Boehringer Ingelheim
Annual Press Conference 2015

Wednesday, 22 April 2015
Boehringer Ingelheim Center, Ingelheim, Germany

The remarks of
Andreas Barner
Hubertus von Baumbach

Members of the Board of Managing Directors

Check against delivery.

2. Chart: 2014 Financial Year – Andreas Barner, Chairman of the Board of Managing Directors, Corporate Board Divisions Human Resources and Research, Development and Medicine

Ladies and gentlemen,

A warm welcome to Boehringer Ingelheim’s Annual Press Conference. We are very pleased at your interest in our company. Today, we want to speak about the results for 2014 and present to you our plans for the coming years. And in addition we would like to engage in discussion with you.

From a medical viewpoint, we were able to celebrate many successes in 2014, primarily, when we consider the results of our research and development activities and registration processes. However, from a corporate viewpoint, there were also a number of challenges to overcome.

On the one hand, we have never submitted so many active ingredients for marketing authorisation as we did last year and we have already begun with their launches. These medicines are valuable, innovative therapies. They will have a positive impact on the company’s success in the years ahead.
On the other hand, we had to address a number of extraordinary issues in the challenging year 2014. Here Boehringer Ingelheim’s positive culture was rewarded. Together we pursue the common goal: competitiveness – in the future too.

3. **Chart: Success in clinical development – Numerous product launches**

The decisive factor in achieving this goal is for us to develop innovative, reliable and effective medicines. 2014 was in this respect an extremely successful year. New medicines we have brought to the market in the last few months include:

- JARDIANCE® for the treatment of type 2 diabetes
- OFEV® for idiopathic pulmonary fibrosis (IPF)
- STRIVERDI® RESPIMAT® for the treatment of chronic obstructive pulmonary disease (COPD)
- And, at the beginning of January 2015, VARGATEF® for advanced lung cancer patients with adenocarcinoma following chemotherapy

Allow me to add a couple of clarifications regarding OFEV®. With this we offer an innovative medicine and an urgently needed therapeutic advance. IPF is a rare condition that causes progressive scarring of the lung tissue that generally leads to death within a few years. OFEV® slows down the progression of the disease. As the only therapy, it reduces the risk of a sudden deterioration, which is accompanied by increased mortality and morbidity.
In 2014, in the field of prescription medicines alone, we were given approval for a total of eight active ingredients in the most important markets, including additional indications for established medicines. This means that we can now make a large number of our medicines available to an expanded patient population.

And there is every indication that, in terms of product launches, 2015 will be similarly successful.

4. **Chart: Many challenges overcome**

Three issues have occupied us intensely internally over the last few years and have also been closely monitored externally. We are pleased to be able to report to you today that we have resolved all three. The US Food and Drug Administration (FDA) lifted the Warning Letter it had issued for our Ingelheim site in Germany. In litigation in the USA regarding PRADAXA®, we concluded a settlement. More on that later. And, last of all, we sold Ben Venue Laboratories in the USA. We have thereby generated the resources to secure our competitiveness.

Even so, we must stress that the market environment is changing rapidly, particularly in the USA. A cause of this was, among others, tougher regulation. This led to additional pressure on the pharmaceutical industry and our own business.

We see a market environment in Germany that is also becoming more difficult. We cannot understand decisions about the additional benefit of some of our medicines. Our diabetes medicines
TRAJEN'TA® and JARDIANCE®, for example. These decisions are certainly not in patients’ interest either.

5. **Chart: Stable operating income in more difficult conditions**

The development of net sales is for us unsatisfactory. As we have clearly felt the headwind of changing conditions, most of all in our important markets, the USA and Japan. Consequently, we in 2014 generated net sales amounting to 13.3 billion euros. As expected, that is less than in the previous year. In view of the changing conditions, we have countersteered on costs. A stable operating income of 2.14 billion euros and return on net sales of 16.1 per cent show that we are heading in the right direction. This all the more noteworthy, given that we have again made high investments in research and development amounting to almost 2.7 billion euros.

Mr von Baumbach will now explain the business figures for 2014 in detail.

6. **Chart: Businesses and Financial Figures 2014 – Hubertus von Baumbach, Corporate Board Division Finance**

Thank you very much, Dr Barner.
Ladies and gentlemen,

I would like to sum up the financial year just ended as follows:

• We solved three problems that have occupied us intensely over the last few years.
• We responded quickly, effectively and with a heightened awareness of costs to the rapidly changing market environment, foremost in the USA. We are therefore satisfied with the operating income.
• Keeping our eyes fixed on what lies ahead, we are focusing on the numerous product launches in all our business areas that will drive the growth of our group of companies in the coming years.

7. **Chart: Development of net sales in 2014**

At the Annual Press Conference last year, we forecast that net sales would remain stable in 2014. It was, however, impossible to foresee at what speed the market environment for research-driven pharmaceutical companies would change. Listed competitors were forced to respond to the situation by issuing profit warnings. As Dr Barner said, we in August 2014 also adjusted our expected net sales to bring them in line with the changed market situation.

At 13.3 billion euros, net sales in 2014 declined. Adjusted for currency effects, the decline amounts to 3.2 per cent. Against the background of the overall conditions, this development was, in fact, not surprising. We are, nevertheless, not satisfied with it.
8. **Chart: R&D share still at high level, operating income sound and stable**

For us, the years 2014 and 2015 stand fully under the sign of launches. Boehringer Ingelheim has never had so many product launches in such a short space of time. This is the result of years of research and development work. And in 2014, with just under 2.7 billion euros, we also made unchanged investments in the research and development of new products. In addition, we invested heavily in launches, in order, for instance, to make clear the patient-relevant benefit of our medicines.

At 2.1 billion euros, last year’s operating income was sound. As Dr Barner has just described, 2014 was marked by the rapidly changing market environment, especially in the USA. This development not only affected Boehringer Ingelheim, but all research-driven pharmaceutical companies suffered to the same degree. We were successfully able to implement counter-measures. We had clearly noticed in 2014 how the challenges we had to face gave the whole company a good shake. All of us had, and still have, our sights set on a common goal – to strengthen our competitiveness, thereby laying the foundations for our further success.

9. **Chart: High liquidity safeguards independence**

Boehringer Ingelheim was founded 130 years ago. Our prime goal was, and remains, the group’s independence. This fundamental principle is firmly anchored in our guiding principles (Leitbild) and
in our corporate strategy. A positive cash flow as the basis for increasing liquidity is a prerequisite for this. Even considering the scheduled repayment of part of our financial obligations, we were still able to keep our net cash flow more or less constant. Liquidity increased thereby to 8.5 billion euros. This not only safeguards our independence. It also gives us the financial flexibility we need for future growth. It should also be pointed out that, as in previous years, our operating cash flow was sufficient to cover our investments in tangible assets many times over.

10. **Chart: Investments in our future**

The amount invested in tangible assets may appear small relative to the previously mentioned expenditure on research and development. For me, however, it is proof of the future-orientation at our sites. Some of our strategic projects:

- With the launches of SPIRIVA® RESPIMAT and SPIROLTO® we assume a considerable increase in demand. We therefore moved ahead in 2014 with the expansion of production capacity at the Dortmund and Ingelheim sites with investments amounting to 35 million euros.
- We want our employees to feel good. Good, healthy nutrition is an important component. For this reason, we are investing 27 million euros in a new staff canteen.
- But, of course, we don’t invest solely here in Germany. In the important growth market China, for example, we expanded production facilities last year at a cost of
34 million euros and also progressed the establishment of a chemical R&D laboratory in Shanghai. Another example is our location in Taizhou/China: by the year 2018, we intend to invest 85 million euros in a new plant for the development and production of poultry and swine vaccines.

11. **Chart: Equity structure remains sound**

Equity amounting to 8.1 billion euros and a balance sheet total of around 20 billion euros gives an equity ratio of around 40 per cent. This represents a further increase compared with the same period in the previous year. We see the amount of equity as a key performance indicator for safeguarding the company’s long-term security and independence.

Incidentally, a large part of our borrowed capital comes from our current and retired employees. This is due to the fact that we have built up reserves amounting to some 3.7 billion euros. Sustained lower interest rates resulted last year in a burden on the financial result amounting to 418 million euros.

12. **Chart: Prescription Medicines most important business mainstay**

Ladies and gentlemen,

I would now like to explain to you how our individual businesses performed.
The Prescription Medicines business is Boehringer Ingelheim’s most important mainstay. Our net sales here amounted to 10.1 billion euros. This represents 76 per cent of total net sales. The Americas continues to be the largest region, with the USA the largest sales market.

SPIRIVA® for the treatment of chronic obstructive pulmonary disease (COPD) remains our best-selling product. In 2014, it generated net sales of over 3.2 billion euros. The second best-selling product is our anticoagulant PRADAXA®, with net sales of 1.2 billion euros, which, currency-adjusted, was up 1.6 per cent last year.

MICARDIS® for the treatment of hypertension is in third place, with net sales of around 1.1 billion euros. Due to the patent expiry, there was a decline in net sales, as expected.

Our diabetes business has established itself as an important and long-term growth driver. Net sales from TRAJENTA® and JENTADUETO® was up almost 37 per cent. The launch of JARDIANCE® is proceeding satisfactorily. With GLYXAMBI®, we are the first company to market a combination of the active ingredient from TRAJENTA® and JARDIANCE® in the USA.

The respiratory product COMBIVENT® still contributed 563 million euros to net sales, despite a currency-adjusted decline of 20.2 per cent.
Patent expiry makes it necessary for us to constantly renew our product portfolio. In fact, we have now many products from recent development on the market. For the coming five years we plan, however, to markedly renew our sales drivers. And our successes in research and development are the drivers of this.

Our biosimilars should contribute in future to our corporate success. Our aim is to become a leading provider of high-quality biosimilars. Our senior management colleagues, Mr Baiker and Mr Hillgrove, would like to present our biosimilars plans in our special media roundtable at 1 pm this afternoon.

13. **Chart: Positive development in CHC business**

The business in over-the-counter medicines – Consumer Health Care (CHC) – enables us to extend the product life cycle of our prescription medicines. After release from compulsory prescription, we can sell the medications directly to patients through pharmacies.

With net sales of over 1.4 billion euros, we are satisfied with the development of our CHC business. This corresponds to 11 per cent of total net sales. Borne by our global brands BUSCOPAN®, DULCOLAX®, MUCOSOLVAN® and PHARMATON®, we grew by 2 per cent compared with the previous year after adjustment for currency effects.
14. **Chart: Animal Health business outperformed market**

The Animal Health business is, like the Prescription Medicines business, based on innovative products and is hence research-driven – our core competence. In 2014, Boehringer Ingelheim outperformed the animal health product market.\(^1\) With net sales once again over one billion euros, the business developed pleasingly. It contributed 8 per cent to our group of companies’ total net sales.

At around 63 per cent, the largest percentage of net sales is attributable to products for livestock. The swine vaccine INGELVAC CIRCOFLEX\(^\circledR\), with net sales of 260 million euros, was the best-selling product in 2014, as in previous years. We observed the greatest growth with the dog vaccine DURAMUNE\(^\circledR\) against infectious diseases – net sales, currency-adjusted, rose 33.1 per cent to 69 million euros.

In the final quarter of 2014, we received marketing authorisation for our new bovine vaccine BOVELA\(^\circledR\). The product was launched in Europe just a few weeks ago.

15. **Chart: Biopharmaceuticals: focus on contract manufacturing**

Let us now take a look at our Biopharmaceuticals business. This is an area in which we are involved primarily in the contract

\(^{1}\) Source: Vetnosis
manufacturing business and in the development of new biological entities (NBEs). The Biopharmaceuticals business, with net sales of 501 million euros, last year accounted for 4 per cent of total net sales.

16. **Chart: Germany in the Boehringer Ingelheim Group**

Ladies and gentlemen,

I would like to conclude with some remarks about Germany as a business location. Albert Boehringer founded our company here in Ingelheim 130 years ago. Boehringer Ingelheim has since developed into a global player, but still maintains strong roots in Germany and is strongly committed to its presence here. The figures show this very clearly. As although we generate only 7 per cent of our total net sales here, we employ 31 per cent of our entire workforce in Germany, invest 35 per cent of our worldwide expenditure on research and development and make 44 per cent of our total investments here.

What is annoying is that “Made in Germany” does not mean “Used in Germany”. Unlike in other countries, our medicines TRAJENTA® and JENTADUETO®, for the treatment of type 2 diabetes, are not on the market in Germany and empagliflozin, under the brand name JARDIANC®E, has not been recognised as having additional benefit. Only Germany is unwilling to recognise the additional benefit. These developments decouple patients in Germany from progress. It is increasingly difficult for
research-driven pharmaceutical companies to continue to conduct business successfully in Germany.

In short: research-driven pharmaceutical companies – Dr Barner will now explain to you in detail how important R&D activities are to us all.

Thank you for your attention.

17. Chart: Strategy and Outlook – Andreas Barner, Chairman of the Board of Managing Directors, Corporate Board Divisions Human Resources and Research, Development and Medicine

Thank you, Mr von Baumbach.

18. Chart: Positive safety and efficacy profile of PRADAXA® reaffirmed

Ladies and gentlemen, you just heard what Mr von Baumbach said: 1.2 billion euros – we generated net sales of this magnitude in the past financial year with PRADAXA®. We would have hoped for more. For last year, analyses were presented of the daily clinical practice of more than 134,000 patients with atrial fibrillation. These were particularly convincing.
Independent institutions, including the FDA, have verified\(^2\):

- **PRADAXA®** leads to fewer cases of ischaemic stroke, that is to say strokes due to blood clots than with warfarin,
- Less intracranial bleeding,
- And thus fewer deaths.

This shows that the good results from the RE-LY\(^\circledR\) trial can be achieved in daily clinical practice. **PRADAXA®** has since launch, in purely mathematical terms, probably already prevented more than 180,000 strokes in patients with atrial fibrillation, compared with patients who received no treatment. This calculation is based on the results of the RE-LY\(^\circledR\) trial and the number of prescriptions worldwide. Naturally, **PRADAXA®** has also prevented a large number of strokes, compared with vitamin K antagonists, as shown, among others, by the FDA analysis just mentioned.

These good clinical data are all the more important, precisely in view of the litigation in the USA. Last year, we decided with a heavy heart to conclude a settlement in the USA, because years spent working through lawsuits would have resulted in very high litigation costs – even if we had won each lawsuit. The settlement enabled us to put an end to this legal issue and focus instead on what we are actually here for – to develop medicines of high therapeutic benefit for patients.

---

\(^2\) In the United States, the licensed doses for dabigatran etexilate are 150mg twice daily and 75mg twice daily for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation. This dose of 75mg twice daily is not authorised in Europe for this indication.
And we are not doing that with PRADAXA® only which is meanwhile approved in many countries around the world for seven medical uses. We have a specific reversal agent too – incidentally as the only pharmaceutical company – that we have developed ourselves. This was a few weeks ago submitted to various authorities for approval, including the FDA and the European Medicines Agency (EMA).

19. Chart: Well-filled research pipeline

Let us now come to our research pipeline in general. With around 100 projects, this is – as in the past – very well-filled. Our R&D teams are working continually on new projects. This means that we can be confident that we will be able to secure our supplies of new medicines in the medium and long term for therapeutic areas with a high medical need and market potential.

At the same time, we are continually expanding our international network of collaboration partners from academia and industry.

I would like to point out four examples of particularly promising collaboration projects:

• **Immuno-oncology**
  In the field of immuno-oncology, we last year commenced a partnership with Tübingen-based company CureVac. Together we will be examining how we can combine existing treatment options, such as our
lung cancer medicine GIOTRIF®, with a therapeutic tumour vaccine developed by CureVac. This innovative vaccine is based on messenger RNA (mRNA) and is designed to mobilise the immune system to fight lung cancer. As part of our strategy in the field of immuno-oncology, we are also working on so-called second generation checkpoint inhibitors, which help the body’s own immune system to track down and combat cancer cells.

• **New ways forward for research into psychiatric diseases**
  
  We are also examining new ways in our research into psychiatric diseases. In our collaboration with US-based Circuit Therapeutics, we want to better understand psychiatric diseases with the aid of optogenetics. The aim here is to control the activity of brain cells with light. The formidable precision of this technology could enable the scientists to develop a new generation of medicines for, for example, forms of depression or schizophrenia that were previously difficult to treat.

• **Immunology pipeline portfolio: psoriasis, spondylarthrosis, Crohn’s disease**
  
  Therapy approaches that alter the immune system are an important focus of our research and development. Psoriasis is such a chronic autoimmune disorder, which affects an estimated 125 million people worldwide. In
March, we presented the results of a phase II trial for our investigational compound BI 655066 at a major congress in the USA. The results are extremely promising and show a nearly doubled rate of significant skin improvements compared with a current standard treatment combined at the same time with higher application safety. We are now planning a confirmatory phase III trial for this substance for the treatment of psoriasis. Spondylarthrosis, a degenerative disease affecting the spine, or Crohn’s disease, a chronic, inflammatory disease of the digestive system, are other areas in which we are testing this compound in in phase II trials.

- **Treatment options for IPF beyond nintedanib**
  With the approval of OFEV® (nintedanib), we have achieved a significant milestone in the development of treatments for the rare disease IPF. Our work, however, is far from over: on the one hand, we are examining other indications for which OFEV® promises to be effective. On the other hand, several groups of in-house research scientists are working together on innovative approaches for the treatment of fibrous lung diseases that do not respond to nintedanib. As part of this work, we are collaborating with leading academic centres, such as the universities of Harvard, Mainz, Groningen and University College London.
20. **Chart: Our new research strategy: focus on four areas of research**

Our new research strategy is geared towards indications and fields with a significant medical need. We are focusing on the four research areas of immunology and respiratory diseases, oncology, cardiometabolic diseases and diseases of the central nervous system. Our intention is to ensure in the long term that we will be able to develop even more innovative products. It is also important to identify new avenues of research and forward-looking technologies at an early stage, while collaboration with the best academic and industrial partners worldwide is ultimately the key to success and we are therefore determined to continue to expand this field.

21. **Chart: High number of clinical trials – significant progress in transparency**

We also focus, of course, on later phases in the development of medicines. We are currently conducting over 100 trials with a total of 100,000 patients. Transparency is for us the top priority. For this reason, we established a process at the beginning of last year that will enable us to make available comprehensive reports on the results of clinical trials. In addition, we make it possible for scientists to analyse data from clinical trials for themselves and even to compare them with data from other companies. Research scientists are given access to the data via an internet portal set up
specifically for this purpose, which we operate jointly with ten other pharmaceutical companies. We have meanwhile made data available from more than 240 clinical trials and have registered all trials launched since 1998 on a web location of the US National Institutes of Health.

In our commitment to transparency, we not only exceed the legal requirements, but also exceed the standards of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Principles for Responsible Clinical Trial Data Sharing.

22. **Chart: Successes 2014 / Outlook 2015**

Let me now close by summing up what drove us in 2014 and what we achieved:

- We brought numerous new medicines to the market.
- We were able to submit a large number of compounds for marketing authorisation.
- We were successful in resolving a number of issues that have occupied us over the last few years.
- And we invested once again in the future.
- For 2015, the focus for us will be on launching new medicines and on our profitability.

All this shows very clearly that, in our view, Boehringer Ingelheim is well-positioned for future growth. Despite the difficult market
environment in 2015, we are therefore planning for a moderate increase in net sales compared with the previous year.

Ladies and gentlemen, Boehringer Ingelheim views the future with confidence, is heading for growth once again and expects our employees’ efforts to again enable us to deliver an excellent performance in 2015.

Thank you very much for your attention.