

## Formycon (FYB GY) | Pharma/Healthcare

September 19, 2022

### New details on FYB206 - stepping into the immuno-oncology market

We confirm our Buy recommendation: Overall, the positive newsflow continues. Following the approval of FYB201 by the European Commission & FDA (both in August 2022), Formycon this morning released details of the previously undisclosed pipeline project FYB206. FYB206 is a biosimilar candidate for Keytruda (developed by Merck) which is used in cancer immunotherapy and treats, among others, melanoma (black skin cancer), non-small cell lung cancer, head and neck squamous cell cancer as well as Hodgkin's lymphoma. The relevant reference market for FYB206 is highly attractive in our view. Since the first approval in 2014, Keytruda has become one of the best-selling drugs, generating global sales of USD 17bn in 2021 - by 2025, sales are even expected to grow to USD 22bn according to GlobalData. Formycon has already achieved the first development stages in the preclinical phase. The next step is to compile a comprehensive data package in order to coordinate the further programme steps with the EMA and FDA. While the patents for Keytruda expire in 2028, Formycon already secured GMP manufacturing capacity at an early stage. Given the attractive underlying market, we believe that the biosimilar competition for Keytruda will be significantly more intense compared to Formycon's other pipeline projects. However, Formycon's entry into the immuno-oncology market clearly underlines (once again) the company's strong ambitions. Next expected event: Release of commercialization partners for FYB202.

**Valuation:** Our unchanged PT of EUR 85 is derived from our rNPV approach (which does not yet include FYB206).

**Buy**

 **unchanged**

**Price\*** **EUR 70.80**

**Price target** **EUR 85.00 (unchanged)**

\* XETRA trading price at the close of the previous day unless stated otherwise in the Disclosures

Market Cap (EUR m) <sup>1</sup>	1,067
Enterprise Value (EUR m) <sup>1</sup>	1,057
Free Float (%) <sup>1</sup>	27.0

Price (in EUR)<sup>1</sup>



Fundamentals (in EUR m) <sup>1</sup>	2019	2020	2021	2022e	2023e	2024e
Sales	33	34	37	38	69	215
EBITDA	-1	-5	-12	-16	23	153
EBIT	-2	-6	-13	-18	22	148
EPS adj. (EUR)	-0.23	-0.54	-1.22	-1.20	1.14	7.85
DPS (EUR)	0.00	0.00	0.00	0.00	0.00	0.00
BVPS (EUR)	4.82	6.16	5.08	24.57	25.71	33.56
Net Debt incl. Provisions	-22	-42	-25	-10	-24	-144
Ratios <sup>1</sup>	2019	2020	2021	2022e	2023e	2024e
EV/EBITDA	-217.9	-112.9	-50.5	-64.6	44.4	6.0
EV/EBIT	-130.5	-94.8	-47.0	-59.1	47.9	6.2
P/E adj.	-139.3	-98.8	-48.4	-59.2	61.9	9.0
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	-4.1	-14.1	-33.5	-43.0	34.1	71.1
EBIT margin (%)	-6.9	-16.7	-36.1	-47.0	31.6	69.1
Net debt/EBITDA	16.5	8.8	2.1	0.6	-1.0	-0.9
PBV	6.6	8.6	11.6	2.9	2.8	2.1

<sup>1</sup>Sources: Bloomberg, Metzler Research

Performance (in %) <sup>1</sup>	1m	3m	12m
Share	-18.1	-4.3	29.4
Rel. to Prime All Share	-12.1	-0.5	61.9

Changes in estimates (in %) <sup>1</sup>	2022e	2023e	2024e
Sales	0.0	0.0	0.0
EBIT	0.0	0.0	0.0
EPS	0.0	0.0	0.0

#### Sponsored Research



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# company note

## FYB206 - a biosimilar candidate for Keytruda

Keytruda (Pembrolizumab) was developed by Merck (not rated) and received its first approval in 2014. Keytruda works by increasing the ability of the body's immune system to help detect and fight tumor cells. Its active ingredient Pembrolizumab is a humanized monoclonal antibody that binds to the PD-1 receptor, blocking the interaction between PD-1 and its ligand PD-L1, and thus, helping the immune system to activate the body's cellular anti-tumor immune response and for instance kill melanoma cells.

Keytruda is effective in numerous oncological indications, among others black skin cancer, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma and non-muscle invasive bladder cancer. Following its approval, Keytruda has become one of the best-selling drugs, generating sales of USD 17bn in 2021 - see table below:

### Top 10 medications FY 2021

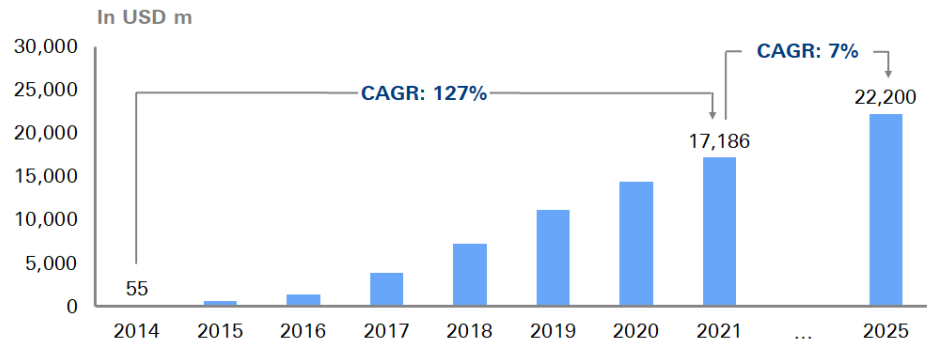
Drug Name	Manufacturer	FY 2021 Sales	Main Indication(s)
Comirnaty vaccine	Pfizer / BioNTech	USD 59.1bn	Covid-19
Humira (Adalimumab)	AbbVie	USD 20.7bn	Rheumatoid and psoriatic arthritis
Spikevax vaccine	Moderna	USD 17.7bn	Covid-19
<b>Keytruda (Pembrolizumab)</b>	<b>Merck</b>	<b>USD 17.2bn</b>	<b>Cancer immunotherapy</b>
Eliquis (Apixaban)	Bristol Myers Squibb & Pfizer	USD 16.7bn	Blood clots
Revlimid (Lenalidomide)	Bristol Myers Squibb	USD 12.8bn	Myelodysplastic syndrome, multiple myeloma
Imbruvica (Ibrutinib)	AbbVie & Janssen	USD 9.8bn	Chronic lymphocytic leukemia/small lymphocytic lymphoma
<b>Eylea (Aflibercept)</b>	<b>Regeneron &amp; Bayer</b>	<b>USD 9.2bn</b>	<b>Age-related macular degeneration (AMD)</b>
<b>Stelara (Ustekinumab)</b>	<b>Janssen</b>	<b>USD 9.1bn</b>	<b>Psoriasis, Crohn's disease</b>
Biktarvy	Gilead Sciences	USD 8.6bn	HIV

Sources: Company data, DRUG (Discovery & Development), Metzler Research

GlobalData even expects Keytruda to become the best-selling drug by sales in 2023 and reach total sales of more than USD 22bn by 2025 (see chart below). Hence, the underlying reference market for FYB206 is highly attractive in our view.

# company note

## Keytruda sales development



Sources: Merck, Statista, Pharma Excipients, GlobalData, Pharma Intelligence Center, Metzler Research

According to Formycon, the first development stages in the preclinical phase have already been achieved. The next step is to compile a comprehensive data package in order to coordinate the further programme steps with the EMA and FDA. Important IP has been patented, including the development of alternative formulations. While the patents for Keytruda expire in 2028, Formycon already secured GMP manufacturing capacity at an early stage.

## First impression on competitive landscape

As described, the biosimilar market for Keytruda is attractive. This should also be reflected in strong future competition. For example, while Formycon only faces two competitors for FYB201 (Samsung Bioepis, Xbrane), the number of competitors for FYB206 should be clearly higher. Since the patents for Keytruda will not expire for about 6 years, there is currently little information on potential biosimilars. To date, only a few companies have announced to work on a Keytruda biosimilar:

- **Xbrane Biopharma** - decided to initiate the development of a biosimilar candidate referencing Keytruda in December 2021
- **NeuClone** - disclosed in 2020 that it is working on a biosimilar referencing Keytruda - project in process scale up phase
- **PlantForm Corporation** - signed an agreement in Brazil to develop a biosimilar for Keytruda (news from April 2021)

# company note

## Key Data

### Company profile

CEO: Dr. Stefan Glombitza

CFO: Dr. Nicolas Combé

Martinsried (Planegg)

Formycon, headquartered in Martinsried-Planegg (Germany) is a leading developer of biosimilars with a focus on ophthalmology and immunology. The current pipeline includes four biosimilars: FYB201 (biosimilar for Lucentis), FYB202 (biosimilar for Stelara), FYB203 (biosimilar for Eylea) and FYB205 (no information published yet). In addition, with FYB207, Formycon has developed an innovative antiviral drug for the treatment of Covid-19 based on a long-acting ACE2-IgG-Fc fusion molecule.

### Major shareholders

Family Offices (43%), Institutional Investors (23%), Founders and Management (7%)

### Key figures

P&L (in EUR m)	2019	%	2020	%	2021	%	2022e	%	2023e	%	2024e	%
<b>Sales</b>	<b>33</b>	<b>-22.9</b>	<b>34</b>	<b>3.2</b>	<b>37</b>	<b>8.0</b>	<b>38</b>	<b>3.0</b>	<b>69</b>	<b>80.9</b>	<b>215</b>	<b>212.0</b>
<b>EBITDA</b>	<b>-1</b>	<b>-116.9</b>	<b>-5</b>	<b>-253.6</b>	<b>-12</b>	<b>-157.5</b>	<b>-16</b>	<b>-32.1</b>	<b>23</b>	<b>243.4</b>	<b>153</b>	<b>550.4</b>
EBITDA margin (%)	-4.1	-122.0	-14.1	-242.5	-33.5	-138.4	-43.0	-28.3	34.1	179.3	71.1	108.5
<b>EBIT</b>	<b>-2</b>	<b>-131.9</b>	<b>-6</b>	<b>-152.0</b>	<b>-13</b>	<b>-132.8</b>	<b>-18</b>	<b>-34.2</b>	<b>22</b>	<b>221.6</b>	<b>148</b>	<b>582.2</b>
EBIT margin (%)	-6.9	-141.4	-16.7	-144.1	-36.1	-115.6	-47.0	-30.3	31.6	167.2	69.1	118.7
<b>Financial result</b>	<b>-0</b>	<b>4.0</b>	<b>-0</b>	<b>-302.7</b>	<b>-0</b>	<b>-57.0</b>	<b>-0</b>	<b>31.7</b>	<b>-0</b>	<b>-80.9</b>	<b>-1</b>	<b>-212.0</b>
<b>EBT</b>	<b>-2</b>	<b>-132.4</b>	<b>-6</b>	<b>-153.7</b>	<b>-14</b>	<b>-131.4</b>	<b>-18</b>	<b>-33.3</b>	<b>22</b>	<b>220.8</b>	<b>256</b>	<b>n.m.</b>
Taxes	0	n.m.	0	n.m.	0	126.1	0	-100.0	4	n.a.	30	585.7
Tax rate (%)	-0.4	n.a.	1.6	n.a.	-0.2	n.a.	0.0	n.a.	19.8	n.a.	11.6	n.a.
Net income	-2	-132.5	-6	-148.8	-14	-135.6	-18	-33.1	17	196.9	226	n.m.
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	5	n.a.	5	0.0
<b>Net Income after minorities</b>	<b>-2</b>	<b>-132.3</b>	<b>-6</b>	<b>-158.7</b>	<b>-13</b>	<b>-127.4</b>	<b>-18</b>	<b>-33.6</b>	<b>17</b>	<b>195.8</b>	<b>118</b>	<b>585.7</b>
Number of shares outstanding (m)	10	6.1	11	10.5	11	0.0	15	36.4	15	0.0	15	0.0
<b>EPS adj. (EUR)</b>	<b>-0.23</b>	<b>-130.4</b>	<b>-0.54</b>	<b>-134.2</b>	<b>-1.22</b>	<b>-127.4</b>	<b>-1.20</b>	<b>2.0</b>	<b>1.14</b>	<b>195.8</b>	<b>7.85</b>	<b>585.7</b>
<b>DPS (EUR)</b>	<b>0.00</b>	<b>n.a.</b>	<b>0.00</b>	<b>n.a.</b>	<b>0.00</b>	<b>n.a.</b>	<b>0.00</b>	<b>n.a.</b>	<b>0.00</b>	<b>n.a.</b>	<b>0.00</b>	<b>n.a.</b>
Dividend yield (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
<b>Cash Flow (in EUR m)</b>	<b>2019</b>	<b>%</b>	<b>2020</b>	<b>%</b>	<b>2021</b>	<b>%</b>	<b>2022e</b>	<b>%</b>	<b>2023e</b>	<b>%</b>	<b>2024e</b>	<b>%</b>
<b>Gross Cash Flow</b>	<b>-1</b>	<b>-117.1</b>	<b>-5</b>	<b>-244.7</b>	<b>-12</b>	<b>-163.0</b>	<b>-16</b>	<b>-31.8</b>	<b>19</b>	<b>217.1</b>	<b>123</b>	<b>542.5</b>
Increase in working capital	1	n.a.	-1	n.a.	-1	n.a.	-1	n.a.	1	n.a.	-1	n.a.
<b>Capital expenditures</b>	<b>1</b>	<b>-4.9</b>	<b>1</b>	<b>14.1</b>	<b>1</b>	<b>5.6</b>	<b>1</b>	<b>-6.4</b>	<b>1</b>	<b>-39.7</b>	<b>2</b>	<b>212.0</b>
D+A/Capex (%)	90.1	n.a.	79.2	n.a.	77.3	n.a.	133.3	n.a.	250.0	n.a.	200.0	n.a.
<b>Free cash flow (Metzler definition)</b>	<b>-3</b>	<b>-326.6</b>	<b>-5</b>	<b>-83.1</b>	<b>-12</b>	<b>-132.2</b>	<b>-17</b>	<b>-34.7</b>	<b>17</b>	<b>203.8</b>	<b>122</b>	<b>604.7</b>
Free cash flow yield (%)	-0.9	n.a.	-0.9	n.a.	-1.9	n.a.	-1.6	n.a.	1.6	n.a.	11.5	n.a.
Dividend paid	0	n.a.	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>Free cash flow (post dividend)</b>	<b>0</b>	<b>n.a.</b>	<b>0</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>
<b>Balance sheet (in EUR m)</b>	<b>2019</b>	<b>%</b>	<b>2020</b>	<b>%</b>	<b>2021</b>	<b>%</b>	<b>2022e</b>	<b>%</b>	<b>2023e</b>	<b>%</b>	<b>2024e</b>	<b>%</b>
<b>Assets</b>	<b>54</b>	<b>35.2</b>	<b>76</b>	<b>41.2</b>	<b>66</b>	<b>-12.3</b>	<b>388</b>	<b>485.4</b>	<b>404</b>	<b>4.1</b>	<b>526</b>	<b>30.0</b>
<b>Goodwill</b>	<b>0</b>	<b>-26.7</b>	<b>0</b>	<b>-36.3</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>
<b>Shareholders' equity</b>	<b>48</b>	<b>45.0</b>	<b>68</b>	<b>41.1</b>	<b>56</b>	<b>-17.6</b>	<b>370</b>	<b>560.0</b>	<b>387</b>	<b>4.7</b>	<b>506</b>	<b>30.5</b>
Equity/total assets (%)	90.0	n.a.	90.0	n.a.	84.5	n.a.	95.3	n.a.	95.8	n.a.	96.2	n.a.
<b>Net Debt incl. Provisions</b>	<b>-22</b>	<b>-80.5</b>	<b>-42</b>	<b>-88.6</b>	<b>-25</b>	<b>40.0</b>	<b>-10</b>	<b>60.7</b>	<b>-24</b>	<b>-144.0</b>	<b>-144</b>	<b>-488.1</b>
thereof pension provisions	0	n.a.	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Gearing (%)	-46.6	n.a.	-62.3	n.a.	-45.3	n.a.	-2.7	n.a.	-6.3	n.a.	-28.4	n.a.
Net debt/EBITDA	16.5	n.a.	8.8	n.a.	2.1	n.a.	0.6	n.a.	-1.0	n.a.	-0.9	n.a.

Sources: Bloomberg, Metzler Research

# company note

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Date of dissemination	Metzler recommendation *		Current price **	Price target *	Author ***
	Previous	Current			
<b>Issuer/Financial Instrument (ISIN): Formycon (DE000A1EWVY8)</b>					
07.09.2022	Buy	Buy	71.10 EUR	85.00 EUR	Diedrich, Tom
19.05.2022	Buy	Buy	69.50 EUR	88.00 EUR	Diedrich, Tom
08.04.2022	Buy	Buy	63.50 EUR	88.00 EUR	Diedrich, Tom
22.10.2021	Buy	Buy	54.00 EUR	86.00 EUR	Diedrich, Tom
05.10.2021	Buy	Buy	50.70 EUR	86.00 EUR	Diedrich, Tom

\* Effective until the price target and/or investment recommendation is updated (FI/FX recommendations are valid solely at the time of publication)

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\*\*\* All authors are financial analysts

### Formycon

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# company note

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