Application Study: European Pharmaceuticals

This study assesses the credit quality of European pharmaceutical corporates, following the release of Scope's Rating Methodology for European Pharmaceutical Corporates on 16 January 2016. Seventeen corporates were selected from a wider peer group and represent a cluster of 'innovative' and 'generic' types, as well as different company sizes. None of these companies have been rated by Scope, therefore it has derived indicative credit assessments based on public information and without projecting into the future.

Scope Ratings expects the credit quality of most European pharmaceutical companies to continue to be at least stable over the coming two years. This is based on an increasingly positive 'innovative balance' (ability to replace negative patent expiry effects with newly approved products) as well as our perception of the good chances of realising above-GDP growth for the innovative arm. As already visible in 2015, late-stage pipelines continue to deliver on innovative content, enabling innovators to maintain high selling prices, at least in the US. Our positive view also reflects our belief that most larger companies have reasonable financial policies, which enable management to realise potential acquisitions, without jeopardising the rating.

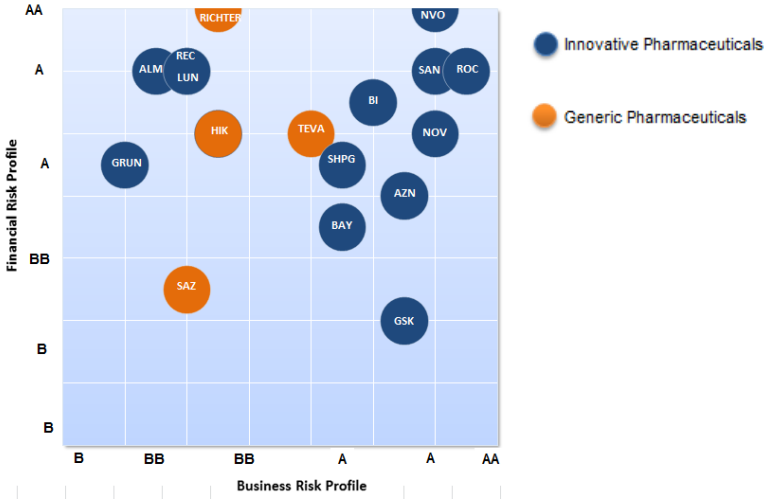
In the case of the generic segment, we see more challenges compared to the innovative, as pricing pressures persist and players need to find profitable niches, or get ready for the 'biosimilars' opportunity, to stem the industry trend towards commoditisation.

Credit quality of assessed corporates

The credit quality of the corporates assessed varies widely, differing by the quality and protection of business risk profiles as well as by financial policy definitions. While large multinational pharmaceutical corporates can still attain very high ratings, smaller and less protected companies remain in the non-investment grade territory. Financial risk metrics are fairly independent from companies' relative sizes, although the larger ones are generally more profitable and cash-rich.

Figure 1 shows Scope's indicative assessment of the credit quality of selected European pharmaceutical corporates. Business and financial risk profiles are combined depending on the rating level (business risk profiles are weighted more for investment grade and vice versa), and finally determined by the rating committee.

Figure 1: Indicative credit assessment of selected corporates in wider peer group



Source: Scope Ratings

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Related Research

Rating Methodology: European Pharmaceuticals
January 2016

European Corporate Outlook,
February 2016

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Bloomberg: SCOP

The European pharmaceutical industry

a) Innovative pharmaceuticals

Global groups dominate market

Today, the innovative pharmaceutical industry is dominated by a number of 'big pharma' companies, which were formed through a consolidation process 15 to 20 years ago. Typically, the result in Europe was the formation of diversified corporate structures – both with regard to companies' total pharmaceutical exposure and through the addition of healthcare businesses, such as over-the-counter (OTC) consumer health, animal health or vaccines. The industry still appears to be fragmented, given the top 10 companies have a global market share of less than 50%. Scope believes that market share data is not the most meaningful parameter but, rather, a company's treatment area exposure.

Diverse structures in Europe

No big pharma company is active in all major medical indications, but, as a consequence of the first round of industry consolidation, many pharmaceutical companies now have diverse product offerings. After increasing pressures from regulators and the market, most big pharma managers have changed their corporate strategy over the past two to three years, and defined a number of core medical indications for their companies. In our view, this aims at forming more focused and efficient product portfolios, as well as flexibility for cost reductions (via divestitures) to improve pricing. We believe the price flexibility of the 'innovators' is important in many countries, as it greatly enhances chances that a newly approved drug is included in the coveted reimbursement lists. Thus, with a parallel motivation to meet and increase internal efficiency benchmarks, management have decided to concentrate on higher-priced and more protected specialty drugs, and to decrease their exposure to generic/less protected products.

Little cyclicality

The pharmaceutical industry is not cyclical, at least not in a macroeconomic, short-term context. If anything, it is exposed to longer-term cyclicality which can result from the drug's life patterns or patent expiry. In our view, the industry is driven strongly by demographic trends, such as ageing populations and general lifestyle patterns. Changes in eating habits for most populations, combined with a general lack of physical activity, have given rise to alarming growth rates in diabetes as well as the worldwide prevalence of cardiovascular ailments and obesity in the last decade. Companies which have taken advantage of this – like Novo Nordisk's focus on diabetes, or Roche's focus on oncology – have flourished.

Well-protected industry…

In Scope's view, the pharmaceutical industry operates in a high-risk, high-reward environment. We believe this has not changed over recent years despite increased pressure on prices. If companies can maintain a healthy balance between patent expirations and the potential for new products, high margins can be sustained – as evidenced in the financial reports of big pharmaceuticals in past years. Our assessment of 'high risk' stems from the high cost to generate leading drugs with annual sales of USD 1bn and above (the so-called 'blockbusters'), which we believe protects the industry through the relatively high, de facto entry barriers: pre-funding of R&D, selling and distribution expenses can easily total more than USD 500m over several years before the first sales for that new drug come in. On the other hand, a successful blockbuster portfolio can easily generate operating margins (EBITDA) of 40% and above, explaining the 'high reward' part of our equation.

Table of Contents

… if innovation maintained

For large, innovative pharmaceutical companies, deriving most of their sales from patented drugs, as well as cash flow and financial stability, fundamentally depend on the product pipeline of new medications and its patent expiration schedule. The ability to counterbalance the effect of patent expiration is critical for any pharmaceutical company, as patent expiry on a blockbuster product can easily result in steeply declining operating profitability if unmitigated by other factors. Thus, a company's ability to launch new products is very important for its potential to reach and sustain comparatively high operating profit margins.

The pharmaceutical industry's classification as a protected environment therefore depends on its ability to innovate and have new products approved. A third hurdle is reimbursement, as this is the final 'entry gate' on the road to a new drug's commercialisation. The sustainability of a strong portfolio composed of patent-protected drugs, with expiring patents replaced by new ones, lays the foundation for a big pharma's protected business model. Protection is provided by:

a) considerable de facto entry barriers and

b) positive effects from regulation, which awards patents for innovative and new drugs.

High degree of regulation

The industry continues to be highly regulated, which has both positive and negative implications for credit quality. The reimbursement of new drugs by most state-owned health insurance systems in various countries has gained importance over recent years as certain drug prices have skyrocketed, led by biological inventions. Successful and new biological anti-cancer drugs, or other specialised products, such as Gilead's new hepatitis C treatments, Sovaldi and Harvoni, have six-digit costs for each annual treatment, but do offer spectacular results. Thus, regulators such as the Food and Drug Administration (FDA) in the US or the European Medicines Agency (EMA) negotiate prices with drug makers after approval – a condition for reimbursement. Inclusion on reimbursement lists is also a prerequisite for successful commercialisation as this, in turn, allows the innovation to be prescribed.

Investment grade innovative pharmaceutical companies

For an innovative pharma company to be rated investment grade according to Scope's methodology, we typically expect: strong R&D capabilities; a valuable and well-balanced product pipeline; a positive balance from the effects of future patent expiries and new drug approvals; and broad product and geographical diversification. The cash flows of investment grade companies tend to be highly predictable and less volatile than the economic cycle, due to increasing revenue trends and a positive pricing element. These companies benefit from stable profitability and strong financial measures.

Non-investment grade innovative pharmaceutical companies

In contrast: small size, a weak pipeline, significant exposure to patent expiry, and weak geographical and product diversification can indicate a non-investment grade rating. The cash flows of non-investment grade companies tend to be less predictable, more volatile, and often experience a long-term contraction of business. Furthermore, these companies often have volatile profitability and weaker financial measures.

b) Generic pharmaceuticals

Less protected generic pharma industry

The 'generic' industry is much less consolidated than its innovative sibling. Unlike the innovative industry, M&A in the generic industry is driven mostly by the goal of achieving a larger scale. Management motivation for takeovers is building an international, if not global, presence in this volume-driven industry to match the scale of large healthcare payment institutions/insurance systems, US pharmacy benefit managers, as well as hospital chains. The total pharmaceutical market by value is dominated by patent-protected products (about 90% of industry sales). In contrast, generic players dominate the market when it comes to the number of prescriptions written (about 80% of the total). Consequently, generic companies generate only 10% of market sales with 80% of the total volume, illustrating the considerable price differential between innovative and copied drugs that have become off-patent. Therefore, the focus on the generic industry is on size, efficient production, and a broad distribution network that enables industry players to quickly capitalise on medicine that, though formerly protected, have now lost its patent.

Speed and global reach are important rating drivers

Time to market and flexibility are important rating drivers for the generic industry because the first company to supply a drug's generic version usually gets rewarded, initially, with high demand and good pricing. This occurs especially in the US, where the first generic company to file is rewarded with a six-month exclusivity period that blocks other suppliers from the market. Drug prices in this exclusivity period are still sufficiently high compared to those under a full competitive field, which usually follows after the initial six months. As a rule of thumb, generic prices in the US for traditional pills get slashed to about 10%-15% of the former protected drug price, while the first generic copy in the market can retain about 40%-50% of the initial level. Products in the generic market are significantly less profitable than those sold by innovative drug makers.

Lower margins reflect almost no pricing power

EBITDA margins of generic companies usually range between 10% and 25% in mature markets. This contrasts with EBITDA margins for specialty pharmas, which can be as high as 45%. The generic market is changing, however, as the first biological drugs have lost their exclusivity. Generic forms of biological drugs (known as 'biosimilars' as these does not overlap 100% with the original) are more complex to build and require the company to invest in R&D before regulatory approval can be obtained. This is a radical break with the past for the traditional generic business model, which did not have innovation or R&D costs and relied exclusively on fast execution and distribution as key success factors. As a result of the significantly higher production and R&D costs, prices for generic biosimilar products are expected to be significantly above those of traditional generic products.

Low entry barriers

Barriers to entry are significantly lower in the generic industry relative to innovative pharma, for which the initial pre-sale investment is not as high. In addition, generic market penetration is supported by political ambition in most countries as it greatly alleviates the burden of ever-increasing costs of healthcare and drugs in the context of notoriously tight state budgets.

Industry has little cyclicality

Similar to the innovative segment, the generic segment is not cyclical, which reflects different industry drivers such as an ageing population and lifestyle factors. In addition, there are a multitude of customers and repeat business with predominantly low ticket prices, attesting to the resilience of this business model. We likewise view the risk of substitution as 'medium' according to our 'General Corporate Ratings Methodology'. This is derived from the assessment we assign to the innovative pharmaceutical industry and follows the logic that a substitute to an originator drug could automatically generate an opportunity for generic companies.

Investment grade-rated generic companies

For a generic company to be rated investment grade according to Scope's methodology, we expect: a well-balanced geographical (preferably global) position, including efficient production and distribution platforms; a positive 'first to file' track record; good product and treatment-area diversification; meaningful market shares in main territories; and, ideally, good specialist manufacturing capabilities.

Non-investment grade-rated generic companies

Non-investment grade ratings reflect a lack of the above, but are foremost driven by comparatively low geographical and product diversification, and insignificant market shares in main territories.

European pharmaceutical corporates assessed in this report

Scope's rating methodology on European pharmaceutical corporates has been applied to 15 research-based and specialty pharmaceutical companies. Scope has excluded biotech companies from the study, instead including European pharmaceutical companies that are relatively small, regional, research-based or specialty-focused.

No.	Company	Group sales in 2015 (EUR m)	Industry
1	Bayer AG	46,324	Innovative
2	Novartis AG	44,473	Innovative
3	Roche Holding AG	41,886	Innovative
4	Sanofi	37,057	Innovative
5	GlaxoSmithKline plc	31,006	Innovative
6	AstraZeneca plc	21,277	Innovative
7	TEVA Pharmaceutical Industries Ltd	17,687	Innovative
8	C.H. Boehringer Sohn AG & Co KG	14,798	Innovative
9	Novo Nordisk A/S	14,462	Innovative
10	Shire plc	5,775	Innovative
11	STADA AG	2,115	Specialist
12	Lundbeck A/S	1,896	Innovative
13	Hikma plc	1,296	Generic
14	Gedeon Richter plc	1,179	Generic
15	Grünenthal GmbH	1,154*	Generic/ Innovative
16	Recordati SpA	1,048	Innovative
17	Almirall SA	685	Generic

Source: Annual reports, Scope Ratings

*: last available year 2014

Assessments done on a standalone basis

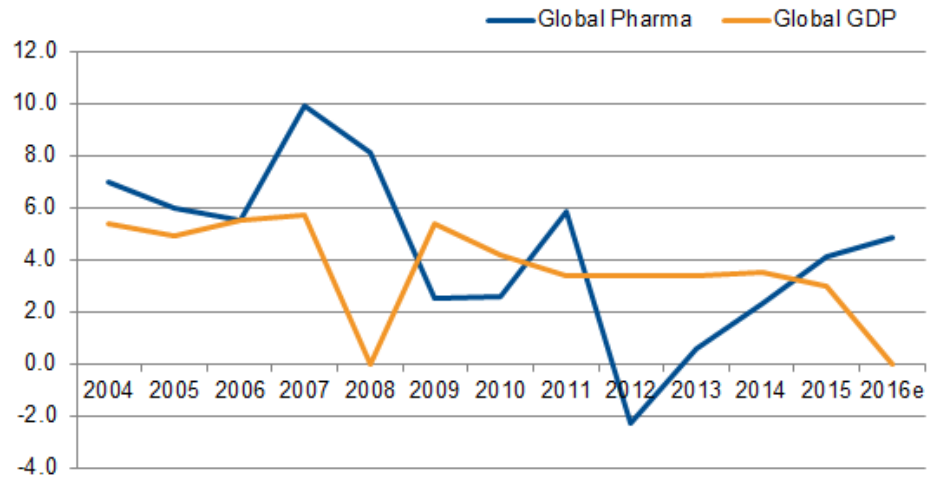
None of the above-listed companies are rated by Scope. A credit quality assessment was performed based on limited information using public information, and without projecting into the future, making these assessments only indicative. This application study also assesses the respective corporates on a standalone basis.

Sector outlook: pharma growth to resume

Scope Ratings believes credit trends in the European pharmaceutical markets will continue to be positive. This is based on the following facts and trends:

- The underlying industry is not dependent on macroeconomic conditions (Figure 2).
- Demographics are supportive.
- Many promising, new innovative drugs have been approved in recent years.

Figure 2: Pharma not synced with macroeconomic trends



Source: Evaluate Pharma, Scope, Eurostat

Pharmaceutical growth trends tend to follow long cycles, typically linked to patents and product life, as well as disease patterns. The relatively low pharma growth rates in 2012 and 2013 were due to relatively high patent expiries, while the below-GDP growth in 2014, in our opinion, mainly reflects significant devaluation of the EUR against the USD (reporting currency). Correcting for the euro's devaluation and reflecting Europe's about 30% contribution to the global pharma market, global growth in 2014 and 2015 could have been about 4 percentage points higher if measured using the local currency.

Given the good rebound in the number of newly approved drugs in the last three years, as well as the continued strong growth of chronic diseases like oncology or diabetes, we believe growth in pharma markets is very likely to pick up in 2016 and beyond. This was underpinned by the good like-for-like revenue growth rates achieved for most European companies in 2015 (Figure 3). AstraZeneca, however, lags behind the more positive sector performance, as the company is still in transition from major patent expiry to new product growth in the future. Similar factors are responsible in both GSK's and Merck's cases. Our positive view on expected growth is also supported by future patent expiries' relatively limited economic impact, reflecting the protected nature of many biological drugs after patent expiry.

Figure 3: Recent growth trends are encouraging

Like-for-like growth rates (YoY; excluding currency effects, M&A)	9 months 2015	2015
AstraZeneca	-1.0%	1.0%
Bayer	10.0%	9.9%
GSK	-1.0%	-1.0%
Merck	1.2%	1.6%
Novartis	5.0%	6.0%
Novo Nordisk	9.0%	8.0%
Roche	6.0%	5.0%
Sanofi	3.6%	2.2%

Source: Individual Annual Reports

Successful new product approvals during the last few years included new breakthrough therapies for Hepatitis C (Sovaldi, Harvoni, Gilead) or multiple sclerosis (Gilenya, Novartis) as well as eye care (Lucentis, Roche), to name but a few. Sales growth was in general strongly supported by the arrival of biological drugs in the form of targeted therapies, which greatly spurred oncological demand, particularly in the last few years. This helped fuel sales growth, combined with the industry's supportive underlying demographic and lifestyle-related factors.

Due to the positive top-line trends, companies were able to keep their innovative balance (replace patent expiries with new products). As a result, average operating margins in the sector improved further and translated into higher cash generation, accompanied by reasonable payout policies and fewer share buybacks.

Scope believes that expected sector credit quality in 2016 will at least continue to be stable. This is supported by our positive pipeline assessment for most companies in the sector. We thus believe that most companies can maintain innovative balances and credit quality during 2016.

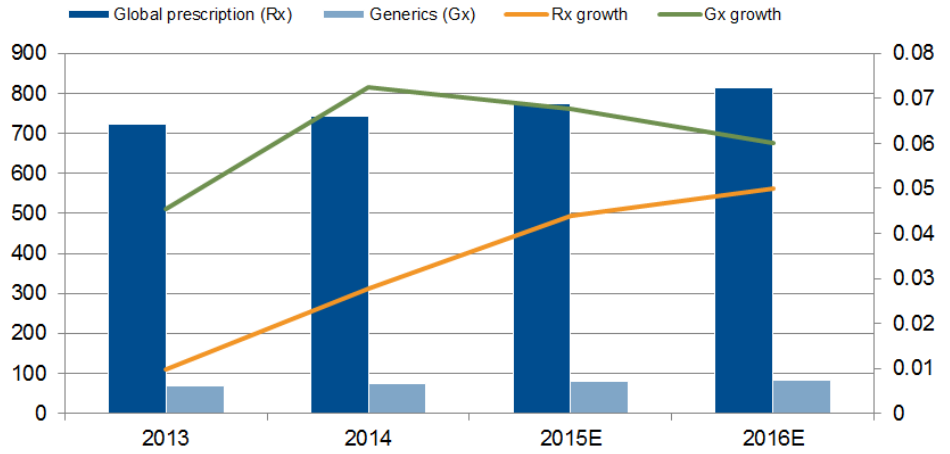
Large-scale M&A, however, continues to be an issue in the global pharmaceutical markets, as evidenced by Pfizer's proposed acquisition of Allergan (although looking more unlikely now) and Shire's takeover of Baxalta. As the former could eventually turn out to be a very sizeable (north of USD 100bn) transaction and create a new world market leader by size, it would have the scale to trigger follow-on transactions.

We believe large-scale M&A is not on the agenda for most European companies as initiators, as the economic rationale for a large takeover is, in most cases, when a pipeline insufficiently replaces patent expiries. Pfizer's motivation for the (now-less-likely) Allergan takeover appears to be at least partly driven by tax inversion and overseas cash application, which is not the case for European players. Thus, at this stage, we do not expect a new 'M&A wave', with potentially adverse effects on credit quality for most European pharma companies in 2016.

Figure 4 illustrates that the global pharma market is dominated by innovative, patent-protected drugs (by value), while the generic market only represents about 10% of the innovative arm. By volume, the opposite applies as over 80% of prescriptions are written for generic drugs. We expect the innovative segment's growth to continue to significantly outperform GDP growth in 2015 and 2016. This is mainly based on the industry's regained productivity, both by volume (number of approved new drugs) and quality (strongly rising expected sales from newly approved products in the US, Figure 4). After the industry easily sailed through the 2012 'patent cliff' (Figure 3), the innovators' balance

between patent expiry effects and new sales potential has become decisively better over recent years, even when only looking at the new product potential in the US.

Figure 4: Global pharmaceutical sales 2013-2016E (USD bn)

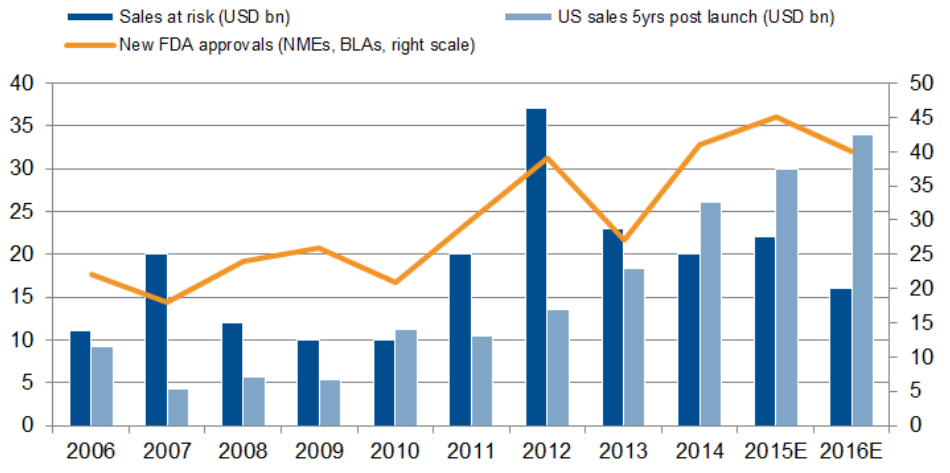


Source: Evaluate Pharma, Scope Ratings estimates

We thus believe industry fundamentals will continue to look good for the next two years, as confirmed by most European companies' positive data in 2015 (Figure 2).

Effective sales at risk are even forecast to decline on an absolute basis in 2016, which can also be due to the rising portion of biological products, which are more complex and expensive to copy, and are thus threatened less by competition after patent expiry compared to for small molecules. The share of biological products is expected to continue increasing to 27% of industry sales by 2020, from 24% in 2015.

Figure 5: Patent approvals and sales at risk



Source: Evaluate Pharma, Scope Ratings

Main geographic focus	Europe
Main treatment area	Cardiovascular
No. of treatment areas	5
No. of blockbusters	5
Top 3 drugs' concentration	30%
NMEs in phase 3	5

Bayer AG ('Bayer') is a diversified life-science group focused on healthcare and agricultural products. Its materials science division (Covestro AG) has just been spun off. Bayer was founded in 1863 and is based in Leverkusen, Germany. Innovative sales accounted for 28% of group revenues in 2015. In 2014 Bayer became a top-three OTC company globally after taking over Merck & Co.'s consumer healthcare business for over EUR 10bn.

Business risk profile

New life-science focus

After the full separation from Covestro, Bayer's revenues will likely exceed EUR 35bn in 2016, of which about 40% will come from innovative sales (about 50% of group EBITDA), and a further EUR 9bn-10bn from consumer health. Bayer was the 13th-largest global pharmaceutical group in 2015, holding good market positions in the cardiovascular and womens' health treatment areas. Its enlarged OTC division adds stability to the group compared to its more volatile materials science division. In crop science, it is a top-three player worldwide. Based on our reasoning below and considering the OTC and agrochemical divisions, we see its business risk profile in the upper A category.

Outstanding patent expiry profile

Bayer has a very good patent expiry profile, as only less than 10% of pharmaceutical sales are exposed to patent expiry by the end of 2017. In addition, with five new molecular entities (NMEs) in late-stage development (phase 3), we believe it has a satisfactory pipeline, partly in very large and promising treatment areas such as oncology and cardiovascular. Recently launched products include the ophthalmology drug Eylea and anti-cancer drug Xofigo, which are likely to drive future pharma growth. In crop protection, patent expiry is less of a threat compared to pharma; while maintaining an innovative product portfolio is very important.

Excellent product portfolio – pharma margins with upside potential

For a mid-sized pharma company, Bayer has a very good product portfolio which includes five blockbuster drugs which are unlikely to be significantly threatened by patent expiry in the next two years. As blockbusters strongly drive its profitability, we expect EBITDA margin in its healthcare division to move higher in future from its present 30%, which is still mediocre in 2015. The crop science division realised significant sales growth over recent years, driven by high, maintained R&D, which led to a strongly extended share of young innovative products.

Excellent diversification across product, therapeutic and crop protection areas

We believe Bayer's pharma product diversification to be excellent, as only 34% of its pharma revenues in 2015 depended on its three top-selling drugs, and just 18% on its top-seller, Xarelto. Bayer is further diversified across five large therapeutic areas, which we believe is good given it is mid-sized player. In our view, the group has a balanced geographical revenue mix, though underexposed to the US (25% of sales) in pharmaceuticals.

Financial risk profile

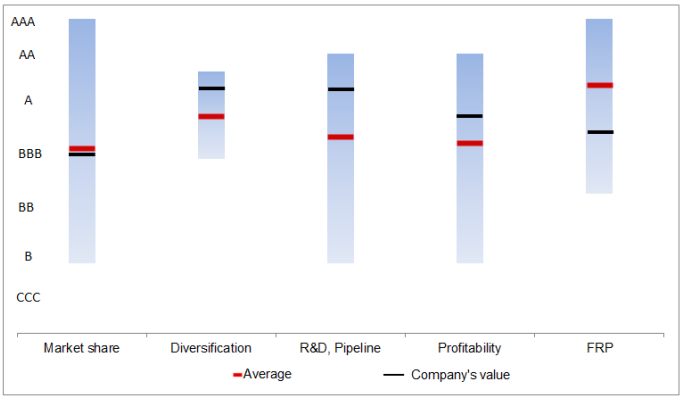
Strong debt protection measures yet to reflect latest acquisition

Credit metrics deteriorated significantly in 2014 following the debt-funded acquisition of Merck's OTC division. However, credit metrics in 2015 were already improving, and we believe the acquisition's effects on the business risk profile are slightly positive. Thus, Scope expects Bayer's financial performance to improve further, and assess its financial risk profile in the BBB category.

Scope's credit quality assessment

Figures in EUR m	2011	2012	2013	2014	2015
Revenues	36,528	39,741	40,157	42,239	46,324
EBITDA	6,918	7,931	7,830	8,587	9,583
EBITDA margin	18.9%	20.0%	19.5%	20.3%	20.7%
Funds from operations (FFO)	5,106	5,882	5,743	6,794	7,128
Free cash flow (FCF)	1,633	764	1,098	1,338	2,414
Net debt	16,863	14,176	10,523	23,313	20,756
FFO/net debt	30%	41%	55%	29%	34%
Net debt/EBITDA	2.4	1.8	1.3	2.7	2.2
FFO-interest cover	9	13	17	19	11

Source: Bayer AG, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Oncology
No. of treatment areas	7
No. of blockbusters	9
Top 3 drugs' concentration	31%
NMEs in phase 3	17

Novartis AG ('Novartis') is a global pharmaceutical group comprising three divisions: pharmaceutical drugs, eye care (Alcon) and generic pharmaceuticals (Sandoz). It maintains a diversified structure, ranking high in both innovative and generic segments. The group is also a global leader in the treatment of sensory organs, oncology and cardiovascular disease. Novartis was founded in 1895 and is based in Basel, Switzerland.

Business risk profile

Largest pharmaceutical company

Novartis is the largest global 'big pharma', based on 2015 results (before the planned merger of Pfizer and Allergan in 2016). In 2014, Novartis swapped divisions with GSK, thereby cementing its global second position in oncology after Roche. It 'joint-ventured' its consumer health and vaccine divisions to GSK. Based on our assessment overall, we believe its business risk profile to be in the AA category.

One of the industry's best pipelines – good patent protection profile

Novartis continues to focus on strong inhouse R&D (24% of sales in 2015), resulting over time in an extremely strong late-stage pipeline with 17 NMEs in phase 3. The risk of patent expiry is low: about 15% of pharmaceutical sales are at risk by end-2017. The pipeline includes Entresto – partly approved for chronic heart failure and with blockbuster potential. In total, we believe the pipeline and new products' potential clearly outweigh upcoming patent expirations (Gleevec, Diovan).

Excellent diversification

Our diversification assessment has yielded very good results for all parameters analysed for its pharmaceutical division (geographies, blockbusters, product concentration and treatment areas). In addition, group diversification – by adding generics and eye care to the mix – is a plus from a rating perspective. As a European-based company, Novartis continues to be strongly exposed to the US, with a blockbuster-rich portfolio spread across seven treatment areas.

A valuable and well-balanced portfolio – good EBITDA margin in pharma

Novartis has a broad and well-balanced portfolio of drugs, nine of which in 2015 were blockbusters – extremely strong among peers, in our opinion. While the group's 29% EBITDA margin in 2015 reflects its overall diversified nature, the pharma division's profitability of 32% is satisfactory.

Financial risk profile

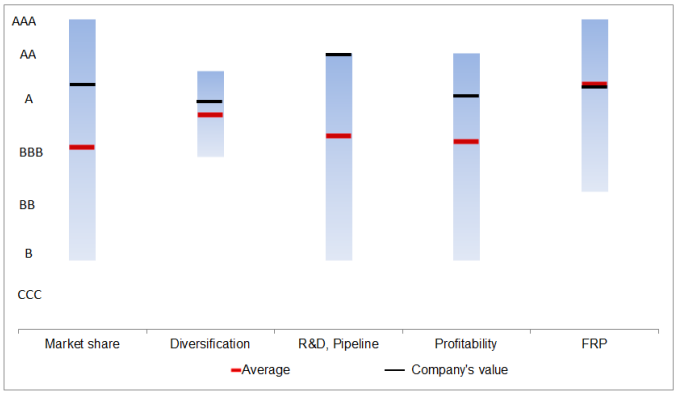
Deterioration in metrics in 2015

Novartis' historically excellent credit metrics deteriorated sharply in 2015, mainly due to its USD 16bn acquisition of GSK's oncology division, while part of its divestiture proceeds were returned to shareholders via share buybacks (USD 4.5bn). We assess its financial risk profile in the high A category.

Scope's credit quality assessment

Figures in USD m	2011	2012	2013	2014	2015
Revenues	58,566	56,673	57,920	52,180	49,414
EBITDA	18,288	16,573	16,316	16,319	14,984
EBITDA margin	31.2%	29.2%	28.2%	31.3%	30.3%
Funds from operations (FFO)	15,100	14,006	13,723	13,507	11,918
Free cash flow (FCF)	5,778	3,879	2,702	2,218	1,080
Net debt	19,096	15,208	10,848	11,099	22,034
FFO/net debt	79%	92%	127%	122%	54%
Net debt/EBITDA	1.0	0.9	0.7	0.7	1.5
FFO-interest cover	24	30	29	26	24

Source: Novartis, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Oncology
No. of treatment areas	4
No. of blockbusters	8
Top 3 drugs' concentration	53%
NMEs in phase 3	10

Roche Holding AG ('Roche') is a top-five global pharmaceutical group, diversified by its significant diagnostics exposure. Founded in 1896, the group operates in four different pharmaceutical treatment areas. The pharma division – which also consists of subsidiaries Genentech in the US and Chugai in Japan – contributes around 80% to group sales. Oncology accounts for about 65% of Roche's pharma sales.

Business risk profile

World leader in oncology

Roche is the leading supplier of oncology drugs worldwide, helped by its ownership of US biotech specialist Genentech and a sizeable diagnostics division (formerly Boehringer Mannheim), ideal for the personalised medicine focus of the industry. Roche continues to be owned by two Swiss families: Hoffmann and Oeri. Based on our assessment below we believe its business risk assessment is in the AA category.

Favourable growth potential from R&D

We believe Roche's growth potential from newly approved drugs, and potentially approved projects in the pipeline, clearly offset downside risks from patent expirations (below 10% of sales). This reflects our opinion that it can even expand the number of blockbusters in the near future, while its three 'mega blockbusters' (Avastin, Herceptin and MabThera/Rituxan) have relatively stable demand despite a few already expired patents. With a high 21% R&D-to-sales ratio in 2015, Roche is among pharma companies that continue to focus on strong inhouse R&D.

Diversification: weakest spot

As a relatively focused pharma company, it is no surprise that diversification compares unfavourably with larger peers, both by treatment area (just four at Roche compared to 6-8 at peers) and product concentration rates. The top three drugs generate over 50% of pharma sales against about 30% at other large peers. Oncology, by far the main treatment area, probably generates over half of the group's profit.

Profitable, blockbuster-rich portfolio

Roche's relatively high EBITDA margin of 39% in its pharma division in 2015 is a direct result of its sizeable and mature blockbuster portfolio. The group had eight blockbuster drugs at the end of 2015, including the three 'mega blockbusters' that generated over CHF 6bn in annual sales each. Also, we do not believe this number will reduce soon, as its leading drugs appear well protected – even after patents expire – and given its promising late-stage pipeline and newly approved drugs. Among the latter, we believe at least two are potential blockbusters (Kadcyla, Esbriet).

Financial risk profile

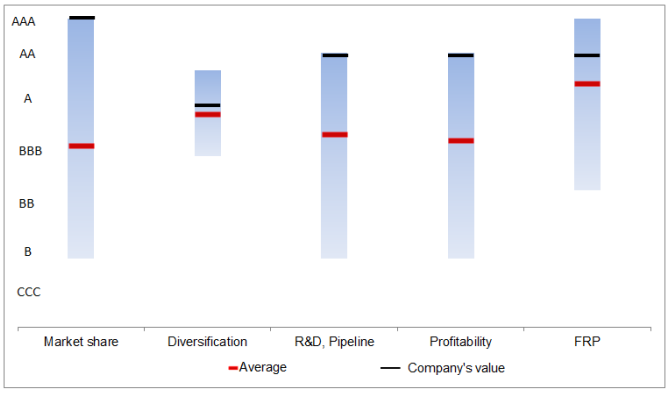
Strong, cash-generative debt protection profile

The high profitability enables very high free cash flows of about than CHF 5bn annually. The company is family-owned, meaning management's risk appetite for large acquisitions or excessive shareholder payouts is conservative, in our opinion. Thus, even after discretionary spending on bolt-on acquisitions, Roche generates positive cash flow each year on average. The financial risk profile is thus assessed at AA**.**

Scope's credit quality assessment

Figures in CHF m	2011	2012	2013	2014	2015
Revenues	42,531	45,499	46,780	47,462	48,145
EBITDA	16,173	17,720	18,933	18,672	17,721
EBITDA margin	38%	39%	40%	39%	37%
Funds from operations (FFO)	13,518	14,842	15,682	15,830	15,550
Free cash flow (FCF)	4,405	6,026	6,257	5,520	4,697
Net debt	19,959	15,527	11,635	20,014	21,990
FFO/net debt	68%	96%	135%	79%	71%
Net debt/EBITDA	1.2	0.9	0.6	1.1	1.2
FFO-interest cover	10	12	15	19	18

Source: Roche, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Anti-diabetics
No. of treatment areas	6
No. of blockbusters	5
Top 3 drugs' concentration	32%
NMEs in phase III	14

Sanofi is a diversified global pharmaceutical company based in Paris, France. It has exposure to innovative pharma (65% of group sales), generics (5%), OTC products (10%), animal health (7%) and vaccines (13%). Its pharma division operates in 10 different treatment areas, and is a leader in the areas of blood, diabetes and vaccines.

Business risk profile

World's fourth-largest pharma

With about EUR 37bn of revenues in 2015, Sanofi is among the few global 'big pharma' companies. The group has a diversified structure, with almost 85% of group sales generated by pharmaceutical products, including vaccines. Other divisions are OTC (9% of revenues in 2015) and animal health (7%). Its highest market shares are in anti-diabetics (around its leading product Lantus), vaccines and rare diseases. After the announced asset-swap for Boehringer Ingelheim, Sanofi's OTC division is likely to make up about 15% of group sales, while the animal-health division will be sold.

Valuable pipeline can offset strong patent expiry on Lantus

The patents on Lantus at EUR 6bn have elapsed and generic competition exists in Europe. While we do not expect a sharp downturn in sales for Lantus, it is clearly the biggest threat when it comes to replacing the potential loss in future profits. In our opinion, sales for Lantus will likely decline gradually, and the newly approved drugs (follow-on product Toujeo, among others), combined with the very good pipeline, should prevent profitability from falling significantly. Apart from Lantus, Sanofi has another four blockbusters in different treatment areas.

Suffering operating margins

In general, its profitability reflects its diversified nature, including lower-margin, non-innovative pharma business (roughly 20% of sales). In 2015, the group EBITDA margin of 27% declined again after the 33% reached in 2013, reflecting price discounts in the US and higher marketing costs.

A diversified and balanced business

The diversification assessment in general is positive for Sanofi, supported by both its group and pharma structures. Geographically, the strong US exposure is a plus, and similar to its leading position in emerging markets. The rating is further supported by its pharma division being spread across six different and sizeable treatment areas.

Financial risk profile

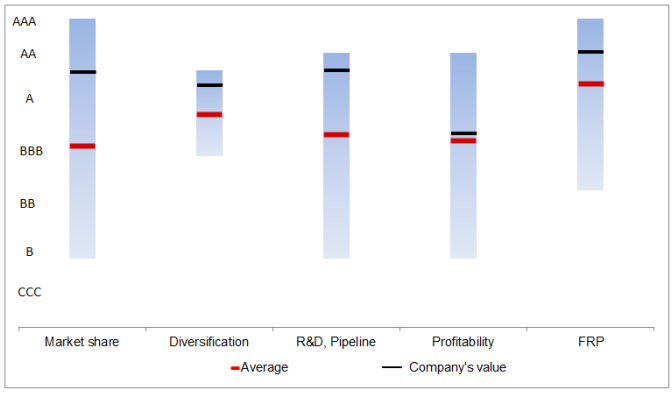
Strong debt protection measures

The credit metrics continue to reflect an AA quality. Free cash flow after dividends averages about EUR 3bn a year, supported by management's financial policy, which keeps the rating in mind. Both our business and financial risk assessments thus reflect AA.

Scope's credit quality assessment

Figures in EUR m	2012	2013	2014	2015
Revenues	34,947	32,951	33,770	37,057
EBITDA	11,531	10,675	9,894	10,065
EBITDA margin	33.0%	32.4%	29.3%	27.2%
Funds from operations (FFO)	9,110	8,154	7,136	8,158
Free cash flow (FCF)	3,669	3,241	2,335	3,798
Net debt	13,340	10,477	12,140	12,459
FFO/net debt	68%	78%	59%	65%
Net debt/EBITDA	1.2	1.0	1.2	1.2
FFO-interest cover	15	17	16	19

Source: Sanofi, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Respiratory
No. of treatment areas	8
No. of blockbusters	4
Top 3 drugs' concentration	31%
NMEs in phase 3	12

GlaxoSmithKline plc ('GSK') is a diversified healthcare company that sells innovative drugs, vaccines, and consumer healthcare products; with significant market shares in anti-infectives, respiratory, anti-virals and vaccines. In March 2015 GSK acquired Novartis's vaccine business and took control of a joint venture (63.5% to GSK) of its consumer healthcare division, and divested its oncology business for GBP 10.7bn. GSK was founded in 1935 and is based in Brentford, UK.

Business risk profile

A global 'big pharma'

About 75% of sales are derived from innovative pharmaceuticals, including vaccines. GSK continues to be a top-10 global pharma player – although slipping to eighth in 2014 from fourth in 2007. Its strongest market positions are in respiratory and vaccines. However, Advair, its leading drug, faces patent expiry. Based on our analysis below, we see GSK's business risk at AA.

Advair patent to expire

Despite the maximum 15% of pharmaceutical sales at risk by end-2017, in our view, mainly from Advair's US-patent expiry, GSK's projected sales are likely to remain relatively stable over the next two years. We believe Advair's future sales will be harmed by price cuts, but mitigated by the loyalty among customers. In addition, newly approved products are helping to close some of the revenue gap, especially in the HIV and vaccine businesses, which include the recently launched potential blockbusters Tivicay and Triumeq, as well as meningitis vaccines acquired from Novartis. With 12 NMEs in phase 3, we believe GSK has a satisfactory R&D pipeline.

Product portfolio – margins

GSK's group and pharmaceutical EBITDA margins are comparatively low for a big pharma, reflecting the loss of blockbuster patents, lower profitable US sales, as well as continued investment into new launches, while maintaining a 15% share of R&D to group sales. Current EBITDA margins of around 32% in the pharma division compare to the about 38% reached in 2013, on an underlying basis.

Well diversified across geographies, products and treatment areas

With about 35% of pharmaceutical revenues in the US, 28% in Europe and 24% in emerging markets, we view GSK's geographical diversification as very good. Within pharmaceuticals, GSK is well diversified in terms of therapeutic areas and products. It operates in eight partly very large treatment areas and its top three drugs only account for about 30% of group revenues.

Financial risk profile

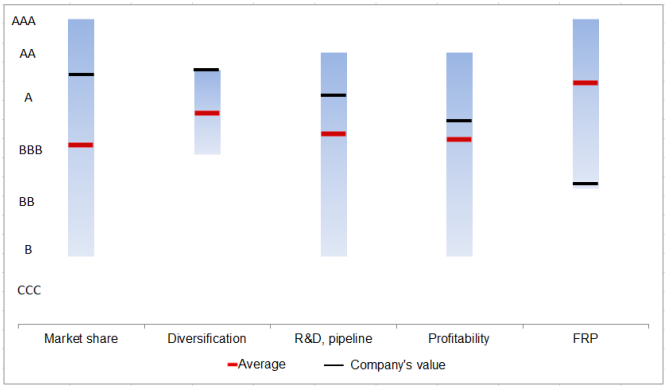
Declining debt protection measures means pressure on the ratings

Credit metrics have declined over the last few years, driven by top-line pressure and lower operating margins. Consistently high restructuring charges, plus the divestiture of the high-margin oncology products to Novartis, have added to this trend. Because of the above, and despite avoiding larger acquisitions and cancelled share buybacks, free cash flow turned negative in 2015 as the dividend was maintained. Given the erosion of credit metrics over time, we see the financial risk profile in the low BBB category.

Scope's credit quality assessment

Figures in GBP m	2012	2013	2014	2015
Revenues	26,431	26,505	23,006	23,851
EBITDA	8,325	7,874	6,122	3,766
EBITDA margin	31.5%	29.7%	26.6%	15.8%
Funds from operations (FFO)	5,749	6,577	5,116	2,685
Free cash flow (FCF)	1,186	1,565	746	-2,691
Net debt	16,765	15,068	16,670	13,146
FFO/net debt	34%	44%	31%	20%
Net debt/EBITDA	2.0	1.9	2.7	3.5
FFO-interest cover	11	11	9	5

Source: GlaxoSmithKline PLC, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Respiratory
No. of treatment areas	8
No. of blockbusters	5
Top 3 drugs' concentration	50%
NMEs in phase 3	17

AstraZeneca plc ('AstraZeneca'), based in London, is among Europe's largest innovative pharmaceutical companies. The group focuses on biopharmaceuticals and is relatively undiversified. Its sizeable blockbusters largely makes it a leader in gastrointestinal and cardiovascular treatment, while its late-stage pipeline has a special focus on immuno-oncology.

Business risk profile

Company in transition

With about USD 24bn revenues in 2015, AstraZeneca has maintained its global top 10 position in the innovative pharma market. This is despite a significant sales decline from 2011 of about USD 10bn, due to strong patent expiry for blockbusters, which led to EBITDA margin falling to about 20% in 2014 – mediocre for a big pharma. The group still leads the market in gastrointestinal and cardiovascular therapies. However, it continues to be in transition as it tries to develop a future product range from its promising immuno-oncology drug pipeline. Based on our reasoning below, we see its business risk profile at a low AA.

Promising late-stage pipeline, but further bad news in the short term

AstraZeneca had 17 innovative compounds in phase 3 as at 31 December 2015, which compares favourably to global peers, both quantitatively and qualitatively. The latter is underscored by its focus on two very sizeable and growing medical indications: respiratory and immuno-oncology, the latter of which uses the human immune system, via potentially chemotherapy-free medicine, to fight various types of cancer. However, our final pipeline assessment does not support the ratings, as we still expect an unfavourable balance of patent expiries and new products in the short term. This is mainly because its leading cardiovascular drug, Crestor, is believed to shed sales of about USD 2bn until 2017, while the first sales of the new drug portfolio is likely to start much more gradually.

Reduced blockbuster portfolio… ...leading to low margins

Due to patents expiring on a number of leading drugs (Seroquel, Atacand, Crestor), AstraZeneca's blockbuster portfolio reduced drastically from 10 in 2010 to an expected five in 2015. The ensuing decline in sales affected the group's margins profoundly, which more than halved from a high of about 43% in 2011. Blockbuster drugs are mature, sizeable products, with comparatively high profitability.

A good diversification across regions and treatment areas

AstraZeneca has a balanced geographical sales generation, in our view, with about 40% of sales in 2014 generated from the most profitable market in the world, the US. Also, its broad spread across eight different treatment areas, including very sizeable ones, add support for the ratings. Its degree of product concentration, however, is not supportive, with the top drug comprising 21% of sales in 2014 and the top three at 50%, comparing less favourably to peers.

Financial risk profile

Declining debt protection measures but …

Debt protection metrics continued to erode in 2015, based on significantly lower cash generation than before. Free cash flow after dividend payments is borderline positive now, but the financial risk profile has deteriorated to a low A.

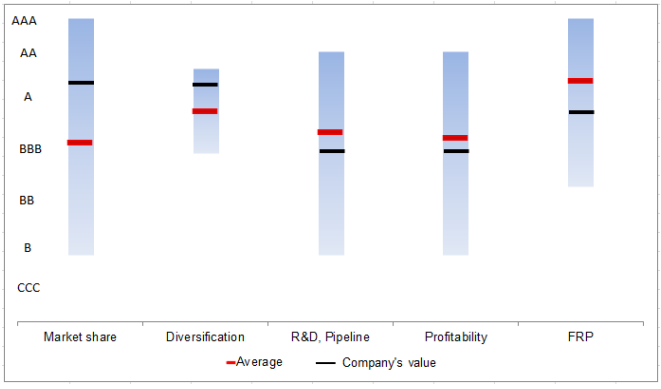
…strong business supports rating indication

Business support (protective industry, good product portfolio, diversification and pipeline) continues to exist, but our rating indication is driven by the much less stable financial risk profile. Larger cash outflows for M&A or from operating needs could mean a downside for the indicative rating.

Scope's credit quality assessment

Figures in USD m	2012	2013	2014	2015
Revenues	27,973	25,711	26,095	23,641
EBITDA	10,411	8,304	5,419	6,101
EBITDA margin	37.2%	32.3%	20.8%	25.8%
Funds from operations (FFO)	7,823	6,985	3,685	4,914
Free cash flow (FCF)	2,356	3,206	1,660	51
Net debt	4,473	3,168	7,375	11,841
FFO/net debt	175%	221%	50%	41%
Net debt/EBITDA	0.4	0.4	1.4	1.9
FFO-interest cover	19	17	10	12

Source: AstraZeneca PLC, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Inhouse specialist expertise	Yes
Production/distribution	Global
First-to-file history	Yes
Pipeline (US)	135
Regulatory track record	Good

TEVA Pharmaceutical Industries Ltd ('TEVA') is a diversified global pharma with interests in generic, specialty and innovative drugs. It also has a joint venture with Procter & Gamble in consumer OTC products (49%). TEVA is the leading generic company worldwide, with about USD 10bn in sales, making its market share about 12%. Its specialty pharma division is sizeable (USD 8.5bn) and is mainly exposed to treatment areas of CNS (central nervous system) with its multiple sclerosis blockbuster, Copaxone, as well as respiratory, oncology and women's health. TEVA is based in Israel.

Business risk profile

Actavis generics takeover pending

TEVA is ahead of the acquisition of Actavis generics for USD 40bn, including a USD 33bn cash component. The transaction (accepted by the target and due for execution in Q2 2016) will shift the focus of the group firmly back to generics. While specialty pharma made up about two-thirds of group EBITDA in 2015, this will be about 50% after the transaction. Therefore, our rating indication gives equal weight to generic and innovative divisions. We view the business risk profile at A.

Global leader in generics

TEVA's position as global leader will be cemented after the acquisition, with market share likely to rise to 20%. The group will thus continue to be the clear market leader in the US, and have a top three position in about 40 countries in total. In specialty pharma, TEVA is mid-sized player, though the leader in multiple sclerosis treatment.

Outstanding diversification in generics, weak spot in specialty

Diversification is excellent for generics, in our view, with regard to geographies, treatment areas, product portfolio, and expertise in specialty products such as biosimilars and vaccines. In 2015, TEVA offered over 1,000 molecules globally. In specialty pharma, diversification is the weak spot from a rating perspective, reflecting its focus on one drug (nearly 50% of sales), one treatment area and one territory (US).

Excellent generic pipeline

TEVA has the broadest pipeline in the industry. At the end of 2015, it had 135 projects, including 34 with a 'first to file' status in the US. Actavis's generics will further improve this, with 220 new drug applications and 74 first-to-filers. In Europe, TEVA had 969 new product applications outstanding in the same period. In its specialty division, the six NMEs in late-stage development are considered adequate, but do not support the rating indication.

Very strong specialty-pharma profitability

Specialty pharma contributed two-thirds to group EBITDA in 2015, thanks to a high EBITDA margin of over 40%, due solely to its large blockbuster, Copaxone. We view the generic margin of about 20% as satisfactory.

Financial risk profile

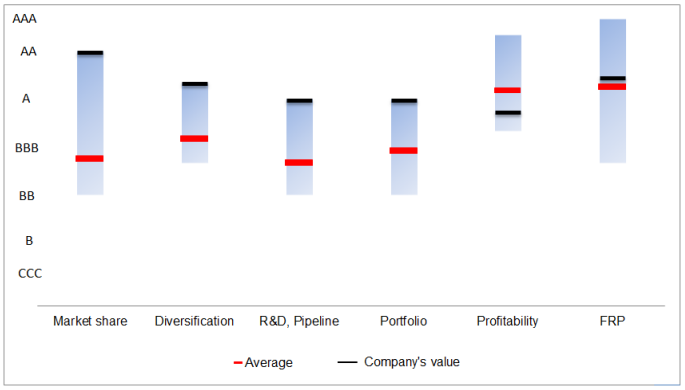
Excellent credit metrics pre-transaction

Credit metrics remained excellent in 2015, thanks to good operating cash generation as well as cash held temporarily in reserve to fund the acquisition. As the cash outflow will be huge, it is probable metrics will go down significantly in 2016. In this context, we see its financial risk profile in the single A category.

Scope's credit quality assessment

Figures in USD m	2012	2013	2014	2015
Revenues	20,317	20,314	20,272	19,652
EBITDA	4,984	3,815	5,846	4,660
EBITDA margin	24.5%	18.8%	28.8%	23.7%
Funds from operations (FFO)	4,073	2,186	4,877	3,615
Free cash flow (FCF)	2,327	874	2,758	652
Net debt	11,093	10,420	7,567	2,653
FFO/net debt	37%	21%	64%	136%
Net debt/EBITDA	2.2	2.7	1.3	0.6
FFO-interest cover	14	7	17	15

Source: TEVA, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Anti-diabetics
No. of treatment areas	3
No. of blockbusters	6
Top 3 drugs' concentration	53%
NMEs in phase 3	6

Novo Nordisk A/S ('Novo') is a global pharmaceutical company based in Denmark. It is the global leader in anti-diabetics based on its 45% market share (by volume). About 75% of the group's operating profits are generated by this division, which also outpaces pharma market growth significantly. Apart from anti-diabetes, its business model includes anti-haemophilia, as well as growth-hormone and hormone-replacement therapies. It is ranked among the top-20 global pharmas, and is projected for a top-10 placing by 2020 based on its high expected growth.

Business risk profile

Protected, uncyclical industry

We assess the pharma sector's cyclicality as low, based on past trends of revenue growth in the sector: average 10-year CAGR of about 5% versus the 4% average global GDP growth. Barriers to entry are also high due to intensive capital needs, the protected market and consolidated nature of the industry. Based on our analysis, we assess Novo's business risk profile with an AA indication.

World leader in anti-diabetics

Novo is expected to continue dominating the global anti-diabetics market, due to its focus on this indication (about 80% of revenues and 70% of operating profit), and as the segment will probably continue to outperform market growth in future.

Strong patent-expiry profile, good innovative track record

With a strong inhouse R&D philosophy, it has established a robust and well-filled pipeline with six molecules in phase 3 in 2015, which is less than large diversified peers, but good given Novo's size. We believe it probable that Novo will significantly offset the likely, patent-expiry-driven fall in sales with extra revenues from newly approved drugs and to-be-approved pipeline candidates in next three years.

Diversification: light and shadow

Geographic diversification is outstanding given its 50% exposure to North America – very good, in our view. On the other hand, product concentration rates and the limited number of therapeutic areas compares unfavourably to peers. The latter can be viewed as the negative side of a focused structure and a blockbuster-rich portfolio.

Very strong and stable profitability

Novo's 'best in class' EBITDA margin of 43% in 2015 – showing a rising trend historically – is the direct result of its six blockbuster drugs and extremely profitable biopharma portfolio, which compares positively even among big pharma peers.

Financial risk profile

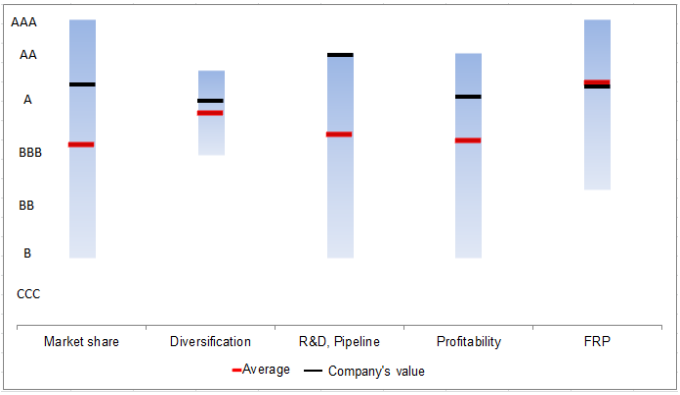
Net cash position and conservative financial policy

Based on the extremely high margins, solid free cash flow generation, and sizeable (but rating-neutral) shareholder remuneration, its financial risk profile is in the AAA category.

Scope's credit quality assessment

Figures in DKK m	2012	2013	2014	2015
Revenues	78,026	83,572	88,806	107,927
EBITDA	32,167	34,292	37,927	50,027
EBITDA margin	41.2%	41.0%	42.7%	46.4%
Funds from operations (FFO)	21,940	26,207	33,840	46,555
Free cash flow (FCF)	10,850	12,583	15,491	26,269
Net debt	-7,753	-6,988	-9,746	-8,353
FFO/net debt	-283%	-375%	-347%	-557%
Net debt/EBITDA	-0.2	-0.2	-0.3	-0.2
FFO-interest cover	-220	-373	-716	8,338

Source: Novo Nordisk, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Respiratory
No. of treatment areas	6
No. of blockbusters	3
Top 3 drugs' concentration	53%
NMEs in phase 3	9

C.H. Boehringer Sohn AG & Co. KG ('Boehringer') is a family-owned and diversified pharmaceutical company, which is the second largest in Germany and is ranked top 20 globally. In pharmaceuticals (about 90% of group sales), it focuses on six main areas: respiratory, oncology, cardiovascular, diabetic, infections and CNS. It recently announced a swap of divisions with Sanofi, to which it sold its consumer healthcare division, and took over Sanofi's activities in animal health.

Business risk profile

Boehringer in transition

The combination of patent expiry and pricing pressures on its three blockbuster drugs means Boehringer faces the task of replacing its high-margin revenues. For these reasons, like-for-like pharma sales were under pressure in 2014 (-5%) and 2015 (+2.6%, helped by new product launches). The group reacted by cutting costs, increasing third-party collaborations and optimising the portfolio (Sanofi swap). Based on our assessment below, we see its business risk profile in the upper A category.

Satisfactory pipeline, but… …commercialisation takes time

In our view, patent expiry could threaten about 10% of its annual pharma revenues. Thus, given blockbusters' high profitability, patent expiry is clearly an issue. While the pipeline is satisfactorily stocked with six NMEs and more already-approved compounds tested for extra indications, we believe it will take time to fully replace the sales lost in the short term. The pipeline – built by the significant R&D commitment (R&D-to-sales of well above 20%) is spread over large and growing treatment areas such as diabetes, oncology, rare disease and respiratory.

Well-balanced geographical exposure

We assess geographical diversification as strong, based on its high US exposure and overall global position. We view its treatment area diversification in pharma as similarly supportive for the ratings, further helped by its sizeable animal-health division. Due to its three blockbusters, product concentration rates compare less favourably to peers.

Mediocre margins despite good product portfolio

Despite a (partly sizeable) blockbuster portfolio covering half of total pharma sales, group profitability (20% EBITDA margin in 2015) compares less favourably to peers. However, Boehringer does not report pharma margins separately.

Financial risk profile

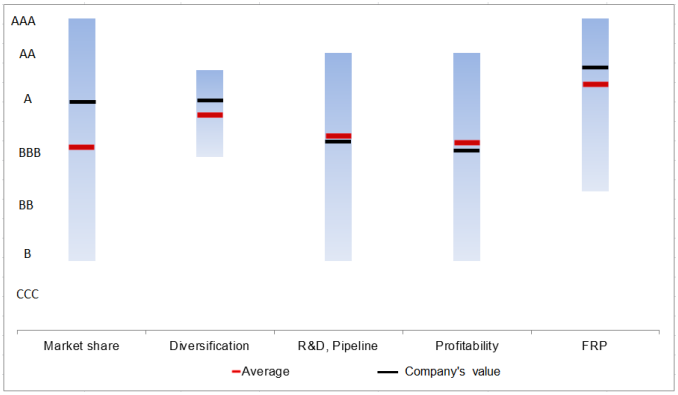
Supportive credit metrics

Despite top-line pressure and relatively low profitability, operating cash generation held up well in 2015. The main adjusted debt component is pensions (limited reporting). The group has very little financial debt and ample balance sheet liquidity. We assess its financial risk profile at AA.

Scope's credit quality assessment

Figures in EUR m	2012	2013	2014	2015
Revenues	14,691	14,065	13,317	14,798
EBITDA	2,750	2,853	2,691	2,855
EBITDA margin	18.7%	20.3%	20.2%	19.3%
Funds from operations (FFO)	2,158	2,133	1,918	2,213
Free cash flow (FCF)	-1,418	771	829	981
Net debt	3,061	2,705	2,394	2,242
FFO/net debt	71%	79%	80%	99%
Net debt/EBITDA	1.1	0.9	0.9	0.8
FFO-interest cover	30.6	31.7	23.8	25.3

Source: Boehringer Ingelheim, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Inhouse treatment area	Rare disease
No. of treatment areas	4
No. of blockbusters	1
Top 3 drugs' concentration	50%
NMEs in phase 3	11

Shire plc ('Shire') is a global innovative supplier of specialty biopharma drugs, based in Dublin, Ireland. Its business model strongly focuses on rare diseases with unmet medical needs. The mid-sized company is currently evolving to a large company through a string of acquisitions. Currently, it is making a takeover bid to shareholders of US-based specialty drug manufacturer Baxalta Incorporated. The takeover is supported by Baxalta's management and would more than double the group's sales.

Business risk profile

Significant growth potential

Shire is likely, in our opinion, to catapult itself into the top-20 global pharmaceutical companies in 2016, if the Baxalta bid goes through. The group could even advance further, as the specialty pharma market enjoys superior growth and both companies have promising late-stage pipeline status. Thus, while Scope's current rating indication is still based on Shire's standalone credit quality, the combined group assessment is likely to be different, depending on the likely positive implications for the business risk profile, as well as the likely negative effects from the extra debt raised. On a standalone basis, we see Shire's business risk profile in the A category.

Excellent pipeline, manageable patent expiry profile

Shire spends between 15% and 20% of product revenues on R&D. This has lead to a late-stage pipeline consisting of 11 NMEs, which compares very favourably to peers. Also, we believe that there is limited patent-expiry downside risk on future sales. Thus, on a net basis it appears to be well placed to realise further sales growth.

Satisfactory diversification

Product sales are strongly exposed to the US (over 70%), while appearing to be under-represented in Europe. Product concentration compares unfavourably to peers as its top three products are sizeable and growing.

Very strong and stable profitability

The EBITDA margin of between 35% and 40% supports the ratings indication in a peer context, due to its exposure to high-margin specialty pharma and its blockbuster drug, Vyvanse (neuroscience).

Financial risk profile

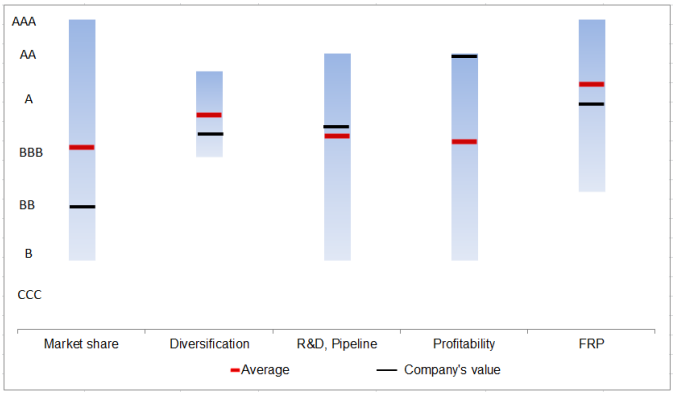
Excellent debt protection measures, but likely to decline significantly

Past credit metrics have been very robust, but will probably change from 2016 owing to sizeable acquisition activity. Depending on the financing mix and definition of future financial policy, the financial risk profile indication is likely to be significantly lower than in the past.

Scope's credit quality assessment

Figures in USD m	2011	2012	2013	2014	2015
Revenues	4,263	4,681	4,934	6,022	6,417
EBITDA	1,404	1,258	2,085	2,296	2,388
EBITDA margin	32.9%	26.9%	42.3%	38.1%	37.2%
Funds from operations (FFO)	1,139	1,056	1,771	2,233	2,304
Free cash flow (FCF)	647	829	1,390	1,926	1,880
Net debt	693	-153	-2,007	-1,934	1,663
FFO/net debt	164%	-692%	-88%	-115%	139%
Net debt/EBITDA	0	0	-1	-1	1
FFO-interest cover	38	36	58	376	64

Source: Shire, Scope Ratings



Source: Scope Ratings

Main geographic focus	Europe
Inhouse specialist expertise	No
Production/distribution	Europe
Top 3 products' concentration	6%
Pipeline (active ingredients)	>150
Regulatory track record	OK

STADA AG ('STADA') is a diversified generic and OTC company based in Germany. About 60% of group sales are derived from generics, including biosimilars, which are in-licensed. STADA has a strong position in the difficult German generic market and is trying broaden its exposures across Europe. Management strives to de-emphasise generics in the mid-term, due to higher growth and higher margins in OTC.

Business risk profile

BB industry risk for generics

We see generic industry risk at a high BB due to our view on the market's low cyclicality, low barriers to entry and medium substitution risk. As we see the OTC segment, STADA's other main division, as similar in nature to the branded consumer-product market, the assessment below focuses on its generic division. Including OTC, we see its business risk profile at BBB.

Third-ranked in Germany

STADA ranks among the top 15 in the global generic market and is the third largest in Germany (10% market share). Its market share appears to have been under pressure, with rather stable revenue trends over the last five years contrasting with above-GDP growth in the global generic market.

Satisfactory diversification

Over 90% of revenues are in Europe, with Germany at almost 25% at group level. While the generic division is strongly diversified across treatment areas and products, its top products' concentration rates are low (largest five products are 6-9% of divisional revenues, which supports the ratings). About 600 products are launched each year, and the 1,300 new approvals for about 150 active pharmaceutical ingredients compare well with peers. STADA's main treatment areas in generics are for pain, women's health, cardiovascular and diabetes.

Good profitability

With an EBITDA margin of 19%, operating profitability compares well to mid-sized peers and supports the rating assessment.

Satisfactory compliance record

In our view, STADA has a good track record in health regulators' site inspections as well as required manufacturing quality and product safety standards. There have been no major disruptions to larger production sites that would cause significant delivery delays. Likewise, for the supply of active pharmaceutical ingredients, we are not aware of any major bottlenecks to date.

Financial risk profile

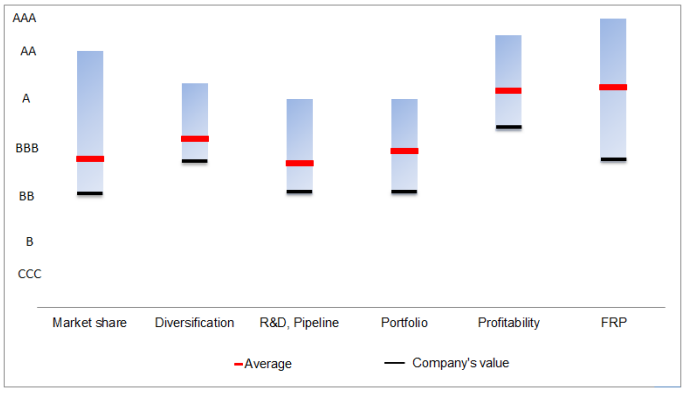
Free cash flow positive status

Credit metrics show stable characteristics in a five-year horizon, with the FFO-net-debt ratio in a 20-30% corridor, and EBITDA covering interest at 5-6x. Importantly, the company could stay free cash generating in the last five years, due to good operating cash generation and low capital expenditure. We view its financial risk profile at a high BB.

Scope's credit quality assessment

Figures in EUR m	2012	2013	2014	2015
Revenues	1,838	2,014	2,062	2,115
EBITDA	349	408	443	402
EBITDA margin	19.0%	20.3%	21.5%	19.0%
Funds from operations (FFO)	460.7	310.7	325.7	431.2
Free cash flow (FCF)	65.5	111.6	170.0	239.9
Net debt	1,551.0	1,731.9	1,749.9	1,655.8
FFO/net debt	30%	18%	19%	26%
Net debt/EBITDA	4.4	4.2	3.9	4.1
FFO-interest cover	5	6	6	6

Source: STADA, Scope Ratings



Source: Scope Ratings

Main geographic focus	US
Main treatment area	Central nervous system
No. of treatment areas	2
No. of blockbusters	0
Top 3 drugs' concentration	45%
NMEs in phase 3	3

H Lundbeck A/S ('Lundbeck') is a pure-research-based pharma specialised in CNS treatment with a focus on brain diseases such as depression, psychosis, Alzheimer's and Parkinson's. Founded in 1915, it is based in Valby, Denmark.

Business risk profile

Company in transition

In 2015, Lundbeck generated slightly higher revenues of DKK 14.5bn (EUR 1.8bn) year on year, corresponding to about a flat like-for-like growth. The company is still in transition phase as its former blockbuster drug, Cipralex, has faced patent expiry for two years, and newly approved products so far cannot fully replace Cipralex' revenues, let alone operating margins. The company had a high operating loss in 2015, also reflecting large expenses for reshaping the company and integrating recent acquisitions following the change in top management. Based on our assessment below, we see its business risk profile at BB.

Good pipeline built by strong R&D commitment

After the patent on Cipralex expired in 2014, more than DKK 3.5bn of very profitable revenues were lost since 2013. The company has stabilised revenues remarkably well since then by acquiring and developing new molecules, which quickly boosted revenues in 2015. With three compounds in late-stage development, we believe its pipeline is thin, but compares well to mid-sized peers. We also see further downside of up to DKK 1.5bn on Cipralex' sales in 2016. But group sales should already have seen its low: helped by the relatively solid R&D (20% on sales), Lundbeck managed to efficiently bridge the 'Cipralex gap' in the last two years.

Portfolio margins

Unsurprisingly, after the large patent expiry in 2014, group margins collapsed, reflecting Cipralex' relatively high profitability. We believe the low was reached in 2015 with a net loss of DKK 5.6bn, but this was mainly due to almost DKK 7bn of impairment and amortisation charges. Newly approved drugs bringing DKK 3.5bn of new revenues in the last two years have largely stabilised margins, and margins will probably rise again in 2016, in our view.

Improved geographical diversification focused heavily on neuroscience

Geographical exposures are balanced, in our view: in 2015, 43% of sales were in the US, 27% in Europe, and 30% in other global markets. Its US exposure rose significantly in 2015, thanks to acquisitions and new US products. Product concentration rates are good, while differentiation of treatment areas is poor as most revenues are from neuroscience.

Financial risk profile

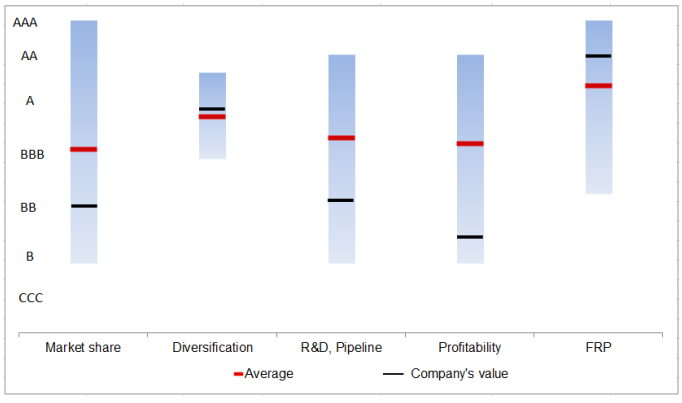
Credit metrics worsened in 2015

Low profitability and relatively strong cash outflow from working capital changes led to credit metrics deteriorating sharply in 2015. However, this was mainly caused by restructuring and the initially low profitability of newly approved drugs. Therefore we believe 2015 was an exception and should not weigh overly high in our assessment of the financial risk profile. Very strong debt protection metrics in the past, and our belief the group will likely improve profitability markedly in 2016, means we still assess the financial risk profile at BBB. An upside to our conservative business risk assessment could be triggered by an EBITDA margin trending towards its historical highs of about 30%.

Scope's credit quality assessment

Figures in DKK m	2012	2013	2014	2015
Revenues	14,802	15,258	13,468	14,588
EBITDA	2,535	2,861	1,552	2,297
EBITDA margin	17.1%	18.8%	11.5%	15.7%
Funds from operations (FFO)	1,912	2,737	1,225	2,084
Free cash flow (FCF)	311	1,875	1,013	1,658
Net debt	-1,129	-2,986	378	3,204
FFO/net debt	-169%	-92%	324%	65%
Net debt/EBITDA	-0	-1	0	1
FFO-interest cover	12	10	3	13

Source: H Lundbeck A/S, Scope Ratings



Source: Scope Ratings

Application Study:
European Pharmaceuticals

Main geographic focus	Europe
Inhouse specialist expertise	Yes
Production/distribution	Global
First-to-file history	Yes
Products launched	92
Regulatory track record	good

Hikma plc ('Hikma') is a generic drug maker focused on specialty generics like injectables and branded products. Its base in Jordan helps with maintaining sound positions in its home market, Middle East and North Africa (MENA). Even so, it has built a sizeable presence in the US (48% of revenues) through acquisitions and organic growth. Hikma has had an acquisitive track record, reflected by the sizeable takeover of Roxane Laboratories, Inc from Boehringer Ingelheim for USD 575m in cash (plus 40m Hikma shares) in early 2016. The transaction will further raise Hikma's US exposure, especially in the lucrative injectables business.

Business risk profile

Among fastest-growing generics

Hikma's size has more than doubled in the last five years due to organic growth and its takeover of Roxane, which is expected to add over USD 600m of revenues in 2016. Hikma had already outgrown the global generic sector in the five years from 2009 to 2014. In the MENA region, the company is the fifth largest in generics. After acquiring Roxane, Hikma will be one of the dominant makers of injectable generic drugs. Based on our assessment presented below, we see the business risk profile at BBB.

Good geographical and segment diversification

As a relatively small player in the global generic segment, we believe it has diversified very favourably away from its home market of MENA, especially into the US which took up almost half of group sales in 2015 – and Roxane will increase the US exposure even more in 2016. Also, we view positively its exposure to injectables and branded generic segments, particularly given its robust operating margins in a niche market.

Profitable portfolio

The group EBITDA margin of 32% in 2015 benefited from its very profitable injectables division and the abnormally high margins for several years in its (so far) relatively small generic division, which is due to product and ingredient shortages from other producers. Though this effect will gradually go away, we believe Hikma is among the most profitable generic businesses worldwide.

Good pipeline

With 220 approvals and 92 launches in 2015, we believe the pipeline is good, containing 1,250 projects in total at the end of 2015. Roxane will add 89 projects and 13 'first to file' opportunities in the US, which are very interesting commercially.

Financial risk profile

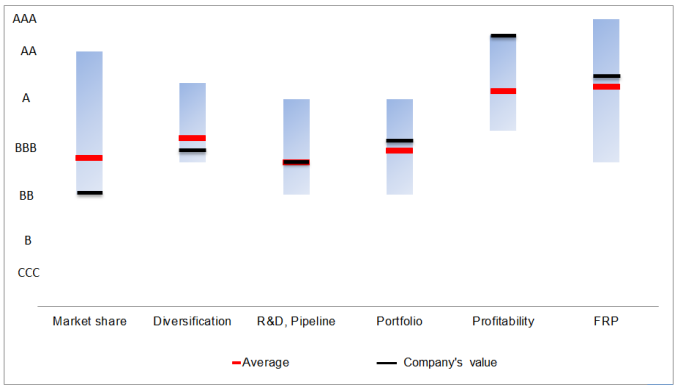
Acquisition: no drag on rating

Credit metrics in the last two years has already embedded a lot of cushion for a potentially large acquisition. We have not netted the YE 2015 cash with debt, as it was used fully for the Roxane acquisition. Thus, net debt in 2015 seems unlikely to increase much this year, while Roxane cash flows will add to Hikma's FFO. Thus, we believe the financial risk profile is an A.

Scope's credit quality assessment

Figures in USD m	2011	2012	2013	2014	2015
Revenues	918	1,109	1,365	1,489	1,440
EBITDA	166	225	443	474	461
EBITDA margin	18.0%	20.3%	32.5%	31.8%	32.0%
Funds from operations (FFO)	202	190	379	381	371
Free cash flow (FCF)	47	31	163	244	177
Net debt	519	508	374	382	728
FFO/net debt	39%	37%	101%	100%	51%
Net debt/EBITDA	3.1	2.3	0.8	0.8	1.6
FFO-interest cover	7	7	12	12	12

Source: Hikma, Scope Ratings



Source: Scope Ratings

Main geographic focus	Europe
Inhouse specialist expertise	Yes
Production/distribution	EUR
First-to-file history	No
Products launched	23
Regulatory track record	good

Gedeon Richter plc ('Richter') is a generic company, but strongly committed to R&D and innovative drugs. It is the largest pharma company in Central and Eastern Europe (CEE). As a relatively small player on a global scale, Richter has a flexible approach between inhouse developed and in-licensed products. The business model focuses on only three treatment areas. Richter is the third-largest supplier with about 5% of the Hungarian pharma market, and is a significant player in female healthcare. The company also has a small wholesale and retail pharma business.

Business risk profile

Company in transition

Based on management's stated strategy, Richter sees itself as innovation-driven. This is reflected in the existing clinical pipeline and the recent approval of its anti-schizophrenia drug, VRAYLAR, in the US. However, its main commercial exposure is to off-patent generic products and the company is currently developing two biosimilars. Thus, judged by its present structure, we allocate Richter to the generic industry, although it is by no means a pure play. Based on our reasoning below, we view its business risk profile at a BBB.

Focused European/CIS player, diversified pharma company

Richter is CEE's biggest pharma. With about one-third of group sales in 2015, the CIS region continues its prominence. Western Europe and CIS accounted for almost 85% of group sales, while the US, Asia and emerging markets are underrepresented. Its product portfolio focuses on three important areas: gynaecology, CNS and cardiovascular, which account for about 70% of group sales combined. Richter's diversified group structure (innovative, generic, wholesale) provides another benefit from a rating assessment view.

Thin pipeline – flexible R&D approach

In 2015, R&D spend was below 10% of revenues. We view this as in line with a generic company, but regarding its strategy to focus on innovation, it compares unfavourably to peers, in our view. The clinical pipeline appears to be thin, with 2 NMEs in late-stage development. However, it has led to the recent approval of a schizophrenia drug, a rather specialised treatment area. From a ratings point of view, we view positively the inhouse development of two biosimilar drugs, as competitive pressure is much less severe in this area compared to traditional generics. In 2014, Richter launched 23 new products, which compares unfavourably to peers.

Good profitability

Richter generated a relatively high EBITDA margin of 27% in 2015, strongly improving over 2014. If sustainable, we believe this will give strong support from a ratings point of view and compare favourably to peers.

Financial risk profile

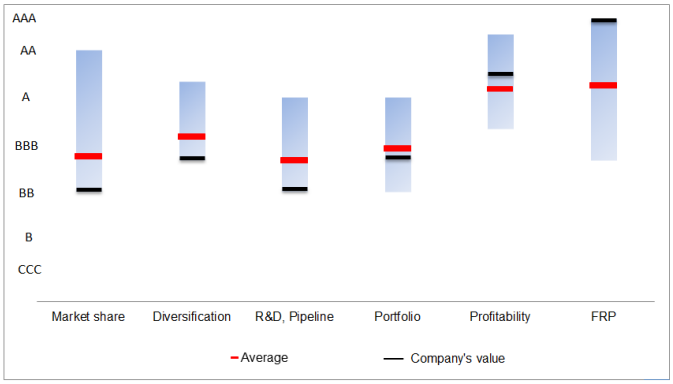
Excellent debt protection measure s

The company continues to have a net cash position due to consistent, and even increasing, free cash flow generation over time, yielding a financial risk profile in the AAA category.

Scope's credit quality assessment

Figures in HUF m	2012	2013	2014	2015	in EUR m
Revenues	326,702	351,424	353,709	365,220	1,179
EBITDA	75,979	75,524	67,110	98,665	318
EBITDA margin	23.3%	21.5%	19.0%	27.0%	
Funds from operations (FFO)	73,182	76,253	60,066	92,022	297
Free cash flow (FCF)	12,604	15,278	24,131	66,511	215
Net debt	-28,194	-44,721	-39,260	-88,663	-286
FFO/net debt	-260%	-171%	-153%	-104%	
Net debt/EBITDA	0	-1	-1	-1	
FFO-interest cover	75,979	75,524	67,110	98,665	

Source: Gedeon Richter, Scope Ratings



Source: Scope Ratings

Main geographic focus	Europe
Main treatment area	Pain
No. of treatment areas	3
No. of blockbusters	0
Top 3 drugs' concentration	35%
NMEs in phase 3	N/A

Grünenthal GmbH ('Grünenthal') is a family-owned, small-sized pharma based in Germany, focusing on the innovative segment in Western Europe and Latin America. By far, its largest indication is pain, with the largest products being narcotics, analgesics and opioids drug classes. It has developed over recent years to its present, focused structure. Recent transactions include the acquisitions of Almirall's Mexican activities and the Andromaco Group in Chile; and the divestment of its Eastern European business in 2012.

Business risk profile

Specialised player focused on pain

While there is not much public disclosure available on Grünenthal, the company derives its unique selling points from a specialisation on pain, and from its regional focus on Western Europe and Latin America (about 90% of revenues combined). As pain is a mature treatment area overall, with a large number of generic products in the market, Grünenthal needs to constantly innovate to mitigate patent-expiry effects and pricing pressure in the market. Based on our assessment below, we see the business risk profile in the BB category.

Strong R&D commitment

With consistently above 20% of sales spent on R&D, Grünenthal belongs to the circle of small- and mid-sized pharma with a strong inhouse R&D focus. Over the years, this effort has built a well-filled pipeline focused on pain and related indications, also with regard to lifecycle-management projects. In 2014, the company executed eight phase-3 clinical trials in the treatment areas of pain and inflammation.

Good diversification given small corporate scale

We assess geographical diversification as satisfactory but not strong, given the relatively low exposure to the most lucrative pharma market, the US. This is partly mitigated, in our view, by its high exposure to Europe and Latin America. In addition, we view the comparatively low concentration rates for top-selling products as a support for the rating.

Low EBITDA margins

The adjusted operating margins are less favourable in a peer group context. This, in our view, reflects its product portfolio of less sizeable drugs, as well as a competitive market which forces a continuously high spending on R&D.

Financial risk profile

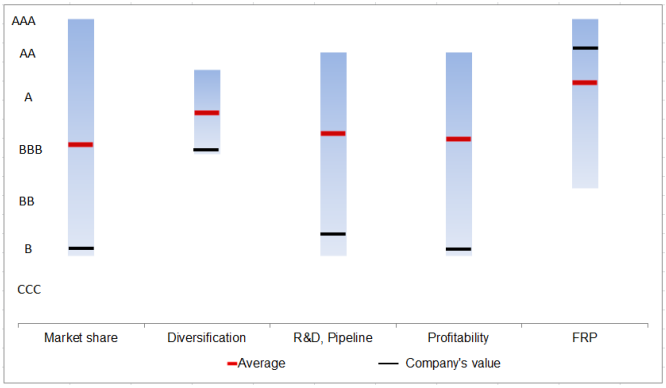
'Best in class' credit metrics

Despite top-line pressure and relatively low profitability, Grünenthal continued to generate satisfactory operating cash flows and almost-balanced free cash flows. The main adjusted debt component is its pension obligation (limited reporting). The group has very little financial debt and ample balance sheet liquidity. We assess the financial risk profile in the AA category.

Scope's credit quality assessment

Figures in EUR m	2012	2013	2014
Revenues	973	901	1.154
EBITDA	113	81	139
EBITDA margin	11.6%	9.0%	12.1%
Funds from operations (FFO)	66	55	95
Free cash flow (FCF)	-4	-23	20
Net debt	-68	-26	-21
FFO/net debt	-96%	-207%	-460%
Net debt/EBITDA	-0.6	-0.3	-0.1
FFO-interest cover	20	10	13

Source: Grünenthal, Scope Ratings



Source: Scope Ratings

Application Study:
European Pharmaceuticals

Main geographic focus	Europe
Main treatment area	Rare disease
No. of treatment areas	3
No. of blockbusters	0
Top 3 drugs' concentration	24%
NMEs in phase 3	3

Recordati SpA ('Recordati') was founded in 1926 and is based in Milan, Italy. FIMEI, a holding company of the Recordati family, owns 51.6%. Recordati is a small manufacturer with a broad portfolio of primary-care and specialty-care medicines, and OTC products. It has built a growing exposure to rare disease in the last years. The best selling product in 2015 was Zanidip (hypertension) with sales of about EUR 115m.

Business risk profile

Small size, but increasingly specialised

With about EUR 1bn in group sales, Recordati is considered small among peers. It develops new molecules internally and is open to commercial and development collaborations with international pharma peers. It aims to capture a growing presence globally with its profitable rare-disease portfolio. Based on our assessment below, our indication for its business risk profile is in the BB category.

Small pipeline overall, reasonably protected patents

Recordati's pipeline reflects its small scale and relatively limited R&D (below 10% of 2015 sales), and two NME late-stage assets. R&D focuses on treating rare disease and urology. The most advanced among these is Carbaglu, an orphan drug already approved in Europe for a metabolic disorder, acidemias. Also, its treatment for hyperammonaemia appears to be the only one in existence. For patent expiries, main products appear well protected against major sales declines in the next two years.

Diversification is credit-positive

For a small pharma company, we view its diversification as beneficial to the overall assessment, owing to its relatively low product concentration rates and its 10% sales exposure to the US. With only three treatment areas, however, it compares less favourably to peers.

Strong EBITDA margin…

The operating (EBITDA) margin has improved over recent years, reaching 30% in 2015. We view this as another strength given its size, and believe it testifies to its good position in the high-margin segment of rare disease.

Finance risk profile

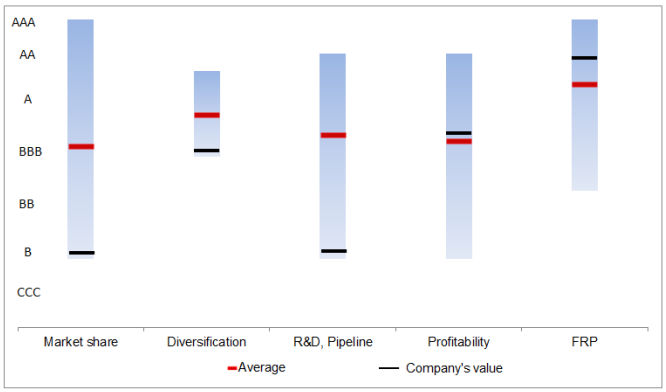
… contributing to strong debt protection

Based on the positive operating trends over the last five years, cash flow generation was consistently strong enough for AA type credit metrics. As a family-owned company, Recordati appears to be cautious regarding larger acquisitions. The dividend, however, has been raised continuously, and absorbed over 50% of net profit in 2015.

Scope's credit quality assessment

Figures in EUR m	2011	2012	2013	2014	2015
Revenues	762	828	942	987	1.048
EBITDA	188	194	231	274	317
EBITDA margin	24.6%	23.4%	24.6%	27.7%	30.3%
Funds from operations (FFO)	141	145	170	206	237
Free cash flow (FCF)	22	37	95	91	103
Net debt	80	178	283	211	132
FFO/net debt	176%	81%	60%	97%	181%
Net debt/EBITDA	0.4	0.9	1.2	0.8	0.4
FFO-interest cover	54	29	16	17	24

Source: Recordati SpA, Scope Ratings



Source: Scope Ratings

Main geographic focus	Spain
Main treatment area	Dermatology
No. of treatment areas	4
No. of blockbusters	0
Top 3 drugs' concentration	30%
NMEs in phase 3	4

Almirall SA ('Almirall') is a global pharmaceutical company based in Barcelona, Spain. After the sale of its main respiratory-related assets to AstraZeneca in 2015, the company's new core treatment area is dermatology. Though with about EUR 300m in dermatology sales, Almirall continues to be a mid-sized player in this indication. In our view, given its high cash balances from divestitures, its strategy is likely to entail further acquisitions in dermatology and related areas. Its business model is centred around building a portfolio of innovative, branded prescription dermatology products, supported by proprietary R&D and in-licensed products.

Business risk profile

Industry: low cyclicality, high entry barriers and medium substitution risk

We believe the innovative industry has lower cyclicality than macroeconomic swings. We assess high entry barriers in this industry because large upfront investments in R&D and marketing are needed before a product can be approved and sold. Substitution risk, in our view, is seen as medium, reflecting limited competing technologies to the existing standards of care.

Small but focused player

In the global dermatology market of roughly EUR 20bn, Almirall is still small, but is the largest in Germany, and top-10 in Europe and the US. Following recent acquisitions (Acqua, Poli, ThermiGen), more transactions, mainly for dermatology, are likely in the near future. The company also still has significant financial resources from divesting respiratory-related assets in 2015. Based on our analysis below, Scope assesses Almirall's business risk indication at BB.

Small scale, but good patent-expiry profile, high number of newly launched products

With four NMEs in phase 3, and only 10% of group revenues spent on R&D, Almirall compares unfavourably to its peers. However, we believe the pipeline will evolve, given its still-transitionary nature. In our view, its product portfolio appears well protected from patent expiry. We also recognise a high number of newly launched products that support its growth potential.

Diversification supports credit quality

Its global positioning (amid a satisfactory US exposure) and relatively low concentration rates of top products support the rating indication. Despite the increasing relevance of dermatology among its four treatment areas, overall diversification is seen as positive.

Volatile profitability

The relatively low EBITDA margin of 19% in 2015 reflects a product portfolio in transition and an absence (so far) of sizeable drugs.

Financial risk profile

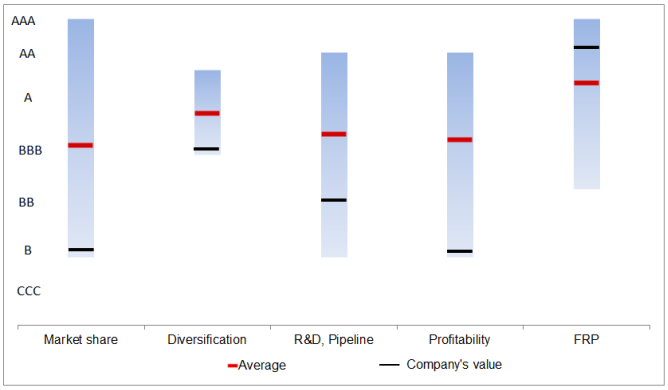
Overcapitalisation unlikely to persist

We do not expect Almirall net cash position to persist as the high cash balances are earmarked, in our view, for future acquisitions.

Scope's credit quality assessment

Figures in EUR m	2011	2012	2013	2014	2015
Revenues	768	683	693	786	685
EBITDA	147	123	-10	143	132
EBITDA margin	19.2%	18.1%	-1.5%	18.1%	19.3%
Funds from operations (FFO)	110	82	-16	51	64
Free cash flow (FCF)	21	43	-89	-25	-16
Net debt	205	17	225	112	-481
FFO/net debt	54%	494%	-7%	45%	-13%
Net debt/EBITDA	1.4	0.1	-21.8	0.8	-3.6
FFO-interest cover	24	28	-2	8	9

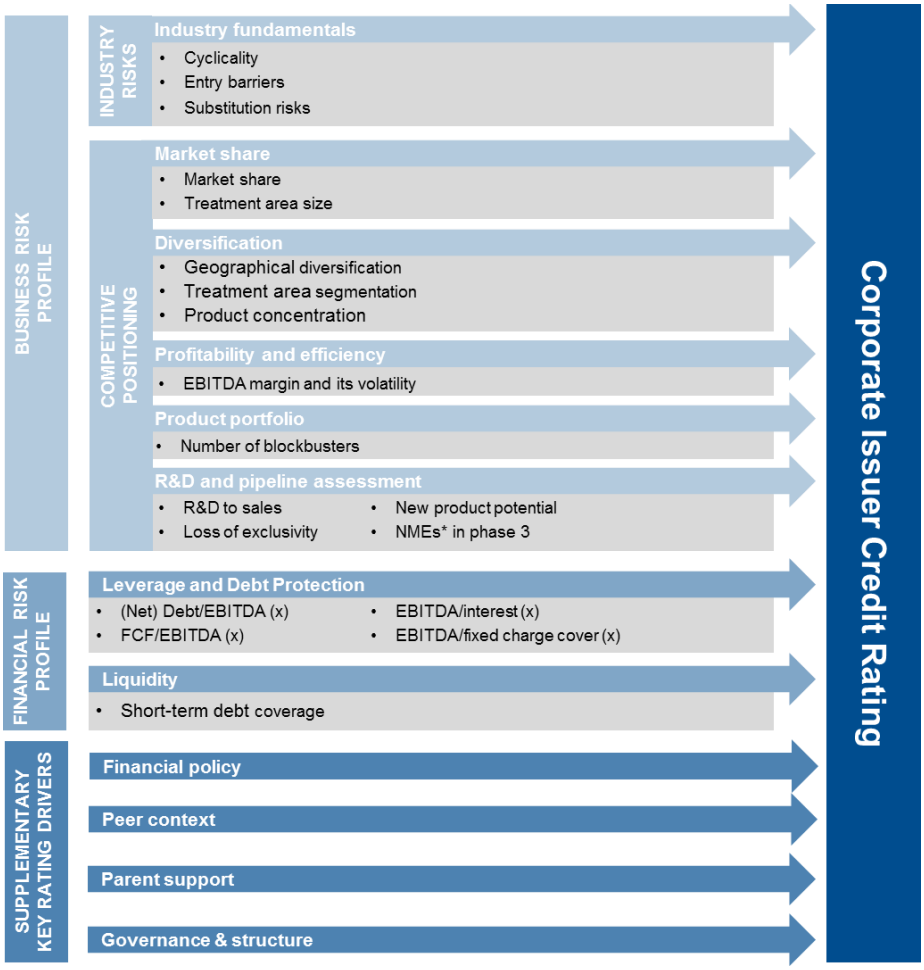
Source: Almirall, Scope Ratings



Source: Scope Ratings

I. Appendix

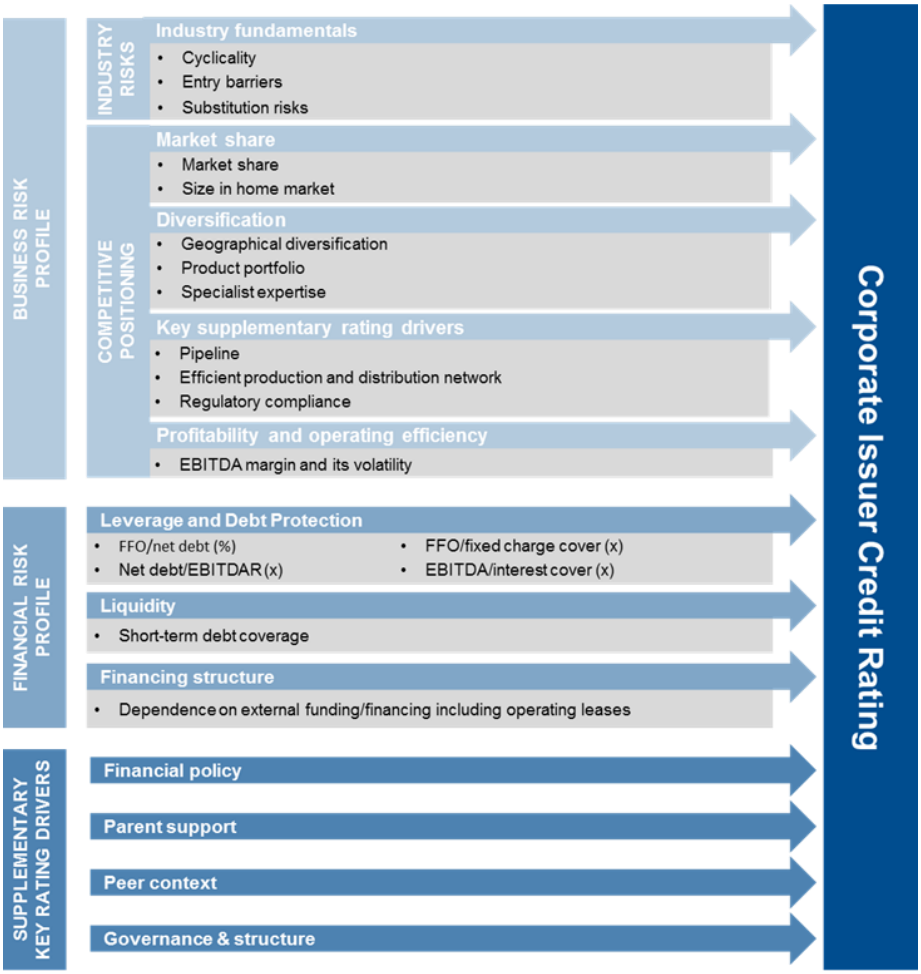
Figure 6: Scope's general rating grid on European innovative pharmaceuticals



Source: Scope Ratings

II. Appendix

Figure 6: Scope's general rating grid on European generic pharmaceuticals



Source: Scope Ratings

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