Formycon

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Lucentis biosimilar scores Phase III success

Formycon has announced that its Lucentis biosimilar FYB201 showed comparable efficacy with branded Lucentis in a global Phase III study in nAMD. With positive data in hand, the launch of FYB201 remains on track for 2020 (US) and 2022 (EU), ahead of most competitors. Formycon has also signed a JV (24.9% stake) with Aristo to develop its Stelara biosimilar FYB202 for approval. Lastly, Eylea biosimilar FYB203 and undisclosed FYB205 are advancing in preclinical studies. End-2017 cash was €15.5m.

Lucentis biosimilar on track for global launch

FYB201 has met the primary endpoint of comparable change in visual acuity at eight weeks compared to Lucentis in the global COLUMBUS-AMD Phase III study. FYB201 is partnered with Bioeq IP in a deal worth over €100m. Bioeq IP, which holds exclusive global marketing rights to FYB201, is seeking marketing partners and aims to launch the product in mid-2020 (US) and 2022 (EU) on patent expirations. Sales of Lucentis were $3.3bn in 2017. Pfenex, Xbrane and Intas are at an earlier stage of development. Samsung Bioepis has an ongoing Phase III, and is the closest rival.

Joint venture with Aristo for Stelara biosimilar

The 24.9/75.1% JV reflects each company's share of expenses and eventual revenues from Stelara biosimilar. It will run a pilot study before embarking on full clinical development until registration of FYB202. We expect the JV to license the asset for commercialisation. Stelara is indicated for psoriasis and Crohn's disease. Patent protection extends to 2023 (US) and 2024 (EU). 2017 sales were $4bn.

Eylea biosimilar candidate approaching the clinic

Formycon and Santo are advancing Eylea biosimilar FYB203 through preclinical studies with the aim of entering clinical trials for nAMD (timeline not provided). The deal 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 pa. Eylea patents expire in 2023 (US) and 2025 (EU). 2017 revenue was $6.3bn. Mylan and Momenta Pharmaceuticals plan to start a pivotal trial of their Eylea biosimilar in H118. Alteogen's ALT-L9 and Coherus's CHS-2020 are preclinical-stage biosimilars of Eylea.

Valuation reflects progression

Formycon's market cap is c €362m and enterprise value (EV) is c €347m. The investment case rests on pipeline progression and additional partnerships.

Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/16	19.53	(4.06)	(0.46)	0.0	N/A	N/A
12/17	29.43	(1.58)	(0.17)	0.0	N/A	N/A
12/18e	28.65	(0.25)	(0.02)	0.0	N/A	N/A
12/19e	27.10	(3.00)	(0.32)	0.0	N/A	N/A

Source: Bloomberg consensus estimates, Formycon data

Price	€38.8
Market cap	€362m

Share price graph

Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	9.34m
Cash at end December 2017	€15.5m

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 being developed in a JV with Aristo Pharma. It also has an undisclosed biosimilar, FYB205, unpartnered.

Bull

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

Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market still immature.
- Lucentis market declined in 2014-17.

Analysts

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Financials: FY17 results

Revenues increased to €29.43m from €19.53m in 2016. This exceeded the company's guidance of €25m, mainly due to payments received from Aristo Pharma associated with the JV. Sales come mainly from the partnering agreements for FYB201 and FYB203. Formycon has guided for the same revenue levels in 2018 as 2017. We believe that revenues will continue to be dependent on current and future potential partnerships, which may involve FYB202.

Total expenses increased to €31m in 2017 from €23.7m in 2016, mostly due to increased personnel expenses (the number of employees increased from 70 to 83) and third-party services (from €8.47m to €18.7m), which relate to the advancement of its development programmes. EBITDA loss was €0.75m vs a loss of €3.37m in 2016 and the net loss was €1.58m vs €4.07m in 2016. These improvements are due to the increase in revenues.

Cash burn in 2017 was €4.68m vs €6.40m in 2016. Formycon raised €6m in July 2017 in a private placement mainly intended to advance FYB202. Cash and equivalents were €15.48m at end December 2017. Short-term receivables were c €10.6m. Formycon has no financial debt.

Exhibit 1: Financial summary

Year end 31 December (€m)	2013	2014	2015	2016	2017
Income statement					
Revenue	**0.40**	**12.70**	**16.9**	**19.53**	**29.43**
Profit before tax (as reported)	(7.77)	0.87	0.60	(4.06)	(1.58)
Net income (as reported)	**(7.77)**	**0.87**	**0.60**	**(4.07)**	**(1.58)**
EPS (as reported)* (€)	(0.90)	0.10	0.06	(0.46)	(0.17)
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	4.11
Total current assets	10.90	12.88	23.41	20.80	26.72
Total assets	**17.20**	**16.91**	**27.15**	**25.19**	**30.83**
Total current liabilities	(2.70)	(3.26)	(1.61)	(3.58)	(4.01)
Total non-current liabilities	(0.50)	(0.53)	(0.66)	(0.72)	(1.27)
Total liabilities	**(3.19)**	**(3.80)**	**(2.28)**	**(4.30)**	**(5.28)**
Net assets	13.90	13.11	24.87	20.89	25.54
Shareholders' equity	**13.90**	**13.11**	**24.87**	**20.89**	**25.54**
Cash flow statement					
Net cash from operating activities	(16.62)	(0.03)	0.52	(5.04)	(4.20)
Net cash from investing activities	(0.04)	(0.57)	(0.60)	(1.35)	(0.51)
Net cash from financing activities	17.43	(0.01)	11.15	0.06	(6.20)
Net cash flow	**0.68**	**(0.61)**	**11.07**	**(6.33)**	**1.51**
Cash & cash equivalent end of year	**0.90**	**0.29**	**20.30**	**13.97**	**15.48**

Source: Formycon accounts, *Bloomberg

Valuation

Formycon's market cap is c €362m and enterprise value (EV) is c €347m. The share price has risen 15% year to date. The company has two assets (FYB201 and FYB203) targeting the entire biologics neovascular age-related macular degeneration (nAMD) market, comprising Lucentis and Eylea. Lucentis had sales of $3.3bn in 2017, projected to reach $3bn in 2020 according to EvaluatePharma's (EP) consensus forecast. Eylea's 2017 sales were $6.3bn, expected to reach $7.5bn in 2020 (source: EP). Assuming a 50% discount and 50% penetration for biosimilars, the target market for Formycon's nAMD products would be $2.62bn, on which Formycon may receive royalties and milestones. Stelara had sales of $4bn in 2017 and EP's consensus forecast is c $6.67bn in 2023 when the patent expires. Using the same assumptions, the potential market for a Stelara biosimilar (eg FYB202) would be c $1.67bn. The company plans to partner the undisclosed biosimilar FYB205 in the future. We also believe that the valuation reflects the background,

expertise and successful track record of the company's management. The investment case rests on the progression of the pipeline in the clinic and additional partnerships.

In our view, the closest peers are Pfenex (market cap $150m; EV $75.5m), Xbrane (market cap SEK371.7m; EV SEK362m), Coherus BioSciences (market cap $938m; EV $741m) and Samsung Bioepis (private). However, these companies are at different stages of development with several other assets in the pipeline, which complicates any peer group comparison. Furthermore, relative valuation metrics, such as P/E, are difficult to assess, given the early-stage and often loss-making nature of these development companies.

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