

Industry Outlook

Moody's Global Corporate Finance

September 2008

European Pharmaceutical Companies

Moody's outlook for European pharmaceutical companies is negative. This represents Moody's expectations for the fundamental credit conditions in the industry over the next 12 to 18 months.

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Summary

- Significant amounts of revenue exposed to patent expiries in 2010-2013.
- Generic manufacturers are becoming increasingly aggressive competitors.
- Pipelines do not always appear sufficient to offset patent expiries.
- The bar has been raised for drug approvals, especially in the US, increasing the risk of delays and non-approvals.
- Pricing pressure from health authorities is trending upward.
- Financial policies becoming more aggressive through M&A and share buybacks.
- Cash flow generation and profitability are still strong, growth opportunities remain good and the industry should not be materially affected by current recessionary pressures.
- Balance sheet and credit metrics remain robust in general and create a cushion to absorb potential negative events.

Overview

European pharmaceutical companies face a challenging period, with patents on drugs representing a significant amount of revenue set to expire between 2010 and 2013. Most Big Pharma companies in Europe must address the fact that product portfolios are maturing and, in several cases, have passed their peak. For a number of companies, today's pipelines appear insufficient to make up for the expected upcoming revenue loss and there are not enough blockbuster candidates in the pipeline to replace the ones coming off patent.



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Furthermore, the US Food and Drug Administration (FDA) seems to have taken a more cautious stance on new drug approvals. This has led to delays and rejections of several new drug applications and we believe this is likely to continue. Although we believe the pharmaceutical industry will adapt to this trend over the intermediate term by more carefully choosing which projects to pursue through clinical testing, a conservative FDA is likely to affect cash flow generation over the short term.

Faced with an aging population and soaring healthcare costs, European regulatory authorities are increasingly becoming more restrictive about which drugs they choose to reimburse and are putting pressure on prices. In other words, regulatory bodies are in our view likely to move more towards a cost/benefit analysis approach. Pricing pressure may also increase in the US, although more slowly than in Europe.

The pricing pressure is likely to favour generic manufacturers, which appear to be becoming more aggressive in "launching at risk" – before patent challenges are fully resolved in the courts – their own versions of patent-protected drugs.

Nonetheless, the industry's profitability and cash flow remain strong and its liquidity good. We also believe there is room for growth over the next 12-18 months as many diseases, such as diabetes or cancer, still present substantial treatment challenges and as the population ages in key markets, such as the US. We also believe that the relatively healthy, though mature, product portfolios of the European companies should continue to fuel operating cash flow. Companies are also cooperating with smaller, research-based firms to boost their pipelines and consulting with governments early in the development stages of some drugs to assess the likelihood of reimbursement.

In our view, there is a continued degree of event risk in the sector but we note that a number of large M&A transactions were completed or announced over the past year. We would therefore expect M&A activity to be somewhat more limited in the near term as companies concentrate on integrating the acquired businesses.

As share prices have suffered in line with setbacks from pipelines and non-approvals from the FDA, companies have also come under pressure to boost share buyback plans. It is likely that financial policies will continue to be more shareholder-friendly than they had been in the first part of the decade. We cannot rule out that acquisition and share buyback activity could put pressure on some ratings over the next 12-18 months.

Rated Universe

Moody's currently rates eight European pharmaceutical companies with approximately US\$45 billion in debt outstanding.

Figure 1

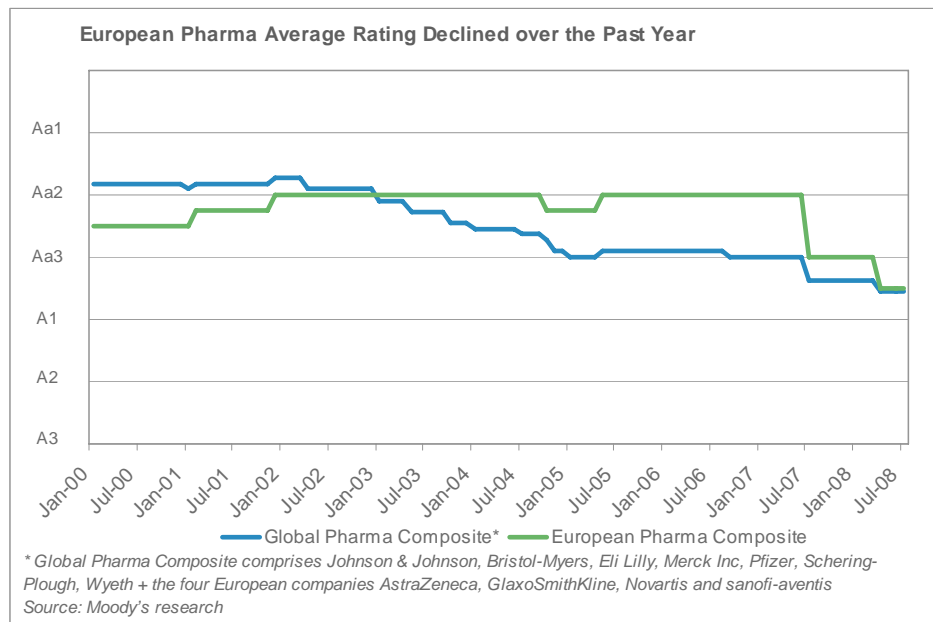
European Pharmaceutical Company Ratings & Outlooks		
Company	Rating	Outlook
Roche	Aa1	RUR
Novartis	Aa2	Stable
sanofi-aventis	A1	Positive
AstraZeneca	A1	Stable
GlaxoSmithKline	A1	Negative
Novo Nordisk	A2	Stable
Merck KGaA	Baa1	Positive
Nycomed	B2	Stable

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Since our last report was published in July 2007, there have been no upgrades and four downgrades in the sector, mainly reflecting shifts in financial policies either through large debt-financed acquisitions (AstraZeneca and Novartis) or increased share buybacks (GlaxoSmithKline). The downgrade of Nycomed's rating in April 2008 reflected the impact of the launch of generic versions of Protonix (pantoprazole) in the US, which is expected to hurt the company's cash-flow generation and slow down its de-leveraging. In July 2008, the rating of Roche was placed on review for possible downgrade following the announcement of an offer to acquire all the outstanding shares of Genentech (A1/RUR) for US\$44 billion.

The only positive move was the change of Merck KGaA's outlook to positive from stable in February 2008. The outlook change was primarily related to the company's rapid de-leveraging following the acquisition of Serono, through the disposal of its generics business. An equity increase had also been put in place to maintain solid financials.

Figure 2



Key Trends and Rating Implications

The industry approaches the 2010-2013 patent cliff

Most major European pharmaceutical companies face the expiration of a number of patents on top-selling drugs beginning in 2010. For AstraZeneca, patents expiring over the 2010-2013 period represent sales of about US\$12 billion – compared to total sales of US\$29.6 billion in 2007. Expiring patents bring with them competition from generics, which can strike a potential blow to cash flow. This is particularly true in the US, where the generic version is often the only drug reimbursed by insurance companies and where sales erosion once a generic is launched can be quite steep. These significant patent expirations can pose a threat to the credit quality of some companies, depending upon the strength of their pipeline.

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Figure 3

Key Patent Expirations (2010-2013)

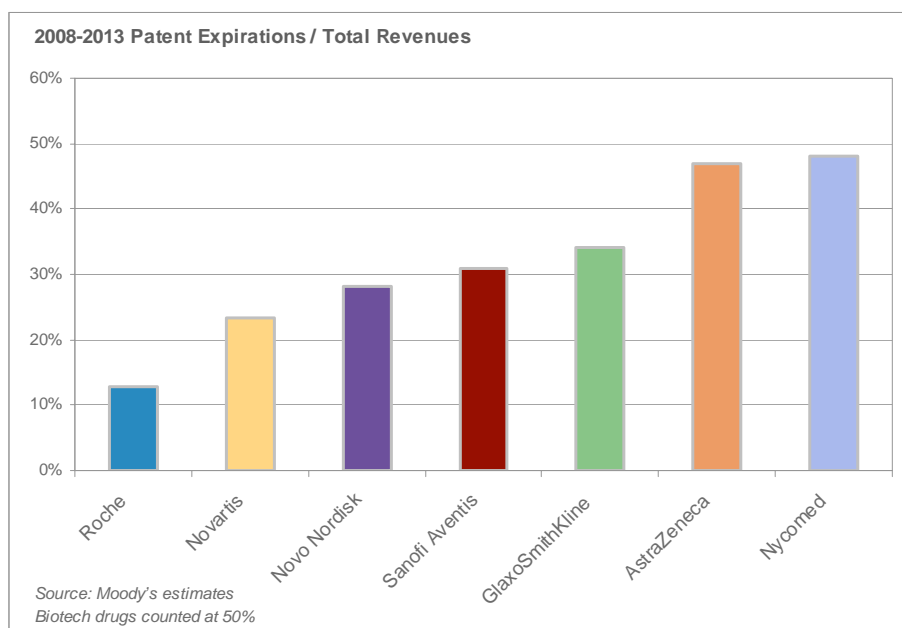
	US	EU
GSK	Advair (2010)* Avandia (2012) Combivir (2012)	Advair (2013)* Avandia (2013) Combivir (2013)
Roche	Boniva (2012)	Boniva (2011) Cellcept (2011) MabThera (2013) Xeloda (2013)
AstraZeneca	Arimidex (2010) Seroquel (2011) Atacand (2011)	Arimidex (2010) Symbicort (2010) Nexium (2010)** Atacand (2011) Seroquel (2011) Crestor (2012)
Novartis	Exelon (2011) Diovan (2012) Exforge (2012) Femara (2012) Aclasta (2013) Zometa (2013)	Sandostatin (2010) Exelon (2011) Diovan (2012) Exforge (2012)
sanofi-aventis	Taxotere (2010) Plavix (2012) Avapro (2012) Actonel (2013)	Taxotere (2010) Actonel (2010) Lovenox (2011) Aprovel (2012) Plavix (2013)
Novo Nordisk	NovoSeven (2010)	NovoSeven (2011)
Nycomed	Protonix (2010)	

* Advair is also protected by patents on the Diskus inhaler that run from 2011 to 2016.

** Nexium's substance patent in Europe was revoked in December 2006, but data exclusivity runs until 2010 in major European markets.

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Figure 4



Companies with heavy exposure to biopharmaceutical drugs, such as Roche or Merck KGaA, seem more protected against generic competition and do not face the same cliff as the others. Roche in particular has a limited exposure to patent expiries over the short to intermediate term. Roche's main patents, on MabThera/Rituxan and Avastin, for example, do not expire until 2013 and 2020, respectively. In addition, a difficult pathway to market for biosimilars is likely to give drugs protection beyond patent expiry dates. For its part, Novo Nordisk benefits from the specificities of the insulin market, which is characterised by a shift from human insulin towards modern insulin that will offer patent protection to the company beyond the current decade. It also is helped by its leadership in insulin delivery systems that are difficult to copy generically.

Some companies have tried to mitigate the impact of a loss of patents by developing areas less sensitive to expiries and the threat posed by generics, such as vaccines or biotech drugs, which bring higher barriers to entry because of the difficulty in copying the compounds or the production process. Others have diversified into the generic drugs business themselves, such as Novartis through Sandoz. Others have branched into diagnostics, such as Roche, or eye care, such as Novartis with its acquisition of a stake in the US company Alcon. Still others have substantial portfolios of broader consumer products, such as GSK with its Aquafresh toothpaste and Lucozade sports drinks brands. On the whole, we view such portfolio diversification positively. While some businesses (e.g. consumer healthcare, diagnostics) have considerably lower margins than the original drugs business, they also bring less volatility. However, we will be monitoring the impact of any economic slowdowns on sales, especially in the US.

Rating Implications

Patent expiries over the next three years – the measurement included in our methodology grid – average 18% of 2007 total European Big Pharma sales and seem to be manageable overall. Patent expiries of a number of key drugs over the 2010-2013 period could pose a threat to the credit profile of some companies if they are not able to offset related sales declines with new product launches. AstraZeneca, which is one of the most exposed to 2010-2013 patent expiries in our rating universe, may be exposed to a slowdown of sales growth around the end of this decade. The company's ability to launch new products at the start of the next decade will be critical in preserving its current credit profile.

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Challenges from generics represent a major threat to future revenues

As mentioned earlier, the other part of the risk posed by patent expiries comes from generics companies, which tend to claim invalidity of patents and may even launch generic copies "at risk" once the exclusivity period of the branded drug ends. It is not surprising then that most global pharmaceutical companies have several key patents being challenged by generic manufacturers.

A number of major patent challenges, mostly in the US market, could put pressure on current ratings, since generic launches, while they are reflected in our ratings grid, represent a significant risk for future cash-flow generation. In Europe, patients are often still reimbursed if they continue to buy a branded product; hence the impact of generic competition on cash flow generation may be less severe, as sales tend to decline much more slowly. In the longer term, however, we would expect Europe to move closer to the US model.

In part due to recent court decisions in the US, including one federal circuit court ruling (In re Seagate Technology) that could make it harder for branded companies to claim triple damages for lost profits in patent infringement cases, generics manufacturers are likely to become even more aggressive in their challenges of branded drugs.

Although litigation is normally protracted, and as such somewhat mitigates the risk of patent challenges, a launch at risk may have immediate and severe effect on sales. For example, Teva Pharmaceuticals launched a generic version of Nycomed's Protonix before the patent issue was resolved, sharply cutting into Protonix' sales. Net sales of Nycomed's out-licensing segment, which essentially comprises Protonix, declined by 57.6% during Q1 2008. With product portfolios becoming ever more mature, we will not rule out that launches at risk could become more common in the short term. That does not mean, however, that generic companies are ultimately in a better position to win those challenges.

One long-running patent challenge appears to be reaching a conclusion. In 2006, Canadian pharma company Apotex launched at risk in the US a generic version of Plavix (clopidogrel), sanofi-aventis' widely used anti-coagulant. Sales of Plavix fell sharply, affecting sanofi-aventis' overall cash generation that year. In June 2007, a US District Court judge in New York upheld Plavix' US patent, which is not due to expire until 2012. Apotex has appealed but we think it is unlikely the decision will be overturned. Since then, Plavix sales have recovered in the US.

Plavix now faces generic threats in Europe - its European patent expires in 2013 - from at least three generic companies. Switzerland's Schweizerhall announced in May 2008 that it received approval to sell its own clopidogrel product in Germany, but the German regulator suspended its approval at the request of sanofi-aventis. However, the German administrative court in Cologne authorised in July 2008 the launch of two clopidogrel besylate products by Yes and a subsidiary of Ratiopharm. Although these generic companies are using a different salt in the composition of the drug, they may hit sales and cash flows generated by Plavix.

AstraZeneca faces patent challenges in the US to four out of five of its top-selling drugs including blockbusters Nexium, Seroquel, Crestor and Pulmicort. With 2007 US sales of US\$2.9 billion for schizophrenia medication Seroquel and US\$3.4 billion for heartburn reliever Nexium, the two drugs represented 47% of AstraZeneca's US sales that year (31% of total group sales), exemplifying the kind of revenue that's at stake in generic challenges.

In ongoing litigation between AstraZeneca and Teva over Seroquel, AstraZeneca was recently awarded a summary judgment in US district court in New Jersey. Although Teva has appealed the verdict, in our view the judgment implies that there will be no generic copy of Seroquel before mid-2009 at the very earliest. Furthermore, the verdict of "No Inequitable Conduct" leaves it up to Teva to prove the intent of AstraZeneca and Moody's believes the barriers for generic competition with Seroquel have increased.

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In order to mitigate the risks of generic challenges, pharmaceutical companies are striking more so-called "exclusivity deals" with generic manufacturers by which the generic firms are allowed to launch a copy before the end of patent expiry period (often a six-month exclusivity period towards the end of the expiry). Both GSK with Avandia and AstraZeneca with Nexium have embarked on such deals. AstraZeneca earlier this year reached an agreement with India's Ranbaxy Laboratories over a challenge to Nexium. The agreement means Ranbaxy's generic copies won't enter the US market until 2014.

Given that such arrangements reduce uncertainty, Moody's generally view them favourably. We do, however, stress that exclusivity deals may not be enough if the patent remains challenged by other generic companies. For example, Teva is still challenging Nexium's patent despite AstraZeneca's exclusivity agreement with Ranbaxy.

In general, biopharmaceutical drugs represent more protection against generic competition as "biosimilars" have a more complex pathway to approval. A company like Roche, for example, through its majority shareholding in Genentech, has very little exposure to patent challenges. And a generic competitor to sanofi-aventis' Lovenox does not appear any closer to being launched, even though the blockbuster anticoagulant no longer has a valid US patent. In Moody's view, companies with a steady franchise of biopharmaceuticals are more protected against generic competitors and their future cash flow has higher visibility.

Rating Implications

Unfavourable outcomes, which would allow generics to be launched before a patent's initial expiry date or launches at risk of important drugs, could affect ratings or outlooks, as has been the case for Nycomed. The downgrade of Nycomed's rating in April 2008 reflected the impact of the launch of generic versions of Protonix in the US, which is expected to negatively impact the company's cash-flow generation and slow down its de-leveraging.

Pipelines of potential blockbusters are shrinking while regulatory review appears to be tightening

Pipelines of European pharmaceuticals have come under increasing pressure in the last year as overall pipeline peak sales estimates measured as a percentage of total sales have decreased. In our view, the problem is linked to two factors:

- A general deterioration in pipelines - pipelines contain fewer compounds with significant sales potential.
- The FDA has become more restrictive in its approval process, resulting in approval delays or even non-approvals.

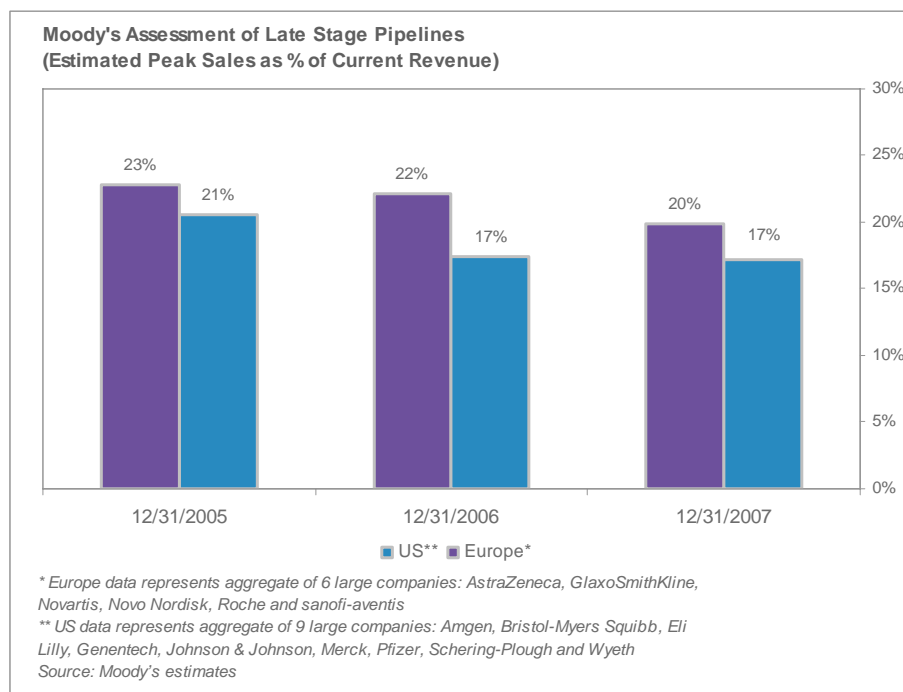
In general, there seem to be fewer drugs with blockbuster potential in the pipelines. Of the European companies, we only consider a few compounds, such as Novo Nordisk's Liraglutide, a type-2 diabetes treatment, and Roche's Actemra, used to treat rheumatoid arthritis, to have blockbuster potential. We acknowledge that it has become more expensive to come up with new drugs. On the other hand, we also believe some companies have put too much emphasis on life-cycle extensions rather than on developing new compounds, although we view favourably the cash flow that is generated by such line-extensions and acknowledge that they provide further protection against generic competition.

Moody's methodology only takes into account drugs that are in Phase III or have been recently launched. Consequently, we are likely to underestimate the real value of the pipeline for companies that have a large share of their compounds in the earlier stages of the pipeline – such as AstraZeneca. We nevertheless caution that early stages of pipeline contain little visibility and high risk of failures. Also, companies heavily focused on and exposed to limited therapeutic areas are likely to have their pipelines underestimated given that we do not account fully for line extensions – affecting estimates of Roche, Merck KGaA and Novo Nordisk.

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Although pharmaceutical companies overall enjoyed continued growth in 2007, the pipeline estimates did not manage to follow suit. In fact, measured by nominal value, we decreased total peak-sales estimates for Roche, sanofi-aventis, Novartis and Novo Nordisk. Roche's estimate was reduced because of revised sales estimates of Mircera, its kidney disease treatment, though we acknowledge that our methodology underestimates the real value of Roche's pipeline given that we only account for 25% of line extensions in our estimate. Sanofi-aventis saw its total pipeline estimate fall mainly due to revised sales estimates of Acomplia, which we no longer believe is capable of boosting sales significantly – even if it should obtain approval in the US. Novartis suffered two setbacks during the year with Prexige obtaining a non-approvable letter by the FDA, whereas Galvus received an approvable letter requiring Novartis to conduct major additional clinical trials before possible approval. As for Novo Nordisk, the discontinuation of the pulmonary insulin, AERx, pushed its estimate of peak sales downwards. AstraZeneca and Merck KGaA both benefited from upwards estimates mainly due to the acquisitions of MedImmune and Serono.

Figure 5: Average Late-Stage Pipeline Assessment Weakens¹



The relative weakening of pipelines should be viewed in light of the apparently more conservative stance taken by the FDA on new approvals in the wake of controversies over the safety of some FDA-approved drugs. The most publicized involved Merck Inc.'s painkiller Vioxx, which was withdrawn in September 2004 after five years on the market after clinical trials showed it was associated with a higher risk of heart attack and stroke. Since then, Moody's believes the FDA has opted for a more cautious approach and either declined approvals or demanded further clinical studies in cases where it previously may have approved. The lower number of FDA approvals on new drug applications – 16 in 2007, the lowest number in 24 years, and down from 36 in 2004 – cannot just be attributed to a weakness in drugs submitted for approval.

As one example of the current regulatory environment, the FDA acted on information in a study published in the New England Journal of Medicine suggesting GSK's top-selling diabetes drug, Avandia, could raise the risk of heart attacks. The FDA decided that Avandia should be sold with a so-called black-box warning, which points out that risk to patients, and this has weighed on the product sales. However, the warning also indicates that currently available data on the risk of heart attacks are inconclusive.

¹ For comparative purposes, some of the charts in this report include European and US companies that qualify as Big Pharma. For that reason, Merck KGaA and Nycomed are excluded from these charts, although they are part of our rated universe of European drugs companies. Merck obtains 32% of its revenue (and about two-thirds of its operating profit) from its chemical operations, hence is not a pure pharma player, while Nycomed operates on a smaller scale and recently went through a transforming acquisition.

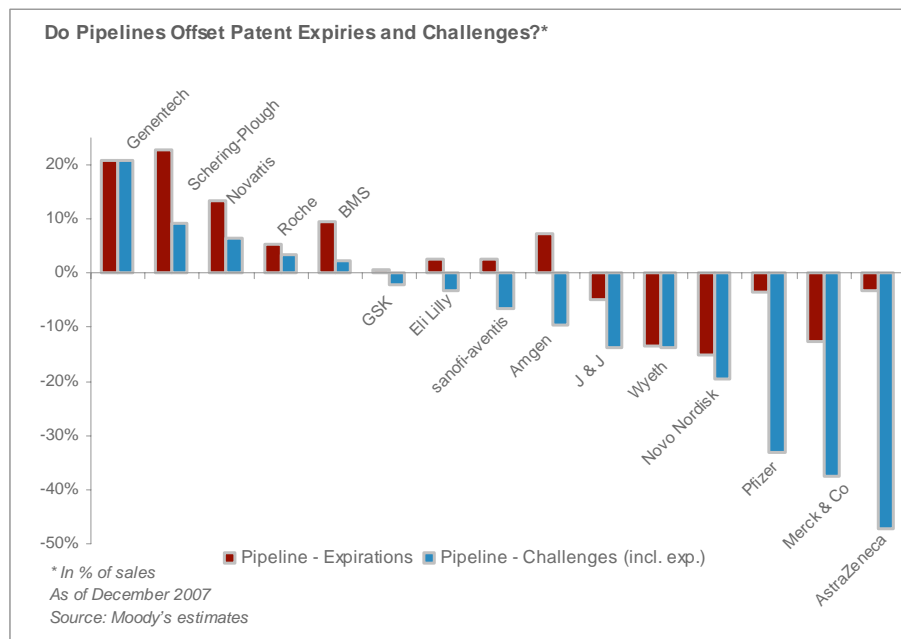
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With several drugs, the FDA has delayed approval while European regulators have given the green light. Sanofi-aventis' obesity drug Acomplia received European approval in June 2006, but an advisory panel to the FDA recommended that it shouldn't be sold in the US because of a potential link to suicide in overweight patients. (Sanofi-aventis plans to submit the drug to the FDA by 2009 for a type-2 diabetes indication.) GSK's cervical cancer vaccine Cervarix was approved in the EU in 2007, but its US approval was delayed as the FDA asked for more information. An approval is unlikely before H2 2009.

Companies focusing on therapeutic areas where patients in general have life-threatening illnesses, such as cancer, are more sheltered from the higher hurdle as we believe the FDA is likely to continue accepting a higher risk-profile for this group of patients.

In addition to in-house research, pharmaceutical companies have also been focusing on co-operation with other companies as a way to strengthen their pipeline. GSK has for a long time pursued a strategy by which it complements drugs discovered in-house with in-licensing agreements with third parties. Recent agreements relate to late-stage pipeline drugs (e.g. Actelion Ltd for the rights to develop and market the sleep disorder drug almorexant) as well as early-stage pipeline drugs (e.g. Regulus Therapeutics LLC to discover, develop and market novel microRNA-targeted therapeutics to treat inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease). Moody's views this externalisation strategy as a positive as we believe it should enable companies to strengthen their product pipelines and somewhat mitigate portfolios' maturity.

Figure 6: Approximately Half of the European "Big Pharma" Pipelines Offset Patent Expiries and Challenges



Rating Implications

Overall, Moody's believes that the pipelines of around half of large European pharma companies should deliver product renewals that are expected to compensate for sales exposed to patent expiries and patent challenges, although the picture has somewhat weakened over the past year. This means that pipelines offset expiries to a reasonable degree but, in the event that some key patent challenges from generics succeed, we might expect negative effects and thus possible negative rating pressures.

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Reimbursement under pressure

Europe and the US have two widely different models for reimbursement of healthcare costs. In Europe, the reimbursement schemes vary from one country to another, however they all have in common that healthcare is seen as a national task – hence there is often only one buyer for healthcare services: the healthcare provider. In the US, healthcare is to a much larger degree privatised, leading to several customers and several sources for reimbursement – providing more headroom for negotiations and price increases.

With baby-boomers approaching retirement and European countries facing a diminishing active workforce, European authorities are seeking to contain rising healthcare costs. Although we estimate that drugs represent a minor percentage of overall European healthcare costs, pharmaceutical companies are a tangible and easy target for keeping costs down given the monopolistic position governments inhabit as sole customers. We now see new trends emerging (though still at early stages): a stronger emphasis on cost-benefit – in particular for expensive drugs – and the non-reimbursement of certain products.

In Europe in 2006, Germany implemented a number of additional healthcare reforms that included adjustments – some of them quite substantial – in the reference prices for major classes of drugs. Germany has also introduced a co-pay exemption for generic products when prices are sufficiently low, which provides generics with an additional marketing argument. Although pricing is not controlled for new drugs, mandatory price cuts and reference pricing may create significant limitations on the profits that pharmaceutical companies are able to earn.

France, the second-largest drugs market in Europe, has taken measures over past years to boost the penetration of generics as a way to save on reimbursement costs. We expect the government to maintain the policy of removing drugs from the reimbursement list, as well as possibly extending the reference price going forward and the continuation of strict government pricing control.

Some governments are increasingly questioning the cost of treatment in cases where they consider the overall benefit to society as marginal. For example England and Wales rely quite heavily on the recommendations of a special health authority, the National Institute for Health and Clinical Excellence (NICE), to decide what treatments are worthwhile, based largely on their cost-effectiveness. NICE's decisions could put cost pressures on some drugs – often biopharmaceutical drugs – whose prices go beyond what NICE determines is cost-effective. Roche's top-selling breast cancer treatment Avastin is not reimbursed in England and Wales. NICE has also ruled against Roche's cancer drug Tarceva and against GSK's breast cancer treatment Tyverb. While most countries have not yet gone that route, we may see increasing pricing pressure on drugs as a result of closer cost-benefit scrutiny.

Pricing pressure in Europe is not new. In the US, future legislative changes are likely to be negative for the branded pharmaceutical industry and may lead to pricing pressure. Most European pharmaceutical companies have been increasing their focus on emerging markets recently with a view to mitigate slower growth and pricing pressure in the more mature markets. Although emerging markets still represent a relatively small proportion of sales, Moody's expects this proportion to increase over time as pharmaceutical companies' further expand their operations, in particular in the so-called BRIC countries - Brazil, Russia, India and China.

Rating Implications

If pricing pressure increases in key markets such as the US or Western Europe or changes to the reimbursement regimes become less favourable, this could result in a slowdown of top-line growth at pharmaceutical companies and reduce profitability and cash-flow generation. However, we view this as a longer-term trend, as these changes usually take time. In addition, pharma companies have all implemented cost-cutting initiatives, which can help mitigate such pricing pressure. We do not expect the current level of pricing pressure to result in pressures on ratings in the near term.

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Financial policies have recently shifted but liquidity remains strong

The pharmaceutical industry - at least the large and diversified companies – has traditionally been highly rated, and the European rating universe essentially comprises such companies. Nevertheless, several recent large M&A transactions have occurred: Novartis is expected to buy Alcon in a two-step deal worth about US\$38 billion and AstraZeneca purchased MedImmune for US\$15 billion. Both led to two-notch downgrades because of the debt that was taken on. In July 2008, Roche announced a cash offer to buy the outstanding shares of Genentech that it doesn't already own in a deal that could be worth US\$43.7 billion. We placed Roche's Aa1 long-term issuer rating on review for possible downgrade, given the potential impact on Roche's financial profile.

The recent increase in the valuation of biotechnology companies and the growing interest from traditional small-molecule pharmaceutical companies in biotechnology contribute to potential sizeable acquisitions, which may result in increased leverage for some of the rated companies. The fact that biotech companies may often generate limited cash-flows but be attractive because of their pipeline is a factor that may contribute to high leverage as the acquired company does not contribute to cash-flow enhancement, at least in the short term. The acquisition of MedImmune by AstraZeneca is an example of this trend, with a fully priced acquisition aimed at strengthening AstraZeneca's depleted pipeline.

Regarding financial policy, we believe that the degree of M&A event risk in this industry remains material, but note that a number of companies, having embarked on large transactions in the past year, may be less active in the short term and instead emphasize integrating the acquired businesses.

We have seen more and more companies embarking upon share buyback programmes in Europe in recent years, the largest one being that of GSK, with a GBP12 billion programme announced in July 2007. But we observe that companies have tended to moderate their share buybacks following material transactions (e.g. AstraZeneca following the acquisition of MedImmune). We also note that GSK recently announced that it would extend its share buyback programme beyond July 2009, preferring to retain the flexibility to make strategic investments.

European pharmaceutical companies used to maintain very strong liquidity profiles with, for some of them, significant cash balances (e.g. Roche, Novartis). Large debt-financed acquisitions or share buybacks have somewhat weakened the liquidity profiles of companies involved in these transactions, although they remain healthy overall. Moody's notes that, although Nycomed had leeway under its financial covenants at year-end 2007, it expects that leeway to diminish during 2008, weakening the otherwise strong liquidity profile of the company.

Rating implications

Large debt-financed acquisitions or significant share buyback programmes are likely to put pressure on pharmaceutical companies' ratings and may result in rating downgrades, in some cases multi-notch downgrades. This has been the case for AstraZeneca, Novartis and GSK, the long-term ratings of which were all downgraded by two notches following large acquisitions for AstraZeneca and Novartis and a GBP12 billion share buyback programme for GSK.

When a large transaction takes place, Moody's reviews the financing package to make sure liquidity remains satisfactory and monitors closely the refinancing plans of the companies. Given their still relatively high ratings compared to other sectors and despite the currently difficult market conditions, large European pharmaceutical companies have been able to continue to access capital markets (both long-term bonds and commercial paper have been issued).

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Other Issues

Litigation

European pharmaceutical companies remain favourably positioned overall in respect of product litigation without any significant pending cases. So far, Novartis' withdrawal of Zelnorm in March 2007 has not exposed the company to any litigation; neither has GSK been exposed to any major lawsuits over Avandia, although Moody's will monitor any such potential developments.

Conclusion

Our fundamental credit outlook for European pharmaceutical companies is negative, as patent expiries, generic competition and depleting pipelines converge to challenge the strength of product portfolios and, in the medium term, their cash-flow generation. In addition, the regulatory hurdles for drug approvals, particularly in the US, seem to have been raised recently.

However, the industry remains profitable, with robust cash-flow generating ability and solid liquidity. Prospects for growth remain good as well, with remaining unmet medical needs as well as an aging population in key markets.

Among the issues Moody's will be monitoring over the next 12-18 months:

- Companies' efforts to replenish pipelines and prepare for upcoming patent expiries through in-house R&D or in-licensing agreements.
- Their reaction to generic competition, which could involve diversifying into new businesses, e.g. moving to create vaccines or biotech drugs that are less susceptible to generic challenges.
- The industry's response to increased regulatory requirements and potential approval delays.
- Governments' potential moves to change reimbursement models, and subsequent pricing pressure.
- Financial policies and how companies balance shareholder pressures and their credit profile.

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Appendix: Macro Stress Scenario Analysis for the European Pharmaceutical Industry

In January 2008, Moody's published its consensus view of global economic activity (a "central scenario"), as well as three plausible stress scenarios (see "Mapping the Near Future: Macro Stress Scenarios for 2008-2009," Moody's Global Risk Perspectives, January 2008).

In brief, the three global risk scenarios outlined are: i) a sharp decoupling by non-U.S. economies from the U.S. economy under a scenario where the U.S. turns very negative, ii) stagflation, inflation escalates while activity is stagnant in the U.S., while the rest of the world continues to grow and iii) stagnation, in which a broad-based global economic slowdown occurs.

We updated this view in July and largely drew the same conclusions – that our central scenario remains at this stage the most probable of all plausible outcomes. The central scenario foresees a gentle decoupling between rapidly growing emerging economies and slower-growth advanced economies, with the overall global economy continuing to grow.

Of these scenarios, we see stagnation as having the largest negative effect on the pharmaceutical industry. Stagnation would likely lead many developed countries with national health systems to seek ways to reduce healthcare expenditures. Potential measures could include implementing greater price or access restrictions on pharmaceutical products. In Europe and the U.S., anaemic growth could lead to increased unemployment and a reduction in the insured population, which enjoys good access to pharmaceutical products. Emerging markets would not be a mitigating factor, as in this scenario the slowdown is broad-based and would also impact these countries.

Moody's Related Research

Analyses

- AstraZeneca, August 2008 (110597)
- GlaxoSmithKline, October 2007 (105330)
- Merck KGaA, November 2007 (105787)
- Novartis AG, December 2007 (106224)
- Roche, August 2008 (110497)
- Sanofi-aventis, October 2007 (105520)

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- US Pharmaceuticals, May 2008 (109201)
- European Pharmaceutical Companies, July 2007 (103728)

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- Global Pharmaceutical Industry, November 2004 (89947)

Global Risk Perspectives

- Mapping the Near Future: Macro Stress Scenarios for 2008-2009, January 2008 (107173)

International Policy Perspectives

- Navigating the Fog: Update on Moody's Macro Stress Scenarios for 2008-09, July 2008 (109919)

To access any of these reports, click on the entry above. Note that these references are current as of the date of publication of this report and that more recent reports may be available. All research may not be available to all clients.

European Pharmaceutical Companies

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