

## Formycon

Pharma & biotech

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### Two submissions and two Phase III trials in 2021

Formycon continues to progress three core biosimilar projects. In H220, it is preparing the FYB201 (Lucentis biosimilar) EMA approval submission and helping in the resubmission of FYB201 to the FDA. FYB203 (Eylea biosimilar) entered Phase III in August. FYB202 (Stelara biosimilar, autoimmunity) is due to enter Phase III imminently. Development income from partners was €16.5m in H120, giving a loss of €1.4m and a cash outflow of €2.1m. Cash was €20.3m on 30 June.

### Two projects, FYB201 and FYB203, targeting nAMD

Formycon has two biosimilar projects targeting the neovascular age-related macular degeneration (nAMD) market. The global exclusive partner for FYB201 is Bioeq, which has licensed US sales to Coherus, a fast-growing biosimilar specialist. Preparations for a 351(k) BLA re-submission to the FDA are ongoing. An EMA submission is also being prepared and an EU sales partner might be announced – although there is no guidance. Lucentis sales were \$3.9bn in 2019. Formycon's Eylea biosimilar FYB203, also for nAMD, is partnered by Klinge. Phase III (400 patients) started in August 2020 ([NCT04522167](#)) and completes in Q321. Sales of Eylea were \$7.5bn in 2019. Formycon foresees a very valuable nAMD market for biosimilars. Initial sales of competitor Beovu (brolucizumab, Novartis), approved in October 2019, have collapsed due to safety concerns. Two other Lucentis biosimilars in late development have strong marketing partners.

### Autoimmunity biosimilar progressing into Phase III

FYB202 (a Stelara biosimilar for Crohn's disease, ulcerative colitis and psoriasis) is guided to start Phase III imminently. FYB202 is being developed through a joint venture deal with Aristo Pharma; Formycon owns 24.9%. Stelara (2019 sales \$6.4bn) has a different mode of action from anti-TNF agents like Humira (\$19bn in 2019 but falling sales in Europe due to biosimilars) so should be somewhat protected from the fierce anti-TNF competition. Formycon funds its share of the JV costs and shares future profits so this project could be very lucrative with controlled risk. Stelara patents expire in 2023 (in the US) and 2024 (in the EU).

### Valuation: project progression in 2021

Formycon's market cap is about €304m with an EV of €285m. Restarting the FDA regulatory review of FYB201 plus filing with the EMA in 2021, the FYB203 Phase III started in August and the imminent start of the FYB202 Phase III should add further value in 2021 especially as these are much lower risk, relatively short trials. Newsflow over H221 and H122 could be very strong. Formycon is well capitalised with strong partner revenues funding development, with the opportunity for a steady future royalty stream and more potential preclinical projects to build further value.

#### Historical and consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/18	43.00	7.10	0.77	0.0	N/A	N/A
12/19	33.16	(2.27)	(0.23)	0.0	N/A	N/A
12/20e	38.45	(2.23)	(0.23)	0.0	N/A	N/A
12/21e	38.20	(6.65)	(0.43)	0.0	N/A	N/A

Source: Refinitiv consensus estimates, Formycon reports

**Price** €30.5  
**Market cap** €305m

#### Share price graph



#### Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	10m
Cash at 30 June 2020	€20.3m

#### Business description

Formycon is focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar awaiting FDA resubmission and EMA filing. FYB202, a biosimilar candidate of Stelara, is in a joint venture and could enter Phase III in Q420. FYB203, an Eylea biosimilar, entered Phase III in Q320.

#### Bull

- Leading biosimilars company addressing markets worth \$17.8bn in 2019.
- Two partnered products plus JV deal.
- Strong cash position with revenues.

#### Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market still maturing.
- Biosimilar competition likely for FYB201

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## Financials: H120 results review

Formycon reported H120 development payments of €16.5m (FY19 €33.2m). The H120 operating loss was €1.4m. We expect product revenues (as royalties and milestones) from 2022-23, which could enable a move towards profit, depending on investments in new projects.

The FYB202 project is run by a joint venture company (undisclosed financials), which requires periodic investment. There was no H120 investment (vs an investment of €4.7m in H119). The balance sheet value of this shareholding remains at €20.7m. There might be a further cash investment in 2021 to fund the Phase III. Formycon commented that further investment can be funded from revenues and cash.

Formycon's share capital of €10m is unchanged since December 2019.

The H120 operating outflow was €1.3m (vs an outflow of €1.5m in FY19). Cash and cash equivalents decreased by €2.12m from €22.35m (€22.11m cash plus €0.3m securities) on 31 December 2019 to €20.23m (€20m cash plus €0.24m securities) as at 30 June 2020.

<b>Exhibit 1: Financial summary</b>					
<b>Year-end 31 December (€m)</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>H120</b>
<b>Income statement</b>					
<b>Revenue</b>	<b>19.53</b>	<b>29.43</b>	<b>43.00</b>	<b>33.26</b>	<b>16.51</b>
Profit before tax (as reported)	(4.06)	(1.58)	7.10	(2.27)	(1.35)
<b>Net income (as reported)</b>	<b>(4.07)</b>	<b>(1.58)</b>	<b>7.10</b>	<b>(2.29)</b>	<b>(1.38)</b>
EPS (€)	(0.46)	(0.17)	0.77	(0.23)	(0.13)
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00
<b>Balance sheet</b>					
Total non-current assets	4.40	4.11	15.97	20.67	20.67
Total current assets	20.80	26.72	19.49	32.88	31.51
<b>Total assets</b>	<b>25.19</b>	<b>30.83</b>	<b>39.70</b>	<b>53.55</b>	<b>52.18</b>
Liabilities	(3.58)	(4.01)	(3.38)	(3.47)	(4.14)
Provisions	(0.72)	(1.27)	(2.85)	(1.89)	(1.21)
<b>Total liabilities</b>	<b>(4.30)</b>	<b>(5.28)</b>	<b>(6.23)</b>	<b>(5.34)</b>	<b>(5.35)</b>
Net assets	20.89	25.54	33.30	48.21	46.83
<b>Shareholders' equity</b>	<b>20.89</b>	<b>25.54</b>	<b>33.30</b>	<b>48.21</b>	<b>46.83</b>
<b>Cash flow statement</b>					
Net cash from operating activities	(5.04)	(4.20)	13.30	(1.48)	(1.74)
Net cash from investing activities	(1.35)	(0.51)	(17.03)	(5.71)	(0.36)
Net cash from financing activities	0.06	6.20	0.56	17.24	(0.00)
<b>Net cash flow</b>	<b>(6.33)</b>	<b>1.51</b>	<b>(3.17)</b>	<b>10.05</b>	<b>(2.12)</b>
<b>Cash &amp; cash equivalent end of year</b>	<b>13.97</b>	<b>15.48</b>	<b>12.31</b>	<b>22.35</b>	<b>20.23</b>

Source: Formycon accounts.

## Three key projects in regulatory or Phase III stages

Formycon's lead project is FYB201, a biosimilar to Lucentis and licensed to Bioeq. FYB201 is being prepared for FDA 351(k) BLA resubmission after the February 2020 withdrawal. This was caused by a change made by the contract manufacturer and is not otherwise product related. The EMA submission is being prepared.

The FYB202 project (Stelara biosimilar) entered Phase I in October 2019. Preparations for the start of the Phase III clinical trial were run and the trial should start enrolment in Q420.

The Eylea biosimilar, FYB203 entered a 400 patient Phase III ([NCT04522167](#)) in August 2020.

Further projects are undisclosed beyond a name: FYB206. A further project (FYB207) is an early development of an antibody candidate to act as a possible prophylactic treatment to prevent or

alleviate SARS CoV-2 infection, for example, amongst healthcare workers. This product might have utility as in-treatment regimen.

The three main projects with identified targets (FYB201, FYB202, FYB203) are each in a deal or joint venture. Although we cite the reference product sales for each project, the biosimilar prices, and so market sizes, will be typically lower by c 15–20% initially and possibly 30–50% if competition is fierce. For approval, a biosimilar must show comparable safety, efficacy and immunogenicity to the original 'reference' products so there should be no reason for prescribers not to switch.

The FDA is keen to make biosimilars available and to enable [interchangeability](#) with reference products. Guidance was issued in 2019.

A new set of [EU rules](#) were approved on 20 May 2019 and allow potential competitors to manufacture biosimilars in Europe from six months before the patent and any supplementary protection expires. Formycon does not expect this to affect the launch of FYB201, but it may enable more rapid launches for other products. The EMA issued more [general information](#) on its approach to biosimilars in October 2019.

## Valuation: Clear pipeline and solid financial position

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Formycon's market cap is €304m with about €1.2m of long-term liabilities. Adding liabilities and subtracting €20.2m cash gives an EV of about €285m (from €232m as of December 2019). Formycon's portfolio is progressing with FYB201 expected to be undergoing both FDA and EMA review during 2021. Two Phase III studies should be running in 2021 on FYB202 (imminent) and FYB203 (underway). The FYB202 joint venture (Formycon share 24.9%) is funded by current resources.

## Investment case summary

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We believe that Formycon should become one of the leading biosimilar companies as its portfolio develops and its projects mature. Formycon has a robust financial position with high development revenues covering most costs, cash for investment and a pipeline targeting major global markets. It can now develop its own proprietary pipeline, which should add further value: we note the FYB206 and FYB207 preclinical projects. We noted previously that there can be technical risks and delays in development for its biosimilars, and unforeseeably some of these became apparent with FYB201 although that could soon be behind the company. The development risks are still much lower than mainstream novel therapeutics.

The main uncertainties are on exact product launch dates, competition, the legal position on patents in some cases and countries, and the ability of partners to market effectively in large, complex global markets. The latter has become a major factor given that the US marketing partner for FYB201 and the potential competitive situation are now clearer. As yet, there is no FYB201 European partner. The lack of clarity on the US and EU returns to Formycon from Bioeq remains an investment uncertainty.

For maximum value potential, Formycon needs to take more financial risk and to fund projects itself. For example, the FYB202 JV could yield higher than normal revenues due to the 24.9% profit share compared to a standard royalty deal but this carries a financial risk. However, all projects should yield steady revenues once marketed and depending on partner commercial success.

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