Formycon (FYB GY) | Pharma/Healthcare

December 05, 2019

Catching the next wave of blockbuster biosimilars

We initiate coverage with BUY: Formycon is a developer of biosimilars. A biosimilar is a biological medication that is highly similar to another already approved biological ("reference product") but is sold for prices that are ~20% lower as biosimilar producers can leverage the reference biologics' established data.Formycon currently has four biosimilars in its pipeline. Its most advanced biosimilar FYB201 - a biosimilar for Lucentis which stands for global sales of more than USD 4bn - has already passed Phase III and we expect the distribution start via its US partner Coherus in Q1/21. By FY 2024, two further biosimilars should be ready to market. Overall, we project total royalties in FY 2030 of EUR 250m against a biosimilar market in Europe that might achieve sales of >EUR 30bn. In addition, Formycon has a strong margin potential and we see margins of >80% as a realistic scenario driven by the fact that later royalties are not offset by any costs as its licensing partners bear all costs related to production, marketing and distribution. Finally, Formycon has strong industrial partners - the commercialization partners belong to the Strüngmann brothers who sold the German generics bellwether Hexal to Novartis in 2005. A solid cash-pile and the strong links into the pharma industry improve the risk profile considerably in our view.

Valuation: We derive our target price of EUR 39 from our risk-adjusted NPV approach which reflects the fact that none of Formycon's biosimilars is approved (yet). With this approach, we can value each biosimilar in the pipeline separately depending on the current stage of development

Fundamentals (in EUR m)	2016	2017	2018	2019e	2020e	2021e
Sales	20	29	43	35	38	41
EBITDA	-3	-1	8	-1	-3	-4
EBIT	-4	-2	7	-2	-3	-5
EPS adj. (EUR)	-0.45	-0.17	0.75	-0.21	-0.35	-0.46
DPS (EUR)	0.00	0.00	0.00	0.00	0.00	0.00
BVPS (EUR)	2.30	2.73	3.53	4.79	4.44	3.98
Net Debt incl. Provisions	-14	-16	-12	-20	-15	-5
Ratios	**2016**	**2017**	**2018**	**2019e**	**2020e**	**2021e**
EV/EBITDA	-60.3	-385.1	29.0	-244.1	-114.1	-82.9
EV/EBIT	-49.9	-188.6	32.6	-147.3	-88.8	-68.2
P/E	-53.5	-193.2	34.5	-154.5	-92.2	-68.7
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	-17.3	-2.6	18.7	-3.5	-7.0	-9.3
EBIT margin (%)	-20.8	-5.3	16.6	-5.8	-9.0	-11.3
Net debt/EBITDA	4.2	20.7	-1.6	16.3	5.8	1.3
ROE (%)	-17.8	-6.8	24.2	-5.1	-7.5	-11.0
PBV	10.4	12.0	7.4	6.7	7.2	8.0

Sources: Refinitiv, Metzler Research

Buy initiation of coverage

Price* EUR 31.10

Price target EUR 39.00

* XETRA trading price at the close of the previous day unless stated otherwise in the Disclosures

Market Cap (EUR m)	319
Enterprise Value (EUR m)	299
Free Float (%)	35.0

Performance (in %)	1m	3m	12m
Share	-6.0	6.1	8.0
Rel. to Prime All Share	-6.3	-1.3	-8.2

Sources: Refinitiv, Metzler Research

Sponsored Research

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Content

Key Data

Company profile

CEO: Dr. Carsten Brockmeyer CFO: Dr. Nicolas Combé Martinsried (Planegg)

Formycon, headquartered in Martinsried-Planegg (Germany) is a leading developer of biosimilars with a focus on opthalmology and immunology. The current pipeline includes four biosimilars: FYB201 (biosimilar for Lucentis), FYB202 (biosimilar for Stelara), FYB203 (biosimilar for Eylea) and FYB205 (no information published yet).

Major shareholders

Family Offices (35%), Institutional Investors (15%), Founders and Management (15%)

Key figures

P&L (in EUR m)	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Sales	**20**	**15.4**	**29**	**48.5**	**43**	**48.2**	**35**	**-18.6**	**38**	**8.6**	**41**	**7.2**
EBITDA	**-3**	**-329.1**	**-1**	**77.7**	**8**	**n.m.**	**-1**	**-115.3**	**-3**	**-117.1**	**-4**	**-42.4**
EBITDA margin (%)	-17.3	-298.5	-2.6	85.0	18.7	819.5	-3.5	-118.7	-7.0	-100.0	-9.3	-32.9
EBIT	**-4**	**-857.2**	**-2**	**62.2**	**7**	**563.4**	**-2**	**-128.5**	**-3**	**-68.5**	**-5**	**-34.6**
EBIT margin (%)	-20.8	-756.1	-5.3	74.6	16.6	412.6	-5.8	-135.0	-9.0	-55.2	-11.3	-25.6
Financial result	**0**	**-79.5**	**-0**	**-580.3**	**-0**	**32.4**	**-0**	**-27.1**	**-0**	**-8.6**	**-0**	**-7.2**
EBT	**-4**	**-801.8**	**-2**	**61.2**	**7**	**549.7**	**-2**	**-129.1**	**-3**	**-67.5**	**-5**	**-34.3**
Taxes	-0	-97.1	-0	-5.6	-0	94.6	0	100.0	0	n.a.	0	n.a.
Tax rate (%)	0.1	n.a.	0.2	n.a.	-0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
Net income	-4	-799.6	-2	61.2	7	550.6	-2	-129.1	-3	-67.5	-5	-34.3
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
Net Income after minorities	**-4**	**-804.1**	**-2**	**61.1**	**7**	**548.9**	**-2**	**-129.1**	**-3**	**-67.5**	**-5**	**-34.3**
Number of shares outstanding (m)	9	0.2	9	2.7	9	0.8	10	6.1	10	0.0	10	0.0
EPS adj. (EUR)	**-0.45**	**-802.5**	**-0.17**	**62.1**	**0.75**	**545.1**	**-0.21**	**-127.4**	**-0.35**	**-67.5**	**-0.46**	**-34.3**
DPS (EUR)	**0.00**	**n.a.**	**0.00**	**n.a.**	**0.00**	**n.a.**	**0.00**	**n.a.**	**0.00**	**n.a.**	**0.00**	**n.a.**
Dividend yield (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.

Cash Flow (in EUR m)	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Gross Cash Flow	**-3**	**-328.6**	**-1**	**77.7**	**8**	**n.m.**	**-1**	**-115.3**	**-3**	**-117.1**	**-4**	**-42.4**
Increase in working capital	**-1**	**n.a.**	**-6**	**n.a.**	**6**	**n.a.**	**-1**	**n.a.**	**-1**	**n.a.**	**-0**	**n.a.**
Capital expenditures	**1**	**107.9**	**1**	**-63.2**	**1**	**108.5**	**1**	**-1.4**	**1**	**8.6**	**1**	**17.9**
D+A/Capex (%)	50.4	n.a.	153.6	n.a.	84.9	n.a.	76.7	n.a.	66.7	n.a.	60.6	n.a.
Free cash flow (Metzler definition)	**-4**	**-542.0**	**5**	**227.3**	**1**	**-71.6**	**-2**	**-234.1**	**-3**	**-79.5**	**-5**	**-59.4**
Free cash flow yield (%)	-1.6	n.a.	1.5	n.a.	0.5	n.a.	-0.5	n.a.	-1.0	n.a.	-1.5	n.a.
Dividend paid	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Free cash flow (post dividend)	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**n.a.**	**n.a.**

Balance sheet (in EUR m)	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Assets	**25**	**-7.2**	**31**	**22.4**	**40**	**28.5**	**53**	**35.0**	**50**	**-5.9**	**46**	**-8.2**
Goodwill	**1**	**-14.8**	**1**	**-17.4**	**1**	**-21.1**	**1**	**-13.3**	**1**	**0.0**	**1**	**0.0**
Shareholders' equity	**21**	**-16.0**	**26**	**22.3**	**33**	**30.1**	**48**	**44.0**	**44**	**-7.2**	**40**	**-10.5**
Equity/total assets (%)	82.9	n.a.	82.9	n.a.	83.9	n.a.	89.5	n.a.	88.2	n.a.	86.0	n.a.
Net Debt incl. Provisions	**-14**	**31.0**	**-16**	**-10.5**	**-12**	**20.0**	**-20**	**-60.7**	**-15**	**22.9**	**-5**	**67.4**
thereof pension provisions	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**0**	**n.a.**	**n.a.**	**n.a.**
Gearing (%)	-67.4	n.a.	-60.9	n.a.	-37.5	n.a.	-41.8	n.a.	-34.8	n.a.	-12.6	n.a.
Net debt/EBITDA	4.2	n.a.	20.7	n.a.	-1.6	n.a.	16.3	n.a.	5.8	n.a.	1.3	n.a.

Sources: Refinitiv, Metzler Research

Executive Summary

German developer of biosimilars

Formycon, headquartered in Labor in Planegg (Germany), is a German developer of biosimilars. A biosimilar is a biological medication that is highly similar to another already approved biological (the reference product). In general, Formycon seeks to license out its biosimilar candidates once specific milestones have been reached. Hence, its partners assume responsibility for the subsequent production and the distribution in Europe and the US. At the moment, Formycon has four biosimilars in its pipeline: FYB201 (biosimilar candidate for Ranibizumab / Lucentis), FYB202 (biosimilar candidate for Ustekinumab / Stelara), FYB203 (biosimilar candidate for Aflibercept / Eylea) and finally FYB205 (no information published yet).

FYB201 - Formycon in the pole position in a USD 4bn market

FYB201 is Formycon's biosimilar candidate for Lucentis which is marketed by Genentech & Novartis and generated sales of USD 4bn in FY 2018. Lucentis is used in the treatment of age-related macular degeneration, the leading cause of blindness in developed countries among people over 50. Patents expire in 2020 in the US and 2022 in Europe. In our view, Formycon is clearly in the pole position regarding the biosimilar development. While also Samsung Bioepis and XBrane are working on a biosimilar candidate, FYB201 is the only candidate that has already passed Phase III studies - we expect the submission of the relevant approval documents to the FDA at the year end 2019. FYB201 is licensed out to Bioeq, a joint venture of Polpharma & the Strüngmann Group with massive experience in the pharmacy sector. In addition, most recently Coherus Biosciences acquired the rights to market FYB201 in the US. Formycon will receive royalties of the marketing proceeds. Given Formycon's pole position and the strong distribution partners, we believe Formycon should generate total royalties of almost EUR 400m between FY2021 and FY2030.

FYB202 - Still limited competition in a USD 5bn market

FYB202 is Formycon's biosimilar candidate for Stelara, developed by Janssen Pharmaceutica (subsidiary of Johnson & Johnson) and marketed since 2009. Patents expire in 2023 in the USA and one year later in Europe. Stelara was originally used in the treatment of psoriasis, an inflammatory, non-infectious skin disease. In the meantime, Stelara was also approved for Crohn's disease (2016) and Ulcerative Colitis (2019). Stelara has been one of the most successful biologics over the last years generating sales of USD 5bn in FY 2018. Given the further increasing prevalence rates for CD and UC, ongoing growth is very likely in our view. Despite the extremely attractive underlying market, competition seems limited at the moment. Beside Formycon, only two further companies are working on a biosimilar. As of today, Formycon is on par with the Australian biosimilar company NeuClone - both companies recently initiated its Phase I clinical studies. In our view, Formycon should generate total royalties of more than EUR 450m between FY 2023 and FY2030.

FYB203 - Formycon well on schedule

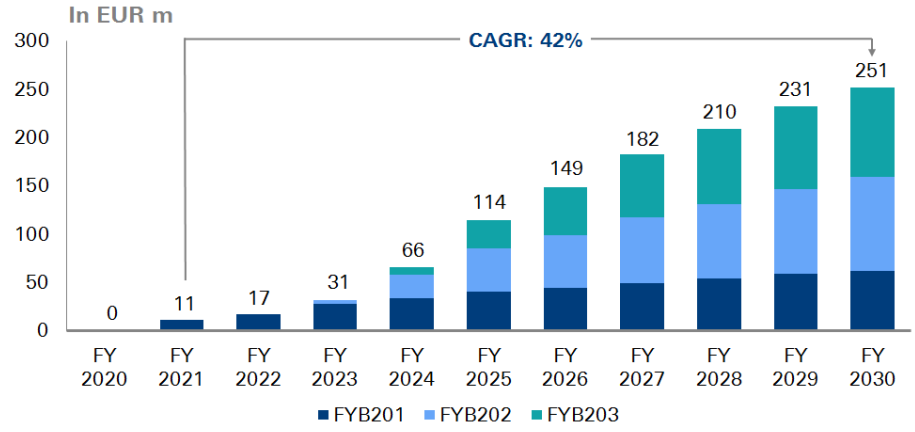
FYB203 is Formycon's biosimilar candidate for Eylea. As Lucentis, Eylea is a VEGF inhibitor, thus, also used in the treatment for age-related macular degeneration. Eylea is marketed by Regeneron in the US while Bayer owns the distribution rights for Europe. Patents expire in 2024 in the USA and 2025 in Europe. Given the fact that treatment costs with Eylea are slightly lower vs. Lucentis, growth rates in the overall underlying market have been even stronger (CAGR FY2012-2018: ~41%). Today, Eylea stands for global sales of EUR 7bn. FYB203 is currently in the advanced pre-clinical stage. While other players are further advanced in the development process (e.g. Mylan already entered Phase III), we see Formycon still well on schedule also given the still relatively long time to patent expiration. As FYB201, FYB203 is based on a licensing deal with Santo Holding (investment company of Strüngmann brothers). Given their large pharmaceutical know-how, we believe Santo Holding has all prerequisites to succeed in the market. Subsequently, Formycon should benefit, generating royalties of more than EUR

400m between FY 2024 and FY FY 2030 according to our forecasts.

Total royalties could reach more than EUR 250m in FY 2030

Based on our estimates for FYB201, FYB202 and FYB203, we expect Formycon to generate total royalties of approx. EUR 250m in FY2030. We see the greatest potential in FYB202 (~40% of proceeds), not least because the competitive situation appears very moderate from today's perspective:

Consolidated proceeds from FYB201, FYB202 and FYB203



Sources: Metzler Research

Significant margin potential

The current earnings level completely underestimates Formycon's margin potential in our view. In the long-term we even see margins of ~80% as a realistic scenario. The reason for our extreme increase in our margin estimates is the fact that the later royalties which Formycon will receive from FY2021 onwards, are not offset by any costs. Both, FYB201 and FYB203 are out-licensed (and we also expect the out-licensing of FYB202 in the next years). This means that Formycon's licensing partners will bear all costs related to the production, marketing and distribution of the biosimilar. Formycon's costs will therefore continue to only consist of costs for the development of new biosimilars. Accordingly, COGS and personnel costs in % of sales should significantly decrease over the next years.

Target price of EUR 39

We initiate coverage with a target price of EUR 39 which is derived from our risk-adjusted NPV approach. Our model reflects the fact that none of Formycon's biosimilars is approved yet. We have defined probabilities for each stage of development, thus, being able to value each of Formycon's three biosimilars separately.

Formycon - SWOT Analysis

Strengths

- Formycon targets **high revenue reference products** ("blockbusters"):
  - **Lucentis** (Global sales: USD 4bn)
  - **Stelara** (Global sales: USD 5bn)
  - **Eylea** (Global sales: USD 7bn)
- Very **experienced management team** with strong background in human biology and pharmacy market
- Solid balance sheet without fin. debt and **sufficient cash reserves** following last capital increase
- Formycon holds a **front-runner position** in the biosimilar market for Lucentis - already passed clinical study Phase III
- **Strong industrial partners** behind - Commercialization partners belong to the Strüngmann brothers who sold their pharma group Hexal in 2005
- **Better risk profile** and lower spending requirements compared to biotech companies

Weaknesses

- Relatively **low market capitalization** and **low liquidity** in the shares
- **No biosimilar has been released** by Formycon yet - even though there is a high probability that three biosimilars will be launched within the next years
- Formycon seeks to license out its biosimilar which **reduces the revenue potential**

Opportunities

- Market for biosimilars should remain the **fastest growing segment** of the pharmaceutical market - expected to grow at >30% going forward
- **Competition** in the market for Stelara **seems very limited** at the moment - beside Formycon, only two further companies are working on a biosimilar candidate in a USD 5bn market
- **Additional partners** with established sales structure could further increase the revenue potential for Formycon
- **FYB205** (no information published yet) could further increase Formycon's sales in the long-term
- Current earnings level completely underestimates the **significant margin potential** - in the long-term margins of above 80% are possible as future royalties will not be offset by any costs
- Expansion into the fast-growing **emerging markets** such as China or Brazil possible

Threats

- Manufacturers of reference products might increasingly react to the launch of biosimilars with a **price offensive** or **patent litigations**
- **Further competitors** (i.e. larger pharmacy companies) might enter the attractive biosimilar market
- **New and alternative treatment methods** may evolve faster than expected for the diseases treated by Lucentis, Eylea and Stelara
- (Low) probability that FYB201, FYB202 or FYB203 will not receive **regulatory approval**

Source: Metzler Research

Investment Case

Business Model

German developer of biosimilars

Formycon, headquartered in Labor in Planegg (Germany), is a German developer of biosimilars. A biosimilar is a biological medication that is highly similar to another already approved biological (the reference product). Formycon seeks to license out its biosimilar candidates once certain defined development milestones have been attained or to further develop these through regulatory approval together with cooperation partners. Formycon is able to cover all technical stages of the biopharmaceutical development chain from analysis and cell line development to preclinical studies and clinical trials, all the way through to the creation and submission of regulatory approval application documents. Its partners usually assume responsibility for subsequent production and the product marketing of the developed biosimilars. As of FY 2018, Formycon generated revenues of EUR 43m with its ~100 employees.

Current pipeline includes 4 biosimilars

As of today, Formycon has a full product development pipeline and is working on four biosimilar projects - detailed information has been published for three of these biosimilar projects:

- FYB201: Biosimilar candidate for Lucentis - an ophthalmic drug used in the treatment of neovascular age-related macular degeneration and other serious eye diseases. Lucentis was originally developed by Genentech and generated global sales of ~USD 4bn in FY 2018. Patents expire in 2020 in the US and 2022 in Europe. FYB201 is Formycon's most advanced biosimilar candidate - phase III clinical trials were already successfully completed in 2018. Bioeq IP AG, the owner of the global commercial rights to FYB201, is expected to submit the regulatory approval dossier to the U.S. Food and Drug Administration at year end 2019. Coherus BioSciences, to which Bioeq gave the exklusive marketing and distribution rights for the U.S., expects to launch FYB201 in 2021 in the USA
- FYB202: Biosimilar candidate for Stelara - a biopharmaceutical drug used in the treatment of certain inflammatory diseases such as moderate to severe psoriasis as well as Morbus Crohn and Ulcerative Colitis diseases. Stelara was originally developed by Janssen Pharmaceutica (subsidiary of Johnson & Johnson) and generated global sales of ~USD 5bn in FY 2018. Patents expire in 2023 in the US and 2024 in Europe. Formycon recently entered into the clinical phase I
- FY203: Biosimilar candidate for Eylea - as Lucentis, Eylea is used in the treatment of neovascular age-related macular degeneration and other eye diseases. Eylea was originally developed by Regeneron Pharmaceuticals and stands for global sales of ~USD 7bn. Patents expire in 2024 in the US and 2025 in Europe. The development of FYB203 is currently in the advanced preclinical phase. Start of the clinical phase III is scheduled for mid 2020
- FYB205: Further biosimilar project, however, no details have been announced yet

Criteria that determine suitable reference products

Choice of "right" biosimilar of particular importance

We would like to briefly highlight which factors impact the choice of the reference products (also with regard to later launches): The choice of the suitable reference product depends on several factors and has to be examined in detail, as it often takes more than eight years from the development to the release of the biosimilar. According to Formycon, the following factors are of particular importance:

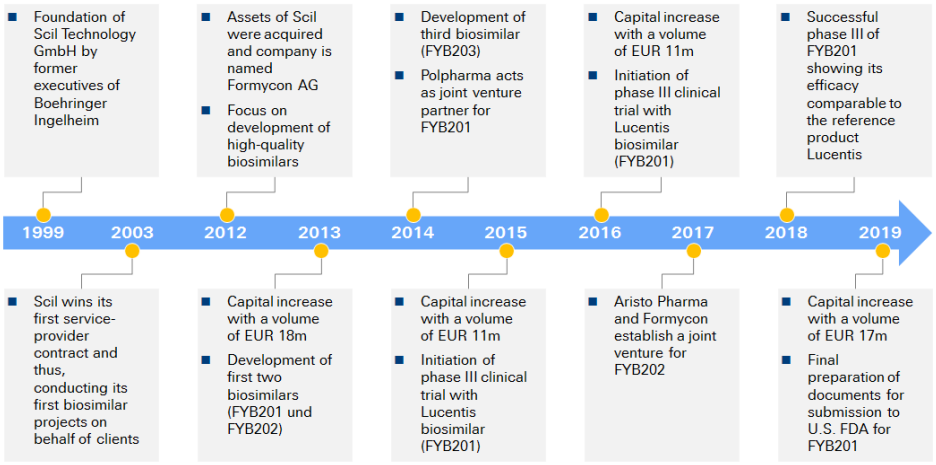
- Patent expiry time / patent landscape: The development of a biosimilar is a lenghty process. Hence, very short patent expiry times of the reference product entail the risk that other competitors will be able to enter the market more quickly with the suitable biosimilar. However, very long expiration times postpone the realisation of sales accordingly
- Market potential: The biologic that generates the highest revenues is not necessarily the most interesting one. This is due to the fact that such biologics also entail a correspondingly high number of competitors - for example, in the Humira biosimilar market, four of the world's largest pharmaceutical manufacturers - Amgen, Mylan, Sandoz and Biogen - are battling for corresponding market shares. In principle, however, the "blockbuster products" are of particular interest for every biosimilar developer
- Requirements in terms of development: Particularly high requirements, also with regard to the development of biosimilars, mean that there will be relatively few competitors later. We have gained the impression that all products in the Formycon pipeline are highly complex in the development process - for instance, Formycon's biosimilar for Lucentis is produced in E.coli bacteria which is a complex process; biosimilar for Eylea is a fusion molecule
- Synergies between biosimilar products: For instance, Formycon has with FYB201 and FYB2013 two biosimilars for age-related macular degeneration in its product pipeline

History of the Group

Renaming to Formycon in 2012

In 1999, Scil Technology GmbH was established in Munich. By 2003, Scil Technology GmbH won its first service-provider contracts. In 2012 assets of Scil Technology were acquired and the company was named Formycon AG. 2013 marked Formycon's first capital increase of EUR 17.5m and its first biosimilar developments were initiated. In 2014 the former licensing partner of FYB201, Santo Holding GmbH, formed a joint venture with the leading Eastern European pharmaceutical manufacturer Polpharma, called Bioeq IP AG. By 2015, Formycon licensed its second biosimilar FYB203 to Santo Holding GmbH and a capital increase of EUR 11.1m was pursued. Formycon released details on FYB202 a biosimilar for the reference product Stelara (Ustekinumab) in 2017. Expansion of the product pipeline into a fourth biosimilar candidate was initiated. In 2017, Formycon established a joint venture with Aristo Pharma for FYB202. The FYB201 biosimilar showed comparable efficacy to its reference product in 2018. In 2019, Formycon undertook a private placement capital increase of EUR 17.3m.

Formycon milestones



Sources: Formycon, Metzler Research

Management and Supervisory Board

Experienced management team

Formycon's management team consists of three members: Dr. Carsten Brockmeyer (CEO), Dr. Nicolas Combé (CFO) as well as Dr. Stefan Glombitza (COO). The team is very experienced in our view and has decades of experience in the pharmaceutical industry:

Formycon management team

Dr. Carsten Brockmeyer (CEO)

Dr. Nicolas Combé

Dr. Stefan Glombitza

Source: Formycon, Metzler Research

- **Dr. Carsten Brockmeyer (CEO):** Dr. Brockmeyer has been CEO of Formycon since 2013. Previously he held various management positions at Hexal AG (incl. general manager of Hexal Biotech), where he was also overseeing the development, manufacturing and quality control of the first biosimilar for epoetin alfa and for filgrastim. He also founded the Brockmeyer Biopharma GmbH in 2010. The journal "The Medicine Maaker" ranked him among the most influential people across the globe in the field of medicine. He obtained his doctoral degree in human biology at Hannover Medical School.
- **Dr. Nicolas Combé (CFO):** Dr. Combé has been CFO of Formycon since

2010. In 2006, he was among the founders of NanoRepro AG where he also served as CFO - in this role he also managed multiple financing rounds and finally the successful IPO of the company. In 2007 he co-founded the company that was later to become Formycon AG. He received his doctoral degree in economics from the University of Marburg.

- **Dr. Stefan Glombitza (COO):** Dr. Glombitza has been COO at Formycon since 2016 with responsibility for the operational development. He started his career at Hexal - following the takeover by Novartis in 2005, he was responsible for the project and portfolio management within Sandoz's generics division. He also became head of the global development centre at the Austrian Sandoz facilities in Kundl and Schaftenau. He studied pharmacy at the University of Regensburg where he also obtained his doctoral degree.

Three members in Formycon's supervisory board

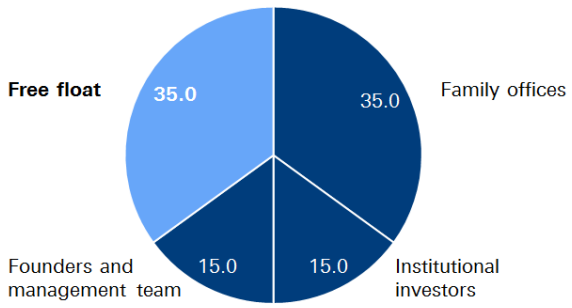
Formycon's supervisory board consists of three members: **(1) Dr. Olaf Stiller** - Chairman of the Supervisory Board - CEO of Paedi Protect AG and Deputy Chairman of the association "Die Jungen Unternehmer/BJU". He also co-founded Formycon AG in 2007 and accompanied the company from its foundation to the listing on the stock exchange **(2) Hermann Vogt** - Deputy Chairman of the Board - Managing Director of AA ASSET CONSULT GmbH, a Frankfurt-based trading firm and finally **(3) Peter Wendeln** - Managing Partner of Wendeln & Cie. Asset Management GmbH.

Shareholder Structure

Free float of 35%

The share capital of Formycon is divided up into 10,000,000 shares of common stock. The nominal value per share is EUR 1.0. The free float amounts to ~35%. The largest shareholder group are family offices with a total share of ~35%. A further 15% of the shares are held by the founders and the management team of Formycon:

Formycon's shareholder structure as of September 2019



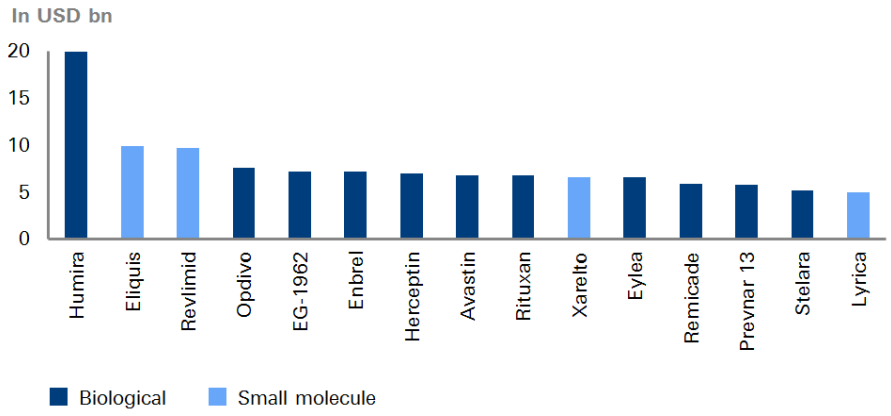
Sources: Formycon, Metzler Research

Biologicals and Biosimilars - What is it all about?

High importance in today's medical treatments

Biologicals serve as reference drugs for biosimilars. Hence, it makes sense to first provide a brief overview on the biologics market before we take a closer look into biosimilars. The first biological was launched on the market in the 1980s - human insulin became the first biological in the USA and Germany. In the beginning, biologicals were hardly widespread, but today it is hard to imagine modern medicine without them. In many cases, biologicals are almost indispensable for the treatment of severe and chronic diseases such as diabetes, autoimmune diseases and cancer. A glance at the top 15 of the most sold drugs also shows the great importance of biologicals. As of FY 2018, worldwide 11/15 of the best-selling drugs are biologicals:

Global top 15 medications as of 2018



Sources: GEN, Metzler Research

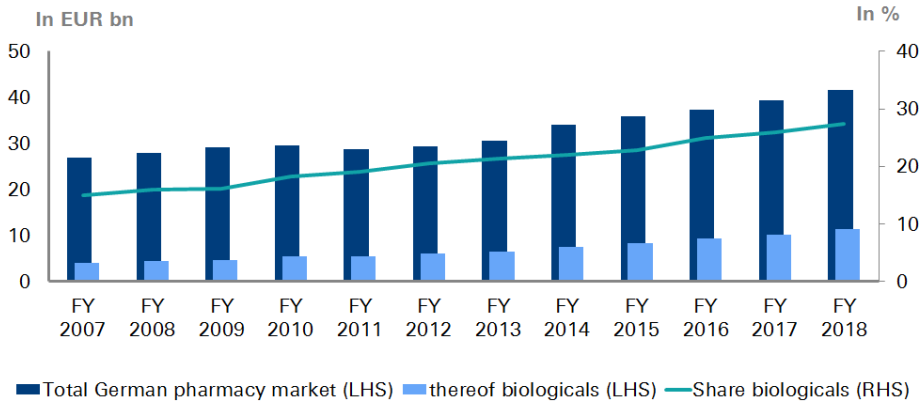
Produced in living cells

Biologicals are drugs whose active ingredient is obtained from living organisms using biotechnological methods. Most biological drugs that are currently used clinically contain protein-based active ingredients. These can vary in size and structural complexity - from simple proteins such as insulin or growth hormones to more complex structures such as monoclonal antibodies. The active substances are produced in cells of various organisms such as yeasts, bacteria or mammals, which are kept in containers (also called bioreactors). The special thing about this is that the production organisms are only able to produce the desired active substances through gene transfer.

Biologicals remain on the rise

In 2018, sales of biologicals in Germany amounted to approximately EUR 11.4bn - a growth of approximately 12% compared to the previous year. In comparison, sales in the entire German pharmaceutical market increased by only around 6%. The rising sales figures for biologicals can be attributed to the increased availability of targeted therapy options due to the many years of strong approval for biologicals. As a result, the share of biologicals in the overall pharmaceutical market has further increased. Since price increases for prescription drugs are excluded by law, this shows that biologicals are becoming increasingly important for the care of patients.

Sales in the German pharmacy market

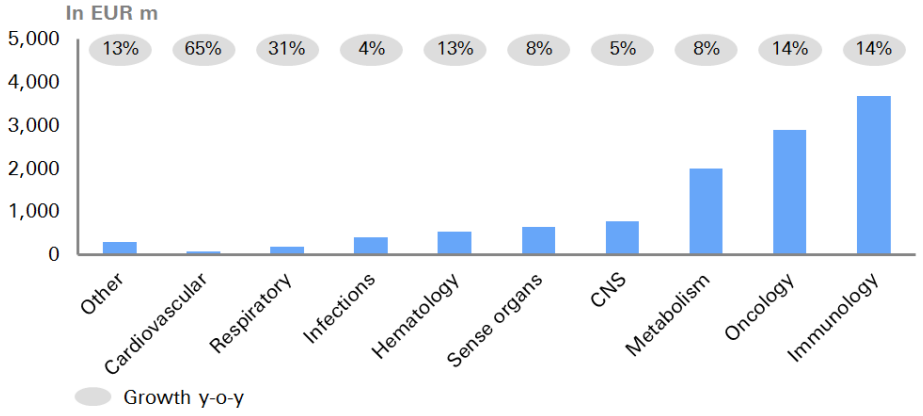


Sources: IQVIA, Metzler Research

Immunology remains main application field

Immunology was the strongest segment in 2018 with 32% of sales. Immunology, oncology and metabolic diseases together accounted for 75% of total biological sales. Within this group, oncology and immunology showed the strongest growth with 14% each. Oncology includes all cancer therapeutics (against solid and haematological tumours). Immunology includes biologicals against autoimmune diseases outside the central nervous system (CNS) (e.g. rheumatoid arthritis or psoriasis).

Immunology remains main application field of biologicals

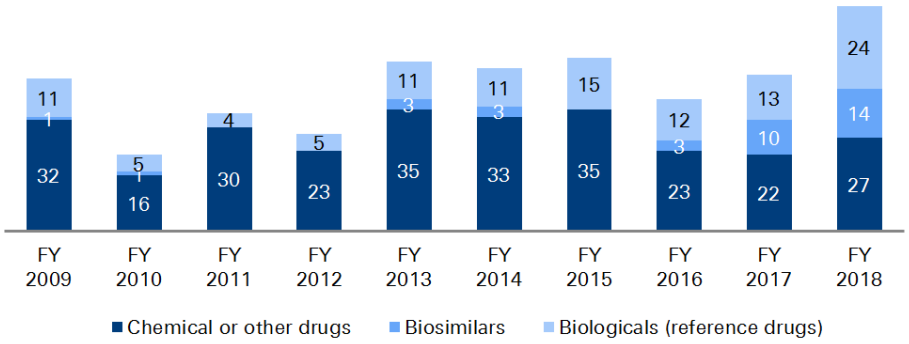


Sources: IQVIA, BCG, Metzler Research

38 approvals for biologicals in 2018

A total of 65 drugs containing a new active substance, a biosimilar active substance or a new combination of known active substances were approved in the EU in 2018. These new approvals include 38 biologicals - a historic all-time high. In total, biologicals accounted for more than half (58%) of new approvals:

New medication registrations in the EU



Sources: EMA, European Commission, BCG, Metzler Research

In total 310 biologicals approved

By the end of 2018, a total of 310 biologicals (including bio-technologically produced vaccines) had been approved for the German market. This corresponds to a growth of 13% compared to the previous year. The focus is on monoclonal antibodies and vaccines, which together account for almost 50% of all biologicals.

The role of biosimilars in the biological market

Biosimilar highly similar to reference products

Following our brief overview on developments in the biologicals market, we will now have a deep dive into biosimilars on which Formycon is focused on. The EMA (European Medicines Agency) defines biosimilars as follows:

"A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines. The European Medicines Agency (EMA) is responsible for evaluating the majority of applications to market biosimilars in the European Union (EU)."

In simple terms, biosimilars are follow-on products of a biopharmaceutical that has been approved for years (reference product). In principle, the biosimilar and the corresponding reference product are structurally comparable. However, due to the complex nature of biologicals and the complex manufacturing processes involved, minor deviations may occur - both the reference product and the biosimilar exhibit molecular variability. This variability, which is also unavoidable between different batches of the reference product, must not, however, affect the safety or efficacy of the medicinal product. This must also be demonstrated in the subsequent approval procedure and will then be confirmed by the relevant approval authorities. An approved biosimilar is therefore just as effective and safe as the reference product. It is also usually used at the same dosage and to treat the same diseases.

Biosimilars versus generics - not exactly the same

Biosimilars significantly more complex in production

Both, biosimilars as well as generics are marketed as cheaper versions of costly name-brand drugs. However, biosimilars and generics are not exactly the same. We highlight the following key differences between biosimilars and generics:

- Generic medicines are chemically synthesized. In contrast, biosimilars are drugs whose active ingredient is obtained from living organisms - for example yeast bacteria or E.coli bacteria
- Given the simplicity of generics and no need for other complex modifications, it is easy to produce exact copies of them. This makes the production process very easy and predictable. On the other hand, both biosimilars and their reference drugs are not synthesised through a simple chemical reaction like generics and require a complex biotechnological process in a cellular environment like any protein from the body instead. As living cells, each manufacturing process is inherently variable, which is why similar and not identical molecules are obtained, despite the controlled production process. Unlike generic medicines, the FDA requires a biosimilar to be highly similar, but not identical to the existing biologic medicine, or "reference product"
- Biosimilars are more complex in production and thus also require significant investments. The development of a biosimilar may take several years and often costs more than USD 200m. In contrast, generics often require only investments of less than USD 5m and the development time is much shorter

Generics vs. biosimilars

	Generics	Biosimilars	Biologics
Scientific requirements	Low	Medium	High
Molecule type	Small, chemical molecules	Long polypeptide chains	Long polypeptide chains
Application	Oral	Parenteral	Parenteral
Production process	Easy and short	Complex	Complex and extensive
Competitors	Many with only limited differences	Some with partial differences	Little and very differentiated
Time to market	~3-4 years	~8 years	~8-10 years
Development costs	<USD 5m	~USD 200m	>USD 800m

Sources: Deutsche Apotheker- und Ärztebank 2015, Metzler Research

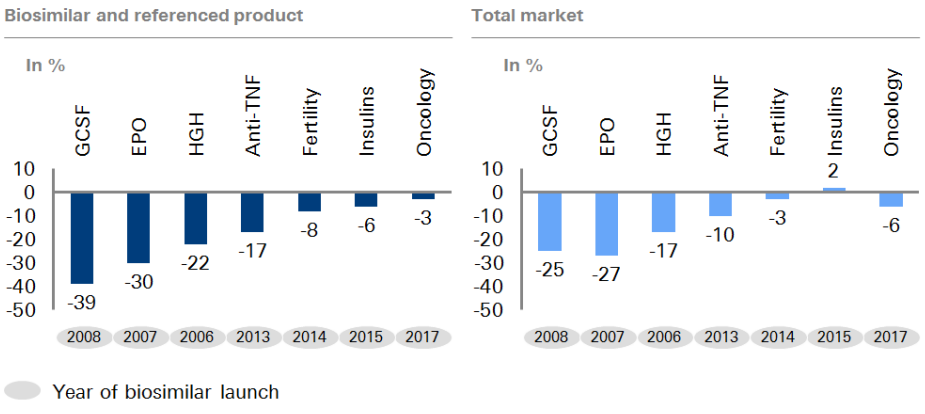
Main rationales of biosimilars

Lower prices main rationale for biosimilars

The main rationale behind the introduction of biosimilars is to increase competition which directly results in reduced prices. Biosimilars are sold for prices that are on average 15-25% lower than those of the reference product (see next chart) - these lower prices are possible because biosimilar sponsors have not incurred the cost of funding innovation or of full clinical trials, and can leverage reference biologics' established data. Specifically, it costs between $75 and 250 million to develop a biosimilar. In contrast,

it costs between USD 800m and USD 1bn to develop a biological.

Change in price per treatment day since introduction of biosimilar

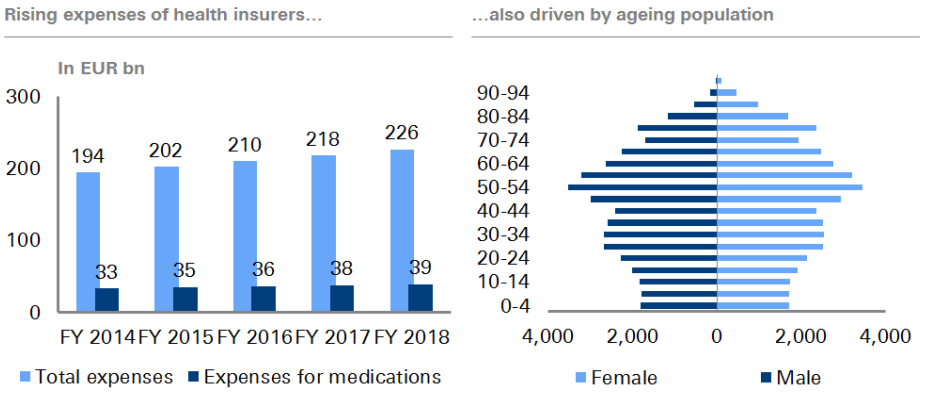


Sources: IQVIA, Metzler Research

Health insurers a main beneficiary of biosimilars

A main beneficiary of the lower prices of biosimilars are the health insurance companies which usually bear the majority of the therapy costs for their insured members. In general, the health insurance companies are increasingly under immense cost pressure which is also driven by the ageing population and hence higher treatment costs. The following graph demonstrates that expenses for insurance companies have risen significantly over the last years. For instance, costs of German health insurers increased by more than 16% over the last four years:

Expenses of German health care insurers



Sources: GKV-Spitzenverband, Destatis, Metzler Research

Governments further support usage of biosimilars

Due to the significantly lower costs and the associated relief for the health systems, the respective countries also have an interest in promoting the use of biosimilars. Most recently, through the modification of the GSAV (German law for security in the pharmaceutical supply) in 2019, the German government has paved the way for a higher opportunity of biosimilar usage. Pharmacies are now required to provide one of the three cheapest alternatives of the prescribed drug, if the physicians do not cross 'aut indem'

on the prescription slip and if the drug on the prescription is not available. Interchangeability along with competitive pricing of its biosimilars may enable Formycon to be a credible substitute to biologics. Furthermore, the US under the government of Donald Trump has become much more liberal with regard to the promotion of biosimilars. Trump has long decried the high costs of drugs and mentioned reducing prices one of his greatest priorities. In the meantime, the FDA has published its "Biosimilar Action Plan" - this plan is focused on improving the efficiency of the biosimilar and interchangeable product development and approval process, maximizing regulatory clarity for biosimilar product development, improving the understanding of biosimilars among patients and supporting the market competition by reducing "gaming" of FDA requirements.

Biosimilars enable access to optimal treatment

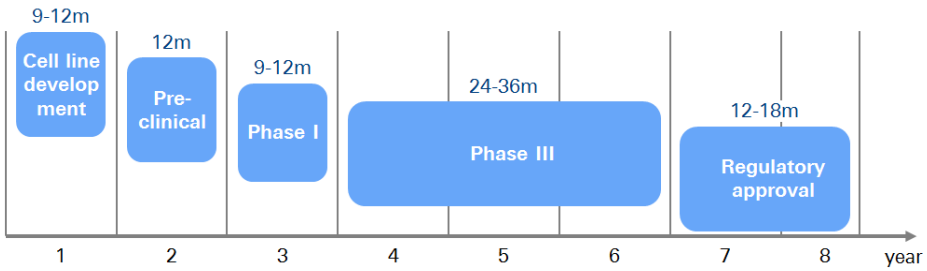
The introduction of biosimilars can not only lower costs for the healthcare system - given the lower prices, biosimilars can also enable consistent and optimal therapeutic access for patients in particular in the emerging markets where the rate of usage of biopharmaceutical drugs is still very low. The biosimilar industry is estimated to be valued at USD 15bn by the beginning of 2020 with USD 5bn to 8bn being accounted to the emerging markets. Biosimilars are attractive for individuals in emerging economies, as they are cheaper than biologics. The stronger purchase power of the US is reflected in the high percentage of expensive biological treatments, 70% opposed to China's 20-25%, respectively. Expansion and development of a biosimilar market in China may increase the accessibility to biological treatments. For the realization of enabling universal healthcare by 2020, China is aiming to integrate biosimilars in its society. By using the EMA and FDA as a guideline, the Chinese Center for Drug Evaluation released their approval framework for biosimilars in 2015 to ensure efficacy, quality and safety. Recently, the Chinese National Medical Products Administration approved its first biosimilar HLX01, a follow-on biopharmaceutical of Rituxan.

Development process of biosimilars

Between start of the development and approval often elapse ~8 years

The development and final approval of a biosimilar requires comprehensive product and process development as well as comparability studies at all development levels. With regard to the quality and the preclinical and clinical objective of this process, it must be ensured that the biosimilar matches its reference product in terms of quality, efficacy and safety. This entire process including the research on the cell line, often takes more than eight years. Since biosimilar companies like Formycon want to launch their biosimilar immediately after the patent period of the reference product has expired, they have relatively little time to decide on which biosimilar to focus on the future given the long process:

Development process for biosimilars



Sources: Sandoz, Metzler Research

Preclinical studies serve as a basis

After the biosimilar candidate and its cell line have been developed, the biosimilar, like any other biopharmaceutical must be tested in preclinical studies before clinical trials with humans can be conducted. This includes, in particular, testing for possible adverse effects, such as whether the drug candidate is toxic, causes cancer or alters the genetic make-up. Animal models are also used for this purpose. The aim of preclinical studies is to uncover possible differences between the reference product and the biosimilar. The preclinical phase is followed by the clinical phase I study. The drug candidate is first tested with healthy volunteers. This involves checking whether the predictions from the animal tests are confirmed. It is also recorded how well the active substance is tolerated by the test persons. Phase II studies are often not necessary. Phase II is mainly used to determine among other things which dosage is best suited for the treatment of the disease. However, these data are usually already known from the reference product and hence, do not have to be tested again.

EMA and FDA most important approval bodies

A phase I study is followed by at least one phase III study - this includes extensive comparability studies with the biosimilars reference product. In some case, confirmatory PK and pharmacodynamic (PD) studies might be sufficient to demonstrate clinical bio-similarity. At the end of the process, the biosimilar is evaluated on the overall body for evidence for bio-similarity. Once all studies and tests have been successfully completed, the biosimilar manufacturer can apply to the relevant authorities for approval. For countries in the EU, the approval process is usually handled by the EMA (European Medicines Agency) in London. The USA, Japan and other countries outside the EU have their own approval bodies - for instance, in the USA the approval process is regulated by the FDA (US Food and Drug Association).

Europe - a pioneer in biosimilars

The approval of medical products in the EU is based on a sound legal framework in which a specific procedure for the authorisation of biosimilars was included in 2004. The EU has pioneered with regard to biosimilar regulation since the biosimilars were approved - already in 2006, the first products Omnitrope (Somatropin) and Zarzio (Filgrastim) from Sandoz were released. Since then, the EU has approved the largest number of biosimilars worldwide (see full list of approved biosimilars in appendix) and, as a result, gained the most extensive experience regarding the use and safety of biosimilars.

US - first biosimilar only approved in 2015

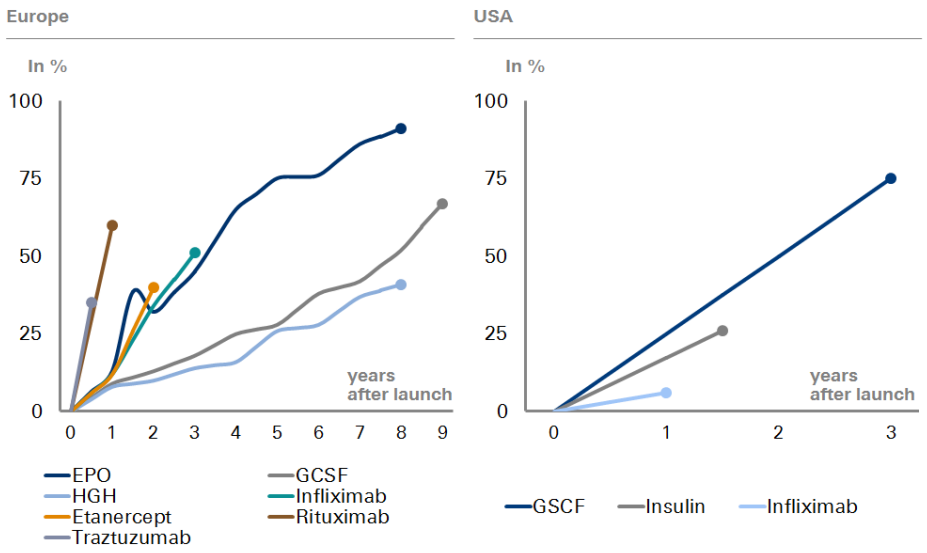
In the US, the basic principles for the approval of a biosimilar were defined much later. In 2009, a law was finally passed governing the shortened approval period and the interchangeability of biosimilars with its reference products. Approval by the FDA is only granted if the biosimilar has the same mechanism of action as well as the same dosage and concentration as the reference product. Due to the late adoption of the laws and the approval process by the FDA, the initial approval of a biosimilar was delayed compared to the EU. The first biosimilar Zarxio with the active ingredient Filgrastim from Sandoz was approved in the US in March 2015 - in contrast, as described Filgrastim was already approved by the EU authorities almost 10 years earlier.

Market share of biosimilars

Biosimilars can gain market shares of well above 50%

Biosimilars can gain large market shares within a relatively short period of time. Particularly in Europe, where the first biosimilars were already launched in 2006, empirical values can be derived. For example, the market for epoetin (EPO) or granulocyte-colony stimulating factor (GCSF) shows that biosimilars can achieve market shares of well over 50%:

Market share of biosimilars in Europe and USA



Sources: IQVIA, Xbrane, Metzler Research

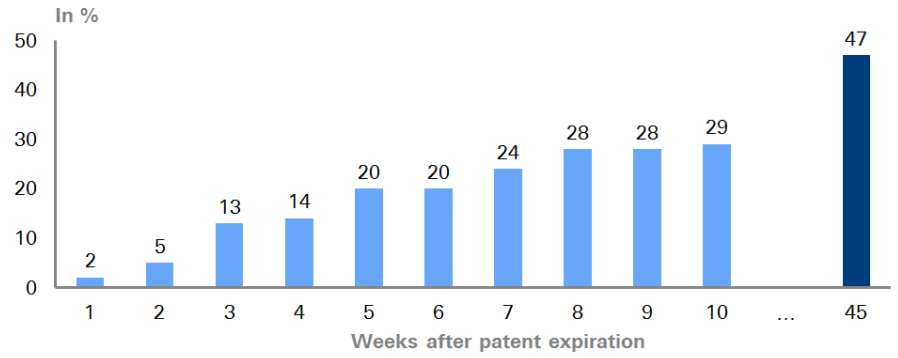
Faster uptake in recent launches

It is interesting to note that the uptake of biosimilars released at a later point in time was significantly faster e.g. Rituximab or Trastuzumab. The feared risk of using biosimilars has been reduced by positive experiences. The initially slow uptake of biosimilars was the result of initial reservations about them. However, the very high use of biosimilars in the meantime shows that these products have now established themselves in the market and have paved the way for further biosimilars. The latest biosimilars have achieved very high market shares in a very short period of time.

Humira biosimilars reached almost 50% market share in less than one year

The best example of the fact that uptake has become significantly faster compared to the early biosimilar launches is the introduction of biosimilars for Humira. Humira, with the active ingredient Adalimumab, is mainly used in rheumatoid arthritis and is also the biologic that generates the highest revenues worldwide (Sales FY 2018: USD 20bn). The excitement about the introduction of biosimilars after patent expiration in October of last year was correspondingly high. Humira-biosimilars gained market share rapidly, with 2% of the market volume covered only a few days after patent expiration. Humira-biosimilars spread fast, just after ten weeks, 29% of the market was claimed by biosimilars. As of August this year, Humira biosimilars have reached a market share of almost 50%:

Market share of Humira biosimilars in Germany



Sources: AG Pro Biosimilars, Insight Health, Metzler Research

Prices of reference drugs significantly impact market share gains of biosimilars

As mentioned, market shares of the individual biosimilar (groups) can vary a great deal. The penetration rate of the biosimilar depends on a variety of factors and is thus often difficult to precisely predict prior to the launch. We would like to highlight some of the relevant factors:

- (1) Price of reference drug: Biosimilars primarily serve the purpose of reducing the costs for the health systems and the co-payments of patients. Accordingly, an important factor for the success of a biosimilar is the price or price difference to the reference product. This also explains the great success of Humira biosimilars. Humira is one of the most expensive biological drugs. A ready-to-use syringe costs around EUR 900 - on average, one syringe has to be injected every two weeks. This results in total annual costs of more than EUR 20,000. In Germany alone, health insurance companies paid more than EUR 1bn for Humira in 2018. The biosimilars are offered with a discount of about 40% compared to the reference product. This results in enormous cost savings and explains the high demand for Humira biosimilars.
- (2) Number of biosimilar competitors: Closely related to (1) is also the number of competitors in the biosimilar market. In general, it can be noted that the higher the number of biosimilar suppliers in the market, the higher the discounts compared to the reference product. This can also be clearly seen in the market for Humira. As a rule, biosimilars are around 20% cheaper than the reference product. However, Humira is the biological drug with the highest sales worldwide - the number of well-known biosimilar manufacturers was correspondingly high. In order to gain market share as quickly as possible, Amgen has entered the market with its Amgevita product with an aggressive pricing strategy. As a result, other biosimilar manufacturers such as Mylan or Sandoz were also forced to significantly lower their biosimilar prices and adjust them to Amgen's price level. Today, discounts for Humira biosimilars are significantly higher than the usual 20%.

Price overview for Adalimumab biosimilars as of Feb 2019

Trade name	Company	Price Package with 2 RFS*	Discount vs. reference product	Price package with 6 RFS*	Discount vs. reference product
Humira (Reference)	**Abbvie**	**1,911**	**-**	**5,324**	**-**
Amgevita	Amgen	1,172	38%	3,420	35%
Hulio	Mylan	1,144	40%	3,354	37%
Hyrimoz	Sandoz	1,144	40%	3,354	37%
Imraldi	Biogen	1,144	40%	3,354	37%

* RFS = Ready-to-fill syringes

Sources: Kassenärztliche Vereinigung Nordrhein, Metzler Research

- (3) Type and duration of treatment: In general, the type of treatment can also influence the penetration rates. Penetration rates are sometimes higher for biosimilars used in acute treatment. This often makes it easier for the physician to make the decision to prescribe a biosimilar. First and foremost, new appointments are made and the therapy is not changed from the reference product to a biosimilar. The situation is different for chronic diseases. As these are follow-up prescriptions, a change in therapy is often more difficult.
- (4) Marketing/distribution power: As in the consumer sector, the marketing and sales power of the biosimilar manufacturers is of great importance for their later success in the biosimilar market. For instance, the Humira biosimilars are produced by Amgen, Mylan and Sandoz with correspondingly great expertise in marketing and distribution. However, distribution strength does not only depend on the size of the company. The much smaller US player Coherus has also been extremely successful in the marketing of its biosimilar product Udenyca (biosimilar for Neulasta - Pegfilgrastim GSCF) and has thus significantly advanced the acceptance of biosimilars in the US market.

Reaction to introduction of biosimilars

How do the manufacturers of reference products react to biosimilars?

Of particular importance is the question of how the manufacturers of reference products react to the introduction of biosimilars. Behind the reference products are usually the world's largest pharmaceutical companies with sufficient market power and financial strength to align prices with those of biosimilar manufacturers. If the reference product were sold at the same price, the biosimilar would have only few chances to gain market share. In this scenario, there is a risk that the biosimilar manufacturer will not be able to generate its R&D costs and realise potential profits. However, we have gained the impression that this risk is negligible. In the past, only Abbvie, manufacturer of Humira, reacted to the introduction of biosimilars in Europe with price reductions. Our impression is also confirmed by the recent statements made by the CEO of the Roche Pharmaceuticals Division. He stressed that Roche is also expecting targeted sales losses from biosimilars (in particular sales losses of CHF 10bn due to patent expirations for the cancer drugs Avastin, Herceptin and MabThera) - but these sales losses from biosimilars would always be offset by newly developed drugs. Roche thus, consciously accepts losses of market share and instead concentrates on the development of new product innovations. Other strategies include:

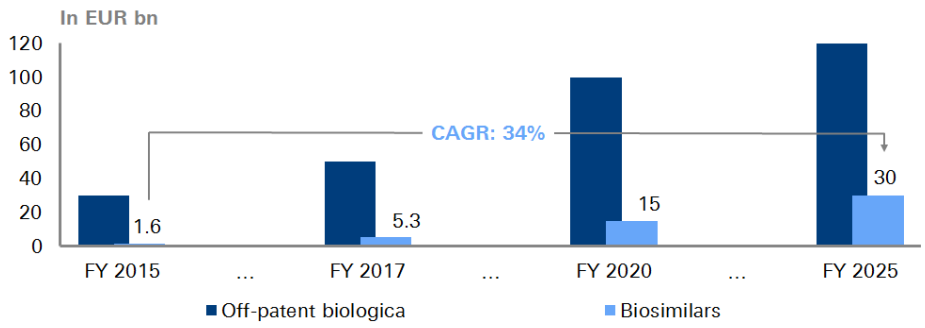
- **Launch of new molecules:** Examples include Neupogen (Filgrastim) - manufactured by AMGEN
- **Reformulation:** Examples include (1) Herceptin (Trastuzumab) - manufactured by Roche - intravenous to subcutaneous injection and (2) MabThera (Rituximab) - manufactured by Roche - intravenous to subcutaneous injection
- **Patent litigation and extension:** Examples include (1) Humira (Adalimumab) - manufactured by Abbvie - and (2) Rituxan (Rituximab) - manufactured by Roche

Future of biosimilars

A USD 30bn market by 2025

Biosimilars are extremely valuable to relieve the burden on health insurers and have been established among doctors, pharmacists and patients both in Europe and in the USA. Thus, we believe that biosimilars should remain the fastest growing segment of the pharmaceutical market in the future. According to estimates by BCC Research, biologicals with a turnover of between USD 100bn and USD 120bn will lose their patent protection by 2025. Worldwide sales of biosimilars, which currently amount to USD 5bn, could rise to around USD 30bn by 2025. This would correspond to an overall market share of 25%. In our view, these figures once again underscore the enormous opportunities that this market offers:

Forecast for global biosimilar market



Sources: BCC Research, IQVIA, Metzler Research

Following our general overview of biologicals and biosimilars, we will now analyse the biosimilar pipeline of Formycon.

Analysis FYB201

We start our analysis of Formycon's pipeline with its first developed and also most advanced biosimilar - FYB201 which is a biosimilar for the reference drug Lucentis:

a.) General information on FYB201 - Ranibizumab used for AMD

Patents expire in 2020 in the US and 2022 in Europe

FYB201 is a biosimilar candidate for Lucentis. Lucentis was developed by Genentech and Novartis. Novartis has the distribution rights outside the US, Genentech is responsible for marketing in the US. Approval for Lucentis was granted in 2006 in the US and one year later in Europe. The patents expire in 06/2020 in the US and 07/2022 in Europe. Lucentis is injected intravitreal. The active ingredient of Lucentis is Ranibizumab, a monoclonal antibody produced from the Escheria Coli bacterium. Ranibizumab belongs to the group of VEGF (Vascular Endothelial Growth Factor) inhibitors. It recognizes and binds specifically to the growth factor A (VEGF-A) present in the eye. Too much VEGF-A causes abnormal growth of blood vessels and swelling in the eye which can lead to impaired vision. By binding to VEGF-A, Ranibizumab can inhibit its activity and thus prevent pathological growth and the formation of swelling. This mechanism makes Ranibizumab in particularly valuable in the treatment of age-related macular degeneration (AMD). Other application fields of Lucentis include macular oedema following retinal vein occlusion (RVO) and diabetic macular oedema (DME).

AMD a major cause of blindness

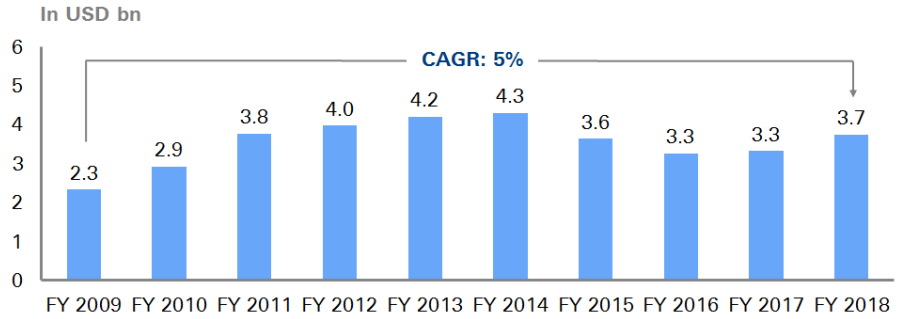
Age-related macular degeneration is the most common chronic eye disease and is the leading cause of blindness in developed countries among people over 50 - the disease causes more than 30% of new blindness. In age-related macular degeneration, the macular, the most important area of vision in the centre of the retina, progressively recedes, leading to a gradual loss of central vision. Due to demographic development and the ageing society, the proportion of patients suffering from AMD has increased significantly in recent years. It is estimated that in Germany alone about 2 million people suffer from AMD, globally up to 50 million people. AMD is not curable, only treatable.

b.) Market analysis - a USD 4bn market opportunity

High-growth phase between 2009 and 2013

Following its launch in 2007, Lucentis has become one of the most successful medications for the treatment of age-related macular degeneration. Today, Lucentis generates sales of almost USD 4bn. The strongest growth rates were recorded until 2013. Prior to the launch of Lucentis, age-related macular degeneration was mostly treated with a Photodynamic Therapy (PDT) with Visudyne (a drug-injected intravenously helping to direct the laser). This therapy involved the use of a specific laser technology that produces non-thermal light required to activate the drug which resulted in a destruction of the unwanted leaking vessels. Even if the therapy was initially successful, there was a 50% chance that the leakage recurred during the next two years. Compared to the Visudyne therapy, Lucentis proved to be a much more effective treatment method. For this reason, Lucentis continued to grow significantly in the subsequent years (CAGR FY2009 - FY 2013: ~16%) and gained market share accordingly.

Lucentis sales development



Sources: Novartis, Genentech, Metzler Research

Lucentis lost market share to Eylea (Aflibercept)

However, the strong growth of Lucentis could not be maintained. This was among others due to the approval of Eylea in 2012 (see also more details on our analysis for FYB203 which is Formycon's biosimilar for Eylea). Eylea is also a biological with the active ingredient Aflibercept. Both, Eylea and Lucentis have been shown to have similar levels of safety and effectiveness. The pre-filled syringes of both drugs cost about the same (~ EUR 1,300), but on average Eylea requires one less injection per year, which means that the corresponding therapy costs are slightly lower. This also explains why some doctors have switched to Eylea for the treatment of their patients. Accordingly, Lucentis' growth rates declined slightly in the subsequent years. However, Lucentis sales have now stabilised again, partly because the drug continues to be highly effective and a "gold standard" in the treatment of AMD.

c.) Competitive landscape - Formycon in pole position

Three players working on Lucentis biosimilar

The underlying Lucentis market is very attractive in terms of pure market size. Hence, Formycon is not the only company working on a corresponding biosimilar for Lucentis. To date, three biosimilar companies have communicated to work on a corresponding biosimilar. Samsung Bioepis should be the main competitor for Formycon going forward in our view. Samsung Bioepis currently has 4 biosimilars in its pipeline and is a joint venture between Samsung BioLogics, a listed Korean biotech company with ~2,300 employees generating ~EUR 500m sales, as well as Biogen, a listed US biotech company with more than 7,000 employees generating ~USD 12bn sales. In addition,Samsung Bioepis is also partnering with Merck Sharp & Dohme. Hence, the company has a lot of know-how and also the relevant sales structure to market their biosimilars. Samsung Bioepis has initiated its phase III studies in 2017. We expect the company to complete phase III within the next ~6 months and to correspondingly submit the relevant approval documents to the FDA.

In addition to Samsung, XBrane recently initiated its phase III studies. Xbrane, a Swedish producer of biosimilars with 5 products in its pipeline, partners with the German pharmaceuticals company Stada Arzneimittel AG. The company is very confident about the future success of its Lucentis biosimilar and is targeting a volume market share of 25% in Europe and US of the total Lucentis market. However, we consider this target to be very ambitious for two reasons: First, XBrane's biosimilar should appear on the market at a later point in time compared to Formycon and Samsung. Second, while Stada is a very established player in Europe, its sales structures in the US are much weaker.

Competitive landscape for Lucentis (Ranibizumab)

Company	Country	Stage of development	Remarks
Formycon	**Germany**	**Phase III completed - FDA filing expected in Q4/2019**	**-**
Samsung Bioepis	South Korea	Phase III - initiated in Sept 2017	Company has total pipeline of 4 biosmilars - commercialization partnership with Biogen and Merck Sharp & Dohme (MSD)
Xbrane Biopharma	Sweden	Phase III - initiated in April 2019	Company has total pipeline of 5 biosmilars - strategic partnership with Stada with 50/50 commercialization split

Sources: Company data, Metzler Research

Formycon in the pole position

Overall, Formycon is in our view in the pole position and hence excellently positioned. It is the only company that has already completed its phase III studies and is now about to submit the relevant approval documents to the FDA. This should enable Formycon to launch its Lucentis biosimilar almost immediately after the patent expiration in the USA. In our view, Formycon should therefore also have a small time lead over Samsung Bioepis (and XBrane). This is also important because recent market research has shown that if the the product, price and marketing are comparable, the order of market entry determines the relative market share.

d.) Our revenue model for FYB201

Our revenue model reflects the licensing deal with Bioeq

We model our sales separately for the European and the US market. In a first step, we forecast the development of the underlying market for Ranibizumab - the active ingredient of Lucentis. Next, we estimate potential penetration rates of biosimilars and hence derive the revenues in the total Lucentis biosimilar market.

For FYB201, Formycon's business model is based on a licensing deal. Licensing partner for FYB201 is Bioeq. Formycon received a single digit million EUR upfront payment and is getting its development costs refunded on a cost plus basis. In addition, Formycon receives a royalty once FYB201 is marketed in the US and Europe. Bioeq was established in 2014 and is a joint venture between: (1) Polpharma: Polpharma is a leading Polish pharmaceutical company and has more than 80 years experience in the development, manufacturing and commercialization of generics. The company operates with seven R&D and production sites where it employs more than 7,000 employees and (2) Strüngmann Group (Santo Holding): In 1989, the brothers Andreas and Thomas Strüngmann founded Hexal, one of the leading manufacturers of generics in Germany. 20 years later, they sold Hexal to Novartis for almost USD 8bn. Through their investment holding Santo Holding, the brothers hold larger stakes in companies in the biotech and healthcare sector. Most recently (7 Nov), Coherus BioSciences acquired the exclusive rights from Bioeq to commercialize FYB201 in the United States. As Formycon, Coherus is a biosimilar company headquartered in the US. However, while Formycon is a pure developer at this point of time, Coherus is also marketing its biosimilars and hence operating with a more risky business model.

To reflect this structure, we estimate the market share of Bioeq in the overall Ranibizumab biosimilar market. To finally derive the sales for Formycon, we multiply these revenues of Bioeq with the royalty rate Formycon receives - we are assuming a royalty rate of 9% which seems realistic in our view.

Revenue model FYB201 - Biosimilar for Lucentis

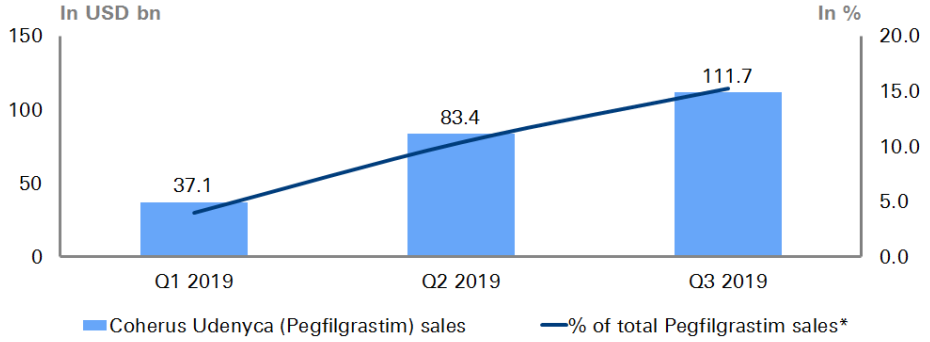
	FY 2017	FY 2018	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e
Europe (patent expiry Jul 2022)														
Ranibizumab sales USDm	**1,888**	**2,046**	**2,251**	**2,363**	**2,481**	**2,481**	**2,357**	**2,310**	**2,264**	**2,219**	**2,174**	**2,174**	**2,174**	**2,174**
Growth y-o-y (in %)	2.9	8.4	10.0	5.0	5.0	0.0	-5.0	-2.0	-2.0	-2.0	-2.0	0.0	0.0	0.0
Ranibizumab sales EURm	**1,671**	**1,734**	**2,009**	**2,110**	**2,215**	**2,215**	**2,105**	**2,063**	**2,021**	**1,981**	**1,941**	**1,941**	**1,941**	**1,941**
Growth y-o-y (in %)	1.1	3.8	15.9	5.0	5.0	0.0	-5.0	-2.0	-2.0	-2.0	-2.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	-	**5.0**	**20.0**	**30.0**	**40.0**	**45.0**	**50.0**	**55.0**	**60.0**	**65.0**
Biosimilar sales EURm	-	-	-	-	-	**111**	**421**	**619**	**809**	**891**	**971**	**1,068**	**1,165**	**1,262**
Growth yoy (in %)	-	-	-	-	-	-	280.0	47.0	30.7	10.3	8.9	10.0	9.1	8.3
Market share Bioeq / EU sales partner (in %)	-	-	-	-	-	**50.0**	**40.0**	**35.0**	**35.0**	**35.0**	**35.0**	**35.0**	**35.0**	**35.0**
Sales Bioeq / Eu sales partner EURm	-	-	-	-	-	**55**	**168**	**217**	**283**	**312**	**340**	**374**	**408**	**442**
Growth y-o-y (in %)	-	-	-	-	-	-	204.0	28.6	30.7	10.3	8.9	10.0	9.1	8.3
Royalty to Formycon (in %)	-	-	-	-	-	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**
Royalty Formycon EURm	-	-	-	-	-	**5**	**15**	**19**	**25**	**28**	**31**	**34**	**37**	**40**
Growth y-o-y (in %)	-	-	-	-	-	-	204.0	28.6	30.7	10.3	8.9	10.0	9.1	8.3
USA (patent expiry Jun 2020)														
Ranibizumab sales CHFm	**1,414**	**1,659**	**1,825**	**1,861**	**1,768**	**1,733**	**1,646**	**1,564**	**1,564**	**1,564**	**1,564**	**1,564**	**1,564**	**1,564**
Growth y-o-y (in %)	0.6	17.3	10.0	2.0	-5.0	-2.0	-2.0	-5.0	-5.0	0.0	0.0	0.0	0.0	0.0
Ranibizumab sales EURm	**1,273**	**1,437**	**1,642**	**1,675**	**1,591**	**1,560**	**1,482**	**1,408**	**1,408**	**1,408**	**1,408**	**1,408**	**1,408**	**1,408**
Growth y-o-y (in %)	-1.3	12.9	14.3	2.0	-5.0	-2.0	-2.0	-5.0	-5.0	0.0	0.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	**10.0**	**17.0**	**22.0**	**27.0**	**32.0**	**37.0**	**42.0**	**47.0**	**50.0**	**50.0**
Biosimilar sales EURm	-	-	-		**159**	**265**	**326**	**380**	**450**	**521**	**591**	**662**	**704**	**704**
Growth yoy (in %)	-	-	-	-	-	66.6	22.9	16.6	18.5	15.6	13.5	11.9	6.4	0.0
Market share Bioeq / US partner Coherus (in %)	-	-	-	-	**75.0**	**50.0**	**44.0**	**40.0**	**35.0**	**35.0**	**35.0**	**35.0**	**35.0**	**35.0**
Sales Bioeq / US partner Coherus EURm	-	-	-		**119**	**133**	**143**	**152**	**158**	**182**	**207**	**232**	**246**	**246**
Growth y-o-y (in %)	-	-	-	-	-	11.1	8.2	6.0	3.7	15.6	13.5	11.9	6.4	0.0
Royalty to Formycon (in %)	-	-	-	-	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**
Royalty Formycon EURm	-	-	-	-	11	12	13	14	14	16	19	21	22	22
Growth y-o-y (in %)	-	-	-	-	-	11.1	8.2	6.0	3.7	15.6	13.5	11.9	6.4	0.0
Total royalties EURm	-	-	-	-	**11**	**17**	**28**	**33**	**40**	**44**	**49**	**54**	**59**	**62**
Growth y-o-y (in %)	-	-	-	-	-	57.5	65.9	18.2	19.5	12.2	10.6	10.7	8.1	5.2

Sources: Evaluate Pharma, Novartis, Roche, Company data, Metzler Research

We believe Formycon has the potential to generate **total royalties of almost EUR 400m** between FY 2021 and FY 2030 with FYB201. Our forecast is based on the following assumptions:

- **Ranibizumab sales:** We expect the market for Ranibizumab to grow moderately in Europe and the US until patent expiry. This growth should be driven by an increasing number of patients suffering from age related macular degeneration - as the population is further ageing, prevalence rates should further increase in our view. Recent H1/19 figures for Ranibizumab (+10% in Europe and USA) confirm our view, that sales in the underlying market should further grow. However, this growth should weaken accordingly with the introduction of biosimilars. Although the number of patients treated is likely to increase, the average treatment prices should fall accordingly. We thus, expect the overall market to decline in the years following the launch of biosimilars. We forecast peak sales of Ranibizumab of ~EUR 3.3bn in FY2030
- **Biosimilar penetration:** In general, we assume that penetration in Europe, as in the past, should increase a little faster, especially because biosimilars have appeared on the market much earlier in Europe. Nonetheless, we expect that Lucentis biosimilars will be able to gain high market shares in the USA as well. On the one hand, this is due to the fact that the therapy costs for the treatment of AMD are very high and biosimilars can therefore significantly reduce the burden on the healthcare system and patients. On the other hand, Lucentis biosimilars will most likely be distributed & marketed by very established players (e.g. Coherus, Samsung Bioepis etc.) with strong links to the relevant decision makers. In the US, we expect Lucentis biosimilars to gain a market share of over 30% within about four years (and ~50% within 8 years). As described above, we believe that penetration in Europe should increase even faster. We expect a penetration rate of 50% within ~4 years.
- **Market share of Coherus & Bioeq:** As described, in the US FYB201 will be marketed by Coherus - the leading biosimilar player in the US. We appreciate this decision also because Coherus did already prove its successful distribution structure with the sale of its Neulasta biosimilar Udenyca. Udenyca has been marketed since January this year and has already generated sales of more than USD 230m in the first nine months:

Coherus sales of Udenyca (biosimilar for Neulasta - Pegfilgrastim)



* Excl. Fulphila sales (biosimilar for Pegfilgrastim marketed by Mylan)
Sources: Coherus, Amgen, Company data, Metzler Research

Based on this demonstrated success, we believe that Coherus also has the potential to become a leading player in the US biosimilar market for Ranibizumab. We expect that Coherus will gain a market share of ~35% in the total Ranibizumab biosimilar market. In Europe, FYB201 will be marketed by Bioeq as of today - however, in our view it is also

possible that an additional sales partner could be introduced in the course of the next two years. However, the joint venture between Polpharma, one of the leading companies, and the Strüngmann Group also has great expertise. For instance, Polpharma already has decades of experience in the commercialization of biopharmaceuticals. Hence, we believe that not only in the US but also in Europe, FYB201 will belong to the leading biosimilars for Ranibizumab. We forecast a market share of 35%.

- Sales Formycon: We are assuming that Formycon receives an average royalty of 9% of the worldwide marketing proceeds

Analysis FYB202

We continue our analysis with FYB202 which is Formycon's biosimilar candidate for Stelara.

a.) General information - Ustekinumab used for Psoriasis, Crohn's Disease and Ulcerative Colitis

Patents expire 2023 in USA and 2024 in Europe

FYB202 is a biosimilar candidate for Stelara, developed by global pharmaceutical company Janssen Pharmaceutica (subsidiary of Johnson & Johnson) and marketed since 2009. The patents expire in 09/2023 in the USA and 07/2024 in Europe. The active ingredient in Stelara is Ustekinumab, a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind to a specific structure in the body. Ustekinumab binds two cytokines in the immune system. These cytokines are involved in inflammations and other important processes. By blocking their action, Ustekinumab reduces the activity of the immune system and, accordingly, the symptoms of the disease.

Stelara is used for the following diseases:

- Psoriasis: Psoriasis is an inflammatory, non-infectious skin disease characterized by distinct red spots with silvery scales and severe itching. The disease occurs in stages and is not curable (only treatable). It is one of the most common chronic diseases worldwide. In Germany alone, more than two million people suffer from the disease; worldwide more than 125 million (nearly 3% of world population). The disease occurs equally frequently in men and woman and generally at every age, with the disease occurring for the first time between the ages of 15 and 25 in over 50% of cases
- Crohn's disease: Crohn's disease is a chronic inflammation of the intestine (especially in the last section of the small intestine and in the large intestine - all layers of the intestinal wall are inflamed). The disease has a relapsing course and leads to severe abdominal pain in combination with strong diarrhoea. As Psoriasis, Crohn is not curable but treatable. In Germany, around 150,000 people suffer from Crohn's disease. The overall incidence of Crohn's disease in Europe is about 6 per 100,000 inhabitants, in the US about 7.0 per 100,000 inhabitants. The first peak of the disease occurs between the ages of 15 and 30 and the second one between the ages of 60 and 70. However, almost 30% of all patients with Crohn's disease are diagnosed before age 20. In general, the frequency is similar in males and females
- Ulcerative colitis: In September and October this year this year, Stelara has also been approved in Europe and the USA for ulcerative colitis (UC). Like Crohn's disease, UC belongs to the group of chronic inflammatory bowel diseases. The inflammation begins in the rectum and spreads continuously to

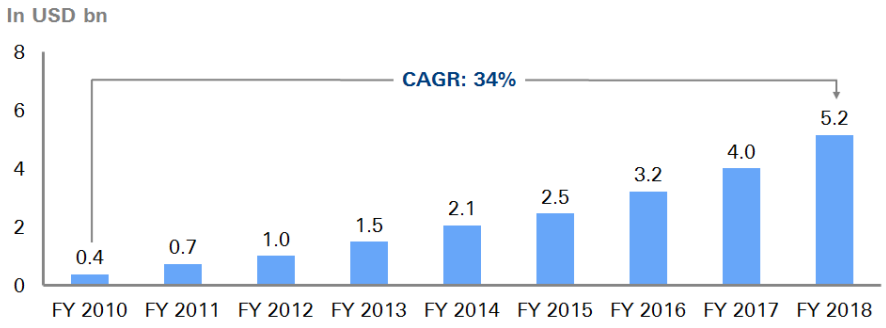
higher parts of the colon. In the affected parts, ulcers occur on the superficial mucous membrane layers. Patients mainly suffer from bloody diarrhoea as well as abdominal pain. The disease is not curable but treatable. In Germany alone about 170,000 people are affected. The disease usually starts with young adults between the ages of 20 and 40

b) Market analysis - a USD 5bn market opportunity

Stelara has become gold standard in treatment of psoriasis and UC

Stelara was newly approved in 2009 and has since become one of the most successful biologics. In FY 2018, Johnson & Johnson generated more than USD 5bn in sales with Stelara, making it one of the world's blockbusters and top 15 biologics in terms of sales. Initially only approved for the use of psoriasis, Stelara was approved for Crohn's disease in 2016 and for ulcerative colitis in 2019, further increasing sales growth. In our view, the great success can also be explained by the extremely high efficacy of the application, also in comparison to alternative therapies. Before the introduction of Stelara, cortisone preparations were mainly used for treatment of Crohn's disease and ulcerative colitis. These often did not show the desired effect, especially for severe relapses of Crohn's disease. In addition, these cortisone preparations were hardly suitable for long-term therapies due to the large side effects.

Stelara sales development



Sources: Evaluate Pharma, Johnson & Johnson, Metzler Research

c.) Competitive landscape - limited number of competitors (yet)

Only 3 companies incl. Formycon working on a biosimilar candidate

In our view, the number of competitors in the biosimilar market for Stelara is still very limited at the moment (**Note:** Some biosimilar companies only publish their progress when entering Phase I or III - hence, the number of competitors might increase over the next years). In addition to Formycon, only two other biosimilar companies have announced to research and develop a corresponding biosimilar. Most recently, Alvotech and Stada agreed on a biosimilar partnership - Stada will exclusively commercialize the products on all key European markets. In addition, Alvotech and Fuji Pharma have entered into an agreement for the exclusive partnership to commercialize the biosimilar in Japan. Alvotech was founded in 2013 and has 7 biosimilars in its pipeline. Other partnerships (except Fuji Pharma) are not published.

In addition, NeuClone, headquartered in Sydney, Australia, has recently initiated phase I clinical trials for its Stelara biosimilar. The company is purely focused on the develop-

ment of biosimilars, in collaboration with its manufacturing partner Serum Institute of India and has a current pipeline of 10 biosimilars. To our knowledge, NeuClone has not published a distribution partner for its Stelara biosimilar yet.

Competitive landscape for Stelara (Ustekinumab)

Company	Country	Stage of development	Remarks
Formycon	**Germany**	**Phase I - since Oct 2019**	**-**
Alvotech	Iceland	n/a	Pipeline of 7 biosimilars - partnership with Fuji Pharma (commercialization in Japan) and Stada (commercialization in Europe)
NeuClone	Australia	Phase I - initiated in H2 2019	Company has total pipeline of 10 biosmilars - developed with Serum Institute in India

Note: Further competitors may exist but did not publish their stage of development yet
Sources: Company data, Metzler Research

Formycon on par with Australien company NeuClone

Overall, we see Formycon well positioned in the biosimilar market for Stelara (Ustekinumab). Formycon already initiated its phase I clinical trials - we see a high probability that the company will be one of the first companies to launch its biosimilar in the US in 2023 & in Europe in 2024 following patent expiry. We believe that Alvotech should be well behind Formycon on schedule. Hence, at the moment NeuClone should be the only competitor that could also be able to release a biosimilar following the patent expiry.

d.) Our revenue model for FYB202

Our revenue model reflects the fact that FYB202 should be out-licensed prior to patent expiry

We model our sales separately for the European and the US market. In a first step, we forecast the development of the underlying market for Ustekinumab - the active ingredient of Stelara. Next, we estimate potential penetration rates of biosimilars and hence derive the revenues in the total Stelara biosimilar market.

For the development of FYB202, Formycon has founded a joint venture with its partner Aristo Pharma. Aristo Pharma is one of the leading German pharmaceutical companies and has emerged from the merger of various German mid-sized pharma companies. Aristo generates revenues of ~EUR 300m with more than 1,200 employees. Aristo Pharma holds 75.1% of the shares in the JV - Formycon the remaining 24.9% - and the development costs are shared in proportion to the ownership stakes. According to our understanding, Formycon will also license out FYB202 but at a much later point in time compared to FYB201 and FYB203. The out-licensing after approval significantly reduces the risk for the licensee - correspondingly, the upfront payment and the royalty rate for Formycon should be higher vs. FYB201 and FYB203. We believe an interested party could pay an upfront fee of ~EUR 100m and promise a royalty rate of ~40% - given the ~25% stake, Formycon would correspondingly receive an upfront payment of ~EUR 25m and royalties of 10% of worldwide marketing proceeds.

Revenue model FYB202 - Biosimilar for Stelara

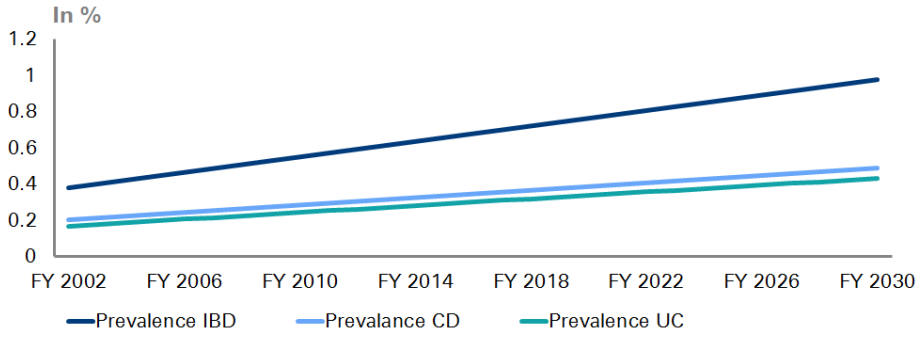
	FY 2017	FY 2018	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e
Europe (patent expiry Jul 2024)														
Ustekinumab sales USDm	**1,244**	**1,687**	**1,974**	**2,171**	**2,388**	**2,579**	**2,672**	**2,591**	**2,464**	**2,391**	**2,391**	**2,391**	**2,391**	**2,391**
Growth y-o-y (in %)	28.4	35.6	17.0	10.0	10.0	8.0	3.6	-3.0	-5.0	-3.0	0.0	0.0	0.0	0.0
Ustekinumab sales EURm	**1,101**	**1,429**	**1,762**	**1,939**	**2,132**	**2,303**	**2,386**	**2,313**	**2,200**	**2,134**	**2,134**	**2,134**	**2,134**	**2,134**
Growth y-o-y (in %)	25.8	29.8	23.4	10.0	10.0	8.0	3.6	-3.0	-5.0	-3.0	0.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	-	-	-	**8.0**	**25.0**	**35.0**	**45.0**	**50.0**	**55.0**	**60.0**
Biosimilar sales EURm	-	-	-	-	-	-	-	**185**	**550**	**747**	**961**	**1,067**	**1,174**	**1,281**
Growth yoy (in %)	-	-	-	-	-	-	-	-	197.2	35.9	28.6	11.1	10.0	9.1
Market share JV / EU sales partner (in %)	-	-	-	-	-	-	-	**50.0**	**35.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**
Sales JV / EU sales partner EURm	-	-	-	-	-	-	-	**93**	**192**	**224**	**288**	**320**	**352**	**384**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	108.0	16.4	28.6	11.1	10.0	9.1
Royalty to Formycon (in %)	-	-	-	-	-	-	-	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**
Royalty Formycon EURm	-	-	-	-	-	-	-	**9**	**19**	**22**	**29**	**32**	**35**	**38**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	108.0	16.4	28.6	11.1	10.0	9.1
USA (patent expiry Sep 2023)														
Ustekinumab sales CHFm	**2,767**	**3,469**	**4,059**	**4,465**	**4,911**	**5,304**	**5,251**	**4,936**	**4,837**	**4,837**	**4,837**	**4,837**	**4,837**	**4,837**
Growth y-o-y (in %)	22.3	25.4	17.0	10.0	10.0	8.0	-1.0	-6.0	-2.0	0.0	0.0	0.0	0.0	0.0
Ustekinumab sales EURm	**2,449**	**2,938**	**3,624**	**3,986**	**4,385**	**4,736**	**4,688**	**4,407**	**4,319**	**4,319**	**4,319**	**4,319**	**4,319**	**4,319**
Growth y-o-y (in %)	19.8	20.0	23.4	10.0	10.0	8.0	-1.0	-6.0	-2.0	0.0	0.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	-	-	**2.0**	**10.0**	**20.0**	**25.0**	**30.0**	**35.0**	**40.0**	**45.0**
Biosimilar sales EURm	-	-	-	-	-	-	**94**	**441**	**864**	**1,080**	**1,296**	**1,512**	**1,728**	**1,943**
Growth yoy (in %)	-	-	-	-	-	-	-	370.0	96.0	25.0	20.0	16.7	14.3	12.5
Market share JV / US sales partner (in %)	-	-	-	-	-	-	**35.0**	**35.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**
Sales JV / US sales partner EURm	-	-	-	-	-	-	**33**	**154**	**259**	**324**	**389**	**453**	**518**	**583**
Growth y-o-y (in %)	-	-	-	-	-	-	-	370.0	68.0	25.0	20.0	16.7	14.3	12.5
Royalty to Formycon (in %)	-	-	-	-	-	-	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**	**10.0**
Royalty Formycon	-	-	-	-	-	-	**3**	**15**	**26**	**32**	**39**	**45**	**52**	**58**
Growth y-o-y (in %)	-	-	-	-	-	-	-	370.0	68.0	25.0	20.0	16.7	14.3	12.5
Total royalties EURm	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**25**	**45**	**55**	**68**	**77**	**87**	**97**
Growth y-o-y (in %)	-	-	-	-	-	-	-	651.9	83.0	21.4	23.5	14.3	12.5	11.1

Sources: Evaluate Pharma, Johnson & Johnson, Metzler Research

In our view, Formycon should generate **total royalties of more than EUR 450m** between FY 2023 and FY 2030. Our forecast is based on the following assumptions:

- **Ustekinumab sales:** With annual growth of more than 30% over the last 8 years, Ustekinumab has been one of the most successful biologics. As described, this strong growth was also driven by the strong growth in the application for inflammatory bowel diseases. Over the next years, experts assume that these inflammatory bowel diseases (incl. Crohn's disease as well as Ulcerative Colitis) should remain further on the rise. For instance, recently Crohn's and Colitis Canada released their findings in a multi-year report. They expect that the number of people living with IBD will will rise by 50% from 270,000 to to 400,000 by 2030 - this corresponds to ~1% of the total population. A further growth driver is in our view the recent approval of Stelara for Ulcerative colitis in Europe and USA. Hence, until patent expiration in September 2023 in the US and July 2024 in Europe respectively, we are assuming ongoing growth in the overall market. Evaluate Pharma assumes annual growth of ~7% over the next years - we are even slightly more optimistic and forecast overall annual growth of ~9%. Recently published growth rates for H1/19 (US and EU >20%) confirm our view. Once the patents for Stelara expire, we expect a decline in the overall market for Ustekinumab as we believe the percentage decay of therapy costs should be greater than the positive % change in the number of treated patients.

Prevalence rates for inflammatory bowel diseases



IBD = Inflammatory Bowel Diseases CD = Crohn's disease UC = Ulcerative Colitis
Sources: Company data, Metzler Research

- **Biosimilar penetration:** In our view, biosimilars for Ustekinumab have the potential to easily reach penetration rates of >50%, especially because therapy costs for Stelara are extremely high: A ready-to-use syringe with a 90mg injection solution costs around EUR 5,000. As a rule, at least four injections per year are necessary, resulting in annual therapy costs of more than EUR 20,000. Therefore, we believe there should be a strong incentive to switch to appropriate biosimilars in order to reduce annual costs by 20-30%. Here, too, we assume that market shares in Europe will grow slightly faster - we assume that four years after patent expiration biosimilars will have a market share of around 50%. In the USA, we also expect long-term market shares of ~50% - but assume that this development takes slightly longer.
- **Market share Joint Venture / Aristo Pharma:** Aristo Pharma has appropriate distribution structures to market FYB202 - e.g. 13 sales locations in Europe and Asia. However, in our view it is well conceivable to bring in (a) further partner(s) with strong sales structures especially for the US market in which

Aristo Pharma has no strong footprint. This would also have a corresponding impact on the market shares. We believe that in FY 2023 Aristo should have a market share of ~35% - in our view Formycon and NeuClone will be able to launch their biosimilar in the year of patent expiration. In the years thereafter, we assume that further competitors might enter the market also given the high attractiveness of the underlying market. We hence assume that the market share of Aristo should correspondingly slightly decline.

- Sales Formycon: We are assuming a royalty rate of 10% - as described we assume that the license partner of FYB202 will pay a significantly higher total royalty rate as at the time of the out-licensing FYB202 may already be approved (or at least filings submitted to FDA). We expect a royalty rate of ~40% - given Formycon's ~25% stake in the JV, Formycon would correspondingly receive ~10% of the worldwide marketing proceeds.

Analysis FYB203

Finally, we will analyse FYB203 which is Formycon's biosimilar for Eylea.

a.) General information - Aflibercept used for AMD

Patents expire in 2024 in USA and 2025 in Europe

FYB203 is a biosimilar candidate for Eylea, developed by global pharmaceutical company Regeneron and marketed since 2011. Eylea is marketed by Regeron in the US while Bayer owns the distribution rights for Europe. The patents expire in 05/2024 in the USA and one year later in Europe. The active ingredient in Eylea is Aflibercept, a recombinant fusion protein serving as an inhibitor for VEGF. Thus, Eylea works similarly to Lucentis and is subsequently also used for the same applications: Application fields include age-related macular degeneration (AMD) and other serious eye diseases such as diabetic macular oedema (DME).

Lucentis vs. Eylea - both offer effective treatment vs. AMD

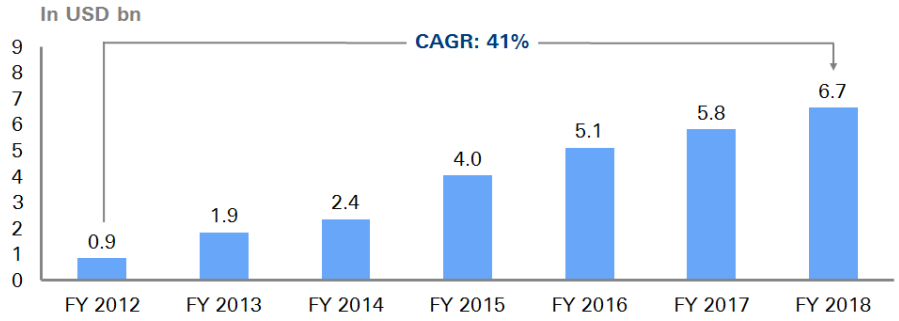
As described, both Lucentis and Eylea are used in the treatment of age-related macular degeneration and other eye diseases. Both medications achieved similar treatment results in the past. For example, in 2015 the Diabetic Retinopathy Clinical Research Network in the New England Journal of Medicine published for the first time the results of a randomized clinical comparison study with more than 600 patients and confirmed a significant improvement in vision for both Eylea and Lucentis. Therapy costs for Eylea are however slightly lower. The pre-filled syringes of both drugs cost ~USD 1,800. However, on average Eylea is injected six times per year compared to about seven Lucentis injections per year, revealing a marginal difference. The type of treatment is often decided by the personal preference of the treating physician and/or the sales power of the underlying companies in the respective targeted countries.

b.) Market analysis - a USD 7bn market opportunity

Eylea - one of the most successful biologicals in recent years

Together with Lucentis, Eylea has become the gold standard for the treatment of age-related macular degeneration over the last years. Eylea belongs to the biologicals with the highest growth rates over the last years. A main driver was the ageing society and the associated higher prevalence rates for age-related macular degeneration. In addition, Eylea also successfully gained market share vs. Lucentis. In our view, this was not only driven by the slightly lower therapy costs of Eylea but also due to the high marketing power and strong sales structure of Regeneron in the US and Bayer in Europe.

Eylea sales development



Sources: Regeneron, Bayer, Company data, Metzler Research

c.) Competitive landscape - Formycon well on schedule

Higher competition given the attractiveness of Eylea market

Eylea is one of the most successful biologicals with annual growth of more than 40% over the last years. Hence, it is not surprising that several companies are working on a corresponding biosimilar. In addition to Formycon, an Eylea biosimilar is also in the product pipeline of Coherus Bioscience (USA), Momenta (USA) as well as Alteogen (South Korea). Coherus is one of the most prominent biosimilar companies. CHS-2020 (Coherus' biosimilar for Eylea) is at the moment in the pre-clinical development (as FYB203). Coherus has a total of five biosimilars in the pipeline. In addition, Coherus has already launched its first biosimilar (Udenyca - biosimilar for Neulasta) with great market success and thus has expertise in the distribution and marketing, particularly in the USA.

The US biotech company Momenta is currently at the forefront of development. Momenta currently has two biosimilars in the pipeline, including M710 - the biosimilar for Aflibercept for which Momenta already initiated the clinical Phase 3 studies. For M710, Momenta cooperates with Mylan, a leading Dutch pharmaceutical company. Mylan has also already launched two biosimilars for the US market in recent years and has thus gained relevant experiences also regarding the sales of biosimilars.

Finally, Alteogen, a Korea-based developer of biologicals, has a biosimilar for Eylea in the pipeline. Surprising is however the fact that Alteogen is initiating a clinical Phase I for its biosimilar. As previously described, Aflibercept is injected into the patient's eye. Thus, the active ingredient does not enter the bloodstream substantially. Therefore, standard laboratory values such as blood values are not particularly meaningful making Phase I irrelevant in theory. For this reason, Formycon also decided in the past to skip Phase I with FYB201 and will also skip Phase I with FYB203.

Competitive landscape for Eylea (Aflibercept)

Company	Country	Stage of development	Remarks
Formycon	**Germany**	**Advanced pre-clinical development**	**-**
Coherus Biosciences	USA	Pre-clinical development	Company has total pipeline of 6 biosmilars - launch of first biosimilar (UDENYCA) in 2019
Momenta	USA	Phase III - initiated in Aug 2018	Company has total pipeline of 2 biosmilars - development and marketing in collaboration with Mylan
Alteogen	South Korea	Preparing to initiate phase I	Company has total pipeline of 3 biosmilars - strategic partnership with Kissei Pharmaceutical (Japan)

Sources: Company data, Metzler Research

Formycon well on schedule in our view

The fact that Momenta is significantly ahead in terms of development is negligible in our view. Relevant patents for Eylea will expire in 2024 in the US and 2025 in Europe. As Formycon will skip the Phase 1 clinical studies, we continue to see the company well on schedule and believe that from today's perspective FYB203 can be launched on time. In addition, Formycon has also already developed (and patent registered) an alternative formulation for Eylea (Eylea formulation runs until 2028 and hence longer than active ingredient). This alternative formulation has to be developed by all other competitors as well if a potential launch is planned before 2028 - this also further strenghtens Formycon's market positioning.

d.) Our revenue model for FYB203

Our revenue model reflects licensing deal with Santo Holding

We model our sales separately for the European and the US market. In a first step, we forecast the development of the underlying market for Aflibercept - the active ingredient of Eylea. Next, we estimate potential penetration rates of biosimilars and hence derive the revenues in the total Eylea biosimilar market.

As for FYB201, Formycon's business model for FYB203 is based on a licensing model. The Santo Holding (Strüngmann Group) serves as the licensing partner - find more information on the Santo Holding in the revenue model for FYB201. Formycon received a single digit million EUR upfront payment and is getting its development costs refunded on a cost plus basis. In addition, Formycon receives royalties once FYB203 is marketed in the US and Europe.

To reflect this structure, we first estimate the market share of Santo Holding (respectively its sales partners) in the overall Aflibercept market. To derive the sales for Formycon, we multiply these revenues of the Santo Holding with the royalty Formycon receives - we are assuming an average royalty rate of 9% which seems realistic in our view and is in line with the company communication.

Revenue model FYB203 - Biosimilar for Eylea

	FY 2017	FY 2018	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e
Europe (patent expiry May 2025)														
Aflibercept sales EURm	1,880	2,185	2,469	2,716	2,906	2,993	2,993	2,993	2,933	2,787	2,731	2,731	2,731	2,731
Growth y-o-y (in %)	15.7	16.2	13.0	10.0	7.0	3.0	0.0	0.0	-2.0	-5.0	-2.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	-	-	-	-	**10.0**	**30.0**	**45.0**	**55.0**	**58.0**	**60.0**
Biosimilar sales EURm	-	-	-	-	-	-	-	-	**293**	**836**	**1,229**	**1,502**	**1,584**	**1,639**
Growth yoy (in %)	-	-	-	-	-	-	-	-	-	185.0	47.0	22.2	5.5	3.4
Market share Santo Holding / EU sales partner (in %)	-	-	-	-	-	-	-	-	**35.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**
Sales Santo Holding / EU sales partner EURm	-	-	-	-	-	-	-	-	**103**	**251**	**369**	**451**	**475**	**492**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	-	144.3	47.0	22.2	5.5	3.4
Royalty to Formycon (in %)	-	-	-	-	-	-	-	-	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**
Sales Formycon EURm	-	-	-	-	-	-	-	-	**9**	**23**	**33**	**41**	**43**	**44**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	-	144.3	47.0	22.2	5.5	3.4
USA (patent expiry May 2024)														
Aflibercept sales USDm	3,700	4,100	4,633	4,865	4,865	4,865	4,865	4,767	4,529	4,438	4,438	4,438	4,438	4,438
Growth y-o-y (in %)	12.1	10.8	13.0	5.0	0.0	0.0	0.0	-2.0	-5.0	-2.0	0.0	0.0	0.0	0.0
Aflibercept sales EURm	3,274	3,475	4,137	4,343	4,343	4,343	4,343	4,257	4,044	3,963	3,963	3,963	3,963	3,963
Growth y-o-y (in %)	10.1	6.1	19.1	5.0	0.0	0.0	0.0	-2.0	-5.0	-2.0	0.0	0.0	0.0	0.0
Biosimilar market share (in %)	-	-	-	-	-	-	-	**8.0**	**18.0**	**25.0**	**30.0**	**35.0**	**40.0**	**45.0**
Biosimilar sales EURm	-	-	-	-	-	-	-	**341**	**728**	**991**	**1,189**	**1,387**	**1,585**	**1,783**
Growth yoy (in %)	-	-	-	-	-	-	-	-	113.8	36.1	20.0	16.7	14.3	12.5
Market share Santo Holding / US sales partner (in %)	-	-	-	-	-	-	-	**25.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**	**30.0**
Sales Santo Holding / US sales partner EURm	-	-	-	-	-	-	-	**85**	**218**	**297**	**357**	**416**	**476**	**535**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	156.5	36.1	20.0	16.7	14.3	12.5
Royalty to Formycon (in %)	-	-	-	-	-	-	-	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**	**9.0**
Royalty Formycon EURm	-	-	-	-	-	-	-	**8**	**20**	**27**	**32**	**37**	**43**	**48**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	156.5	36.1	20.0	16.7	14.3	12.5
Total royalties EURm	-	-	-	-	-	-	-	**8**	**29**	**49**	**65**	**78**	**86**	**92**
Growth y-o-y (in %)	-	-	-	-	-	-	-	-	277.1	70.7	32.4	19.5	9.7	8.0

Sources: Evaluate Pharma, Regeneron, BAYER, Company data, Metzler Research

We believe Formycon should generate **total cumulative royalties of more than EUR 400m** between FY 2024 and FY 2030. Our forecast is based on the following assumptions:

- **Aflibercept sales:** Overall, we consider the market for age-related macular degeneration to be highly attractive. In our opinion, the general growth driver

continues to be the ageing of the society and the associated higher prevalence rates for eye diseases such as AMD. Our impression is also confirmed by numerous studies - for instance, the National Eye Institute (NEI) estimates that in 2050 around 5.4m patients in the US will suffer from AMD compared to ~2m patients in 2010. We expect the strong growth of Aflibercept to continue over the next two years. Growth rates in the first half of 2019 (+13% y-o-y in both Europe and USA) confirm our view. In the following years, however, we assume that the launch of Lucentis biosimilars in 2021 in the USA and 2022 in Europe will lead to significantly lower growth in the market for Aflibercept - the relative attractiveness of Aflibercept should decline due to the higher therapy costs vs. Ranibizumab (biosimilars). We also expect the market to decline with the introduction of Eylea biosimilars - the percentage price decline in the market should exceed the increase in treatable patients in our view. We calculate peak sales in the market of ~EUR 5.6bn.

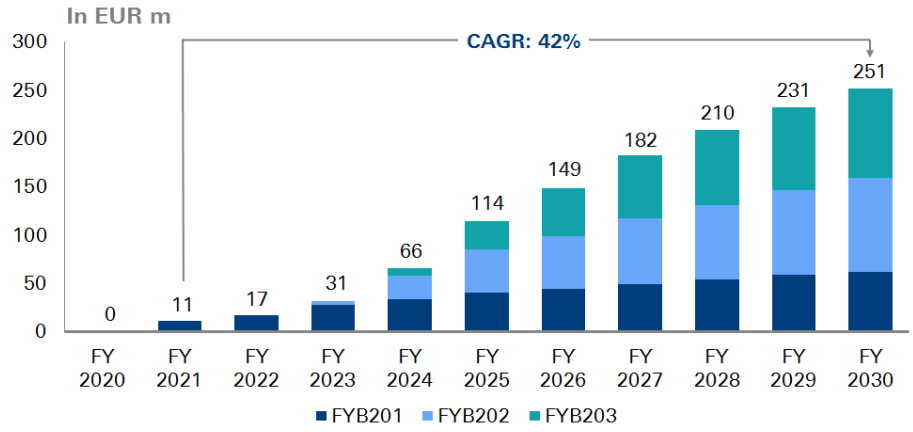
- Biosimilar penetration: Patents for Eylea are still valid for >4 years in the USA and >6 years in Europe. In the meantime, biosimilars should continue to establish themselves in the market. We therefore assume that penetration rates of Eylea biosimilars should increase even faster compared to Lucentis. In addition, from today's perspective it can be assumed that beside Formycon Coherus, Momenta and Alteogen will be launching their biosimilar as well. This should further increase attention and acceptance of Eylea biosimilars. In Europe we expect a market share of around 50% within just four years, in the USA around 40% within six years.
- Market share of Santo Holding: As described, FYB203 is licensed out to the Santo Holding. The holding is the investment company of the Strüngmann brothers, who have a lot of know-how in the pharmaceutical field. Nevertheless, Santo Holding has no distribution structures in place for biosimilars. Thus, it can be assumed that suitable distribution partners will be sought at a later point of time. This makes it more difficult for us to estimate future market shares. However, the fact that the company has already found a strong distribution partner for FYB201 (Coherus) gives us confidence. We expect Formycon, Coherus and Momenta to gain similar market shares in Europe and the USA. We are assuming a long-term market share of the Santo Holding of ~30% in the total Eylea biosimilar market in our model.
- Sales Formycon: As for FYB201, we are assuming that Formycon receives an average royalty of 9% of the worldwide marketing proceeds

Consolidated revenues

Total royalties of ~EUR 250m in FY2030

Based on our estimates for FYB201, FYB202 and FYB203, we expect Formycon to generate total royalties of approx. EUR 250m in FY2030. We see the greatest potential in FYB202 (~40% of royalties), not least because the competitive situation appears very moderate from today's perspective.

Consolidated proceeds from FYB201, FYB202 and FYB203



Sources: Metzler Research

Financials

Sales until FY2021 mainly reflect reimbursed development costs

FYB201 and FYB203 are already out-licensed. This means that Formycon continues to be responsible for the research & development of these two biosimilars. However, the development costs incurred are completely reimbursed by its partners (Santo Holding and Bioeq). These reimbursements are recognized as sales in Formycon's P&L. The magnitude of the development costs typically varies with the current stage of development - typically development costs peak during the complex and extensive clinical phase III studies. In contrast to FYB201 and FYB203, FYB202 is not out-licensed but managed in a joint venture with Aristo Pharma instead. However, despite this fact Formycon also receives at least a partial reimbursement of development costs, albeit to a much lesser extent compared to FYB201 and FYB203. Since the first biosimilar is not expected to be released until FY 2021, Formycon's sales in the next three years mainly consist of these reimbursed development costs which might also vary in the next years - find our M' estimates also for the reimbursements in the table below:

Financial summary

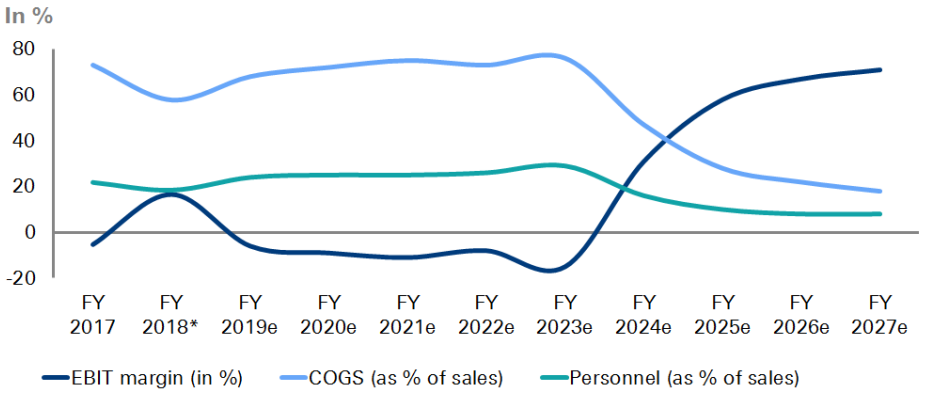
in EUR m	FY2018	Guidance FY 2019	M'e FY2019	M'e FY2020	M'e FY2021
Sales	**43**	**35**	**35**	**38**	**41**
Growth yoy (in %)	48.2	-18.6	-18.6	8.6	7.2
thereof development costs for **FYB201**	n/a	-	20	12	5
thereof development costs for **FYB202**	n/a	-	-	6	5
thereof development costs for **FYB203**	n/a	-	15	20	20
Gross profit	**19**	**-**	**10**	**11**	**10**
Gross margin (in %)	43.0	-	30.3	28.5	25.2
EBITDA	**8**	**-**	**-1**	**-3**	**-4**
Margin (in %)	18.7	-	-3.5	-7.0	-9.3
EBIT	**7**	**-**	**-2**	**-3**	**-5**
Margin (in %)	16.6	-	-5.8	-9.0	-11.3
EPS	**0.8**	**Slightly negative**	**-0.2**	**-0.3**	**-0.5**

Sources: Formycon, Metzler Research

Formycon has very high margin potential

Formycon's current P&L is relatively simple: Formycon recognizes sales for FYB201 and FYB203 in the amount of the R&D costs incurred in the period - this is thus a zero-sum game (Note: These R&D costs are mainly included in COGS - cost of purchase services as well in personnel costs). In addition, Formycon receives at least minor reimbursements for FYB202. Additional amounts are invested in new programs and the broadening of the pipeline which however should lead to further value creation. Additional costs incur at the group level, for instance administration costs etc.. This structure usually results in negative profitability. However, this earnings level in our view completely underestimates Formycon's significant margin potential. In the long term, we even see margins of ~80% as realistic. The reason for the strong increase in our estimates is the fact that the later royalties, which Formycon is expected to receive from 2021 onwards, are not directly offset by any costs. As described, FYB201 and FYB203 are out-licensed. In addition, we also expect FYB202 to be licensed out in the coming years. This means that Formycon's partners will bear all costs, from the production of the biosimilars to marketing costs and other selling costs. Formycon's costs therefore continue to consist solely of the development of new biosimilars. Accordingly, both material costs and personnel costs in % of sales should significantly decrease over the mid- to long-term:

Margins a function of COGS and Personnel



* Note: FY 2018 includes one-off gain from FYB202 development
Source: Formycon, Metzler Research

Capital increase in March to fund participation in FYB202 joint venture

In March this year, Formycon carried out a cash capital increase. The gross proceeds amounted to ~EUR17m. These proceeds will primarily be required to fund the participation in the joint venture. As described, Aristo Pharma and Formycon founded a joint venture for the development of FYB202 (biosimilar for Stelara) in which Formycon holds 24.9%. It was agreed that development costs and other project investments will be covered in accordance with the participation quota. We calculate with total development costs of approx. EUR 140m - this results in costs for Formycon of ~EUR 35m. To date, Formycon has invested a total of ~EUR 21m in the development of FYB202. Hence, according to our calculations, Formycon will have to add ~EUR15m to the joint venture within the next two years - this corresponds to the proceeds from the capital increase.

Dividends possible in the long-term

As of today, none of the developed biosimilars have yet been released, so Formycon is not yet making any profits. Nevertheless, Formycon has significant potential in terms of profitability and may be able to pay dividends to shareholders at least in the very long term.

Valuation - Risk-adjusted NPV approach

rNPV approach reflects different stages of development of biosimilar candidates

For the calculation of our price target, we are using a risk-adjusted net present value (rNPV) approach. For this purpose, we have defined probabilities to enter the next stage of development - e.g. the probability to pass preclinical studies and to enter Phase I amounts to 95% in our model. Based on these probabilities, we can calculate the total probability for approval for each development stage. For instance, if Formycon has finally developed the cell line of its biosimilar, the total probability that this biosimilar will be finally approved amounts to ~70% (this probability is also in line with prior research - e.g. Nickisch and Greuel (2012) who estimate a total probability of approval between 50%-75% for biosimilar companies). This probability is correspondingly increasing with each stage of development - e.g. if Formycon has entered Phase III, the total probability for approval already amounts to 78%. Our total probability for approval is relatively high (especially compared to common probabilities used in the valuation of biotech companies) which is reasonable however, given the fact that the reference product is

already launched on the market.

Probabilities used for rNPV calculation

Stage of development	Probability to enter next stage	Total probability for approval in current stage
Preclinical studies	95%	69%
Phase I clinical studies	95%	73%
Phase III clinical studies	85%	77%
Regulatory approval (FDA, EMA)	90%	90%

Sources: Metzler Research

In a second step, we calculated net present values for each individual project (e.g. FYB201, FYB202 and FYB203) including a terminal value. For FYB201 and FYB203, we have included the royalties Formycon should receive from its licensing partners as well as the reimbursed R&D costs. As described, we are assuming that FYB202 will also be out-licensed following the successful approval. Hence, for FYB202, we not only include the royalties and reimbursed R&D costs, but also the possible upfront payment (M'e: EUR 25m) Formycon should receive for the license of FYB202.

Our NPV calculations are based on the following assumptions:

- We are using a discount rate (WACC) of 10.8% which is based on the following factors: Risk-free rate of 1.0%, market risk premium of 6.5% and Beta of 1.5
- For the terminal value calculation of each project, we are using a terminal growth rate of -10%. Overall, we assumed that after ~10 years of marketing of the biosimilar, the overall life cycle of the product will be impacted by alternative treatment methods, leading to a gradual decline of sales

To risk-adjust this figure and correspondingly derive our rNPV for each product, we multiplied the NPV with the the probability for approval given the recent development stage of the biosimilar. With regard to these probabilities, FYB203 has a special feature: As described, no phase I clinical study will be required - Eylea is injected intravitreal, hence, blood values are not meaningful. This means that for Eylea the probability for approval is higher than implied by the current stage of development.

Finally, we also considered Formycon's incurred costs - we include COGS, personnel costs, taxes as well as capital expenditures (capex) in our model. However, we do not risk-adjust these costs as the costs considered result mainly from the development of new biosimilars and are therefore independent from the outcome of FYB201, FYB202 and FYB203. The following tables provide an overview of the calculations presented.

Risk-adjusted NPV model (1)

	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e	FY 2031e	FY 2032e	FY 2033e	FY 2034e	FY 2035e
FYB201 Europe																	
Stage of development*	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Royalties EURm	0	0	0	5	15	19	25	28	31	34	37	40	41	41	37	33	30
Growth y-o-y (in %)	n/a	n/a	n/a	n/a	204%	29%	31%	10%	9%	10%	9%	8%	4%	0%	-10%	-10%	-10%
Reimbursements EURm	10	6	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	10	5	2	4	10	12	14	14	13	13	13	13	12	11	9	7	6
rNPV EURm	10	5	2	3	9	10	12	12	12	12	12	12	11	10	8	6	5

Terminal value EURm	26
Terminal value EURm	23
Total NPV EURm	193
Total rNPV EURm	176

FYB201 USA																	
Stage of development*	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Royalties EURm	0	0	11	12	13	14	14	16	19	21	22	22	22	20	18	16	15
Growth y-o-y (in %)	n/a	n/a	n/a	11%	8%	6%	4%	16%	14%	12%	6%	0%	0%	-10%	-10%	-10%	-10%
Reimbursements EURm	10	6	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	10	5	11	9	9	8	8	8	8	8	8	7	6	5	4	3	3
rNPV EURm	10	5	10	8	8	7	7	7	7	7	7	6	6	5	4	3	3

Terminal value EURm	13
Terminal value EURm	11
Total NPV EURm	133
Total rNPV EURm	121

FYB202 Europe																	
Stage of development*	3	4	4	5	6	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%
Royalties EURm	0	0	0	0	0	9	19	22	29	32	35	38	41	44	46	46	41
Growth y-o-y (in %)	n/a	n/a	n/a	n/a	n/a	n/a	108%	16%	29%	11%	10%	9%	8%	6%	4%	0%	-10%
Reimbursements EURm	0	3	3	2	4	0	0	0	0	0	0	0	0	0	0	0	0
Payments JV EURm	0	0	-3	--3	10	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	0	3	0	0	9	6	10	11	13	13	13	12	12	12	11	10	8
rNPV EURm	0	2	0	0	7	4	8	8	9	9	9	9	9	8	8	7	6

Terminal value EURm	36
Terminal value EURm	26
Total NPV EURm	176
Total rNPV EURm	129

* 1 = Cell-line development 2 = Preclinical studies 3 = Phase I studies 4 = Phase III studies 5 = Regulatory approval (FDA, EMA) 6 = Approved

Sources: Metzler Research

Risk-adjusted NPV model (2)

	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e	FY 2031e	FY 2032e	FY 2033e	FY 2034e	FY 2035e
FYB202 USA																	
Stage of development*	3	4	4	5	6	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%	73%
Royalties EURm	0	0	0	0	3	15	26	32	39	45	52	58	63	65	65	59	53
Growth y-o-y (in %)	n/a	n/a	n/a	n/a	n/a	370%	68%	25%	20%	17%	14%	13%	8%	4%	0%	-10%	-10%
Reimbursements EURm	0	3	3	2	4	0	0	0	0	0	0	0	0	0	0	0	0
Payments JV EURm	0	0	-3	-3	10	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	0	3	0	0	11	9	14	16	17	18	19	19	18	17	16	13	10
rNPV EURm	0	2	0	0	8	7	10	11	12	13	14	14	13	13	11	9	7

Terminal value EURm	46
Terminal value EURm	33
Total NPV EURm	244
Total rNPV EURm	178

FYB203 Europe																	
Stage of development*	2	4	4	4	5	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%
Royalties EURm	0	0	0	0	0	0	9	23	33	41	43	44	45	46	46	41	37
Growth y-o-y (in %)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	144%	47%	22%	5%	3%	2%	2%	0%	-10%	-10%
Reimbursements EURm	8	10	10	10	3	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	7	9	8	7	2	0	5	11	15	16	15	14	13	12	11	9	7
rNPV EURm	7	9	8	6	1	0	4	8	11	12	12	11	10	9	8	7	6

Terminal value EURm	32
Terminal value EURm	25
Total NPV EURm	194
Total rNPV EURm	155

FYB203 USA																	
Stage of development*	2	4	4	4	5	6	6	6	6	6	6	6	6	6	6	6	6
Probability of approval %	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%	77%
Royalties EURm	0	0	0	0	0	8	20	27	32	37	43	48	52	54	54	49	44
Growth y-o-y (in %)	n/a	n/a	n/a	n/a	n/a	n/a	157%	36%	20%	17%	14%	13%	8%	4%	0%	-10%	-10%
Reimbursements EURm	8	10	10	10	3	0	0	0	0	0	0	0	0	0	0	0	0
NPV EURm	7	9	8	7	2	5	11	13	14	15	15	16	15	14	13	10	8
rNPV EURm	7	9	8	6	1	4	8	10	11	11	12	12	12	11	10	8	7

Terminal value EURm	38
Terminal value EURm	29
Total NPV EURm	220
Total rNPV EURm	175

* 1 = Cell-line development 2 = Preclinical studies 3 = Phase I studies 4 = Phase III studies 5 = Regulatory approval (FDA, EMA) 6 = Approved

Sources: Metzler Research

Risk-adjusted NPV model (3)

	FY 2019e	FY 2020e	FY 2021e	FY 2022e	FY 2023e	FY 2024e	FY 2025e	FY 2026e	FY 2027e	FY 2028e	FY 2029e	FY 2030e	FY 2031e	FY 2032e	FY 2033e	FY 2034e	FY 2035e
Unallocated costs																	
COGS EURm	**24**	**27**	**30**	**31**	**30**	**30**	**32**	**33**	**33**	**33**	**33**	**33**	**33**	**33**	**32**	**29**	**25**
as % of sales	68%	72%	75%	75%	69%	46%	28%	22%	18%	16%	14%	13%	13%	12%	12%	12%	12%
Personnel EURm	**8**	**10**	**10**	**10**	**13**	**10**	**11**	**12**	**15**	**16**	**17**	**18**	**19**	**19**	**18**	**17**	**14**
as % of sales	24%	25%	25%	26%	30%	16%	10%	8%	8%	8%	8%	7%	7%	7%	7%	7%	7%
Taxes EURm	**0**	**0**	**0**	**-1**	**-1**	**4**	**13**	**20**	**26**	**31**	**35**	**39**	**41**	**42**	**42**	**39**	**35**
Tax rate %	0%	0%	0%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Capex	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**2**	**3**	**3**	**3**	**4**	**4**	**4**	**4**	**3**	**3**
as % of sales	3%	3%	3%	3%	3%	2%	2%	1%	2%	2%	2%	1%	1%	1%	1%	1%	1%
Total costs	**33**	**38**	**42**	**41**	**44**	**46**	**58**	**66**	**76**	**83**	**89**	**93**	**97**	**98**	**96**	**88**	**78**

Total NPV EURm	**557**

Sources: Metzler Research

rNPV approach derives target price of EUR 39

The Enterprise Value for Formycon consists of the sum of our risk-adjusted NPV's for each individual project less the incurred costs. Adding Formycon's net cash position of EUR 12m as of FY2018, we derive our equity value of EUR 390m. Dividing the equity value by Formycon's 10m outstanding shares results in our target price of EUR 39. Our target price implies upside potential of more than 25%.

rNPV Analysis - Summary

Approach	Value
rNPV of FYB201 Europe	EUR 176m
rNPV of FYB201 USA	EUR 121m
rNPV of FYB202 Europe	EUR 129m
rNPV of FYB202 USA	EUR 178m
rNPV of FYB203 Europe	EUR 155m
rNPV of FYB203 USA	EUR 175m
Total rNPV	**EUR 934m**
Unallocated costs*	EUR 557m
Enterprise Value	**EUR 377m**
Net debt (cash)	EUR -12m
Equity Value	**EUR 390m**
Shares outstanding	10m
Target Price	**EUR 39**

*including COGS, Personnel, Taxes and Capex

Sources: Metzler Research

Our DCF model is very sensitive to our selected input factors. We hence provide a sensitivity analysis of our estimated fair value vs. the terminal growth rate and our dis-

count rate:

Sensitivity analysis of the estimated fair value versus terminal growth rate and discount rate

In EUR

Discount rate (in %) \ Terminal growth rate (in %)	-16.0	-14.0	-12.0	-10.0	-8.0	-6.0	-4.0
9.3	43.5	44.3	45.4	46.6	48.2	50.2	52.8
9.8	41.1	41.8	42.8	43.9	45.3	47.0	49.3
10.3	38.8	39.5	40.3	41.3	42.6	44.1	46.1
10.8	36.7	37.3	38.1	**39.0**	40.0	41.4	43.1
11.3	34.7	35.3	36.0	36.8	37.7	38.9	40.4
11.8	32.9	33.4	34.0	34.7	35.6	36.6	38.0
12.3	31.2	31.7	32.2	32.8	33.6	34.5	35.7

Source: Metzler Research

Appendix

Appendix 1: Approved biosimilars - USA

Biosimilar	Ingredient	Reference Product	Company	FDA approval
Ziextenzo	Pegfilgrastim	Neulasta	Sandoz	Nov 2019
Hadlima	Adalimumab	Humira	Samsung Bioepis	Jul 2019
Ruxience	Rituximab	Rituxan	Pfizer	Jul 2019
Zirabev	Bevacizumab	Avastin	Pfizer	Jun 2019
Kanjinto	Trastuzumab	Herceptin	Amgen	Jun 2019
Eticovo	Etanercept	Enbrel	Samsung Bioepis	Apr 2019
Trazimera	Trastuzumab	Herceptin	Pfizer	Mar 2019
Ontruzant	Trastuzumab	Herceptin	Samsung Bioepis	Jan 2019
Herzuma	Trastuzumab	Herceptin	Celltrion	Dec 2019
Truxima	Rituximab	Rituxan	Celltrion	Nov 2018
Udenyca	Pegfilgrastim	Neulasta	Coherus	Nov 2018
Hyrimoz	Adalimumab	Humira	Sandoz	Oct 2018
Nivestym	Filgrastim	Neupogen	Pfizer	Jul 2018
Fulphila	Pegfilgrastim	Neulasta	Mylan	Jun 2018
Retacrit	Epoetin	Epogen	Hospira	May 2018
Ixifi	Infliximab	Remicade	Pfizer	Dec 2017
Ogivri	Trastuzumab	Herceptin	Mylan	Dec 2017
Mvasi	Bevacizumab	Avastin	Amgen	Sep 2017
Cyltezo	Adalimumab	Humira	Boehringer Ingelheim	Aug 2017
Renflexis	Infliximab	Remicade	Samsung Bioepis	Apr 2017
Amjevita	Adalimumab	Humira	Amgen	Sep 2016
Erelzi	Etanercept	Enbrel	Sandoz	Aug 2016
Inflectra	Infliximab	Remicade	Celltrion	Apr 2016
Zarxio	Filgrastim	Neupogen	Sandoz	Mar 2015

Sources: FDA, Metzler Research

Appendix 2: Number of approved and launched biosimilars - Europe

Ingredient	Reference Product	Number of biosimilars
Somatropin	Genotropin	1
Epoetin	Epogen	5
Filgrastim	Neupogen	7
Infliximab	Remicade	4
Follitropin alfa	Bemfola	2
Insulin glargin	Lantus	2
Etanercept	Enbrel	2
Enoxaparin	Clexane	1
Teriparatid	Forsteo	2
Rituximab	Rituxan	5
Adalimumab	Humira	8
Insulin lispro	Humalog	1
Trastuzumab	Herceptin	5
Bevacizumab	Avastin	2
Pegfilgrastim	Neulasta	6

Sources: Company data, Metzler Research

Balance sheet

(in EUR m)	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Assets	25	-7.2	31	22.4	40	28.5	53	35.0	50	-5.9	46	-8.2
Fixed assets	**4**	**17.6**	**4**	**-6.5**	**20**	**391.4**	**25**	**24.5**	**26**	**1.5**	**31**	**21.7**
Intangible fixed assets	1	-12.7	1	-13.3	1	-10.6	1	0.0	1	0.0	1	0.0
Goodwill	1	-14.8	1	-17.4	1	-21.1	1	-13.3	1	0.0	1	0.0
Other intangible assets	0	19.3	0	31.3	0	60.6	0	44.9	0	0.0	0	0.0
Tangible assets	3	30.8	3	-4.5	3	6.7	4	7.1	4	10.2	5	12.9
Technical plant and equipment	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Financial assets	0	n.a.	0	n.a.	16	n.m.	21	29.4	21	0.0	26	24.2
Other financial assets	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Current assets	**21**	**-11.2**	**27**	**28.5**	**19**	**-29.3**	**27**	**45.0**	**24**	**-13.2**	**14**	**-40.9**
Inventories	1	172.2	1	-8.6	1	110.4	1	-2.1	2	37.0	2	12.2
Receivables and other assets	6	118.6	11	74.1	5	-50.6	6	18.6	7	8.6	7	7.2
Cash and cash items	3	381.1	5	50.4	7	62.9	17	131.8	12	-26.9	2	-83.7
Deferred taxes	0	n.a.	0	n.a.	1	n.a.	1	81.8	1	8.6	1	7.2
Shareholders' equity and liabilities	24	-8.6	29	19.5	39	36.5	53	34.9	49	-6.2	45	-8.6
Shareholders' equity	**21**	**-16.0**	**26**	**22.3**	**33**	**30.1**	**48**	**44.0**	**44**	**-7.2**	**40**	**-10.5**
Subscribed capital	9	0.2	9	2.7	9	0.8	9	0.0	9	0.0	9	0.0
Reserves	12	-25.3	16	37.4	24	47.0	38	61.4	35	-9.0	30	-13.3
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Outside capital	**3**	**130.7**	**3**	**0.4**	**5**	**73.1**	**4**	**-18.3**	**4**	**4.5**	**5**	**9.3**
Liabilities	2	255.7	2	-23.5	3	81.4	2	-30.1	2	8.6	3	17.3
Financial debt	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Accounts payable, trade	2	255.7	2	-23.5	3	54.5	2	-18.0	2	8.6	3	17.3
Other liabilities	0	n.a.	0	n.a.	0	n.a.	0	-100.0	0	n.a.	0	n.a.
Deferred taxes liabilities	0	n.a.	0	n.a.	1	n.a.	0	-3.8	0	0.0	0	0.0
Balance sheet total	25	-7.2	31	22.4	40	28.5	53	35.0	50	-5.9	46	-8.2

Sources: Refinitiv, Metzler Research

Profit & loss account

(in EUR m)	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Sales	20	15.4	29	48.5	43	48.2	35	-18.6	38	8.6	41	7.2
Change in finished goods and work in progress	0	n.a.	0	n.a.	1	36.5	-1	-249.6	0	100.0	0	n.a.
Own work capitalised	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Total output	**20**	**15.4**	**29**	**50.7**	**44**	**48.1**	**34**	**-21.7**	**38**	**11.4**	**41**	**7.2**
Other operating income	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Operating expenses	24	44.0	31	31.2	36	17.7	36	-0.8	41	14.6	45	9.5
Cost of materials	15	73.3	21	37.6	25	17.4	24	-4.2	27	14.2	30	12.2
Personnel expenses	5	32.5	6	23.6	8	25.4	8	3.7	10	15.5	10	7.2
Depreciation and amortization	1	-25.2	1	12.3	1	15.2	1	-11.0	1	-5.6	1	7.2
Write-downs on intang. fixed assets and tang. assets	1	-25.2	1	12.3	1	15.2	1	-11.0	1	-5.6	1	7.2
Other operating expenses	2	-11.4	3	11.7	3	3.1	3	20.2	4	20.0	4	-3.0
EBIT	-4	-857.2	-2	62.2	7	563.4	-2	-128.5	-3	-68.5	-5	-34.6
Financial result	0	-79.5	-0	-580.3	-0	32.4	-0	-27.1	-0	-8.6	-0	-7.2
Income from investments	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Interest income (net)	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Result of ordinary activities	**-4**	**-801.8**	**-2**	**61.2**	**7**	**549.7**	**-2**	**-129.1**	**-3**	**-67.5**	**-5**	**-34.3**
EBT	-4	-801.8	-2	61.2	7	549.7	-2	-129.1	-3	-67.5	-5	-34.3
Taxes on income	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Tax rate (%)	0.1	128.1	0.2	171.7	-0.0	-101.2	0.0	100.0	0.0	n.a.	0.0	n.a.
Net income	-4	-799.6	-2	61.2	7	550.6	-2	-129.1	-3	-67.5	-5	-34.3
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.
Minority rate (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
Net Income after minorities	-4	-804.1	-2	61.1	7	548.9	-2	-129.1	-3	-67.5	-5	-34.3
Unappropriated consolidated net income	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Adjustment calculation												
Net Income after minorities	-4	-804.1	-2	61.1	7	548.9	-2	-129.1	-3	-67.5	-5	-34.3
Adjustments of net income	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Adjustment rate (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
Adj. net income after minorities	-4	-804.1	-2	61.1	7	548.9	-2	-129.1	-3	-67.5	-5	-34.3
Number of shares outstanding	9	0.2	9	2.7	9	0.8	10	6.1	10	0.0	10	0.0
EPS (EUR)	-0.45	-802.5	-0.17	62.1	0.75	545.1	-0.21	-127.4	-0.35	-67.5	-0.46	-34.3
EPS adj. (EUR)	-0.45	-802.5	-0.17	62.1	0.75	545.1	-0.21	-127.4	-0.35	-67.5	-0.46	-34.3

Sources: Refinitiv, Metzler Research

Cash flow/ratios/valuation

	2016	%	2017	%	2018	%	2019e	%	2020e	%	2021e	%
Cash Flow/ Net Debt (in EUR m)												
Gross Cash Flow	-3	-328.6	-1	77.7	8	n.m.	-1	-115.3	-3	-117.1	-4	-42.4
Increase in working capital	-1	n.a.	-6	-386.4	6	197.9	-1	-109.6	-1	-27.6	-0	72.8
Capital expenditures	1	n.a.	1	n.a.	1	n.a.	1	n.a.	1	n.a.	1	n.a.
D+A/Capex (%)	50.4	n.a.	153.6	n.a.	84.9	n.a.	76.7	n.a.	66.7	n.a.	60.6	n.a.
Free cash flow (Metzler definition)	-4	-542.0	5	227.3	1	-71.6	-2	-234.1	-3	-79.5	-5	-59.4
Free cash flow yield (%)	-1.6	n.a.	1.5	n.a.	0.5	n.a.	-0.5	n.a.	-1.0	n.a.	-1.5	n.a.
Dividend paid	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Free cash flow (post dividend)	0	n.a.	0	n.a.	0	n.a.	0	n.a.	0	n.a.	n.a.	n.a.
Net Debt incl. Provisions	-14	31.0	-16	-10.5	-12	20.0	-20	-60.7	-15	22.9	-5	67.4
Gearing (%)	-67.4	n.a.	-60.9	n.a.	-37.5	n.a.	-41.8	n.a.	-34.8	n.a.	-12.6	n.a.
Net debt/EBITDA	4.2	n.a.	20.7	n.a.	-1.6	n.a.	16.3	n.a.	5.8	n.a.	1.3	n.a.
Ratios (in %)												
Liquidity												
Quick ratio	563.8	n.a.	652.1	n.a.	531.2	n.a.	821.8	n.a.	655.5	n.a.	322.1	n.a.
Current ratio	581.5	n.a.	666.5	n.a.	567.7	n.a.	859.1	n.a.	703.8	n.a.	370.2	n.a.
Pay-out ratio	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.
Balance sheet structure												
Equity/total assets	82.9	n.a.	82.9	n.a.	83.9	n.a.	89.5	n.a.	88.2	n.a.	86.0	n.a.
Equity to fixed assets	474.9	n.a.	621.0	n.a.	164.4	n.a.	190.2	n.a.	173.9	n.a.	128.0	n.a.
Long-term capital to total assets	82.9	n.a.	82.9	n.a.	83.9	n.a.	89.5	n.a.	88.2	n.a.	86.0	n.a.
Long-term capital to fixed assets and inventories	415.2	n.a.	544.5	n.a.	155.1	n.a.	181.7	n.a.	163.4	n.a.	120.9	n.a.
Liabilities to equity (leverage)	11.1	n.a.	6.9	n.a.	9.6	n.a.	4.7	n.a.	5.5	n.a.	7.2	n.a.
Profitability/efficiency												
Working capital to sales	18.1	n.a.	32.2	n.a.	8.5	n.a.	12.0	n.a.	12.9	n.a.	12.5	n.a.
EBIT margin	-20.8	n.a.	-5.3	n.a.	16.6	n.a.	-5.8	n.a.	-9.0	n.a.	-11.3	n.a.
EBITDA margin	-17.3	n.a.	-2.6	n.a.	18.7	n.a.	-3.5	n.a.	-7.0	n.a.	-9.3	n.a.
Net ROS	-20.8	n.a.	-5.5	n.a.	16.5	n.a.	-5.9	n.a.	-9.1	n.a.	-11.4	n.a.
Cash flow margin	-17.3	n.a.	-2.6	n.a.	18.7	n.a.	-3.5	n.a.	-7.0	n.a.	-9.3	n.a.
ROE (after Tax/Min.)	-17.8	n.a.	-6.8	n.a.	24.2	n.a.	-5.1	n.a.	-7.5	n.a.	-11.0	n.a.
Productivity												
Average number of employees ('000)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	n.a.	n.a.
Sales per employee (EUR '000)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT per employee (EUR '000)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Valuation												
PER	-53.5	n.a.	-193.2	n.a.	34.5	n.a.	-154.5	n.a.	-92.2	n.a.	-68.7	n.a.
PBV	10.4	n.a.	12.0	n.a.	7.4	n.a.	6.7	n.a.	7.2	n.a.	8.0	n.a.
EV/EBITDA	-60.3	n.a.	-385.1	n.a.	29.0	n.a.	-244.1	n.a.	-114.1	n.a.	-82.9	n.a.
EV/EBIT	-49.9	n.a.	-188.6	n.a.	32.6	n.a.	-147.3	n.a.	-88.8	n.a.	-68.2	n.a.
Dividend yield (%)	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.	0.0	n.a.

Sources: Refinitiv, Metzler Research

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Date of dissemination	Metzler recommendation * Previous	Current	Current price **	Price target *	Author ***

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