Formycon

FY19 results – strong position, new projects

Formycon ended 2019 with a strong €22.4m cash position and three main projects. A new project to manufacture antibodies against SARS-CoV-2 is underway to treat COVID-19. Formycon's lead project, Lucentis biosimilar FYB201, treats neovascular age-related macular degeneration (nAMD) and is partnered with Bioeq AG (Bioeq). Bioeq aims to resubmit the BLA to the FDA in H220. FYB202 (a Stelara biosimilar) is in a joint venture with Aristo Pharma and is slated to enter Phase III in Q320. FYB203 (an Eylea biosimilar) is partnered with Klinge and could enter Phase III in mid-2020. FY19 revenue from partners was €33.2m. The reported operating loss was €2.3m with an operational cash outflow, including JV investment, of €6.2m.

FYB201 and FYB203 target crowded nAMD market

Formycon has two biosimilar projects targeting the nAMD market. The global exclusive partner on FYB201, Bioeq, withdrew the FDA BLA after a late plant reconfiguration. Resubmission is expected by management in H220, and we expect an EMA filing soon after. Bioeq licensed US sales to Coherus, a growing US biosimilar specialist. Lucentis 2019 sales were $3.9bn. Formycon's preclinical Eylea biosimilar FYB203, also for nAMD, is licensed to Klinge. Phase III is planned to start in mid-2020. Sales of Eylea in 2019 were $7.2bn. Formycon assumes a very valuable nAMD market for biosimilars, but competition has intensified with the approval of Beovu (brolucizumab, Novartis), a long-acting product targeting first-line use. Two other Lucentis biosimilars in late development now have strong marketing partners.

A stellar opportunity progressing through a JV

Formycon has made significant progress on FYB202 (a Stelara biosimilar for Crohn's disease, ulcerative colitis and psoriasis) through a joint venture deal with Aristo Pharma; Formycon owns 24.9%. Stelara (2019 sales $6.4bn) has a different mode of action from anti-TNF agents like Humira ($19bn in 2019 but falling sales in Europe due to biosimilars) so should be somewhat protected from the fierce anti-TNF competition. The project is in Phase I and guided to start Phase III in Q320. Formycon funds its share of the costs, but then shares the profits, so this could be very lucrative. Stelara patents expire in 2023 (in the US) and 2025 (in the EU).

Valuation: Hit by COVID-19 market correction

Formycon's market cap is about €253m with an EV of €232m. Restarting the regulatory review of FYB201, the FYB202 Phase III start and clinical development of FYB202 should add value in H220. Formycon raised €17.3m of equity in FY19 so is well capitalised with strong partner revenues to fund development.

Historical and consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/18	43.00	7.10	0.77	0.0	N/A	N/A
12/19	33.16	(2.27)	(0.23)	0.0	N/A	N/A
12/20e	39.12	(4.63)	(0.44)	0.0	N/A	N/A
12/21e	36.70	(11.00)	(0.49)	0.0	N/A	N/A

Source: Refinitiv consensus estimates, Formycon reports

Price	€25.3
Market cap	€253m

Share price graph

Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	10m
Cash at end December 2019	€22.4m

Business description

Formycon is a biotechnology company focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar awaiting FDA resubmission. FYB202, a biosimilar candidate of Stelara, is being developed in a joint venture with Aristo Pharma and could enter Phase III in Q320. FYB203 is an Eylea biosimilar in late preclinical.

Bull

- Leading biosimilars company addressing markets worth $17.8bn in 2019.
- Two partnered products plus JV deal.
- Strong cash position with revenues.

Bear

- No EMA guidance for intraocular biosimilars.
- US biosimilar market still maturing.
- Tough competition likely for FYB201

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Financials: FY19 results review

Formycon reported 2019 revenues of €33.2m as development payments vs €34.5m in 2018 ((there was also a payment of €8.5m making €43m in total). The operating loss was €2.3m (vs €0.7m). We expect product revenues (as royalties and milestones) from 2022, which could enable a move towards profit, depending on investments in new projects.

The FYB202 project is run through a joint venture company (undisclosed financials), which requires periodic investment. There was an H119 investment of €4.7m in the FYB 202 GmbH & Co joint venture, KG, which added to the €15.97m invested in H118 to give a balance sheet asset of €20.7m. There was no H219 investment in the JV (zero in H218). We expect a H120 investment.

Formycon raised €17.3m gross at €29.90 per share in Q319 in which Formycon's share capital increased to €10m after issuing 577,397 new shares. Formycon stated that the funds will be used for proprietary biosimilar developments.

Underlying 2019 operating outflow was €1.5m, before the €4.7m JV investment, which is the investment in the FYB202 project. Hence the effective operational cost was €6.2m. After the €17.3m cash raised, cash and cash equivalents increased from €12.3m (€7.3m cash plus €5m securities) to €22.4m (€22.1m cash plus €0.3m securities) as of 31 December 2019.

Exhibit 1: Financial summary

Year-end 31 December (€m)	2015	2016	2017	2018	2019
Income statement					
Revenue	**16.92**	**19.53**	**29.43**	**43.00**	**33.26**
Profit before tax (as reported)	0.60	(4.06)	(1.58)	7.10	(2.27)
Net income (as reported)	**0.60**	**(4.07)**	**(1.58)**	**7.10**	**(2.29)**
EPS (as reported)* (€)	0.06	(0.46)	(0.17)	0.77	(0.23)
Dividend per share (€)	0.00	0.00	0.00	0.00	0.00
Balance sheet					
Total non-current assets	3.74	4.40	4.11	15.97	20.67
Total current assets	23.41	20.80	26.72	19.49	32.88
Total assets	**27.15**	**25.19**	**30.83**	**39.70**	**53.55**
Liabilities	(1.61)	(3.58)	(4.01)	(3.38)	(3.47)
Provisions	(0.66)	(0.72)	(1.27)	(2.85)	(1.89)
Total liabilities	**(2.28)**	**(4.30)**	**(5.28)**	**(6.23)**	**(5.34)**
Net assets	24.87	20.89	25.54	33.30	48.21
Shareholders' equity	**24.87**	**20.89**	**25.54**	**33.30**	**48.21**
Cash flow statement					
Net cash from operating activities	0.52	(5.04)	(4.20)	13.30	(1.48)
Net cash from investing activities	(0.60)	(1.35)	(0.51)	(17.03)	(5.71)
Net cash from financing activities	11.15	0.06	6.20	0.56	17.24
Net cash flow	**11.07**	**(6.33)**	**1.51**	**(3.17)**	**10.05**
Cash & cash equivalent end of year	**20.30**	**13.97**	**15.48**	**12.31**	**22.35**

Source: Formycon accounts, *Bloomberg

Three key projects

Formycon's lead project is FYB201, a biosimilar to Lucentis and licensed to Bioeq. The FYB202 project (Stelara biosimilar) entered Phase I in October 2019. Preparations for the start of the Phase III clinical trial, which is scheduled for Q320, are underway. The Eylea biosimilar, FYB203, is in late preclinical and management is planning the start of Phase III in mid-2020. Further projects are undisclosed beyond a name: FYB206. A project recently announced is the production of antibodies to neutralise SARS CoV-2 virus to potentially treat COVID-19.

The three main projects with identified targets are each in a deal or joint venture. Although we cite the reference product sales for each project, the in-market biosimilar price will be typically lower by c 15–20% initially and possibly 30–50% if competition is fierce. One element in these markets is that switching rates from established reference products to slightly cheaper biosimilars have often been slow. For approval, a biosimilar must show comparable safety, efficacy and immunogenicity to the original 'reference' products so, technically, there should be no reason for prescribers not to switch. In May 2019 the FDA set out guidelines to establish full interchangeability with reference products. These guidelines might mean further clinical trials are needed but, if followed, they could enable routine switching and so faster penetration to give higher biosimilar market shares.

A new set of EU rules were approved on 20 May 2019 and allow potential competitors to manufacture biosimilars in Europe from six months before the patent and any supplementary protection expires. Formycon does not expect this to affect the launch of FYB201, but it may enable more rapid launches for other products, for example FYB202 in 2023. The EMA issued more general information on its approach to biosimilars in October 2019.

FYB201: Viewing a competitive space

Lucentis (ranibizumab, Roche (US) Novartis (EU)) had 2019 sales of $3.9m, up from 2018 sales of $3.7bn; sales growth in the US was 8%. Ranibizumab is a humanised monoclonal antibody fragment produced in *Escherichia coli* cells by recombinant DNA technology; it binds vascular endothelial growth factor-A (VEGF-A). The main competitor product Eylea (Regeneron) initially took sales and market growth from Lucentis due to a longer dosing interval. The position has now stabilised. Lucentis patents expire in 2020 in the US and 2022 in Europe. Both products are dosed by intravitreal injection

FYB201 is fully licensed to Bioeq, based in Zug. Bioeq comprises a joint venture between Polpharma (a Polish pharmaceutical company) and Santo, the Strüngmann family's investment company. The clinical studies for FYB201 were run by a Bioeq subsidiary, Bioeq GmbH, based in Germany. In 2019, Bioeq licensed the US rights to Coherus, a US biosimilar specialist.

Coherus is developing and in-licensing a variety of products, including an Eylea biosimilar. It has one approved and marketed product so far (UDENYCA (pegfilgrastim-cbqv) for oncology), which generated $356m in sales in 2019. As disclosed in the 2019 10k filing, Coherus paid Bioeq an upfront payment of €5.0m and a milestone payment of €5.0m, with future development and regulatory milestone payments totalling up to €25.0m. Coherus will share 50–55% of gross profits on US sales of FYB201. For its current product, Coherus had a 2019 gross margin of 95% before sales costs (38%). It is not exactly disclosed what percentage of these royalties Bioeq will share with Formycon; management has indicated tiered royalties (up to double digit) on net sales. The 2013 press release noted milestone and sales payments totalling hundreds of millions of euros, but not further specified (eg in terms of commercial milestone amounts).

The Phase III study, COLUMBUS-AMD (NCT02611778), reported its primary endpoint in May 2018, which confirmed comparable efficacy between FYB201 and Lucentis in patients with nAMD (included in wet AMD). The clinical primary endpoint measured the change in the best corrected visual acuity after eight weeks. All secondary endpoints were also met. The Phase III is now completed with no issues about the safety and immunogenicity of FYB201 observed.

The project suffered an unexpected setback in early 2020 as the BLA, filed by Bioeq in Q419, was withdrawn. The reason was a reconfiguration of the manufacturing plant by the contract supplier in response to a separate regulatory matter on a unrelated product. The exact issue is not disclosed but it is not related to FYB201 product quality or characteristics. The FDA wanted more data and Bioeq and Formycon estimated that this would take four months, pre COVID-19, to acquire. No further clinical work was stated to be needed. Once the data is available, the BLA dossier will be updated and resubmitted; Formycon indicated in May that this may occur in H220. This puts the

project in track for a possible US 2022 launch. We assume that an EMA filing will also be made by late 2020.

Competitors in nAMD include:

- Samsung Bioepis (Korea, sales via Biogen) with a Phase III of SB11 (ranibizumab biosimilar) completed in December 2019. Interim results on 18 May showed equivalence.[1] Biogen in December bought exclusive rights for both SB11 and the Eylea biosimilar SB15 ($100m upfront for the rights and another $210m in milestone payments tied to development, regulatory and sales targets). Biogen has acquired a gene therapy eye-care company, Nightstar, and these additional products will help develop a potentially strong eye-care franchise. We expect an FDA BLA application in H220 making this now on a similar timescale to FYB201.
- Xbrane (Sweden) is partnered with STADA, a privately-owned German-based generics and OTC company that sells (some) in-licensed biosimilars. The global Phase III (NCT03805100, XPLORE) of Xlucane (ranibizumab biosimilar) is still recruiting. Xbrane now expects, due to COVID-19 measures, that Xplore will be fully recruited by Q320. This means that data should be available in H121 with regulatory filings possible in H221. Lucentis loses its European patent protection in July 2022. STADA and Xbrane have partnered with Bausch + Lomb in the US making this a strong competitor, given the specialist eye-care franchise. However, Xlucane might be the third product to reach the US market.
- Roche has a novel antibody, faricimab, in a Phase III (primary data Q321, completion Q422) that targets both VEGF-A and angiopoietin-2 (Ang-2). The excellent Phase II performance was based on one injection every 16 weeks; this could be a premium product after 2023. Roche has a Lucentis medical device port delivery system in Phase III.
- Novartis gained FDA approval in late 2019 for Beovu (brolucizumab) and in the EU in February 2020. Beovu is a single-chain antibody fragment inhibitor of all isoforms of VEGF-A used to treat exudative AMD. There were two Phase III clinical trials (HAWK and HARRIER) in 1,400 patients using Eylea as a comparator. It claims a long dosing interval of up to every 12 weeks. This product might gain first-line use and put pressure on the biosimilar market. As of 2 March 2020, more than 57,000 Beovu vials had been shipped in the US. There have been some post-approval safety issues raised but these seem within expected limits, according to Novartis.

A market complication will be biosimilar versions of Avastin. Avastin has the same mode of action as Lucentis but is a large monoclonal rather than a smaller fragment. Avastin is used off label for nAMD as it is cheaper; generic versions could accentuate this gap. This use is believed to be decreasing because the larger Avastin pack size gives handling and sterility issues.

FYB202: A stellar project

Formycon is developing a biosimilar, FYB202, to Stelara (ustekinumab, Jansen). The product is an antibody that binds interleukin-12 (IL-12) and IL-23. These potent cytokines drive the immune response so neutralising them controls autoimmune diseases such as Crohn's disease and psoriasis. Ustekinumab is not used for rheumatoid arthritis (a massive market) but is effective for psoriatic arthritis (Veale and Fearon, 2015). Stelara has its main US patent expiry in September 2023 in the US and in January 2024 in Europe. Global sales were $6.4bn in 2019, up from $5.2bn in 2018 driven by the 2017 approval in Crohn's disease and a 2019 approval for ulcerative colitis.

The general market for these anti-inflammatory therapies targeting cytokines such as IL-12 and tumour necrosis factor (TNF) is likely to be competitive with the patent expiries of global franchises such as Humira (adalimumab, an anti-TNF monoclonal), mainly used for rheumatoid arthritis, but

[1] The study achieved its primary endpoints, which were the change from baseline in best corrected visual activity (BCVA) at week 8 and central subfield thickness (CST) at week 4. The least squares (LS) mean change in BCVA was 6.2 letters for SB11, compared with 7.0 letters for reference ranibizumab. The LS mean change in CST was −108.4 µm for SB11 vs −100.1 µm for reference ranibizumab. The confidence interval (CI) of the difference between the two treatments in BCVA and CST was within the predefined equivalence margins.

also Crohn's disease, ulcerative colitis and psoriatic arthritis. Stelara has a different mode of action to anti-TNF therapies as it binds a different set of inflammatory messenger proteins.

In Europe, the Humira patent expired in October 2018 and four Humira biosimilars are sold: Amgevita (Amgen), Hyrimoz (Sandoz), Hulio (Mylan/Fujifilm Kyowa Kirin Biologics) and Imraldi (Biogen/Samsung Bioepis). International (mainly European) 2019 Humira sales were $4.3bn, a 31% decline.

In the US, 2019 sales were $14.9bn, up 8.6%. The primary patent expired in 2016 and three biosimilars are already approved: Amjevita (adalimumab-atto, Amgen), Hyrimoz (adalimumab-adaz, Sandoz) and Cyltezo (adalimumab-adbm, Boehringer Ingelheim), with Imraldi (Biogen/Samsung Bioepis) under FDA review. However, so far remaining patents and agreements with Amgen mean that these biosimilar launches will be delayed and then phased over 2023.

FYB202 is licensed to privately owned Aristo Pharma through a joint venture vehicle, FYB 202 GmbH & co KD. Formycon holds 24.9% (Aristo owns 75.1%) and will therefore fund this proportion of the clinical and development costs, amount undisclosed, but will receive that share of profits. Phase I started in October 2019 (no trial record is available). This implies Phase III is now slated to start in Q320, which Formycon has previously indicated could lead to a 2023 launch. Icelandic company Alvotech is in a preclinical development of a Stelara biosimilar with Fuji. Alvotech now has a broad collaboration with STADA for European marketing. Australian NeuClone is in Phase I.

FYB203: An eye on the future

FYB203 is a preclinical project to develop an Eylea biosimilar. Regeneron had 2019 Eylea sales of $7.5bn (up from $6.7bn) split $4.6bn US and $2.9bn international. A prefilled syringe format was launched in December 2019, a product lifecycle management tactic. (Formycon is also developing prefilled syringe formats) Eylea is used in a similar way to Lucentis but has a different mode of action as it binds both VEGF-A and placental growth factor; Lucentis binds only VEGF-A. The Eylea maintenance dose interval is every eight weeks, double that of Lucentis, although Formycon notes that clinical surveys show that the use patterns are similar. US Eylea patents start to expire in 2020 but there seem to be patent extensions (Sharma et al., 2018) that should prevent biosimilar competition in the US until 2024. European patents expire in 2025. In addition, Eylea formulation patents do not expire until 2027–28. Formycon has filed patents for an alternative formulation that has shown preclinical intraocular bioequivalence.

Formycon has a global licensing deal with Santo Holding (with rights now transferred to Klinge Biopharma GmbH) and gains sales-related royalties. Management expects that a Phase III will start in mid-2020.

Competitors include a joint development programme between Momenta Pharmaceuticals and Mylan NV on the Eylea biosimilar, M710/ MYL-1701P. A Phase III trial (NCT03610646) in 324 patients is underway and was due to report primary data in Q120, last updated in December 2019. The collaboration between Samsung Bioepis and Biogen on SB15 was noted above, but there is no US trial record for SB15 as yet. Alteogen (South Korea) has a Phase I project, ALT-L9, so it might be a potential future competitor.

Clearing SARS-CoV-2, a new project

Formycon has announced a preclinical project to produce antibodies against the SARS-CoV-2 virus to treat COVID-19. This is at the development stage with the company designing and evaluating potential antibodies. The press release indicates that this effort is to make an antibody-based therapeutic that would be standard to manufacture and have a long circulating half-life in patients. Use of antibodies in an infection should reduce the viral load in the blood thereby potentially shortening the infection time and limiting disease severity while an effector T-cell response is mounted to destroy infected cells and stop viral replication. Antibodies bind the viral particles in

blood preventing them infecting more cells and enabling them to be cleared and destroyed. A product would be expected to be compatible with the use of (in parallel with) small molecule drugs, like remdesivir (Gilead), that target viral replication inside cells. Antibodies cannot target virus replicating inside cells.

Formycon indicated that a candidate might emerge by Q420 enabling a possible clinical programme from Q321.

Valuation: Clear pipeline and solid financial position

Formycon's market cap is €253m with about €1.2m of long-term liabilities. Adding liabilities and subtracting €22.4m cash gives an EV of about €232m (formerly €294m as of June 2019). Value progression was dented by the March 2020 bear market although the shares have partly recovered. The unfortunate delay to FYB201 delays the royalty/milestone stream. More concerning is the threat from Novartis' recently luanched product Beovu - although there seem to be some initial safety concerns on that product.

The other projects are further behind, but FYB202 (Stelara biosimilar) could develop quickly through the JV with a Phase III expected to start in Q320. Formycon's 24.9% share of costs will need funding; this is worthwhile as it gives an increased profit share, but the amounts required are not disclosed. The Stelara franchise appears not to be targeted by many developers but the related Humira (anti-TNF) EU market is a battleground with competitors queuing to pile in to the US. Stelara might be a more protected market as not all Crohn's and psoriasis patients will use anti-TNF products, which might safeguard margins.

It is harder to assess FYB203. An Eylea biosimilar should sell well and the Eylea biosimilar market seems less competitive. The Momenta Pharmaceuticals - Mylan joint venture is the clear leader so far in late Phase III. We expect further entrants over the next few years including trials of SB15 from Samsung Bioepis after the Biogen deal.

Investment case summary

Formycon has a robust financial position with high development revenues covering most costs, cash for investment and a pipeline targeting major global markets. It can now develop its own proprietary pipeline, which should add further value: we note FYB206 and the SARS-CoV-2 antibody preclinical developments. We noted previously that there can be technical risks and delays in development for its biosimilars, and unforeseeably some of these became apparent with FYB201. Other products may be affected by the COVID-19 epidemic complicating and delaying clinical development. These development risks are still much lower than mainstream novel therapeutics; although the early-stage SARS CoV-2 antibody project is more risky.

The main uncertainties are on exact product launch dates, competition and the ability of partners to market effectively in large, complex global markets. The latter has become a major factor given that marketing partners for FYB201 and its competitors are now clear. The lack of clarity on the returns to Formycon from Bioeq is an uncertainty. We still believe that Formycon should become one of the leading biosimilar companies as its portfolio develops and projects mature. For maximum value potential, Formycon needs to take more financial risk and to fund projects itself.

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