Press Release // May 12, 2025

Formycon reports strong operational performance and financial results for first quarter of 2025

- Strong operational start to the year with market approvals for FYB203 (Aflibercept) in Europe and the United Kingdom as well as new commercialization partnerships with Teva and Lotus
- Encouraging market launch of FYB202/Otulfi®[1] (Ustekinumab) by partner Fresenius Kabi in the U.S. and Europe generates initial meaningful revenue within the first month after market entry
- First quarter financial figures in line with expectations – full-year guidance confirmed
- Invitation to today's conference call at 3:00 p.m. (CEST)

Planegg-Martinsried, Germany – Formycon AG (FSE: FYB, Prime Standard, "Formycon") today reports on the Group's business development and financial results for the first quarter of fiscal year 2025. The reporting period was marked by operational milestones and positive regulatory trends, successful product launches, the expansion of international commercialization partnerships but also by challenging macroeconomic conditions.

Dr. Stefan Glombitza, CEO of Formycon AG, stated: "Q1 was a turbulent quarter for our industry and Formycon alike. Nevertheless, we achieved several important milestones during the reporting period. These include, in particular, the successful market launch of our Stelara®[2] biosimilar FYB202/Otulfi® in the U.S. and Europe, as well as the approval of our Eylea®[3] biosimilar FYB203 in Europe and the United Kingdom. Just a few weeks after launch, FYB202 already generated notable revenue contributions. This encouraging start, against the backdrop of increasing biosimilar penetration, confirms the product's international market potential. We remain firmly focused on the strategic advancement of our pipeline and are particularly well positioned with our Keytruda®[4] biosimilar FYB206 to drive further growth."

Enno Spillner, CFO of Formycon AG, added: "With our pioneering development strategy for FYB206, we are significantly reducing development costs while reinforcing our leading role in the global competition for a biosimilar to Keytruda®. Despite increasing economic challenges in the U.S. market, we are operating well within our communicated financial guidance. Even in light of volatile capital markets and macroeconomic uncertainties, including U.S. trade policy, Formycon remains strategically and operationally on track. We reaffirm our guidance for the current fiscal year and remain committed to achieving sustainable, EBITDA-positive growth."

Strong start to the year marked by key operational achievements

In January 2025, FYB203 (Aflibercept), a biosimilar to Eylea®, was approved by the European Commission under the brand names AHZANTIVE®[5] and Baiama®[6]. UK approval followed in February. Teva Pharmaceuticals will market FYB203 on a semi-exclusive basis across major parts of Europe. In addition, Formycon entered into a commercialization agreement with Lotus Pharmaceutical for the Asia-Pacific region.

Formycon's commercialization partner Fresenius Kabi initiated the U.S. launch of FYB202 (ustekinumab), a biosimilar to Stelara®, at the end of February with an encouraging start. Shortly

thereafter, the European launch followed in early March. In the meantime, FYB202 also received important marketing authorizations in the United Kingdom and Canada. To further expand its global presence and maximize commercial potential, Formycon also initiated a partnership with MS Pharma for the MENA region. After the reporting period, FYB202/Otulfi® was assigned a permanent, product-specific reimbursement code (Q-code) in the U.S., facilitating reimbursement by private and public payers.

Based on the positive feedback from the U.S. Food and Drug Administration (FDA), Formycon decided to waive the Phase III trial with FYB206 (Pembrolizumab) in February 2025 as the therapeutic comparability of FYB206 with the reference medicine Keytruda® can be sufficiently demonstrated based on comprehensive analytical data and data from the ongoing Phase I study. The Phase I trial in malignant melanoma continues as planned. This decision accelerates development of the biosimilar and reduces the investments over the coming years by more than €75 million. In a recently published "reflection paper"[7], the European Medicines Agency (EMA) has also signaled its support for this approach, reinforcing Formycon's position as a pioneer among pembrolizumab biosimilar developers.

FYB201 (ranibizumab biosimilar) is available in 20 countries worldwide and has continued to strengthen its position in various markets. Competitive discounting by ranibizumab providers in the U.S. prompted Formycon's commercialization partner Sandoz AG to adjust its marketing strategy and to implement a temporary pause in the commercialization of FYB201/Cimerli®[8] for approximately one year, starting at the end of Q1 2025. Following the pause, the product is to be strategically repositioned to target new customer segments. The product remains available in other regions, including Europe and MENA, where it is marketed by Teva and MS Pharma, respectively. With the planned launch of the pre-filled syringe in 2025, further market penetration is expected, particularly in Europe. Further markets such as in Latin America are targeted for expansion.

Alongside its advanced biosimilar programs, Formycon continues to drive the development of new pipeline candidates. The candidates FYB208, FYB209, and FYB210 are currently in early stages of development. FYB208 is expected to enter the clinical phase later this year upon achieving Technical Proof of Similarity.

Following Formycon's successful inclusion in the SDAX at the end of 2024, the company's visibility as one of Germany's key technology stocks was further enhanced at the beginning of 2025 through its admission to the TecDAX.

Group revenue and EBITDA in line with expectations – FYB202 revenue contributions reflect a successful market launch

Formycon Group generated revenues of €5.3 million in Q1 2025 (Q1/2024: €17.7 million). The year-on-year decline was anticipated and reflects the revenue mix shift. In the prior-year period, significant milestone revenues were recognized from the commercialization partnership with Fresenius Kabi related to the FYB202 project. As development of the pre-filled syringe for the two ophthalmic biosimilars FYB201 and FYB203 progressed successfully, revenues from reimbursed development services declined as expected accordingly.

Despite being on the market for only about one month in the U.S. and Europe, FYB202/Otulfi® generated revenues of €0.74 million in the first quarter, demonstrating a positive market launch. Further

increasing revenue contributions are expected over the course of the year, positioning FYB202 as a key revenue driver for the Group in 2025.

As expected, revenues from the ranibizumab biosimilar FYB201 were below the prior-year level. This was attributable to continued price pressure and the previously announced temporary pause in U.S. commercialization by partner Sandoz, which took effect on April 1, 2025. Direct revenue contributions from commercialization of the Lucentis®9 biosimilar FYB201 amounted to €0.6 million (Q1/2024: €1.9 million). A further significant portion of revenue from FYB201 was realized through the 50% at-equity investment in Bioeq AG. The at-equity result is not included in revenue and is reported below EBITDA (see below).

Group EBITDA for the first three months amounted to €-13.2 million (Q1/2024: €-5.5 million), primarily reflecting the aforementioned decline in revenues. However, the initial revenue contribution from FYB202/Otulfi® is viewed positively. The Stelara® biosimilar was launched at the end of the first quarter in the U.S. and Europe and remains in the early stage of market ramp-up. Increasing research and development expenses related to early-stage biosimilar candidates also impacted Group EBITDA accordingly.

Adjusted Group EBITDA amounted to €-11.8 million (Q1/2024: €2.9 million) and was in line with expectations. The result was primarily attributable to the weaker performance of FYB201 in the U.S. and the resulting lower earnings contribution from Bioeq AG (at-equity result), which amounted to €1.4 million (Q1/2024: €4.3 million).

Working capital as of March 31, 2025, stood at €29.4 million (December 31, 2024: €55.1 million). The year-over-year change reflects initial investment savings in FYB206, where development costs are capitalized and thus cash-effective but not EBITDA-relevant. The existing shareholder loan of €48.0 million remains fully available and can be drawn flexibly.

Formycon confirms its full-year 2025 guidance and continues to pursue sustainable and EBITDA-positive development. Management still anticipates achieving positive EBITDA as early as 2026, but no later than 2027.

Key financial figures at a glance (in € million):

	FY 2025 Guidance	**Result Q1 2025**	**Result Q1 2024**
Revenue	55.0 to 65.0	5.3	17.7
EBITDA	-20.0 to -10.0	-13.2	-5.5
(adjusted) EBITDA	-20.0 to -10.0	-11.8	2.9
Working Capital	25.0 to 35.0	29.4	84.2

Conference call and webcast

The Executive Management Board of Formycon AG will discuss the company's development and key financial figures during a conference call. The earnings call, which will be webcast live, will take place today, May 12, 2025, at 3:00 p.m. (CEST) in English.

To participate in the conference call, please register at:
https://webcast.meetyoo.de/reg/dv2D4A5Z3vhL

After registering, participants will receive a confirmation email with individual dial-in details and the date.

The presentation and audio broadcast can be accessed via the following webcast link:
https://www.webcast-eqs.com/formycon-2025-q1

Following a short presentation, the Executive Board will be available to answer analysts' questions. The webcast will be recorded and will be available to view afterwards on 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] Stelara® is a registered trademark of Johnson & Johnson
[3] Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.
[4] Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co, Inc, Rahway, NJ/USA
[5] AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH
[6] Baiama® is a registered trademark of Klinge Biopharma GmbH
[7] EMA Reflection Paper www.ema.europa.eu/en/reflection-paper-tailored-clinical-approach-biosimilar-development
[8] CIMERLI® is a registered trademark of Coherus BioSciences, Inc.
[9] Lucentis® is a registered trademark of Genentech 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, have been approved by the FDA, EMA, and MHRA; FYB202 is also approved in Canada. Another four 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, listed in the Prime Standard of the Frankfurt Stock Exchange: FYB / ISIN: DE000A1EWVY8 / WKN: A1EWVY and is part of the SDAX and TecDAX selection indices. 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 systems. 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.

Contact:
Sabrina Müller,
Director Investor Relations & Corporate Communications,
Formycon AG
Fraunhoferstr. 15
82152 Planegg-Martinsried
Germany

Tel.: +49 (0) 89 - 86 46 67 149
Fax: + 49 (0) 89 - 86 46 67 110
Sabrina.Mueller@formycon.com

Disclaimer:
This press release may contain forward-looking statements and information which are based on Formycon's current expectations and certain assumptions. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, performance of the company, development of the products and the estimates given here. Such known and unknown risks and uncertainties comprise, among others, the research and development, the regulatory approval process, the timing of the actions of regulatory bodies and other governmental authorities, clinical results, changes in laws and regulations, product quality, patient safety, patent litigation, contractual risks and dependencies from third parties. With respect to pipeline products, Formycon AG does not provide any representation, warranties or any other guarantees that the products will receive the necessary regulatory approvals or that they will prove to be commercially exploitable and/or successful. Formycon AG assumes no obligation to update these forward-looking statements or to correct them in case of developments which differ from those anticipated. This document neither constitutes an offer to sell nor a solicitation of an offer to buy or subscribe for securities of Formycon AG. No public offering of securities of Formycon AG will be made nor is a public offering intended. This document and the information contained therein may not be distributed in or into the United States of America, Canada, Australia, Japan or any other jurisdictions, in which such offer or such solicitation would be prohibited. This document does not constitute an offer for the sale of securities in the United States.