shareholder loan of €48.0 million was extended. The credit line remains fully available and can be utilized flexibly until May 2026.

Forecast for the Formycon Group for the full year 2024 remains unchanged

For the fourth quarter, Formycon expects business to continue as planned. In addition to further operational progress with the biosimilar candidates, revenues are expected to be slightly higher than the average of the first three quarters. The milestone payments received from Fresenius Kabi for the approvals of FYB202 will lead to a stable cash position in the fourth quarter.

The guidance for the full year 2024, which was already revised upwards for adjusted EBITDA and working capital in the context of the half-year results, is thus confirmed.

Forecast in € million	**Q1/2024**	**H1/2024**	**9M/2024**
Revenue	55 to 65	55 to 65	55 to 65
EBITDA	-25 to -15	-25 to -15	-25 to -15
Adjusted EBITDA	*-15 to -5*	*-5 to +5*	-5 to +5
Working Capital	*10 to 20*	*35 to 45*	35 to 45

Conference Call and Webcast

The Executive Board of Formycon AG will discuss the company's performance and key financial figures, as well as the recent uplisting to the Prime Standard of the Frankfurt Stock Exchange, in a conference call. The earnings call, which will be webcast live, will take place in English on **November 28, 2024 at 3:00 p.m. (CET).**

To participate in the conference call, please register at:
https://webcast.meetyoo.de/reg/TkZPrWBERFjh

After registration, participants will receive a confirmation email with individual dial-in data.

The presentation and audio broadcast can be accessed via the following webcast link:
https://www.webcast-eqs.com/login/formycon-2024-q3

After a brief presentation, the Management Board will be available for analysts' questions. The conference call will be recorded and can subsequently be accessed via the Formycon website at:
https://www.formycon.com/en/investor-relations/publications/

1) Otulfi® is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries
2) AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH
3) Baiama® is a registered trademark of Klinge Biopharma GmbH
4) Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co, Inc, Rahway, NJ/USA

5) Lucentis® is a registered trademark of Genentech Inc.
6) CIMERLI® is a registered trademark of Coherus BioSciences, Inc.
7) ONGAVIA® is a registered trademark of Teva Pharmaceutical Industries
8) Stelara® is a registered trademark of Johnson & Johnson
9) Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.

About Formycon

Formycon AG (FSE: FYB) is a leading, independent developer of high-quality biosimilars, follow-on products of biopharmaceutical medicines. The company focuses on therapies in ophthalmology, immunology, immuno-oncology and other key disease areas, covering almost the entire value chain from technical development through clinical trials to approval by the regulatory authorities. For commercialization of its biosimilars, Formycon relies on strong, well-trusted and long-term partnerships worldwide. With FYB201/Ranibizumab, Formycon already has a biosimilar on the market in Europe and the USA. Two further biosimilars, FYB202/ustekinumab and FYB203/aflibercept, received FDA approval; FYB202 is also approved in Europe. Another three biosimilar candidates are currently in development. With its biosimilars, Formycon is making an important contribution to providing as many patients as possible with access to highly effective and affordable medicines. Formycon AG is headquartered in Munich and is listed on the Frankfurt Stock Exchange: FYB / ISIN: DE000A1EWVY8 /WKN: A1EWVY. Further information can be found at: https://www.formycon.com

About Biosimilars:

Since their introduction in the 1980s, biopharmaceutical drugs have revolutionized the treatment of serious and chronic diseases. By 2032, many of these drugs will lose their patent protection – including 45 blockbusters with an estimated total annual global turnover of more than 200 billion US dollars. Biosimilars are successor products to biopharmaceutical drugs for which market exclusivity has expired. They are approved in highly regulated markets such as the EU, the USA, Canada, Japan and Australia in accordance with strict regulatory procedures. Biosimilars create competition and thus give more patients access to biopharmaceutical therapies. At the same time, they reduce costs for healthcare providers. Global sales of biosimilars currently amount to around 21 billion US dollars. Analysts assume that sales could rise to over 74 billion US dollars by 2030.

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