

Formycon

Biosimilar opportunities

Formycon is preparing to exploit the emerging opportunity for biosimilars. By 2020, protein-based therapeutics with sales of >\$70bn will lose patent protection. Its first two biosimilar programmes are progressing well and could be partnered in 2015. There should be significant demand for Formycon products because of the size of the markets and the challenges of developing biosimilar products with the correct characteristics.

First biosimilars could be partnered in 2015

Formycon is focused on using its knowledge of protein-based therapeutics to develop biosimilars to compete against established branded products once they are not protected by patents. Its first two biosimilar programmes are under way and it is preparing to expand its product and technology pipeline. The first programme could be partnered in mid-2015 after completion of Phase I, the key value inflection point for biosimilars, and the second six months later.

Formycon has expertise to develop biosimilars

The development costs and risks associated with biosimilars are lower than with novel biologicals and a product can enter the clinic in only two years. However, the process is much more complicated than that of generics for small molecules, so the price of biosimilars will probably be c 30% below the branded original. Formycon's experience in analysing protein structures in detail and its extensive libraries of cell lines should enable it to produce biosimilars with characteristics sufficiently similar to the original drug.

Biologicals with sales of >\$70bn to face competition

Biologic drugs with sales of over \$70bn are expected to lose patent protection and face competition from biosimilars by 2020. The regulatory route for biosimilars is also becoming clearer following the EMA's decision in September 2013 to approve Hospira's and Celltrion's Inflectra as a biosimilar to infliximab (Remicade), which generated sales of \$6.2bn in FY12.

Valuation: EV of c €50m

The EV of Formycon is c €50m and the company had €4.6m in cash at H113. The current valuation reflects the potential size of the biosimilar market and relatively low development risks and costs.

Consensus estimates Year end Revenue PBT **EPS** DPS P/E Yield (€m) (€m) (€) (€) (x) (%) N/A 12/11 0.1 (0.18)0.00 N/A (1.3)12/12 0.1 (2.4)(0.33)0.00 N/A N/A N/A 12/13e 0.6 (7.2)(0.97)0.00 N/A 12/14e 8.0 (9.8)(1.01)0.00 N/A N/A Source: Thomson Reuters

Pharma & healthcare







7 4m

4.6m

Business description

Net (debt)/cash (€) as at Jun '13

Shares in issue

Formycon is a biopharmaceutical company, based in Munich, which is focused on developing biosimilars to compete with existing biological drugs.

Bull

- Experience of company and management
- Biologic products with sales of >\$70bn to lose patent protection by 2020
- Biosimilars expected to be priced at modest discount to branded originals

Bear

- Regulatory uncertainty for biosimilars
- Complex characteristics of original product cannot be replicated
- Competition from originals and other biosimilars

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