Formycon (FYB GY) | Pharma/Healthcare

FYB206 - unlocking huge growth opportunities

Recently, the first commercialization partner for FYB203 (biosimilar candidate for Eylea - phase III clinical trial since Aug 2020) has been announced. Klinge Biopharma, the exclusive owner of the commercialization rights for FYB203, has entered into an agreement with Coherus for the commercialization in the US. Coherus already distributes FYB201 in the US since Oct last year. In our view, this is good news for Formycon for two reasons: First, Coherus already has a solid track record regarding the distribution of biosimilars (e.g. UDENYCA). The commercialization of Formycon's FYB201 (CIMERLI) to date is also promising - a market share of 6% has already been achieved. Second, Coherus has an experienced retina commercial team in place now - and should correspondingly be able to leverage these resources for the commercialization of FYB203. In addition, we decided to now include FYB206 in our rNPV model - Formvcon's biosimilar candidate for Keytruda. FYB206 is currently in the adv. preclinical stage for which the project rights are 100% owned by Formycon. We calculate peak sales of EUR 740m (2035) highlighting the attractiveness of the underlying Pembrolizumab market. Overall, we consider the prospects to be promising. News flow should remain positive e.g. release of commercialization partners for FYB202.

Changes in estimates: Our FY 2023 & FY 2024 earnings estimates decline, reflecting investments into the own pipeline (FYB202, 206, 207, 208, 209). However, with the introduction of FYB202/FYB203 in FY 2025, profits should increase considerably - for FY 2025, we forecast a 3-digit EBITDA (M'e: EUR 159m). Our PT increases to EUR 124 as we have now included FYB206 in our rNPV model.

Fundamentals (in EUR m) ¹	2019	2020	2021	2022e	2023e	2024e
Sales	33	34	37	38	71	120
EBITDA	-1	-5	-12	-16	-17	24
EBIT	-2	-6	-13	-18	-20	21
EPS adj. (EUR)	-0.23	-0.54	-1.22	-1.13	-0.83	0.96
DPS (EUR)	0.00	0.00	0.00	0.00	0.00	0.00
BVPS (EUR)	4.82	6.16	5.08	26.21	25.38	26.34
Net Debt incl. Provisions	-22	-42	-25	-15	2	-14
Ratios ¹	2019	2020	2021	2022e	2023e	2024e
EV/EBITDA	-217.9	-112.9	-50.5	-80.5	-74.3	53.0
EV/EBIT	-130.5	-94.8	-47.0	-71.9	-65.0	62.3
P/E adj.	-139.3	-98.8	-48.4	-76.8	-103.3	89.2
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	-4.1	-14.1	-33.5	-42.0	-24.4	20.1
EBIT margin (%)	-6.9	-16.7	-36.1	-47.0	-27.9	17.1
Net debt/EBITDA	16.5	8.8	2.1	1.0	-0.1	-0.6
PBV	6.6	8.6	11.6	3.3	3.4	3.3
1						

¹Sources: Bloomberg, Metzler Research

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EUR 124.00 (87.00)

Price target

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



Performance (in %) ¹	1m	Зm	12m
Share	-3.5	21.2	70.6
Rel. to Prime All Share	-10.5	3.7	85.5
Changes in estimates (in %) ¹	2022e	2023e	2024e
Changes in estimates (in %) ¹ Sales	2022e 1.0	2023e 3.7	2024e -44.1
	LOLLO		20210

Sponsored Research



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Newsflow on FYB203

Recently, the first commercialization partner for FYB203 (Formycon's biosimilar candidate for Eylea - Aflibercept - phase III clinical trial since August 2020) has been announced. Klinge Biopharma, which is the exclusive owner of the commercialization rights for FYB203, has entered into an agreement with Coherus BioSciences (not rated) for the exclusive commercialization in the US.

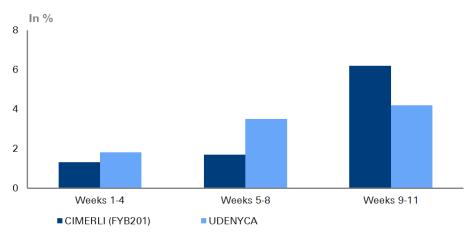
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<u>As a reminder:</u> Coherus Biosciences already owns the commercialization rights for FYB201 in the US (Formycon's biosimilar for Lucentis - Ranibizumab) - the launch of FYB201 (under the brand name CIMERLI) has taken place in October last year.

In our view, this is good news for Formycon, mainly for two reasons:

- Coherus has proven in the past that they can successfully commercialize biosimilars among others with their own biosimilar UDENYCA (Pegfilgrastim biosimilar of Neulasta) which generated sales of almost USD 500m in FY 2020. The commercialization of FYB201 (CIMERLI) to date is also promising in our view. Based on sales for 93 key accounts in the US, CIMERLI has already achieved a market share of 6%. With the introduction of the Q-Code (Coherus expects a unique Q-Code in early 2023), which improves the reimbursement, the sales performance for FYB201 is expected to further accelerate. For FY 2023, Coherus forecasts sales of more than USD 100m for CIMERLI.
- Second, Coherus already has an experienced retina commercial team in place now - and should correspondingly be able to leverage these resources for the commercialization of FYB203 (Note: Both, FYB201 and FYB203 are used in the treatment of age-related macular degeneration - AMD).



Market share of CIMERLI (FYB201) in the US

Sources: Coherus, IQVIA WSP data, Metzler Research

Integration of FYB206 in our model

We decided to now include FYB206 in our rNPV model. FYB206 is Formycon's biosimilar candidate for Keytruda and currently in the advanced preclinical stage for which the project rights are 100% owned by Formycon.

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As a reminder: Keytruda (active ingredient: Pembrolizumab) was developed by Merck (not rated) and received its first approval in 2014. The patents of Keytruda expire in 2028 in the US and in 2030 in Europe. Keytruda works by increasing the ability of the body's immune system to help detect and fight tumour cells. Its active ingredient Pembrolizumab is a humanized monoclonal antibody that binds to the PD-1 receptor, blocking the interaction between PD-1 and its ligand PD-L1, and thus, helping the immune system to activate the body's cellular anti-tumor immune response and for instance kill melanoma cells. Keytruda is effective in numerous oncological indications, among others black skin cancer, non-small cell lung cancer (NSCLC), head and neck squamous cell cancer, classical Hodgkin lymphoma and non-muscle invasive bladder cancer. Following its approval, Keytruda has become one of the best-selling drugs, generating sales of USD 17bn in 2021 see table below:

Manufacturer	FY 2021 Sales	Main Indication(s)
Pfizer / BioNTech	USD 59.1bn	Covid-19
AbbVie	USD 20.7bn	Rheumatoid and psoriatic arthritis
Moderna	USD 17.7bn	Covid-19
Merck	USD 17.2bn	Cancer immunotherapy
Bristol Myers Squibb & Pfizer	USD 16.7bn	Blood clots
Bristol Myers Squibb	USD 12.8bn	Myelodysplastic syndrome, multiple myeloma
AbbVie & Janssen	USD 9.8bn	Chronic lymphocytic leukemia/small lymphocytic lymphoma
Regeneron & Bayer	USD 9.2bn	Age-related macular degeneration (AMD)
Janssen	USD 9.1bn	Psoriaris, Crohn's disease
Gilead Sciences	USD 8.6bn	HIV
	Pfizer / BioNTech AbbVie Moderna Merck Bristol Myers Squibb & Pfizer Bristol Myers Squibb & Pfizer	Pfizer / BioNTechUSD 59.1bnAbbVieUSD 20.7bnModernaUSD 17.7bnMerckUSD 17.2bnBristol Myers Squibb & PfizerUSD 16.7bnBristol Myers Squibb & PfizerUSD 12.8bnBristol Myers Bristol Myers QuSD 12.8bnUSD 12.8bnBristol Myers Bristol Myers QuSD 9.8bnUSD 9.8bnJanssenUSD 9.1bn

Top 10 medications FY 2021

Sources: Company data, DRUG (Discovery & Development), Metzler Research

Why is Keytruda so successful? In relation to NSCLC, a recent study measured the greater effectiveness of Keytruda in first-line therapy compared to chemotherapy. The 5-year-OS-rates (overall survival rates) with Keytruda ranged from 16.6% to 21.9%, compared to 8.5% and 10.1% with classic chemotherapy. In addition, Keytruda is characterised by fewer interactions with other drugs or diseases, is approved for a greater number of uses and generally has comparatively mild side effects. Keytruda is the market leader for the treatment of previously untreated NS-CLC. Furthermore, a study was terminated in which Keytruda was tested in combination with an immuno-oncology agent. The independent data monitoring committee concluded that the combination was not better than solo Keytruda, however, more severe side effects occurred for patients taking the dual therapy. Based on the increasing prevalence of cancer and the superiority vs. other medications & therapies, Keytruda should remain a blockbuster over the next years in our view.

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We make the following assumptions in our model with regard to FYB206:

- For the underlying market of Pembrolizumab, we forecast growth of around 10% over the next years - in line with market estimates, e.g. BioSpace forecasts a CAGR of 11% between 2021 and 2030 for the total market of monoclonal antibodies in cancer treatment.
- We expect the biosimilar penetration to increase rapidly following the introduction of the corresponding biosimilars - e.g. a biosimilar penetration of around 50% within four years is a realistic scenario in our view for two reasons: First, the establishment of biosimilars should continue to grow in the next years as biosimilars are similarly efficient but significantly cheaper compared to the reference product. Second, the savings potential for Keytruda in particular is high - e.g. while Keytruda offers a highly effective treatment to a subset of patients, it is associated with exorbitant treatment costs (e.g. more than USD 100,000 a year).
- The market share of FYB206 is difficult to forecast at present. On the one hand, the competitive environment cannot yet be predicted and to date - only Xbrane (not rated) has announced that they already initiated the development of a Keytruda biosimilar in December 2021. However, based on the sheer underlying market size, it can be assumed that Formycon will compete with a larger number of other biosimilar manufacturers. On the other hand, no commercialization partners have yet been determined (due to the early stage of FYB206). In our model, we currently assume a market share of 12%.
- Finally, we expect Formycon to receive around 40% of global FYB206 commercialization sales. Formycon owns 100% of the project rights of FYB206. We assume that the remainder (60%) will be distributed among the future commercialization partners.

Based on these assumptions, we calculate peak sales of EUR 740m (in 2035), again highlighting the huge opportunity ahead of Formycon:

Revenue model for FYB206 - Biosimilar for Keytruda

	FY2020	FY2021	FY2022e	FY2023e	FY2024e	FY2025e	FY2026e	FY2027e	FY2028e	FY2029e	FY2030e	FY2031e	FY2032e	FY2033e	FY2034e	FY2035e	FY2036e
Europe (patent expiry 2030)																	
Pembrolizumab sales (USDm)	6,028	7,421	8,312	9,143	10,057	10,962	11,949	12,905	13,808	14,774	13,001	11,961	11,244	10,794	10,470	10,261	10,158
Growth y-o-y (%)	26	23	12	10	10	9	9	8	7	7	-12	-8	-6	-4	-3	-2	-1
Pembrolizumab sales EURm	5,288	6,289	7,916	8,465	9,312	10,150	11,064	11,949	12,785	13,680	12,038	11,075	10,411	9,994	9,695	9,501	9,406
Growth y-o-y (%)	24	19	26	7	10	9	9	8	7	7	-12	-8	-6	-4	-3	-2	-1
Biosimilar penetration (%)	0	0	0	0	0	0	0	0	0	0	15	30	40	50	55	60	60
Total biosimilar sales (EURm)	0	0	0	0	0	0	0	0	0	0	1,806	3,323	4,164	4,997	5,332	5,700	5,643
Growth y-o-y (%)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	84	25	20	7	7	-1
Market share FYB206 (%)	0	0	0	0	0	0	0	0	0	0	12	12	12	12	12	12	12
Sales FYB206 (EURm)	0	0	0	0	0	0	0	0	0	0	217	399	500	600	640	684	677
Royalty to Formycon (%)	0	0	0	0	0	0	0	0	0	0	40	40	40	40	40	40	40
Sales Formycon (EURm)											87	159	200	240	256	274	271
Growth y-o-y (%)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	84	25	20	7	7	-1

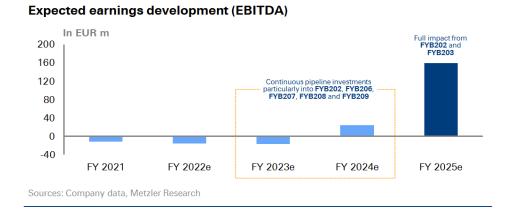
US (patent expiry 2028)																	
Pembrolizumab sales (USDm)	8,352	9,765	12,695	14,599	16,059	17,664	19,078	20,413	21,842	19,221	17,683	16,622	15,957	15,479	15,169	15,017	14,867
Growth y-o-y (%)	32	17	30	15	10	10	8	7	7	-12	-8	-6	-4	-3	-2	-1	-1
Pembrolizumab sales EURm	9,521	1,144	13,329	15,767	17,343	19,078	20,604	22,046	23,589	20,759	19,098	17,952	17,234	16,717	16,383	16,219	16,057
Growth y-o-y (%)	35	-88	1065	18	10	10	8	7	7	-12	-8	-6	-4	-3	-2	-1	-1
Biosimilar penetration (%)	0	0	0	0	0	0	0	0	0	15	30	40	50	55	60	60	60
Total biosimilar sales (EURm)	0	0	0	0	0	0	0	0	0	3,114	5,729	7,181	8,617	9,194	9,830	9,731	9,634
Growth y-o-y (%)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	84	25	20	7	7	-1	-1
Market share FYB206 (%)	0	0	0	0	0	Ō	0	0	0	12	12	12	12	12	12	12	12
Sales FYB206 (EURm)	0	0	0	0	0	0	0	0	0	374	688	862	1,034	1,103	1,180	1,168	1,156
Royalty to Formycon (%)	0	0	0	0	0	0	0	0	0	40	40	40	40	40	40	40	40
Sales Formycon (EURm)																	733
Growth y-o-y (%)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	142	39	22	11	7	2	-1
Sales Formycon (EURm) 																	733
Growth y-o-y (%)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	142	39	22	11	7	2	-1

Source: Metzler Research, company data

Updated estimates - harvesting profits from 2025

We have lowered our earnings estimates for FY 2023 and FY 2024 - this is mainly driven by the fact that we expect Formycon to considerably invest into the own pipeline going forward. These investments particularly relate to FYB202 (biosimilar candidate for Stelara), FYB206 (biosimilar candidate for Keytruda), FYB207 (antiviral drug for the treatment of Covid-19), FYB208 (undisclosed) and finally, FYB209 (undisclosed). Accordingly, we now expect a negative EBITDA of EUR -17m for FY 2023 - and a profit slightly above break-even in FY 2024. However, with the introduction of FYB202 and FYB203 in FY 2025, profits should then increase considerably - e.g. for FY 2025 we forecast a triple-digit EBITDA contribution (M'e EBITDA FY 2025: EUR 159m).

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Valuation - new PT of EUR 124

We continue to value Formycon shares based on our risk-adjusted net present value (rNPV) approach. We have defined probabilities for each stage of development, thus, being able to value FYB201, FYB202, FYB203, FYB206 and FYB207 separately.

- WACC: We are using a discount rate (WACC) of 12.7% which is based on the following factors: Risk-free rate of 2.0%, market risk premium of 6.5% and Beta of 1.6.
- Terminal growth rate: 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.

rNPV Analysis - Summary

Pipeline	Value / Costs
rNPV of FYB201 US (EURm)	171
rNPV of FYB201 Europe (EURm)	296
rNPV of FYB202 US (EURm)	753
rNPV of FYB202 Europe (EURm)	503
rNPV of FYB203 US (EURm)	266
rNPV of FYB203 Europe (EURm)	142
rNPV of FYB206 US (EURm)	779
rNPV of FYB206 Europe (EURm)	387
rNPV of FYB207 US (EURm)	81
rNPV of FYB207 Europe (EURm)	45
Total rNPV (EURm)	3,423
Unallocated costs* (EURm)	1,564
Enterprise Value (EURm)	1,859
Net debt (cash) (EURm)	-15
Equity Value (EURm)	1,874
Shares outstanding (m)	15
Target Price (EUR)	124

* including COGS, Personnel, Taxes and Capex Source: Metzler Research

Sensitivity	/ analysi	5						
n EUR				Termina	al sales growt	h (in %)		
~		-16	-14	-12	-10	-8	-6	-4
	11.2	135	138	142	146	151	158	166
	11.7	128	131	134	138	143	149	156
	12.2	122	124	127		135	140	147
<u>WACC</u> (in %)	12.7	116	118		124	128	132	138
	13.2	110	112		117	121	125	130
	13.7	104	106	109	111	114	118	123
	14.2	99	101	103	106	108	112	116

Information for professional clients and eligible counterparties - not to be passed on to private clients

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Key Data

Company profile

CFO: Dr. Nicolas Combé

Martinsried (Planegg)

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CEO: Dr. Stefan Glombitza 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 FYB206 (biosimilar for Keytru-da). In addition, with FYB207, Formycon has developed an innovative antiviral drug for the treatment of Covid-19 based on a long-acting ACE2-IgG-Fc fusion molecule.

Major shareholders

Family Offices (43%), Institutional Investors (23%), Founders and Management (7%)

Key figures												
P&L (in EUR m)	2019	%	2020	%	2021	%	2022e	%	2023e	%	2024e	%
Sales	33	-22.9	34	3.2	37	8.0	38	3.0	71	87.6	120	68.0
EBITDA	-1	-116.9	-5	-253.6	-12	-157.5	-16	-29.1	-17	-9.0	24	238.4
EBITDA margin (%)	-4.1	-122.0	-14.1	-242.5	-33.5	-138.4	-42.0	-25.3	-24.4	41.9	20.1	182.4
EBIT	-2	-131.9	-6	-152.0	-13	-132.8	-18	-34.2	-20	-11.3	21	203.0
EBIT margin (%)	-6.9	-141.4	-16.7	-144.1	-36.1	-115.6	-47.0	-30.3	-27.9	40.6	17.1	161.3
Financial result	-0	4.0	-0	-302.7	-0	-57.0	89	n.m.	4	-95.2	-2	-156.0
EBT	-2	-132.4	-6	-153.7	-14	-131.4	72	630.3	-16	-121.8	18	215.8
Taxes	0	n.m.	-0	n.m.	0	126.1	0	-100.0	-3	n.a.	4	215.8
Tax rate (%)	-0.4	n.a.	1.6	n.a.	-0.2	n.a.	0.0	n.a.	20.0	n.a.	20.0	n.a.
Net income	-2	-132.5	-6	-148.8	-14	-135.6	72	629.4	-13	-117.5	14	215.8
Minority interests	0	n.a.	0	n.a.	0	n.a.	0	n.a.	5	n.a.	5	0.0
Net Income after minorities	-2	-132.3	-6	-158.7	-13	-127.4	72	631.3	-13	-117.5	14	215.8
Number of shares outstanding (m)	10	6.1	11	10.5	11	0.0	15	36.4	15	0.0	15	0.0
EPS adj. (EUR)	-0.23	-130.4	-0.54	-134.2	-1.22	-127.4	-1.13	7.7	-0.83	26.3	0.96	215.8
DPS (EUR)	0.00	n.a.										
Dividend yield (%)	0.0	n.a.										
Cash Flow (in EUR m)	2019	%	2020	%	2021	%	2022e	%	2023e	%	2024e	%
Gross Cash Flow	-1	-117.1	-5	-244.7	-12	-163.0	-16	-28.8	-14	10.6	20	243.3
Increase in working capital	1	n.a.	-1	n.a.	-1	n.a.	1	n.a.	-0	n.a.	-1	n.a.
Capital expenditures	1	-4.9	1	14.1	1	5.6	2	87.3	2	-6.2	1	-44.0
D+A/Capex (%)	90.1	n.a.	79.2	n.a.	77.3	n.a.	83.3	n.a.	116.7	n.a.	300.0	n.a.
Free cash flow (Metzler definition)	-3	-326.6	-5	-83.1	-12	-132.2	-20	-57.4	-16	16.4	20	225.4
Free cash flow yield (%)	-0.9	n.a.	-0.9	n.a.	-1.9	n.a.	-1.5	n.a.	-1.3	n.a.	1.6	n.a.
Dividend paid	0	n.a.	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cash flow (post dividend)	0	n.a.	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Balance sheet (in EUR m)	2019	%	2020	%	2021	%	2022e	%	2023e	%	2024e	%
Assets	54	35.2	76	41.2	66	-12.3	801	n.m.	800	-0.1	817	2.1
Goodwill	0	-26.7	0	-36.3	0	0.0	21	n.m.	21	0.0	21	0.0
Shareholders' equity	48	45.0	68	41.1	56	-17.6	395	604.0	382	-3.2	397	3.8
Equity/total assets (%)	90.0	n.a.	90.0	n.a.	84.5	n.a.	49.3	n.a.	47.8	n.a.	48.6	n.a.
Net Debt incl. Provisions	-22	-80.5	-42	-88.6	-25	40.0	-15	39.6	2	112.4	-14	-823.2
thereof pension provisions	0	n.a.	0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Gearing (%)	-46.6	n.a.	-62.3	n.a.	-45.3	n.a.	-3.9	n.a.	0.5	n.a.	-3.5	n.a.
Net debt/EBITDA	16.5	n.a.	8.8	n.a.	2.1	n.a.	1.0	n.a.	-0.1	n.a.	-0.6	n.a.

Sources: Bloomberg, Metzler Research

Disclosures

Recommendation history

Recommendations for each financial instrument or issuer - mentioned in this document - published by Metzler in the past twelve months

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Date of dissemi- nation	Metzler recom Previous	mendation * Current	Current price **	Price target * Author ***	
Issuer/Financial	Instrument (ISIN	l): Formycon (D	E000A1EWVY8)		
31.10.2022	Buy	Buy	74.20 EUR	87.00 EUR Diedrich, Tom	
19.09.2022	Buy	Buy	70.80 EUR	85.00 EUR Diedrich, Tom	
07.09.2022	Buy	Buy	71.10 EUR	85.00 EUR Diedrich, Tom	
19.05.2022	Buy	Buy	69.50 EUR	88.00 EUR Diedrich, Tom	
08.04.2022	Buy	Buy	63.50 EUR	88.00 EUR Diedrich, Tom	

* Effective until the price target and/or investment recommendation is updated (FI/FX recommendations are valid solely at the time of publication)

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

*** All authors are financial analysts

Formycon

13. Metzler, a company affiliated with Metzler and/or a person that has worked on compiling this report has reached an agreement with the issuer relating to the production of investment recommendations.

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