

Formycon

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H117 results show further business progress

In H117 Formycon disclosed that FYB202 is a proposed biosimilar of Stelara and it recently announced that it is in the process of entering into a co-investment agreement with Santo Holding to advance FYB202 through regulatory approval. The global Phase III study of Lucentis biosimilar FYB201 for neovascular age-related macular degeneration (nAMD) is progressing according to plan with US and EU launches slated for 2020 and 2022. Lastly, FYB203 (Eylea biosimilar) and FYB205 (undisclosed) are advancing in preclinical studies. Cash and equity at end H117 was €14.4m.

Stelara biosimilar disclosed and partnership close

Formycon disclosed that FYB202 is a proposed biosimilar candidate of Stelara (ustekinumab, 2016 sales \$3.2bn). Stelara is indicated for plaque psoriasis, psoriatic arthritis and Crohn's disease. EvaluatePharma's consensus forecasts predict a market of \$4.5bn in 2020. Stelara's patent protection ends in 2023 in the US and 2024 in the EU. Executing on its strategy, Formycon is in the process of partnering FYB202 with Santo Holding; according to the signed term sheet, it will have a 30% participation in total costs and revenue.

Phase III of Lucentis biosimilar approaches milestone

Formycon and its partner Bioeq IP continue the global Phase III clinical trial of lead asset FYB201, a biosimilar of Lucentis (2016 revenues \$3.2bn). Formycon expects to achieve an undisclosed key milestone in the near future. Total development, regulatory and commercial milestones could be over three-digit million euros. The companies' aim is to launch in the US in mid-2020 and the EU in 2022 on Lucentis' patent expiration. We continue to view FYB201 as a potential first-to-market mover, as competitors are behind.

Eylea biosimilar candidate and FYB205 on track

FYB203 is a proposed biosimilar of Eylea for nAMD (2016 sales \$5bn); it is partnered with Santo Holding in a deal that involves an upfront payment of single-digit million euros and ongoing payments for its product development activities up to regulatory approval; sales revenue may reach double digits per annum. Eylea patents expire in 2023 in the US and 2025 in the EU. With no other known competitors, we believe Formycon is uniquely positioned in the growing Eylea market. FYB205 is an undisclosed biosimilar in preclinical phase and unpartnered.

Valuation: Shares up c 50% year-to-date

Formycon's current market cap is c €330m and enterprise value (EV) is c €310m. Progression of the pipeline and additional partnerships may unlock further value.

Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/15	17.30	0.60	N/A	0.0	N/A	N/A
12/16	19.53	(4.06)	(0.44)	0.0	N/A	N/A
12/17e	26.60	(0.10)	(0.01)	0.0	N/A	N/A
12/18e	28.65	(0.20)	(0.02)	0.0	N/A	N/A

Source: Bloomberg consensus estimates, Formycon data

Price €36.5
Market cap €341m

Share price graph



Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue (post July 2017 equity raise)	9.3m
Cash at end June 2017	€14.4m

Business description

Formycon is a biotechnology company focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar in Phase III; FYB203 is an Eylea biosimilar in the preclinical stage. They are both partnered. FYB202, a biosimilar candidate of Stelara is in the process of being partnered. It also has an undisclosed biosimilar FYB205, unpartnered.

Bull

- Leading biosimilars company addressing an \$11-12bn market.
- Two partnered products and an additional agreement in preparation in potential multi-million euro deals.
- Potential first-to-market advantage for FYB201.

Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market immature.
- Lucentis market declined in 2014-16.

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H117 results review

Formycon's revenues in the first half of the year were €8.10m (vs €8.76m in H116) mainly due to the two out-licensed products, FYB201 and FYB203. In line with previous guidance, the company expects to generate revenues of €25m for FY17. Implementation of the term sheet for FYB202 in H217 will contribute towards this target and improve the baseline results for the company.

Operating expenses were €11.02m in H117 (vs €10.02m in H116) which includes research and development activities for FYB202. The company expects R&D expenses to increase towards the end of FY17 as development of its product pipeline continues. Formycon reported an operating loss of €2.88m in H117 vs €1.17m in H116. The net result was a loss of €2.91m in H117 compared to €1.18m in H116. The company generated €470k in cash due to a change in inventories and trade receivables of €4.27m following a switch in the invoice cycle. Cash and equivalents was €14.42m at end H117, which does not include an additional €6m raised in July 2017 when the company issued 190.5k shares at €31.5/share (2% of the share capital). Formycon has no financial debt.

Exhibit 1: Financial summary					
Year end 31 December (€m)	2013	2014	2015	2016	H117
Income statement					
Revenue	0.40	12.70	16.9	19.53	8.10
Profit before tax (as reported)	(7.77)	0.87	0.60	(4.06)	(2.91)
Net income (as reported)	(7.77)	0.87	0.60	(4.07)	(2.91)
EPS (as reported) (€)	N/A	N/A	N/A	N/A	N/A
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00
Balance sheet					
Total non-current assets	6.25	4.03	3.74	4.40	4.30
Total current assets	10.90	12.88	23.41	20.80	16.95
Total assets	17.20	16.91	27.15	25.19	21.25
Total current liabilities	(2.70)	(3.26)	(1.61)	(3.58)	(2.28)
Total non-current liabilities	(0.50)	(0.53)	(0.66)	(0.72)	(0.98)
Total liabilities	(3.19)	(3.80)	(2.28)	(4.30)	(3.26)
Net assets	13.90	13.11	24.87	20.89	17.99
Shareholders' equity	13.90	13.11	24.87	20.89	17.99
Cash flow statement					
Net cash from operating activities	(16.62)	(0.03)	0.52	(5.04)	0.76
Net cash from investing activities	(0.04)	(0.57)	(0.60)	(1.35)	(0.29)
Net cash from financing activities	17.43	(0.01)	11.15	0.06	(0.02)
Net cash flow	0.68	(0.61)	11.07	(6.33)	0.45
Cash & cash equivalent end of year	0.90	0.29	20.30	13.97	14.42

Source: Formycon accounts

Valuation

Due to successful business execution, Formycon's share price has increased by nearly 50% year-to-date, with the market cap rising from €222m to c €330m. This translates into an enterprise value (EV) of c €310m, including the recent €6m raise. The company has two assets (FYB201 and FYB203) targeting the entire biologics nAMD market, which had global sales of \$8.2bn in 2016 and is projected to reach c \$10bn in 2020 according to EvaluatePharma. Assuming a 50% discount to the potential market size and applying a 50% penetration for biosimilars, the overall target market for Formycon's nAMD products would be c \$2.5bn, on which Formycon may potentially receive royalties and milestones. As an example, Stelara had sales of \$3.2bn in 2016 and EvaluatePharma's consensus forecast is c \$4.9bn in 2022. Using the same assumptions as above, the potential market for a biosimilar of Stelara (such as FYB202) would be c \$1.25bn in 2023 when the patent expires. We also believe that the valuation reflects the background, expertise and successful track record of the company's management. Progression of the pipeline in the clinic and additional partnerships should unlock further value.

In our view, Formycon's closest peers are Pfenex (market cap €62m; EV €12m at a \$1.17/€ exchange rate), Xbrane (market cap €61.3m; EV €13.7m at a SEK9.6/€ exchange rate) and Coherus BioSciences (market cap €582m; EV €546m at a \$1.17/€ exchange rate). However, relative valuation metrics, such as P/E, are difficult to assess, given the early-stage and often loss-making nature of these development companies. Furthermore, all are at different stages of development with multiple assets in the pipeline, further complicating any peer group comparisons.

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