Formycon

Pharma & biotech

14 October 2021

H121 update: Future markets take shape

Formycon progressed all key projects in H121. FYB201 (partnered with Bioeq) is a Lucentis biosimilar to treat neovascular age-related macular degeneration (nAMD). The US FDA is reviewing the BLA with an August 2022 decision due; the European EMA review should complete in mid-2021. FYB201 will be marketed by Teva in Europe and by Coherus in the US. FYB202 (a Stelara biosimilar in a joint venture with Aristo Pharma) is waiting for its Phase III readout in psoriasis. FYB203 (an Eylea biosimilar partnered with Klinge) is in late Phase III in nAMD. FYB207 is a novel COVID-19 therapy with a €12.7m grant and H122 Phase I/IIa trials planned. Formycon had €33.6m cash on 30 June 2021. H121 revenue was €20.3m (H120: €16.5m). The loss rose to €10.2m (FY20: loss of €5.9m) due to investment into unpartnered projects.

FYB201 and FYB203 target $11.9bn nAMD market

Formycon forecasts a very valuable nAMD market for biosimilars and has two late-stage candidates. Bioeq submitted a US BLA in August for FYB201, the Lucentis biosimilar; the FDA review will complete by August 2022. The FYB201 EMA filing occurred in June with typically about a year to approval. The Lucentis biosimilar market already has one approval: Byooviz. FYB201 is licensed to Coherus in the US and to Teva in Europe, Canada, Israel and NZ. The clinical study report for Formycon's FYB203 is expected by Formycon in Q32022. It is licensed to Klinge Biopharma. Potential competition will be strong.

Stelara biosimilar waiting for Phase III results

FYB202 (a Stelara biosimilar for Crohn's disease, ulcerative colitis and psoriasis) has completed recruitment. Formycon expects the clinical study report in mid-2022. It is a joint venture with Aristo Pharma; Formycon owns 24.9% and made a €1m further investment in H121. Formycon therefore shares the potentially lucrative profits. Stelara 2020 sales were $7.7bn with patents expiring in 2023 (US) and 2024 (EU). There are strong competitors including Samsung Bioepis and Amgen.

Valuation: Strong portfolio plus novel COVID therapy

Formycon's market cap is €552m, giving an EV of about €531m (€638m in May 2021). In 2022, the outcome of the regulatory reviews of FYB201, the possible BLA filing of FYB202 and the presentation of FYB203 Phase III data should drive the market value as key projects are steadily de-risked. Progress on FYB206 and the promising COVID-19 therapy FYB207 moving into clinical trials in 2022 should provide further upside. Formycon is well capitalised with strong partner revenues. The company has issued guidance of €34.2m of revenues in 2021.

Consensus estimates

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/19	33.3	(2.3)	(0.23)	0.0	N/A	N/A
12/20	34.2	(5.9)	(0.58)	0.0	N/A	N/A
12/21e	34.2*	(7.7)	(0.81)	0.0	N/A	N/A
12/22e	53.5	4.1	(0.43)	0.0	N/A	N/A

Source: Refinitiv, Formycon reports. Note: *Management guidance

Price	€50
Market cap	€560m

Share price graph

Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	11m
Cash at end June 2021	€33.6m

Business description

Formycon is a biotechnology company focused on biosimilars. Its lead product is FYB201, a Lucentis biosimilar that should gain approvals potentially from mid-22. FYB202, a late Phase III biosimilar of Stelara, is in a JV with Aristo Pharma. FYB203 is an Eylea biosimilar completing Phase III. A preclinical SARS-CoV-2 therapy may enter the clinic in H122.

Bull

- Leading biosimilars company addressing markets worth $19.6bn in 2020.
- Two partnered products plus JV deal giving strong revenues and limiting cash use.
- Novel COVID-19 therapy could enter Phase I/IIa in H122 and might become a key treatment.

Bear

- Tough biosimilar competition developing for all three key products with Byooviz approval.
- US biosimilar market still maturing.
- Unclear future COVID-19 market with competition from oral antivirals emerging.

Analyst

Dr John Savin MBA +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

Financials: H121 results review

Formycon reported H121 revenues of €20.3m from development payments, versus €16.5 in H120 and €34.2m for all of FY20. The H1 loss was €10.2m (vs a loss of €1.4m in H120). Cash was €33.6m (2020: €42m after the capital raise of €25.75m). The R&D cost was €30.4m, offset by partner payments. The underlying H121 operating outflow was €7.6m showing the direct H121 investment in FYB206 and FYB207.

There was €0.9m of capital and intangible investment. The FYB202 project is run through a joint venture company (FYB 202 GmbH & Co. KG, undisclosed financials). There was a further €1m H121 financial investment in the JV giving a 30 June balance sheet value of €21.7m.

Exhibit 1: Financial summary Formycon Group

Year-end 31 December (€m)	H121	H120	2020
Income statement			
Revenue	20.3	16.5	34.2
Profit before tax (as reported)	(10.2)	(1.4)	(5.9)
Net income (as reported)	(10.2)	(1.4)	(5.9)
EPS* (€)	(0.9)	(0.1)	(0.6)
Balance sheet			
Total intangible and fixed assets	4.4		4.0
Total working capital	11.2		8.8
Total financial investments (JV)	21.7		20.7
Cash and equivalents and securities	33.6		42.1
Total assets	70.9		75.6
Equity	58.8		68.0
Liabilities and provisions	12.1		7.6
Total liabilities	70.9		75.6
Cash flow statement			
Net cash from operating activities	(7.6)		(5.1)
Net cash from investing activities (inc JV)	(1.9)		(0.7)
Net cash from financing activities	0.9		26.6
Net cash flow	(8.6)		19.9
Cash & cash equivalent end of period	33.6		42.1

Source: Formycon accounts. Note: *10.25m average shares in 2020; 11.046m shares on 30 June 2021

Three progressing key projects

Formycon's pipeline is shown in Exhibit 2.

Exhibit 2: Formycon pipeline

Project	Partner/JV	Target	2020 market		Status	Next milestone	Notes
			US	RoW			
FYB201	Bioeq/ Coherus (US) and Teva (Eur)	Lucentis (nAMD)	$1.9bn	$1.6bn	Pre-regulatory	■ FDA BLA outcome Aug 2022 ■ EMA outcome mid 2022	In regulatory phase
FYB202	JV with Aristo Pharma	Stelara (inflammation)	$5.24bn	$2.47bn	Full recruited	Clinical report expected mid-2022	Market opens from Sept 2023. Formycon owns 24.9%
FYB203	Klinge Biopharma	Eylea (nAMD)	$4.95bn	$2.96bn	Phase III endpoint Q421	Clinical report possible Q3 2022	Market opens from 2024 if patent extensions apply
FYB206	N/A	N/A			Preclinical	NA	Undisclosed major opportunity
FYB207	N/A	SARS-CoV-2 (COVID-19)	Depends on level of endemic COVID-19		Preclinical, €12.7m grant	Phase I/IIa could start in H122	Two candidates in evaluation, selection due by late 2021

Source: Edison Investment Research based on Formycon announcements, sales from other company announcements and ClinicalTrials.gov

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 about 15–20% initially and possibly 30–50% if competition is fierce.

FYB201: The last leg before launch

Lucentis (ranibizumab, Roche, US, and Novartis, EU) is a humanised monoclonal antibody fragment. It binds vascular endothelial growth factor-A (VEGF-A), preventing the growth of blood vessels across the retina. It is given by intravitreal injection. Lucentis patents expired in 2020 in the United States and expire in 2022 in Europe.

FYB201 is licensed to Bioeq, a joint venture between Polpharma (a Polish pharmaceutical company) and Santo. The US sales will be through Coherus, a US biosimilar specialist. In June 2021, Teva became the marketing partner for Europe, Canada, Israel and New Zealand. This leaves a number of territories where partners need to be signed. Formycon management has indicated tiered royalties (up to double digit) on net sales.

Competitors in nAMD include:

- Samsung Bioepis (Korea) gained FDA approval for ranibizumab-nuna in September 2021. European and UK approval was gained in August 2021. It will be sold by Biogen as Byooviz from June 2022. Biogen also holds exclusive rights to Samsung Bioepis's Eylea biosimilar SB15 giving a potentially strong franchise.
- Xbrane (Sweden) is partnered with STADA, a private generics and OTC company. The Phase III of Xlucane (ranibizumab biosimilar) reached its primary endpoint in May 2021. STADA and Xbrane have partnered with Bausch + Lomb in the United States, making this a strong competitor.
- Roche has a bispecific antibody, faricimab, under FDA (fast track) and EMA regulatory review. This extends treatment intervals to three months or longer and could be a premium product.
- Novartis gained FDA and EMA approval for Beovu (brolucizumab) with a 12-week dosing interval. There are safety issues (inflammation) and these have severely restricted sales .
- A market complication remains biosimilar versions of Avastin, sometimes used off-label for nAMD as they are cheaper. It is not approved for use in the eye.

FYB203: Eylea biosimilars line up the data.

FYB203 is a project to develop an Eylea (aflibercept) biosimilar. Eylea is injected into the eye, like Lucentis, but has a different mode of action as Eylea binds to both VEGF-A and placental growth factor. 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 United States 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 Klinge Biopharma and will gain sales-related royalties. The Bioeq Phase III (MAGELLAN-AMD, NCT04522167) is scheduled to reach its primary endpoint in October 2021. Formycon expects the outcome to be announced in Q322.

There are a number of competitive products in development with two strong players:

- Samsung Bioepis (partnered with Biogen) ran a Phase III trial, NCT04450329, that reached its primary endpoint in April 2021. Regulatory filings in 2022 seem possible.
- Amgen Biosimilars is running a Phase III (NCT04270747) with ABP 938. This is a 566-patient study of complex design. The primary endpoint is scheduled to be reached in June 2022.
- Momenta Pharmaceuticals (now part of Jansen) is developing M710/ MYL-1701P. A Phase III trial (NCT03610646) in 355 patients completed in November 2020.
- Alteogen (South Korea) listed a Phase I trial (NCT04058535) for ALT-L9. Media reports state that it completed successfully and that an IND might be filed in the United States.

- Sam Chun Dang Pharm (China) is developing SCD411 in a Phase III (NCT04480463). It should read out the primary endpoint in Q122. We assume this will be partnered if sold outside China.

FYB202: Chasing a major immunology market

Formycon is developing a biosimilar, FYB202, to Stelara (ustekinumab, Jansen), the second biggest anti-inflammatory product after Humira. The biosimilar market for anti-inflammatory therapies is likely to be competitive as the patents on Humira (adalimumab, an anti-TNF monoclonal) expire. Other biological agents are already off patent.

FYB202 is licensed to Aristo Pharma through a joint venture: FYB 202 GmbH & Co KG. Formycon holds 24.9% (Aristo owns 75.1%) and funds this proportion of the costs and so will receive that share of profits. A further €1m investment was made in H121. The Phase III 'VESPUCCI' trial, NCT04595409, completed recruitment in June 2021 and the clinical report is expected by Formycon in mid-2022. Stelara's US patent expires in September 2023; in Europe expiry is in January 2024.

Stelara has a different mode of action to anti-TNF therapies as it binds interleukin-12 (IL-12) and IL-23. Ustekinumab is not used for rheumatoid arthritis (a massive market) but is effective for psoriatic arthritis (Veale and Fearon, 2015). It is also indicated for Crohn's disease and ulcerative colitis. Competitors identified by us are as follows.

- Samsung Bioepis is close to the primary endpoint of a 201-patient Phase I (NCT04772274) of SB17. If this completes in late 2021, Phase III might start in 2022.
- BioFactura Australia, working with Avance, has a Phase I in 228 patients (NCT04843631) that is due to end in January 2022.
- Amgen Biosimilars is developing ABP 654. Its 352-patient psoriasis Phase III (NCT04761627) is due to report data from March 2023.
- Biosimilars specialist Alvotech is running a 294-patient Phase I (NCT04744363) in partnership with Fuji for Japan and STADA in Europe. It could read out in April 2022.
- Australian NeuClone has successfully run a Phase I study with the outcome noted in October 2020. It is partnered with the Serum Institute of India.

FYB207: clearing SARS-CoV-2

Formycon has a preclinical COVID-19 project, FYB207, to produce a fusion protein against the SARS-CoV-2 virus to clear virus quickly from the blood. The Formycon approach uses the natural target of the SARS-CoV-2 virus to trap the virus and enable its destruction. Two preclinical candidates are being evaluated. One of these should be selected to go into clinical trials during 2022. The €12.7m grant announced in July 2021 will help to fund development. We expect that the virus will become endemic so potent treatments will still be needed. The area is competitive; we note recent good data from an oral anti-viral medicine, molnupiravir, from Merck. Regeneron's approved antibody mixture, REGN-COV2, binds virus and blocks SARS-CoV-2.

Valuation: Maturing pipeline, solid financial base

We believe that Formycon should become one of the leading biosimilar companies as its portfolio develops and projects mature. Formycon's market cap is €552m with €12.1m of liabilities. Adding liabilities and subtracting €33.6m cash gives an EV of about €531m (compared to €638m in May 2021). Formycon has a robust financial position with high development revenues covering many costs, cash for investment and a pipeline targeting major global markets. The main uncertainties are on exact product launch dates, competition, and the ability of partners to market effectively.

General disclaimer and copyright

Any Information, data, analysis and opinions contained in this report do not constitute investment advice by Deutsche Börse AG or the Frankfurter Wertpapierbörse. Any investment decision should be solely based on a securities offering document or another document containing all information required to make such an investment decision, including risk factors. This report has been commissioned by Deutsche Börse AG and prepared and issued by Edison for publication globally.

Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia