

Group Security is a member of the Alliance for Cyber Security of the German Federal Office for Information Security

The entire Merck Group has global security guidelines and information protection management for IT and "non-IT" areas, each with organizational and technical standards for access rights as well as information and data protection. Attention in the IT area is focused on hardening the corresponding systems and, for example, identifying cyber attacks. Group Security is a member of the Alliance for Cyber Security of the German Federal Office for Information Security. A pilot data leakage prevention project is currently being introduced at Merck to protect sensitive business information. The effectiveness of internal (IT) protection measures is monitored on an ongoing basis and reviewed by Group Security, Group Internal Auditing and third-party auditors.

The potential losses resulting from e-crime cannot be generally categorized, not least on account of the multitude of different possible ways it can be committed; its impact on the net assets, financial position and results of operations would depend on the individual case. Despite the protective measures already being taken by Merck to great effect, the occurrence of the risk of e-crime is considered possible, with an estimated substantial impact. It is therefore classed as a medium risk.

Risks due to failure of business-critical IT applications or to failure of data center capacity

IT applications used globally in process steering form the basis for the contractual delivery of products and solutions to the customers of the Merck Group around the world. Fluctuations in the quality of internal IT services can lead to the failure of business-critical IT applications, which would have a direct influence on Merck's ability to deliver. Similarly, the failure of a data center can impair service quality or trigger the complete failure of critical applications.

The primary objective of Information Services in the Merck Group is to maintain service quality in keeping with the service levels agreed with the Group functions and divisions. To achieve this objective, Merck uses a quality management system certified to ISO 20000:2005, which comprises steering measures to maintain a consistent standard of quality. In addition to day-to-day operating processes, this also provides directives on how to act in a crisis situation in the form of a regularly tested crisis management plan. As part of this crisis management, Merck operates several redundantly designed data centers so that service quality will be maintained even in the event of the failure of one data center.

Despite the mitigating measures taken, functional continuity plans and the unlikely probability of occurrence, the impact of a failure of business-critical IT applications owing to fluctuations in the quality of internal IT services and its influence on the net assets, financial position and results of operations is considered a medium risk.

Environmental and safety risks

As a company with global production operations, Merck is exposed to risks of possible damage to people, goods and its reputation. Audits, consulting and training on environmental protection and occupational health and safety minimize these risks to people and the environment. In order to ensure the continuity of plant and equipment, Merck monitors these risks both at our own sites as well as at suppliers and contract manufacturers. By adhering to high technical standards, our rules of conduct, and all legal requirements in environmental protection and occupational health and safety, we ensure the preservation of goods and assets. Sufficient appropriate accounting measures have been taken for the environmental risks known to us. Nevertheless, Merck classifies these as a medium risk since a critical negative impact to liquidity cannot be ruled out.

Quality management system certified to ISO 20000:2005 used to ensure consistent quality of IT services

NPS EX. 2086
Part 2
CFAD v. NPS
IPR2015-00990

Overall view of the risk and opportunity situation and management assessment

Although the number of risks reported is higher than the specific opportunities, Merck considers the distribution of risks and opportunities to be balanced. A balanced overall view within the Group is also supported by the fact that total revenues and business success are built on a diversity of pharmaceutical and chemical products for a variety of industries. As the markets differ in their structure and economic cycles, this diversification helps to lower risk. The overall view of the opportunity and risk profile of the four divisions would also be further balanced by the proposed acquisition of AZ Electronic Materials moving forward. This diversification also reflects Merck's strategy to continue its development as an integrated pharmaceutical and chemical company.

The most significant individual risks in the divisions have been named in the report above, with business-related risks being the most significant to us alongside legal risks.

Although the assessment of the individual risks has altered over the fiscal year as a result of changing external conditions, the risk situation of the Group as a whole is not significantly different compared to 2012. There have been no new additions in the area of high risks in particular. Merck has observed only minor changes in the area of medium risks. Thanks to the mitigating measures taken – such as the consistent implementation of management action (organizational responsibility and process improvements), the increased insurance coverage and accounting precautions – Merck's significant risks in particular have been further minimized in net terms.

The overall view of the risk situation of the Group, which is derived from the summary of the risks described on the basis of their impact and probability of occurrence, leads Merck to the assessment that the risks are not of a nature to threaten the existence of the Group as a going concern, either individually or collectively. Merck is confident that it will continue to successfully master the challenges arising from the above risks in the future as well.

In terms of opportunities, we feel that the greatest potential lies in the business-related topics of the operational areas. Thanks in particular to the expansion of our business in emerging markets, the optimization of the Merck Serono R&D organization, the newly founded biosimilars initiative and other activities as part of the "Fit for 2018" transformation and growth program, Merck has launched changes that hold significant opportunities in the medium to long term beyond the underlying forecast period.

Merck pursues the opportunities that arise and shows their expected effects in the forecast development of its key performance indicators – sales, EBITDA pre one-time items and business free cash flow. Merck will actively seek out opportunities beyond this and move ahead their implementation. In the event that opportunities arise in addition to the forecast developments, or that these occur more quickly than anticipated, this could have correspondingly positive effects on Merck's net assets, financial position and results of operations.

Report on Expected Developments

The following report provides a forecast for the development of the Merck Group and its divisions in 2014 focusing on the three most significant financial key performance indicators (KPIs) for the Merck Group and its businesses: sales, EBITDA pre one-time items and business free cash flow. We take into account the company's weighing up of risks and opportunities in accordance with our operational plans and medium-term assumptions.

In December 2013 Merck made an offer to AZ shareholders to acquire AZ Electronic Materials. From today's perspective the acquisition is expected to close in the course of 2014 (the successful completion of the transaction is conditional upon antitrust clearance, among other things). The following report provides on the one hand the expected developments of the Merck Group excluding the impact from a potential acquisition of AZ Electronic Materials. On the other hand, we provide separately a forecast for the Merck Group and for the Performance Materials division, which would be affected by the acquisition of AZ Electronic Materials assuming the first-time consolidation of AZ Electronic Materials in the Merck Group in the second quarter of 2014.

Forecast for the Merck Group

Merck Group | Forecast 2014

€ million	Actual results 2013	Forecast 2014	Key assumptions
			Slight organic growth offset by currency headwinds in all divisions
Sales	10,700.1	slight organic growth	Organic development of the divisions: Merck Serono stable as Rebif® sales decline is offset by Emerging Markets growth, moderate organic growth in Merck Millipore and Consumer Health, volume growth in Performance Materials, which will be offset by price erosion
EBITDA pre one-time items	3,253.3	stable	Positive full-year impact from realized efficiencies offset by major investments in Biosimilars and the loss of royalty income
Business free cash flow	2,960.0	slight decrease	EBITDA pre one-time items of Corporate and Other stable Slight decrease due to higher investments in property, plant and equipment driven by strategic growth projects

We foresee stable sales for the Merck Group in 2014 as slight organic growth is offset by an unfavorable impact from foreign exchange developments, which are anticipated to impact the sales of all divisions. While we expect the U.S. dollar-euro exchange rate to remain at around the 2013 level, an unfavorable foreign exchange development for the Merck Group is expected to stem from Emerging Markets and Japan.

Merck Serono sales are expected to remain stable excluding foreign exchange effects. While Rebif® sales are expected to decline, we should see ongoing positive growth momentum from our Emerging Markets region. For the Consumer Health and Merck Millipore divisions, we expect moderate organic growth rates, while the positive volume growth in the Performance Materials division might be offset by price erosion, which is expected to occur next year.

From the second quarter of 2013 onwards, Merck saw the decline in royalty income at Merck Serono, which will fully come through in the course of 2014. The net decrease in EBITDA pre one-time items from expired royalty income and related royalty expenses with respect to Avonex® and Enbrel® amounts to approximately € 75 million. This reduction will be more pronounced due to the settlement agreement on the patent dispute with AbbVie concerning Humira®, which was reached at the beginning of 2014. On the other hand, the commercial agreement reached with Bristol-Myers Squibb in 2012 on the co-promotion of Glucophage® in China is expected to partly mitigate the negative impact.

Despite lower Rebif® sales, significant decline in royalty income and anticipated currency headwinds, the aim is to achieve the 2013 level of EBITDA pre

Despite the Rebif® sales decline, the significant reduction in royalty income and the anticipated unfavorable foreign exchange environment, Merck aims to achieve in 2014 EBITDA pre one-time items at the level of 2013. In the course of 2013 Merck realized most of the efficiencies from the "Fit for 2018" transformation and growth program, which will have a positive incremental effect reducing the cost base on a full-year basis in 2014. EBITDA pre one-time items of Corporate and Other is expected to remain stable. Restructuring costs on the current portfolio are planned to decrease from € 166 million in 2013 to approximately € 100 million in 2014. We expect an underlying improved tax ratio of 23% to 25% in 2014.

As publicly stated over the last two years, Merck has embarked on a transformation journey that will last several years. The focus of this transformation journey will now shift more toward organic and inorganic growth. Therefore, Merck plans to accelerate R&D activities on strategic growth initiatives such as Biosimilars and OLED (organic light-emitting diodes) and to direct marketing and selling resources even more to growth markets. Merck's ambition to take M&A initiatives has become clear through the announcement of the intention to acquire AZ Electronic Materials. Merck's business free cash flow is expected to decrease slightly in comparison with 2013 as higher investments in property, plant and equipment in strategic projects such as the construction of a pharmaceutical production facility in China are planned.

The Merck Executive Board decided to transfer two product groups, Neurobion® (a vitamin B-based analgesic) and Floratil® (a probiotic anti-diarrheal), from the Merck Serono division to the Consumer Health division as of January 1, 2014. This move, which transfers the sales and all related expenses for both product groups, will enable a better strategic focus for both divisions, while fostering synergies in the organization. Consequently, approximately € 265 million in sales, around € 100 million in EBITDA pre one-time items and around € 77 million in business free cash flow will be shifted from Merck Serono to Consumer Health based on 2013 results. Within Consumer Health, we expect these two product groups to grow moderately in line with the existing Consumer Health portfolio in 2014.

While the acquisition of AZ Electronic Materials is anticipated to lead to a moderate increase in sales and EBITDA pre one-time items and to a slight increase in business free cash flow of the Merck Group in 2014 compared to 2013, a significant increase is expected in sales, EBITDA pre one-time items as well as business free cash flow for the Performance Materials division.

Forecast for the Merck Serono division

Merck Serono | Forecast 2014

€ million	Actual results 2013	Forecast 2014	Key assumptions
			Balanced product portfolio and solid organic growth in Emerging Markets expected to offset Rebif® decline in the U.S. and Europe and expected biosimilar entries for Fertility in Europe
			Unfavorable impact from foreign exchange development will lead to slight decrease in nominal sales
Sales	5,953.6	organic stable on a comparable basis	Neurobion® and Floratil® transfer to Consumer Health division will reduce sales by ~€ 265 million based on actual 2013 results
			Development in line with sales, tight cost management will help to balance the reduction in royalties from Avonex®, Enbrel® and Humira®
			Higher R&D expenses in Biosimilars unit
EBITDA pre one-time items	1,955.0	slight decrease on a comparable basis	Neurobion® and Floratil® transfer to Consumer Health division will reduce EBITDA pre one-time items by ~€ 100 million based on 2013 actual results
			Initiation of further investments in growth projects and slight decrease of EBITDA pre will lead to lower business free cash flow
Business free cash flow	1,875.7	moderate decrease on a comparable basis	Neurobion® and Floratil® transfer to Consumer Health division will reduce 2013 business free cash flow by ~€ 77 million based on actual 2013 results

Due to the aforementioned decision to transfer two product groups, Neurobion® and Floratil®, from the Merck Serono division to the Consumer Health division as of January 1, 2014, the base for the Merck Serono division will decrease by approximately € 265 million in sales, around € 100 million in EBITDA pre one-time items and around € 77 million in business free cash flow, based on 2013 results of the transferred brands. Accordingly, the 2014 forecast for the Merck Serono division is based on the 2013 results reduced by the transfer.

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