Formycon

Pharma & biotech

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Surfing the next wave of biosimilars

Formycon is a pure-play biosimilar company focused on third-wave biosimilars (those coming off patent after 2020), an overlooked opportunity for most biosimilar developers. The company has four compounds, two of which are partnered. FYB201 is a biosimilar of Lucentis for neovascular age-related macular degeneration (nAMD) undergoing a global Phase III study; the company is aiming for US and EU launch in 2020 and 2022, respectively, upon patent expiries. FYB203 is a proposed biosimilar of Eylea, also for nAMD, in preclinical studies. Both compounds are partnered in deals worth over €100m and target all available biologics in the nAMD market. The liquidity position at end September 2016 was €19m.

Potential first-mover advantage in a $3.2bn market

The lead asset is FYB201, a biosimilar of Lucentis (ranibizumab, Roche/Novartis, 2016 sales $3.2bn), to treat nAMD. Development and commercial partner Bioeq IP AG is running a global Phase III clinical trial aiming for US launch in 2020 and the EU in 2022 upon patent expiries. Although there are a number of other proposed Lucentis biosimilars in development, we believe that Formycon could have a first-to-market advantage, given its current stage of development.

Pursuing Eylea's growing $5bn opportunity

FYB203 is in preclinical studies and partnered with Santo Holding. FYB203 is a proposed biosimilar of Eylea (aflibercept, Regeneron/Bayer, 2016 sales $5bn); there are no other biosimilars of Eylea in development that we are aware of. Eylea is gaining market share from Lucentis due to a number of advantages, a trend that consensus expects to continue. The Eylea patents expire in 2023 (in the US) and 2025 (in the EU); we believe Formycon is aiming for launch upon expiries.

Well-positioned in nAMD with a pipeline beyond

We believe Formycon is well-positioned to participate in the entire nAMD market (EvaluatePharma consensus forecast $9-10bn total sales in 2020) regardless of the dynamics between Eylea and Lucentis. Additionally, Formycon has two undisclosed biosimilars, FYB202 and FYB205, which it plans to partner at a later stage.

Valuation: Upside from progression, partnerships

Formycon's market cap is c €225m and its enterprise value (EV) is c €206m. Progression of the pipeline and additional partnerships should unlock further value.

Consensus estimates

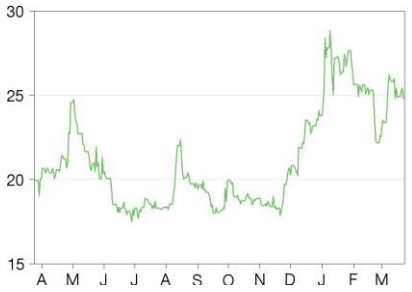
Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/15	17.30	0.60	N/A	0.0	N/A	N/A
12/16e	19.50	N/A	(0.28)	0.0	N/A	N/A
12/17e	30.80	N/A	0.04	0.0	N/A	N/A
12/18e	29.75	N/A	(0.22)	0.0	N/A	N/A

Source: Bloomberg, Formycon data

Price*	**€24.8**
Market cap	**€225m**

*Price as at 23 March 2017

Share price graph



Share details

Code	FYB
Listing	Deutsche Börse Scale
Shares in issue	9.1m
Last reported liquidity position (€m) at end September 2016	19

Business description

Formycon is a biotechnology company focused on biosimilars. The lead product is FYB201, a Lucentis biosimilar in Phase III. FYB203 is an Eylea biosimilar in the preclinical stage. They are both partnered. It also has two undisclosed biosimilars FYB202 and FYB205.

Bull

- Leading biosimilar company addressing a $9bn-$10bn 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 immature.
- Lucentis market declining.

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Company description: Pure-play biosimilar company

Formycon is a biotechnology company focused on biosimilars whose patents expire from 2020 onwards, known as third-wave biosimilars. This long-term approach represents an untapped opportunity as the majority of biosimilar developers are focused on products with patent expirations prior to 2020. The company has two partnered products in development. FYB201 is a biosimilar of Lucentis, for neovascular age-related macular degeneration (nAMD). Partner Bioeq IP AG (a joint venture of Santo Holding and Polpharma) is conducting a Phase III study aiming for launch in the US in 2020 and in the EU in 2022 upon patent expiration. FYB203, partnered with Santo Holding, is a proposed biosimilar of Eylea in preclinical studies. FYB202 and FYB205 are two undisclosed biosimilars in the preclinical stage; the company plans to partner them in the future. Formycon was established out of Scil Technology in 2012. It is based in Munich-Martinsried, Germany, and had 71 employees at January 2017.

Exhibit 1: Pipeline overview

Product	Indication	Stage	Comments
FYB201	nAMD	Phase III	Lucentis biosimilar. Comparative trial for registration in US and EU
FYB203	nAMD	Preclinical	Proposed Eylea biosimilar. No guidance on timelines provided
FYB202	Undisclosed	Preclinical	Undisclosed product
FYB205	Undisclosed	Preclinical	Undisclosed product

Source: Edison Investment Research, Formycon

Strategy

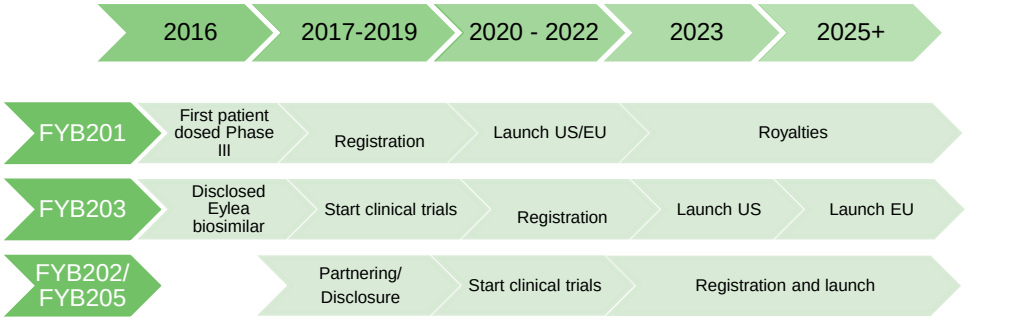
Formycon's strategy is to generate new third-wave biosimilars and partner them at a later date. It divides its strategy into three phases:

- Phase I "Start-up" (2012 to 2016) – this phase involved project design, fund-raising and out-licensing of FYB201 and FYB203. This phase has now been successfully completed.
- Phase II "Execution" (2017 to 2020) – this phase involves pipeline expansion and out-licensing of its two unpartnered products, FYB202 and FYB205.
- Phase III "Royalty" (from 2020 onwards) – the company plans to monetise the projects developed in the previous two phases by generating recurring cash flows from its partnerships.

Recent newsflow and upcoming catalysts

During 2016 Formycon filed patent applications of anti-VEGF products, dosed the first patient in the FYB201 Phase III trial and disclosed that FYB203 is a proposed biosimilar of Eylea. Going forward, we expect the company to progress its products FYB201 and FYB203 through clinical trials, and start receiving royalties upon successful registration and commercialisation from 2020. Formycon may disclose more details on FYB202 and FYB205 and announce partnerships.

Exhibit 2: Present and upcoming activities



Source: Edison Investment Research. Note: FYB202 and FYB205 development plan is Edison's own estimate.

Two partnered products covering the nAMD market

FYB201: A biosimilar of Lucentis

Formycon and partner Bioeq IP AG are conducting a global Phase III trial intended for registration in the EU and US. The trial started following approval from regulators, with the design based on scientific advice from the EMA and FDA. Furthermore, based on the quality of analytical and preclinical data provided by Formycon, the company was allowed to directly start a comparative Phase III study, without the need for Phase I or II trials, accelerating development by around one year. The primary endpoint is change of retinal thickness after one month. The trial plans to recruit 650 patients and run for three years; Formycon is aiming for launch upon patent expiration in the US in 2020 and the EU in 2022.

FYB201 was partnered with Santo Holding in December 2013. Swiss Pharma International (a company of the Polpharma Group) later joined the partnership and formed a joint venture with Santo Holding named Bioeq IP AG. Bioeq is responsible for conducting and funding clinical trials, registration and commercial activities in an exclusive worldwide licence that included an upfront payment (€7.4m was recognised in revenue in H114 following the deal, compared to only €0.2m revenues in H113; we believe the increase in revenues was largely owing to the upfront payment) in addition to further regulatory and sales milestones that could be over the three-digit million euros range according to Formycon.

Lucentis is marketed by Roche in the US and by Novartis outside the US; global sales in 2016 were $3.2bn. The Lucentis market is expected to decline to approximately $2.4bn by 2020 according to EvaluatePharma.

Exhibit 3: Basics of neovascular AMD and treatments

nAMD	nAMD is caused by the abnormal growth of blood vessels beneath the retina, which may leak fluid and blood and cause swelling. It is associated with age and prevalence in 2015 was 1.5 million patients in the US (DataMonitor).
Lucentis	Lucentis (ranibizumab, Roche/Novartis) is an antibody fragment of 48.4 kDa structurally similar to Avastin (bevacizumab, Roche). Lucentis is a vascular endothelial growth factor (VEGF) inhibitor that prevents endothelial cells that form blood vessels from growing. Lucentis was first licensed in the US in 2006 for the treatment of neovascular age-related macular degeneration (nAMD). It has subsequently been approved for macular oedema following retinal vein occlusion (RVO), diabetic macular oedema (DMO), non-proliferative diabetic retinopathy and proliferative diabetic retinopathy in patients with DMO across the world. An injection costs approximately $2k in the US, and is given monthly for approximately 24 months.
Eylea	Eylea (aflibercept, Regeneron/Bayer) is a fusion protein that binds to VEGF and placental growth factor (PGF). It was first licensed in the US in November 2011 for nAMD. Indications are the same as Lucentis. An injection costs approximately $1.8k in the US, given once per month for the first three months and then once every other month for approximately 24 months.
Avastin	Avastin (bevacizumab, Roche) is an anti-VEGF monoclonal antibody for oncology. It is used off-label for nAMD at c $50/shot given once a month.

Source: Edison Investment Research

Although there is no commercial experience of a Lucentis biosimilar in the EU nor in the US, we believe that there is a strong case for a Lucentis biosimilar in terms of healthcare costs savings; based on previous experience with biosimilars of complex molecules, initial discounts of 10-15% in the US and 20-25% in the EU, with further discounts up to 50-70% could be feasible, depending on the country and healthcare system. Market penetration of Lucentis biosimilars will also vary, but we see an average of 50% after four to five years on the market as achievable. Despite declining sales of Lucentis, we believe that this could at least be partially offset by increased patient uptake, due to the fact that biosimilars have increased patient access, eg 44% in 2006-14 in EU-5. Taking this into account and EvaluatePharma's projection of $2.4bn Lucentis sales by 2020, we believe the potential market for a Lucentis biosimilar could be c $600m in 2025 at a 50% discount and 50% market penetration for biosimilars. We believe Bioeq is well-positioned to launch FYB201 upon patent expiration in 2020 in the US and 2022 in the EU, potentially being first to market and capturing significant market share.

Although there are a number of other Lucentis biosimilars in development (summarised in Exhibit 4), we believe Formycon could have a crucial first-to-market advantage. Intas's Razumab launched in India in 2015, but it is unclear if it satisfies biosimilarity standards in the US and Europe. Pfenex

has released clinical data on PF582, but the asset is unpartnered (following Pfizer returning rights in 2016) and there is no guidance on further trials. Xbrane intends to launch its Lucentis biosimilar in Iran later this year, but it is in the preclinical stage for highly regulated markets such as the EU, US, Japan, Australia and Canada.

Exhibit 4: Competition

Company	Product	Status	Comments
Intas	Razumab	Market (India)	Not clear if it is a biosimilar by US and EU standards. Launched in India in June 2015 at 25% discount vs Lucentis. Was temporarily withdrawn from the market due to safety issues and subsequently re-launched to specialist centres. Phase III trial.
Pfenex	PF582	Phase I/II study completed. No timeline for Phase III given	In February 2015 Pfenex signed a deal with Hospira (later acquired by Pfizer) for $51m upfront + $291m milestones and tiered double-digit royalties on net sales. In August 2016 Pfenex regained rights from Pfizer following a strategic review of its biosimilar pipeline. No meaningful differences in intraocular pressure, visual acuity or central retinal thickness between PF582 and Lucentis
Xbrane	Xlucane	Preclinical	In vitro biosimilarity to Lucentis established. Launch in Iran expected in 2017. Looking for a global partner to start clinical trials for highly regulated markets.

Source: Edison Investment Research

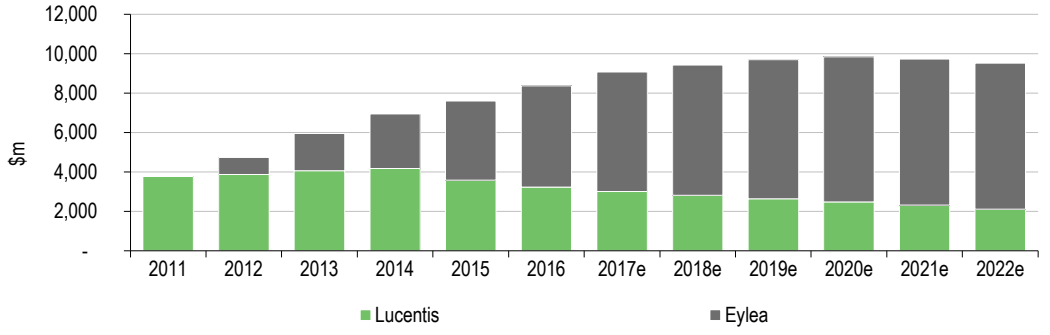
FYB203: Pursuing the growing Eylea market

The second product is FYB203, a proposed biosimilar of Eylea. As with FYB201, the product is partnered with Bioeq in a 2015 deal. So far Formycon has received an upfront payment of single-digit million euros and ongoing payments for its product development activities up to regulatory approval. In addition, the company will participate in sales revenue once the project is marketed, which may reach double digits. FYB203 has yet to start clinical trials and no guidance on potential timing has been provided by Formycon.

Eylea (aflibercept, Regeneron/Bayer) has gained market share from Lucentis due to its more convenient dosage and better perception among ophthalmologists. 2016 sales of Eylea were $5bn, up almost 30% vs 2015. With no other Eylea biosimilar in development that we are aware of, we think it is a good strategy to position in the growing Eylea market to continue gaining market share in nAMD. The consensus forecast is for sales of $7.4bn in 2022 (EvaluatePharma). Eylea's patents expire in 2023 in the US and in 2025 in the EU.

Both Lucentis and Eylea compete against off-label bevacizumab which is much cheaper, but not licensed for nAMD. Moreover, packaging does not allow for single use; therefore several doses must be taken from the same vial resulting in a waste of product and potential safety issues; hence it has not achieved widespread use in major markets. In the EU, Roche and Novartis have strongly opposed the use of Avastin off label.

Exhibit 5: Historical and consensus revenues of nAMD products



Source: Edison Investment Research, Roche, Novartis, Bayer, Regeneron. Note: 2017-22 projections from EvaluatePharma.

Biosimilars: A fast-growing market

Biosimilars are biological medicinal products that contain a version of the active substance of an authorised original biological product in a given territory. Biosimilars must have the same amino acid sequence as the original products, the same posology and the same route of administration, with demonstrated equivalent safety and efficacy. Unlike small molecule generics, biosimilars are not exact copies due to post-translational modifications such as different glycosylation patterns, hence the nomenclature "similar". These modifications are normal in biologics when changes in the manufacturing process are made. A biosimilar product typically needs to be tested in clinical trials, a PK/PD Phase I study and potentially a Phase III, often skipping Phase II, as well as analytical and preclinical studies. Thus, developing a biosimilar costs on average $100-200m and takes seven to eight years, much less than the average $1.5-1.8bn and 10-15 years for an original biologic.

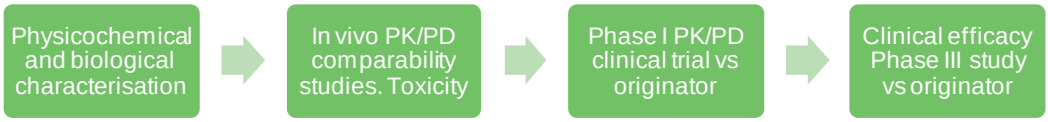
The first wave of biosimilar molecules were based on more simple biologics, with molecular weights of 5-20 kDa, eg insulin, granulocyte colony-stimulating factor (filgrastim, GCSF), human growth hormone (somatropin, HGH) and epoetin (erythropoietin, EPO). More recently biosimilars of complex molecules such as monoclonal antibodies (c 140 kDa), which require strong analytical and manufacturing capabilities to meet regulators' requirements for biosimilarity, have been marketed.

The worldwide biosimilars market is currently valued at c $2bn and is expected to grow to c $6bn by 2020 (Markets and Markets). This growth is expected to be mainly driven by payers' desire to reduce healthcare costs. In particular, there are a number of expensive, complex monoclonal antibodies whose patents expire by 2020 in major markets. Particularly, a number of monoclonal antibodies with sales in excess of $6bn are expected to lose patent protection by 2020 in the EU and/or US: Humira (adalimumab, sales of $14bn in 2015); Enbrel (etanercept, $9bn); Rituxan (rituximab, $7.3bn); Avastin (bevacizumab, $7bn); and Herceptin (trastuzumab, $6.8bn).

Biosimilars market and regulatory pathway

The EMA and FDA pathways are similar. Sponsors meet with the agencies prior to starting development to discuss the strategy to follow. Required studies typically include analytical studies, animal studies (toxicity), and clinical studies (PK/PD) and potentially a head to head clinical study comparing the safety and efficacy of the biosimilar product and the reference biologic. One of the differences is that the EMA does not decide on interchangeability, and it is up to member states to decide if a biosimilar is interchangeable with the reference biologic product.

Exhibit 6: Steps in the development of a biosimilar



Source: Edison Investment Research, European Medicines Agency and Food and Drug Administration

The European Medicines Agency (EMA) was the first regulatory agency in a Western market to implement a biosimilars pathway. The EMA issued its first guidelines in 2005 and updated them in 2014. The EMA has common guidelines for all biosimilars: the Similar Biological Medicinal Products guidelines; the quality guidelines and the clinical and non-clinical issues guidelines. Additionally, the EMA has product-specific guidelines. Since 2005, 23 biosimilars have been licensed in Europe (Exhibit 7). Sales of biosimilars in Europe amounted to $490m in 2014 (GaBi), with variable discounts and market share across countries, products and therapy areas.

A regulatory framework was created in the US in 2010 for the approval of biosimilars. The Biologics Price Competition and Innovation Act (BPCIA) was created to be a cost containment mechanism of the Affordable Care Act (also known as *Obamacare*). The biosimilar application is made via section

351(k) of the Public Health Service (PHS) Act. In general, the PHS Act gives some flexibility and requires that the biological product is "highly similar" with no "clinically meaningful differences" between the proposed biosimilar and the reference product. Since the enactment of the BPCIA, four biosimilars have been approved in the US through this pathway. The FDA has recently issued draft guidance on interchangeability. Interchangeable biosimilars are those that may be substituted for the reference product without the permission of the prescribing physician.

Despite four approvals, only one biosimilar has been launched in the US market. Sandoz's Zarxio, the biosimilar version of Amgen's Neulasta (pegfilgrastim), was launched in September 2015 at a 15% discount and had captured a 13% share of the filgrastim market as of June 2016 (Amgen has 65% and Teva's Granix has 21%, according to IMS). The biosimilars of infliximab, etanercept and adalimumab are still patent protected. Zarxio is reimbursed under Medicare Part B (which generally covers products in the outpatient setting, often injectable drugs administered by a practitioner). Zarxio is also replacing Neulasta in many formularies of pharmacy benefit managers; CVS and United Health have switched to Zarxio.

Exhibit 7: Licensed biosimilars in the EU and the US

Europe	US
Filgrastim: Accofil, Grastofil, Nivestim, Filgrastim Hexal, Zarzio, Biogastrim, Ratiogastrim, Tevagrastim	**Filgrastim**: Zarxio
Insulin: Abasaglar, Lusduna	**Etanercept**: Erelzi**
Follitropin: Bemfola, Ovaleap	**Infliximab**: Inflectra**
Somatropin: Omnitrope	**Adalimumab**: Amjevita**
Epoetin: Retacrit, Silapo, Abseamed, Binocrit, Epoetin Alfa Hexal	
Infliximab: Inflectra, Remsima, Flixabi	
Etanercept: Benepali	
Enoxaparin: Inhixa, Thorinane	
Rituximab: Truxima*	

Source: Edison Investment Research, European Medicines Agency and Food and Drug Administration.
Note: *CHMP positive opinion; not approved yet. **Approved but not yet launched owing to patents.

There are several factors driving biosimilar market uptake and performance. Biosimilar penetration is meaningful when there is a significant price difference between the branded product and biosimilar, and when there are no other treatment options than the molecule for which the biosimilar is available. The main factor is the healthcare budget and financing policies. Governments across Europe have sought to limit healthcare expenditure and implement budgetary savings. Payers are the most influential factor for market uptake of biosimilars (Exhibit 8).

Exhibit 8: Market drivers

Factors	Comments
Payers	**National tender system**: Markets with a predominant tender system are based on price discount and capacity to supply the market. This is mainly seen in Nordic countries and some eastern European countries (Poland and Hungary). For instance, Remsima in Norway won its first tender in 2014 at a 38% discount, which went up to a further 69% in the 2015 tender, gaining virtually 100% market share and entirely displacing the originator.
	Hospital/plan purchasing: Hospitals and healthcare plans negotiate with companies and discounts from list price can be achieved, particularly when several hospitals or plans group and increase negotiation power. This is seen especially in the EU-5.
	Free competition: Companies set a price and free market dynamics drive penetration. Payers have no involvement in setting the price. Countries that exhibit this approach are Finland, Belgium and Switzerland.
Country-specific guidelines and mandates	Germany has a quota system that allows biosimilars to reach a certain penetration level before any reference pricing is introduced; this has driven uptake to over 50% and c 50% discounts in biosimilar epoetin. Automatic pharmacy substitution is not allowed in most European countries, but it does happen in some Eastern countries and France has allowed automatic substitution for naïve patients. In countries where substitution happens, adoption has been close to 100% (eg Poland, Latvia and Bulgaria).
Prescribers	The main barrier to widespread switching has been lack of experience and the amount of data on the safety and efficacy when patients stable on the originator are switched to the biosimilar. Therefore, incentivising the use of biosimilars via quotas, mandatory switching and specific training has generated more clinical data, making physicians more comfortable switching patients on branded products to biosimilars.
Competitors	Competition among biosimilars is mainly based on price, especially in tender markets (eg Remsima and Inflectra in Norway).
Patients	Patients influence uptake mainly through associations and advocacy groups, to gain access to otherwise expensive medicines.
Originator companies	Main strategies involve price reductions, sometimes matching the biosimilar discount; IP litigation; and life cycle management (LCM) to extend products' lives (eg Humira's new citrate-free formulation causes less pain to patients and strengthens the product's IP).

Source: Edison Investment Research

Market penetration has varied: from 5%-10%, in some countries to 100% in others, depending on the factors previously cited. In general, maximum penetration is achieved in countries with tender systems in which substitution happens; acute treatments (eg products for chemotherapy side-

effects like filgrastim) can have greater penetration as the rotation of patients is higher. For example, infliximab biosimilar reached an average 30% volume market share in Europe at an average 30% discount rate in mid-2015 (IMS). Thus, biosimilars have increased access to expensive biologics that otherwise would not have reached certain groups of patients, especially patients with chronic conditions in those countries without state funding or with inadequate private insurance coverage. In the period of 2006-14 biosimilars have increased patient access by 44% in the EU-5.

Management, organisation and shareholders

Management board

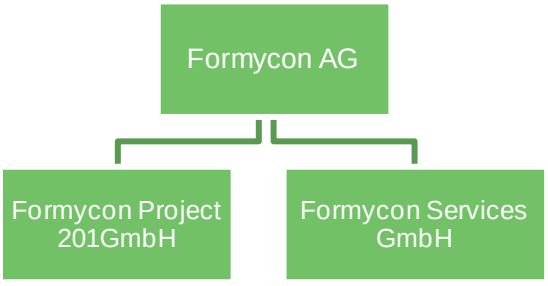
Consistent with the board organisation of German companies, Formycon has a two-tier board in which executive directors are in the executive board and non-executive directors are in a separate supervisory board. The composition of Formycon's management board is as follows:

- Dr Carsten Brockmeyer, PhD, has extensive experience in the pharmaceutical industry as scientific director at Baxter International, and at Hexal Biotech, where he oversaw the development of the first biosimilar of epoetin alpha and of a biosimilar of filgrastim. He became Formycon's CEO in 2013.
- Dr Nicolas Combé, PhD co-founded Formycon AG in 2008 and has been CFO of Formycon since 2010.
- Dr Stefan Glombitza joined Formycon in 2016 as COO. He has more than twenty years of extensive experience in the pharmaceutical industry and has particular expertise in the generics sector, first at Hexal and later at Sandoz when Hexal was acquired by Novartis.

Organisation

Formycon Group follows an organisational structure designed to execute on its strategy and business model. Research and development activities are conducted by Formycon AG, both for its own projects as well as on behalf of its product-specific subsidiary Formycon Project 201 GmbH. In addition, Formycon Services GmbH is a separate subsidiary that offers specialised services to biotechnology and pharmaceutical companies.

Exhibit 9: Formycon's organisational structure



Source: Formycon, Edison Investment Research

Shareholders

Exhibit 10: Principal shareholders

Name	Ownership (%)
Institutional investors	50
Founders and management	20
Free float*	30
IP Concept Luxembourg SA	1.90
Semper Constantia Privatbank AG	0.96
Alceda Fund Management SA	0.63
Zurcher Kantonalbank	0.60
UBS	0.39

Source: Bloomberg. Note: *Main shareholders in free float are shown below.

Financials

Formycon is a development-stage company and has no marketed products. Revenues increased to €12.7m in 2014 and €16.92m in 2015, mainly from out-licensing activities to Santo Holding and income from its services division. According to the company's guidance, 2016 revenues will be c €20m.

Expenses increased from €11.8m in 2014 to €16.6m in 2015, mostly associated with research and development. No R&D expenses were capitalised. The company expects expenses to accelerate in 2016 and subsequent years due to the investment in FYB202 and FYB205. Formycon reached an operating profit of €0.87m in 2014 and €0.54m in 2015. Net income was €0.87m in 2014 and €0.60m 2015.

The company raised funds in 2013 of €17.5m and €11m in 2015. As a result of the cash received from out-licensing agreements, the company's operating cash flow almost broke even in 2014 (an outflow of €0.03m) and was positive in 2015 (€0.5m). Formycon has no financial debt. The company's last reported liquidity position was €19m at end September 2016.

Exhibit 11: Financial summary

Year end 31 December (€m)	2012	2013	2014	2015
Income statement				
Revenue	**0.60**	**0.40**	**12.70**	**16.9**
Profit before tax (as reported)	(2.40)	(7.77)	0.87	0.60
Net income (as reported)	**(2.40)**	**(7.77)**	**0.87**	**0.60**
EPS (as reported) (€)	N/A	N/A	N/A	N/A
Dividend per share (€)	0.00	0.00	0.00	0.00
Balance sheet				
Total non-current assets	7.19	6.25	4.03	3.74
Total current assets	0.45	10.90	12.88	23.41
Total assets	**7.64**	**17.20**	**16.91**	**27.15**
Total current liabilities	(3.38)	(2.70)	(3.26)	(1.61)
Total non-current liabilities	0.00	(0.50)	(0.53)	(0.66)
Total liabilities	(3.38)	(3.19)	(3.80)	(2.28)
Net assets	4.26	13.90	13.11	24.87
Shareholders' equity	**4.26**	**13.90**	**13.11**	**24.87**
Cash flow statement				
Net cash from operating activities	2.16	(16.62)	(0.03)	0.52
Net cash from investing activities	(4.15)	(0.04)	(0.57)	(0.60)
Net cash from financing activities	1.52	17.43	(0.01)	11.15
Net cash flow	**0.50**	**0.68**	**(0.61)**	**11.07**
Cash & cash equivalent end of year	**0.21**	**0.90**	**0.29**	**20.30**

Source: Formycon accounts

Valuation

Formycon's market cap is c €225m and its enterprise value (EV) is c €206m, based on the last reported liquidity position of €19m. Formycon has two disclosed biosimilars in development targeting an originator nAMD market of $9-10bn; assuming a simple 50% discount and 50% penetration for biosimilars therefore suggests a target market for Formycon's lead products of $2-2.5bn, on which Formycon may receive royalties and milestones. We believe these lead assets constitute the bulk of the current valuation. The two undisclosed assets are more difficult to assess until further information is made available regarding the markets being targeted. We also believe that the valuation reflects the background, expertise and successful track record of the company's management. Progression of the pipeline in the clinic and additional partnerships should unlock further value.

In our view, the closest peers are Pfenex (market cap €134m; EV €46m at a $1.07/€ exchange rate) and Xbrane (market cap €20m; EV €17m at a SEK9.5/€ exchange rate) and Coherus (market cap €1.2bn; EV €1.2n at a $1.07/€ exchange rate); however, relative valuation metrics, such as P/E, are difficult to assess, given the early-stage and often loss-making nature of these development companies. Furthermore, all are at different stages of development with multiple other assets in the pipeline, further complicating any peer group comparison.

Sensitivities

Formycon is subject to the risks associated with biosimilars, including the ability to meet the biosimilarity requirements of regulatory agencies, showing equivalent safety and efficacy to the reference products in clinical trials, achieving regulatory approval and successful launch and commercialisation. We see somewhat reduced clinical risk as these are similar versions of approved products. For FYB201 market launch in the US upon Lucentis patent expiry in 2020 and in the EU in 2022 seems feasible. However, Roche and Novartis may seek to employ various strategies, including lower pricing, in order to prevent biosimilar Lucentis from gaining market share. Additionally, other competitors may launch at the same time and hamper market penetration. For FYB203, no data on biosimilarity has been disclosed so far. Additionally, the company has not outlined the development plans, ie start of clinical trials, potential registration and launch of the product. Although we are not aware of other companies developing a biosimilar of Eylea, other competitors may emerge in the future.

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