Formycon

H118 results: FYB201 registration closer

Formycon has reported record H118 revenues, boosted by the one-off transfer of FYB202 into a joint venture with Aristo Pharma and payments stemming from the out-licensed assets FYB201 and FYB203. We believe that Formycon biosimilars FYB201 (Lucentis) and FYB203 (Eylea) are set to enter neovascular age-related macular degeneration (nAMD) market post-2020. Cash and equivalents at end-H118 were €11.8m and should give a cash runaway until 2020 based on H118 cash burn. Formycon guides for FY18 revenues of €35m.

FYB201 on track to lead Lucentis biosimilars

In May 2018, Formycon announced that the primary endpoint in the COLUMBUS-AMD Phase III study of FYB201 had been met. The last patient completed treatment in June 2018; Formycon expects to release further information in H218. Partner Bioeq IP (which holds exclusive global rights to FYB201 in a €100m+ deal) will use these data for regulatory filings in the US and EU, and aims to launch the product in 2020 (US) and 2022 (EU) on patent expiration(s). Global Lucentis sales increased in H118 to $1.9bn (H117: $1.7bn), but have fallen since H114 ($2.1bn), reflected in part by the increased use of Eylea and continued off-label use of Avastin in nAMD. We believe this may introduce some uncertainly into the sales of Lucentis, but think the case for a low-cost alternative in the form of a biosimilar of the branded Lucentis remains strong.

Moving further along in nAMD and beyond

Formycon's Eylea biosimilar FYB203 (out-licensed to Santo Holding) is in advanced preclinical studies with the aim of entering clinical trials for nAMD (timeline not provided). Total development, regulatory and commercial milestones could be over three-digit million euros. Global sales of Eylea were $3.3bn in H118 (H117: $2.8bn). Eylea patents expire in 2023 (US) and 2025 (EU). With other innovative treatments set to enter the nAMD market over the coming years, developing (and out-licensing) assets outside nAMD will be key to mitigating their risk and diversifying future revenue streams. The execution of the FYB202 (Stelara biosimilar) deal with Aristo Pharma is evidence of this; we think that near-term updates on FYB202 and, in the longer term, on FYB205 (undisclosed biosimilar), are important for growth.

Valuation: Share price flat year to date

Formycon's market cap is c €301m and its EV is c €289.2m. Progression of assets in nAMD and additional indications will be key drivers for adding value.

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	33.60	2.70	0.29	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

Pharma & biotech

27 September 2018

Price	€32.05
Market cap	€301m

Share price graph

Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	9.4
Cash and cash equivalents at end-June 2018	€11.8m

Business description

Formycon is a biotechnology company focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar that has completed Phase III; FYB203 is an Eylea biosimilar in the preclinical stage. They are both out-licensed. FYB202, a biosimilar candidate of Stelara, is being developed in a joint venture with Aristo Pharma. Formycon also has an undisclosed biosimilar, FYB205.

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 sale declined since 2014.

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Financials: H118 results review

Formycon reported revenues of €25.4m in H118 (vs €8.1m in H117). This was primarily driven by inward cash flow from the compensation for development work received for out-licensed projects. This was further boosted by rebooking and the transfer of IP associated with FYB202 into the joint venture with Aristo Pharma (€8.5m non-cash). The company guides for FY18 revenue of €35m.

Total operating expenses increased to €17.3m in H118 from €11.0m in H117, mostly due to increased third-party services, which relate to the clinical and preclinical development of its products. Net income was €7.6m vs a loss of €2.9m in H117. Formycon generated €12.9m cash from operations, vs c €0.8m in H117, resulting in cash and equivalents of €11.8m at end-H117. Formycon has no financial debt.

Exhibit 1: Financial summary

Year-end 31 December (€m)	2014	2015	2016	2017	H118
Income statement					
Revenue	**12.70**	**16.92**	**19.53**	**29.43**	**25.41**
Profit before tax (as reported)	0.87	0.60	(4.06)	(1.58)	8.21
Net income (as reported)	**0.87**	**0.60**	**(4.07)**	**(1.58)**	**7.59**
EPS (as reported)* (€)	0.10	0.06	(0.46)	(0.17)	0.83
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00
Balance sheet					
Total non-current assets	4.03	3.74	4.40	4.11	20.27
Total current assets	12.88	23.41	20.80	26.72	21.83
Total assets	**16.91**	**27.15**	**25.19**	**30.83**	**42.20**
Total current liabilities	(3.26)	(1.61)	(3.58)	(4.01)	(6.56)
Total non-current liabilities	(0.53)	(0.66)	(0.72)	(1.27)	(2.51)
Total liabilities	**(3.80)**	**(2.28)**	**(4.30)**	**(5.28)**	**(9.07)**
Net assets	13.11	24.87	20.89	25.54	33.13
Shareholders' equity	**13.11**	**24.87**	**20.89**	**25.54**	**33.13**
Cash flow statement					
Net cash from operating activities	(0.03)	0.52	(5.04)	(4.20)	12.92
Net cash from investing activities	(0.57)	(0.60)	(1.35)	(0.51)	(16.56)
Net cash from financing activities	(0.01)	11.15	0.06	6.20	(0.02)
Net cash flow	**(0.61)**	**11.07**	**(6.33)**	**1.51**	**(3.66)**
Cash & cash equivalent end of year	**0.29**	**20.30**	**13.97**	**15.48**	**11.82**

Source: Formycon accounts, *Bloomberg

Valuation

Formycon's market cap is c €292.4m and EV is c €280.6m; the share price has remained flat year-to-date despite positive news on the development of FYB201. We believe that Formycon's product candidates are well positioned to capture a significant portion of the biologics nAMD market, which is forecast to reach c $10bn in 2020, according to Evaluate Pharma. However, there is a degree of uncertainty surrounding how much of the market assets FYB201 (Lucentis biosimilar) and FYB203 (Eylea biosimilar) can capture (and, by extension, revenue from royalties).

For example, positive Phase III readouts for Novartis's anti-VEGF single chain antibody fragment (RTH258) and a planned regulatory filling during H218 could see the top-line treatment for nAMD move beyond Eylea before commercialisation of FYB203 is realised (post patent expiries in 2023).In conjunction to this, a recent (September 2018) landmark ruling by UK courts (which deemed off-label use of Avastin lawful) could see sales of Lucentis continue to decline, introducing further uncertainty into the peak sales that FYB201 could capture. This being said, both Eylea and Lucentis are well established in the clinic and are still likely to maintain multi-billion dollar sales until their patents expire. Favourably priced biosimilars (ie FYB201 and FYB203), which can

demonstrate safety and efficacy in-line with these treatments, are likely to capture a significant portion of their sales and may even provide economical alternatives to dissuade the off-label use of Avastin, which is not licensed for the treatment of nAMD.

Achieving first-to-market status for out-licensed assets FYB201 and FYB203 will be important for maximising revenues if they reach commercialisation (post clinical and regulatory hurdles). We see competition in the Lucentis biosimilar market primarily from Samsung Bioepis's SB11 (currently in Phase III); Xbrane's Xlucane and Coherus's CHS-3351, which are in the early stages of development. We continue to believe that Formycon has a potential first-to-market advantage for a biosimilar of Lucentis in regulated markets. For FYB203 (Eylea), competition comes primarily from Mylan's and Momenta Pharmaceuticals' M710, which is ready to start pivotal clinical trials. Alteogen's ALT-L9 and Coherus's CHS-2020 are in early stages of development and it is not clear whether they intend to enter the same regulated markets as Formycon.

Outside nAMD, we believe that near-term updates on FYB202 and, in the longer term, on FYB205 will provide further upside.

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