Press Release // November 13, 2025

Formycon publishes nine-month results and confirms guidance – Pipeline progress and strong partnerships drive fiscal year 2025

- Guidance for 2025 confirmed – Revenue and earnings development in line with expectations
- FYB202 (Stelara®[1] biosimilar): Market penetration in the US and Europe continues
- Significant pipeline progress: FYB201 – Launch of the first pre-filled syringe for a ranibizumab biosimilar in Europe; settlement for FYB203 enables US launch; patient recruitment for FYB206 pharmacokinetic (PK) study successfully completed
- New regulatory guidelines in the US accelerate biosimilar approvals and confirm Formycon's development strategy
- International partnerships in Europe, Australia, and Latin America expand market presence
- Invitation to today's conference call at 3:00 p.m. (CET)

Planegg-Martinsried, Germany – Formycon AG (FSE: FYB, "Formycon") today reports on the Group's business development and financial results for the first nine months of fiscal year 2025. During the reporting period, the company successfully expanded its operational activities and consistently pursued its strategic priorities in the areas of development, financing, partnerships, and competitiveness. Based on these positive developments, Formycon confirms its existing guidance for the 2025 fiscal year.

Enno Spillner, CFO of Formycon, commented: "Operational development and financial performance in the third quarter were in line with expectations. In addition, we confidently anticipate a dynamic fourth quarter and expect significant sales momentum from the ongoing market penetration of our Stelara® biosimilar FYB202 in the US and Europe. In particular, the exclusive US distribution agreement concluded by Fresenius Kabi with CivicaScript promises a significant increase in sales in the fourth quarter. In addition, we expect further positive momentum from the advanced commercialization discussions for our Keytruda®[2] biosimilar candidate FYB206 in selected regions. Our rigorous, streamlined development program without a Phase III study has enabled us to advance the clinical development of FYB206 significantly faster and more cost-efficiently. The successful completion of patient recruitment once again underscores our pioneering role in global biosimilar development and at the same time strengthens our appeal for future partnerships. With strict cost control and the solid financing structure from our first corporate bond in the summer, we are well positioned to achieve our annual targets."

Group revenues and earnings development on track – guidance for 2025 confirmed

In the first nine months of 2025, the Formycon Group generated revenues of approximately €19.5 million (9M/2024: €41.1 million). While the previous years' figures included one-time payments from license and milestone agreements for FYB202, current revenues increasingly derive from recurring proceeds from the marketing of approved biosimilars, from development services for out-licensed or jointly developed projects, and from service payments for supply chain coordination.

Revenues from the ranibizumab biosimilar FYB201 from direct participation in commercialization proceeds amounted to €1.5 million (9M/2024: €6.0 million). As previously reported, Sandoz temporarily paused commercialization in the US from the second quarter of 2025 for tactical market reasons; based on current information, resumption is planned for the first quarter of 2026. In the remaining 24 markets outside the US - including Europe and the MENA region - FYB201 continued to be marketed, and development proceeded as expected. After the end of the reporting period, FYB201 was launched as the first ready-to-use syringe of a ranibizumab biosimilar in the first European countries. The syringe system sets new standards in quality and innovation and increases the marketing potential of the ranibizumab biosimilar FYB201 in Europe.

The Stelara® biosimilar FYB202 (Otulfi®[3]/Fymskina®[4]) developed according to plan during the reporting period. Following the market launch by our partner Fresenius Kabi in March, market development is progressing steadily. In the US, FYB202 is primarily distributed through the pharmacy benefit channel. An exclusive distribution agreement with CivicaScript and other contracts have now been concluded. In Europe, FYB202 has already been launched in 18 countries. In Germany, our distribution partner Ratiopharm has additionally been handling sales for FYB202/Fymskina® since this summer. Revenues from direct participation in the commercialization of FYB202 amounted to €3.2 million (9M/2024: €0). Milestone payments of €0.5 million were also realized for approvals in additional regions. Based on the contracts concluded and the expected order volumes, Formycon anticipates a significant increase in revenue contributions from FYB202 in the final quarter of 2025.

The Group's earnings before interest, taxes, depreciation and amortization (EBITDA) amounted to €-21.4 million in the reporting period (9M/2024: €-17.7 million) and were thus in line with planning. This development mainly reflects the temporary decline in sales revenues resulting from the transition phase between one-time license payments and the increasing share of sales from commercialized products. Adjusted EBITDA amounted to €-21.7 million (9M/2024: €2.9 million) and includes the earnings contribution from the 50% stake in Bioeq AG.

The at-equity result of Bioeq AG for the first nine months was €-0.3 million (9M/2024: €20.6 million), reflecting the temporary marketing pause for FYB201 in the US. The forecast for EBITDA and adjusted EBITDA in the range of €-20 million to €-10 million for the full year remains unchanged.

The current positive developments in easing regulatory requirements, such as the waiver of Phase III clinical trials as a standard requirement, are paving the way for shorter and less expensive development cycles and allowing Formycon to focus its structures on greater efficiency. Based on the successful

development and approval of three biosimilar products, the company is leveraging the experience it has gained to pool capacities in a targeted manner, further optimize the use of resources, and significantly reduce costs. The growing use of digital technologies and artificial intelligence is increasingly helping to make development processes focused, lean, and thus competitive. Formycon is aiming for EBITDA-profitable corporate development in the medium term and expects that a positive EBITDA result can ideally be achieved in 2026, but no later than in the 2027 fiscal year.

In the second quarter of 2025, Formycon AG successfully placed its first corporate bond 2025/2029 (ISIN NO0013586024 / WKN A4DFJH) in Nordic Bond format with a total volume of €70 million on the capital market. The four-year, floating-rate bond (maturity: July 2029) bears interest based on the 3-month Euribor plus a margin of 7.00% p.a.; interest payments are made quarterly. Investor feedback during the roadshow and after the placement confirms confidence in Formycon's promising growth strategy and business model.

In connection with the successful placement of a €70 million corporate bond, the working capital forecast was already raised in the first half of the year. Working capital amounted to €83.2 million in the first nine months (9M/2024: €65.8 million), securing the financing of ongoing development activities and operating business in the medium and long term.

Operational development on track – strategic progress and settlement and license agreement confirm outlook for the full year

Dr. Stefan Glombitza, CEO of Formycon AG, said: “In fiscal year 2025, we further refined our strategy in the areas of development, partnerships, and competitiveness and achieved important milestones. With the introduction of the innovative FYB201 prefilled syringe, we are setting new standards in ophthalmic care and creating additional differentiation in the European market. The settlement of the patent dispute with Regeneron regarding FYB203 also marks a decisive step forward in the US market entry of our Eylea®[5] biosimilar and strengthens our position in one of the largest biosimilar markets worldwide. The latest initiative by the US health authority to simplify the approval process for biosimilars marks a significant regulatory advance with immediate relevance for our industry. The planned facilitations can significantly shorten development times and at the same time make them more cost-effective. We anticipated this change early on and aligned our clinical strategy for our Keytruda® biosimilar candidate FYB206 accordingly in consultation with the FDA. The streamlined design of our clinical program already shows that scientific excellence can be successfully combined with economic efficiency. These developments confirm our approach and create additional opportunities to develop and bring biosimilars to market faster, more cost-effectively, and with high quality.”

In the third quarter of 2025, Formycon advanced the development of key biosimilar projects as planned and achieved significant operational progress. This includes, in particular, further progress with the pembrolizumab biosimilar candidate FYB206. Following positive regulatory feedback, a Phase III study was not required as therapeutic comparability can be demonstrated by comprehensive analytical data and the ongoing Phase I Pharmacokinetic (PK) study. Patient recruitment for this ongoing Phase I PK

study was already completed in July. Formycon expects results for the primary endpoint in the first quarter of 2026.

Further important steps toward market expansion and portfolio differentiation were taken after the end of the reporting period: One focus was on the launch of the pre-filled syringe version of the ranibizumab biosimilar FYB201 (Ranivisio®[6]) in Europe by our partner Teva. At the beginning of October, a settlement and license agreement for FYB203 was concluded with Regeneron, which resolves all the patent disputes in connection with the aflibercept biosimilar FYB203/Ahzantive®[7] in the US. From today's perspective, this means that the biosimilar, which has already been approved by the FDA, could enter the market in the fourth quarter of 2026. Exclusive commercialization in the United States and Canada will be carried out by the distribution partner Valorum Biologics based on the license agreement concluded at the end of June 2025.

In addition, exclusive commercialization agreements for FYB203 were signed with Actor Pharmaceuticals for Australia and with Megalabs for Latin America. A co-marketing partnership was agreed with Horus Pharma for selected European countries. These partnerships will expand FYB203's future geographic market coverage and penetration and strengthen Formycon's competitive position. At the same time, development activities for early-stage projects continued as planned.

Key financial performance indicators at a glance

in € million	**Results 9M 2024**	**Results 9M 2025**	**Guidance 2025**
Revenue	41.1	19.5	55.0 to 65.0
EBITDA	-17.7	-21.4	-20.0 to -10.0
Adjusted EBITDA	2.9	-21.7	-20.0 to -10.0
Working Capital	65.8	83.2	55.0 to 65.0

Balance sheet IFRS

in € million	September 30, 2025	December 31, 2024
Assets	789.1	771.7
Non-current assets	676.1	676.7
Other intangible assets	457.2	444.1
Right-of-use (ROU) assets	10.2	10.7
Property, plant and equipment	3.5	3.8
Investment accounted for using the equity method	151.6	151.9
Financial assets	53.7	66.1
Current assets	113.0	95.0
Inventories	0.5	0.3
Trade and other receivables	10.1	23.7
Contract assets	6.3	7.0
Other financial assets	0.7	0.01
Prepayments and other assets	15.8	22.1
Income tax receivables	0.1	0.09
Cash and cash equivalents	79.5	41.8
Equity and liabilities	789.1	771.7
Equity	402.7	461.8
Subscribed capital	17.7	17.7
Capital reserve	497.3	496.0
Balance sheet profit	-112.2	-51.8
Non-current liabilities	356.9	276.0
Non-current lease obligations	8.4	9.1
Non-current financial liabilities	247.0	164.2
Other non-current liabilities	0.3	0.5
Deferred tax liabilities	101.2	102.2
Current liabilities	29.4	33.9
Current lease obligations	1.5	1.5
Current financial liabilities	7.2	8.7

Other current liabilities	6.0	4.3
Trade payables	12.7	17.4
Current income tax liabilities	2.0	2.0

Condensed statement of comprehensive income

in € million	Result 9M 2025	Result 9M 2024
Revenue	19.5	41.1
Cost of sales	37.2	32.5
Research and development expenses	9.5	13.4
Selling expenses	1.0	0.8
Administrative expenses	13.0	13.4
Other expenses and income	0.4	0.3
Operating profit (loss) / EBIT	-41.6	-19.3
Net finance income	-19.7	2.0
Profit before tax	-61.3	-17.3
Income tax expense	0.9	- 3.6
Profit (loss) / Comprehensive income (loss) for the period	-60.4	-20.9

Condensed cash flow statement

in € million	Result 9M 2025	Result 9M 2024
Cash flow from operating activities	-3.7	-41.0
Profit (loss) for the period	-60.4	-20.9
Depreciation and amortization	20.2	1.7
Net finance result	19.7	-2.0
Other non-cash expenses / income	0.0	5.2
Changes in working capital	16.8	-24.9
Net cash used for investing activities	-19.3	-2.9
Outflow for investments in long-term assets	-32.1	-26.2

Proceeds from loans issued	12.8	23.3
Net cash from financing activities	60.7	50.6
Proceeds from issuance of shares	0.1	83.0
Proceeds from financial liabilities	68.6	-
Outflows for financial liabilities and interest paid	-8.0	-32.4
Cash-effective change in cash and cash equivalents	37.7	6.8
Cash and cash equivalents at the end of the period	79.5	33.8
Cash and cash equivalents at the beginning of the period	41.8	27.0

Conference call and dial-in details

The Executive Board will discuss the company's performance and key financial figures and provide an outlook for the remainder of fiscal year 2025. The conference call, which will be broadcast live on the Internet, will take place on **Thursday, November 13, 2025**, at **3:00 p.m. (CET)** in English.

To participate in the conference call, please register at:

https://webcast.meetyoo.de/reg/KYTa1G3ju56X

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

The presentation and audio webcast can be accessed via the following link:

https://www.webcast-eqs.com/formycon-2025-q3

Following a brief presentation, the Executive Board will be available to answer questions from analysts. The conference call will be recorded and subsequently available on the Formycon website at: https://www.formycon.com/en/investors/publications/.

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1) *Stelara® is a registered trademark of Johnson & Johnson*
2) *Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co, Inc, Rahway, NJ/USA*
3) *Otulfi® is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries*
4) *Fymskina® is a registered trademark of Formycon AG*
5) *Eylea® is a registered trademark of Regeneron Pharmaceuticals Inc.*
6) *Ranivisio® is a registered trademark of Bioeq AG*
7) *AHZANTIVE® is a registered trademark of Klinge Biopharma GmbH*

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 and FYB202/ustekinumab, Formycon already has two biosimilars on the market. Another biosimilar, FYB203/aflibercept, has been approved by the FDA, EMA, and MHRA. Four pipeline 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 selection index. 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.

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