EDISON

Formycon

Pharma & biotech

FYB201 FDA filing imminent

Formycons global partner Bioeq IP plans to file FYB201, a Lucentis biosimilar candidate, to treat neovascular age-related macular degeneration (nAMD), with the FDA imminently in Q419. Bioeq has exclusively licensed US marketing rights for FYB201 to Coherus BioSciences, which plans to launch it in 2021. EU launch is planned for 2022. H119 revenues were €17.2m from partners for product development services. There are three main projects. Bioeq/Coherus BioSciences is the partner on FYB201, Santo on FYB203 (an Eylea biosimilar candidate) and there is a joint venture with Aristo Pharma on FYB202 (a Stelara biosimilar candidate). FYB202 has started its Phase I trial. Formycon guides for FY19 revenues of about €35m. End-September cash was €9.6m, plus €19.6m in other liquid assets, including the final €12.3m of proceeds from the €17.3m private placing in March 2019.

FYB201 and FYB203 target the major nAMD markets

Formycon has two biosimilar projects targeting the nAMD market. Based on positive 2018 data, exclusive global partner, Bioeq, plans to make a US regulatory filing in Q419. If approved, US partner Coherus will market and distribute FYB201. A regulatory filing in the EU is expected in Q120 with an EU launch possible in 2022. Global 2018 Lucentis sales rose 9% to $3.7bn. Formycon's preclinical Eylea biosimilar candidate, FYB203, also for nAMD, is licensed to Santo in a deal worth over €100m according to management. Global sales of Eylea were $6.7bn in 2018; core patents expire in 2023 (US) and 2025 (EU). Formycon assumes a strong biosimilar demand due to healthcare cost pressures.

A stellar opportunity through a JV

Formycon has made progress on FYB202 (a Stelara biosimilar for Crohn's disease, psoriasis and ulcerative colitis) through a joint venture with Aristo Pharma; Formycon owns 24.9%. Stelara (2018 sales $5.2bn) has a different mode of action to anti-TNF agents (lead product Humira, $19.9bn in 2018) so should be protected from the competition developing in the anti-TNF area. Phase I trial has initiated. Formycon needs to fund its share of the costs, €4.7m in H1, but shares the profits so this could be lucrative. Stelara patents expire in 2023 (US) and 2024 (EU).

Valuation: Yet to reflect likely progress from Q419

Formycon's market cap is about €310m with an effective EV of €290m. Starting the regulatory review of FYB201 in Q4 should add value. Including cash, unpaid placing proceeds and trade receivables, September liquid assets were €29.2m.

Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/17	29.4	(1.58)	(0.17)	0.0	N/A	N/A
12/18	43.0	7.10	0.77	0.0	43.1	N/A
12/19e	39.4	(3.77)	(0.40)	0.0	N/A	N/A
12/20e	40.4	(7.01)	(0.74)	0.0	N/A	N/A

Source: Refinitiv consensus estimates, Formycon data

Price	**€33.2**
Market cap	**€332m**

Share price graph

Share details

Code	FYB
Shares in issue	10m
Cash at end September 2019	€9.6m

Business description

Formycon is a biotechnology company developing biosimilars. The main lead is FYB201, a Lucentis biosimilar candidate that has completed Phase III and is entering regulatory review. FYB203 is an Eylea candidate biosimilar in preclinical trials. They are both out-licensed. FYB202, a biosimilar candidate of Stelara, is being developed in a joint venture.

Bull

- Leading biosimilars company addressing markets worth $15.6bn in 2018.
- Two partnered products plus JV deal.
- Potential first-to-market advantage for FYB201 with sales partner Coherus.

Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market still immature.
- No apparent Bioeq sales capability yet.

Analysts

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