

Bayer Pharma 2000









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Executive Vice President
Bayer Pharma

HSBC
Frankfurt, February 4, 2000



Bayer Jan-Sep 99

Net sales in Euro million 20,499
growth 1999/98 4.5%

| Net sales in Euro million | | Jan-Sep 99 | 99/98 |
|---------------------------|--|------------|-------|
| Polymers |  | 6,817 | +1% |
| Chemicals |  | 2,951 | -7% |
| Agfa (Jan-June) |  | 2,260 | n.m. |
| Agriculture |  | 2,447 | +3% |
| Health Care |  | 6,024 | +21% |
| Diagnostics |  | 1,204 | +59% |
| Consumer Care |  | 1,254 | +5% |
| Pharma |  | 3,566 | +18% |



Bayer Pharma 2000 *The Agenda*

- **Business Performance Q1 - Q3 1999**
- **Addressing the challenges of the Pharmaceutical Industry**
 - Strategies to ensure profitable growth
 - Invest in new technologies and capabilities for future business growth



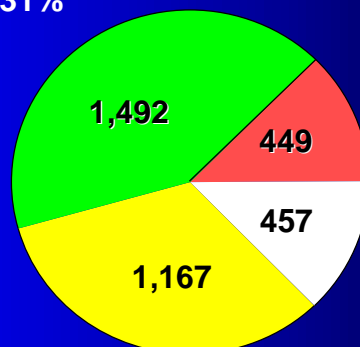
Bayer Pharma Jan-Sep 99 Net sales in Euro million **3,566**
Growth Q1-Q3 99/98 **+18%**
Growth Q1-Q3 99/98 in LC **+15%**

North America **+31%**

Europe **+5%**

Japan **+19%**

Overseas **+12%**













Top 10 Countries

37% of our net sales are generated in the US

Net sales in Euro million

Jan-Sep 99 99/98

| | | | |
|---------|---|-------|------|
| USA |  | 1,335 | +32% |
| Japan |  | 448 | +19% |
| Germany |  | 365 | +1% |
| Italy |  | 183 | +8% |
| France |  | 168 | +19% |
| Canada |  | 151 | +15% |
| UK |  | 113 | -5% |
| Spain |  | 106 | +5% |
| Brazil |  | 44 | -21% |
| Mexico |  | 41 | +11% |













Top 10 Products

Net sales in Euro million

Jan-Sep 99

99/98

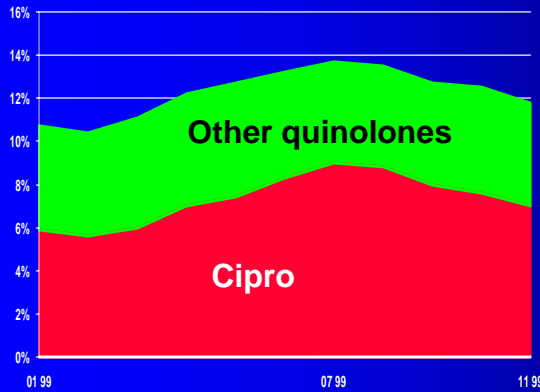
| | | | |
|---------------------|--|-------|-------|
| Ciprobay |  | 1,058 | +17% |
| Adalat |  | 717 | +9% |
| Kogenate |  | 261 | -6% |
| Lipobay / Baycol |  | 199 | +289% |
| Glucobay / Precose |  | 196 | +9% |
| Gamimune N |  | 176 | +53% |
| Nimotop |  | 89 | -3% |
| Fraction V Products |  | 66 | +30% |
| Trasyol |  | 52 | +16% |
| Prolastin |  | 50 | +17% |



Cipro

Growing the business in an expanding quinolone segment

Prescriptions shares in antibiotics (US)



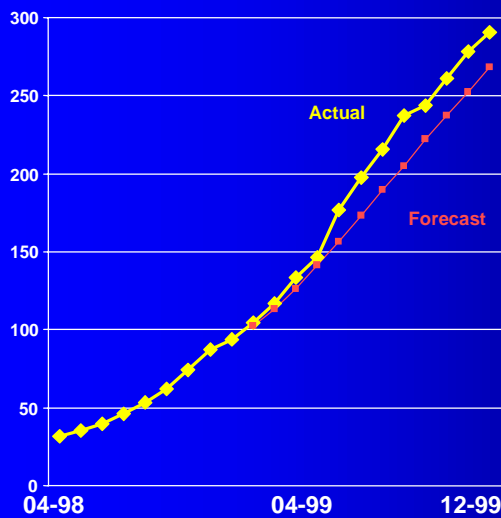
Source: IMS

- New entrants have expanded quinolone share of antibiotics
- Cipro prescriptions have grown by 9 % MAT Dec./99
- All other quinolones grew by 8.6 % in the same period
- Total antibiotics market grew by 1.7 %
- World wide sales Q1 - Q3 1999: Euro 1,058 billion (17% growth over 98)



Baycol / Lipobay Growth gaining momentum in 1999

Worldwide sales - moving annual total Euro million



- Launched in all major markets
- Target sales of Euro 93 million in 1998 achieved
- MAT December 1999 Euro 292 million achieved
- Target 2000: double 1999 sales



Bayer Pharma 2000: *Addressing the challenges of the Pharmaceutical Industry*

- **Strategies to ensure profitable growth**
 - Lifecycle management of current products to maximize profit/NPV
 - Rapid development and global launches of new products
 - Focus/streamline operations to achieve operational excellence

- **Invest in new technologies and capabilities for future business growth**



Cipro *Life Cycle Management to fully exploit the potential*

- **Extending indications (pediatric)**
 - Developed for UTI, first patients recruited
 - Access to new market segments
 - Extension of patent protection in USA until mid 2004
- **Developing once daily formulation**
 - Developed for UTI
 - Launch Q1, 2003 in USA and other major markets by Q4, 2003
- **Launch of iv formulation in Japan in September 2000**
 - First iv quinolone in Japan
 - Double Cipro sales in Japan
- **Otic outlicensed to Alcon (launched in 1998)**
- **Providing more convenient forms (flexibags)**



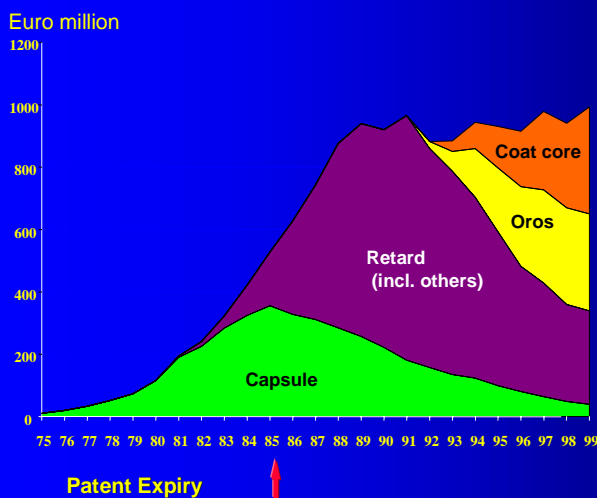
ADALAT

A
Drug
Achieving
Levels of
Amazing
Turnover

More than 14 billion Euro over 25 Years !



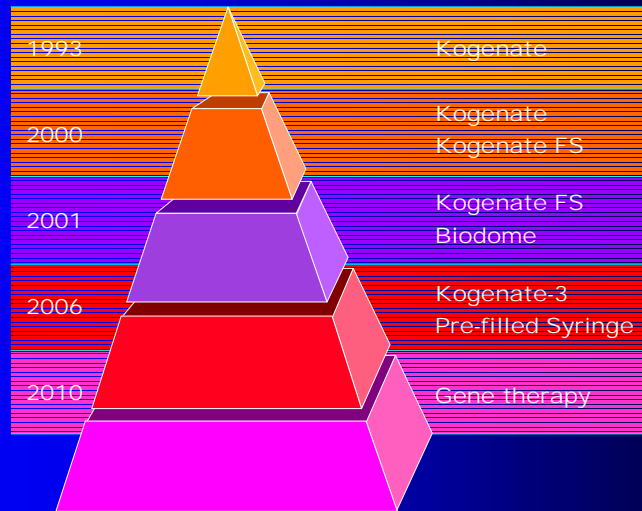
Adalat - Continuing to be the textbook case of life cycle management



- Ongoing launches for once daily 20 mg (e. g. Canada, UK)
- INSIGHT study results to be published June 2000 (ESH Gothenburg)
- CV Symposium Berlin May 2000
- ACTION study fully recruited; treatment period ends Q4 2002
- ENCORE I results to be published Q3 2000
- ENCORE II results to be published Q1 2002



Coagulation Product Life Cycle Management



Investments in Hemophilia

- \$600 million R&D + Tech Op investments in recombinant technology that has significantly enhanced the safety of hemophilia products.
- Over the next 5 years scheduled investments of over \$500
 - Second Kogenate FS production suite
 - Building modifications for transfer device
 - New filling & freeze drying facility
 - Kogenate III
 - Gene Therapy



Baycol / Lipobay - Strategic elements of growth

High Dose

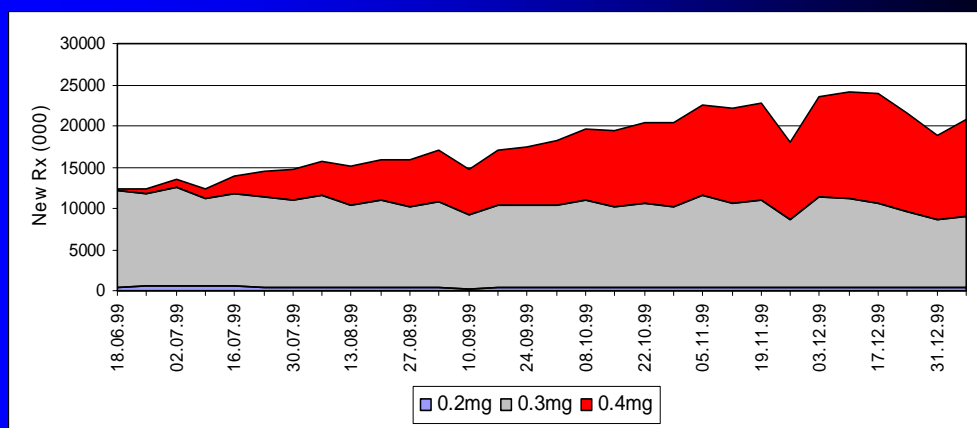
- Launch of 0.4 mg in USA on July 6th 1999.
Approval in the UK (Reference Member State) in December 99, launch Jan 15, 2000.
Mutual Recognition Procedure initiated, approval mid 2000.
- Submission of 0.8 mg in US September 1999,
launch scheduled for September 2000.

Differentiation

- Ongoing comparator studies, Atorvastatin vs Baycol (0.4 & 0.8 mg), efficacy (LDL, HDL) and plaque stabilization.



USA Baycol - weekly new prescriptions

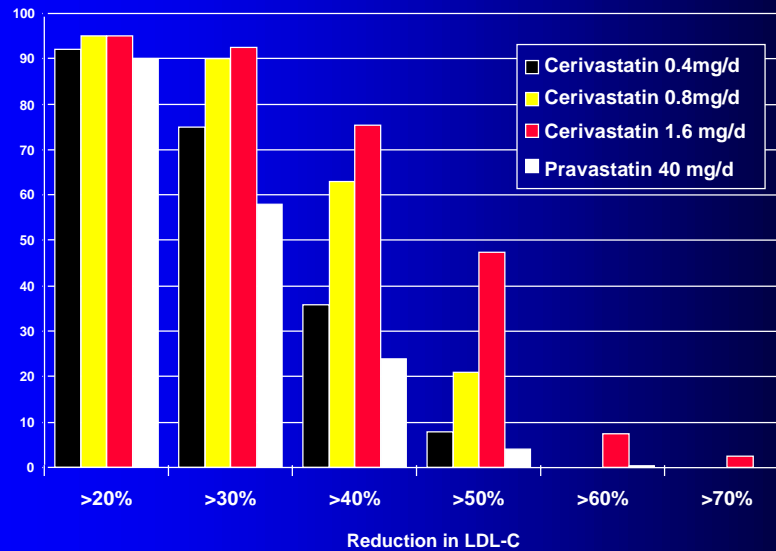


Source: IMS' NPA+weekly



Lipobay - "Lower the better"

Responder Rates (%) in LDL-Cholesterol Reduction



Baycol / Lipobay - Strategic elements of growth

Intervention

- Reduction in risk of the first stroke in the elderly (RESPECT)
- Reduction in risk of the first myocardial infarction in diabetics (LDS)
- Reduction of mortality in end stage renal disease (CHORUS)
- Reduction of recurrent myocardial infarction (PRINCESS)

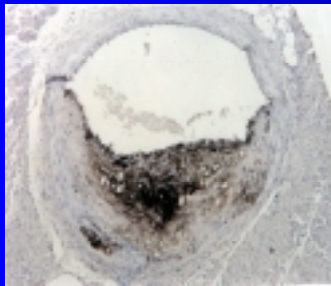
Role beyond LDL-C reduction: Additional benefits become clinically more relevant in the treatment of hyperlipidemia

- Normalization of endothelial function in coronary arteries (ENCORE I)
- Prevention of arteriosclerosis (ENCORE II / ENCORE Japan)
- Plaque stabilization in coronary heart disease (CAPACITY)
- Endothelial function in post-menopausal women (ECHOPOST)
- Opportunity in Osteoporosis
- Combination therapy with Nifedipine

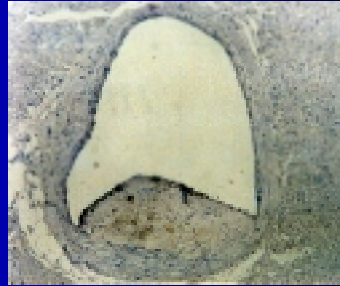


Lipobay/Baycol *has demonstrated plaque stabilizing effects*

Reduction of inflammation



Control



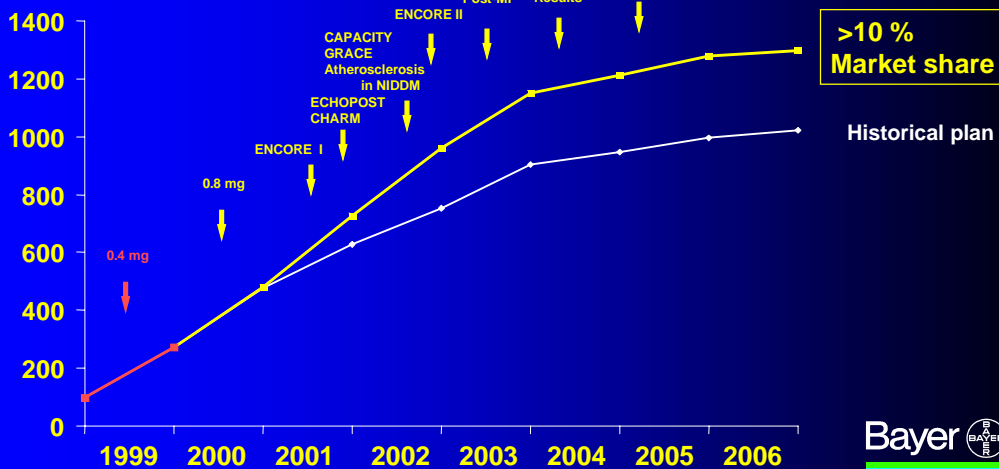
Cerivastatin

Shiomi et al. Br. J. Pharmacol. (1999) 126, 961 - 968



Baycol / Lipobay - Worldwide Sales Projections

Euro Million



Avelox[®]



**... is the ideal respiratory antibiotic
providing reliable efficacy
now and in the future**



Avelox : Excellent clinical and bacteriological response

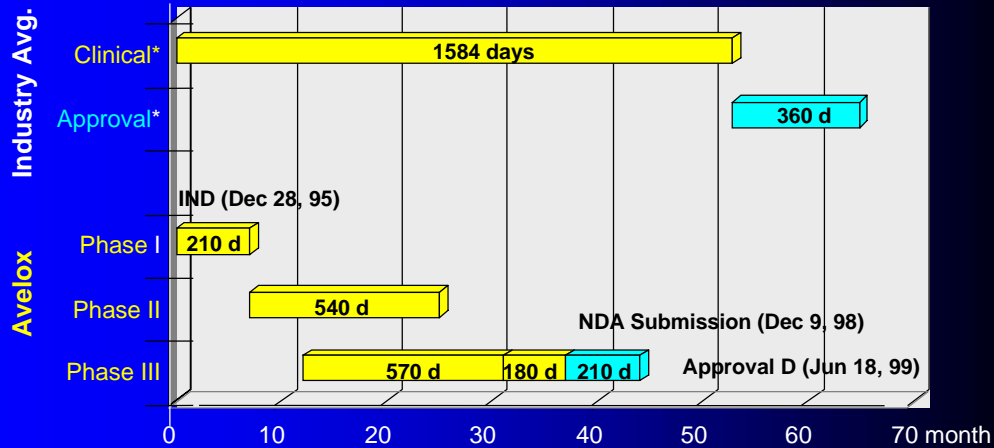
| | Clinical Response | Bacteriological Response | Comment |
|--|-------------------|--------------------------|---|
| <i>Acute Exacerbations of Chronic Bronchitis</i> | 89% | 92% | Significantly better eradication of H. influenza than Clarithromycin |
| <i>Community Acquired Pneumonia</i> | 94% | 91% | Excellent bacteriological efficacy against beta lactam or macrolide resistant strains |
| <i>Acute Sinusitis</i> | 92% | 96% | Significantly better bacteriological success than cefuroxime axetil |

Safety and tolerability profile

- No hepatic-, renal- and phototoxicity
- No QT - related cardiac events
- Low CNS side effects (dizziness < 3%) and discontinuation rates (3.3%)



Avelox developed in record time! 33% less than industry standard (IND - Approval)

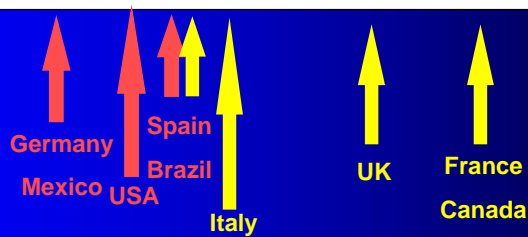


* Source: Tufts CSDD



Avelox Launch Timing: Maximizing value through a global launch program

| 1998 | | | | 1999 | | | | 2000 | | | | 2001 | | | | 2002 | |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|------|--|
| 3. Qtr | 4. Qtr | 1. Qtr | 2. Qtr | 3. Qtr | 4. Qtr | 1. Qtr | 2. Qtr | 3. Qtr | 4. Qtr | 1. Qtr | 2. Qtr | 3. Qtr | 4. Qtr | 1. Qtr | 2. Qtr | | |

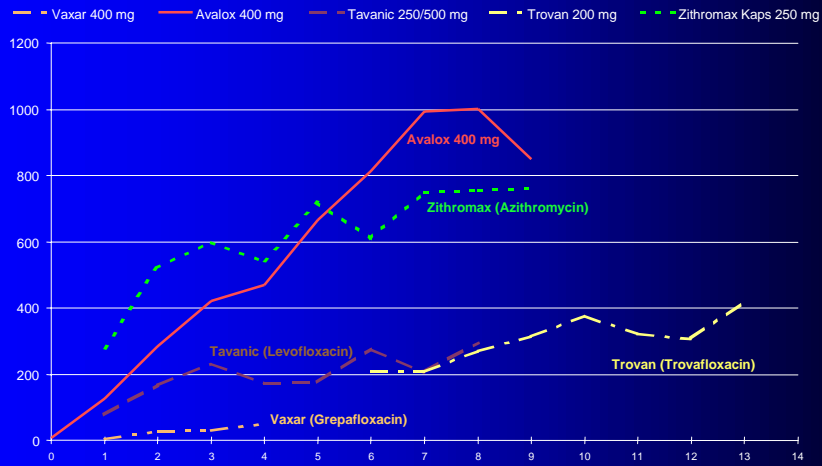


Germany - Sept. 1999
Mexico - Oct. 1999
USA - December 99
Spain - January 2000

Brazil - February 2000
Italy - April 2000
UK - December 2000
France - May 2001
Canada - June 2001



Avalox vs. competitors in Germany Pharmacy sales in DM '000, weeks after launch



Source: IMS, Frankfurt



FDA Review of Avelox NDA

‘What Bayer has done for *Avelox* sets a new standard for testing and assessment of new anti-infective agents.’

Dr. Mark Goldberger, Director, FDA Division of Special Pathogens and Immunological Drug Products



Cipro / Avelox:

Expanding the anti-infective franchise

■ Cipro

- Urinary tract infection
- Infections treated in hospitals
 - contribute 70% of sales
 - low resistance development
 - well tolerated, 200 million patients treated

■ Avelox

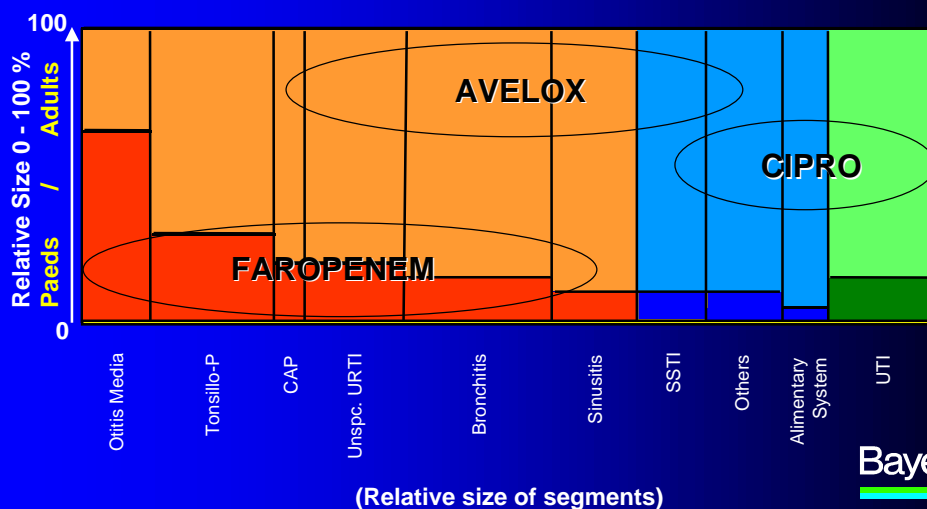
- Community based respiratory tract infection
 - improved efficacy against respiratory pathogens
 - low resistance development potential
 - well tolerated

Maximization of value through clinically based co-positioning



Schematic segmentation

Optimal co-positioning



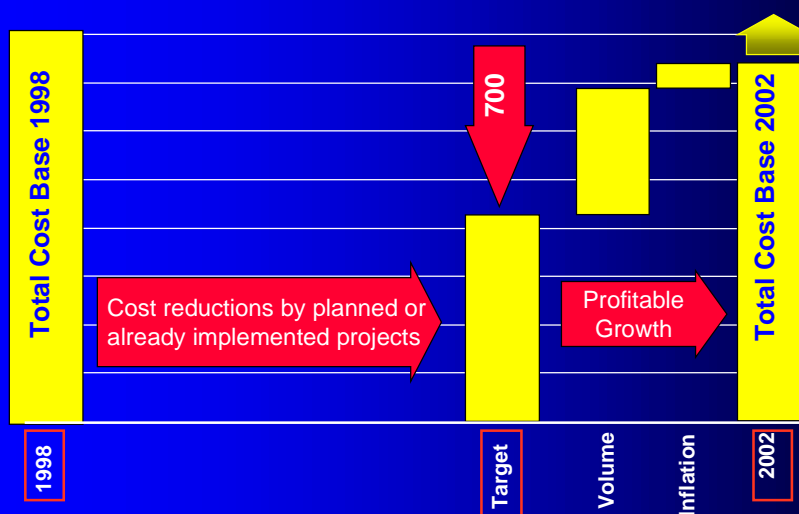
ProMem - Metrifonate

- Amendment to NDA was submitted to the US FDA on August 4, 1999 for treatment of mild to moderate Alzheimer's disease
- Maximum dose in the amendment to NDA is 0.9 mg/kg/day or one 40 mg or one 50 mg tablet once daily
- FDA decision is expected within 6 months after submission date.

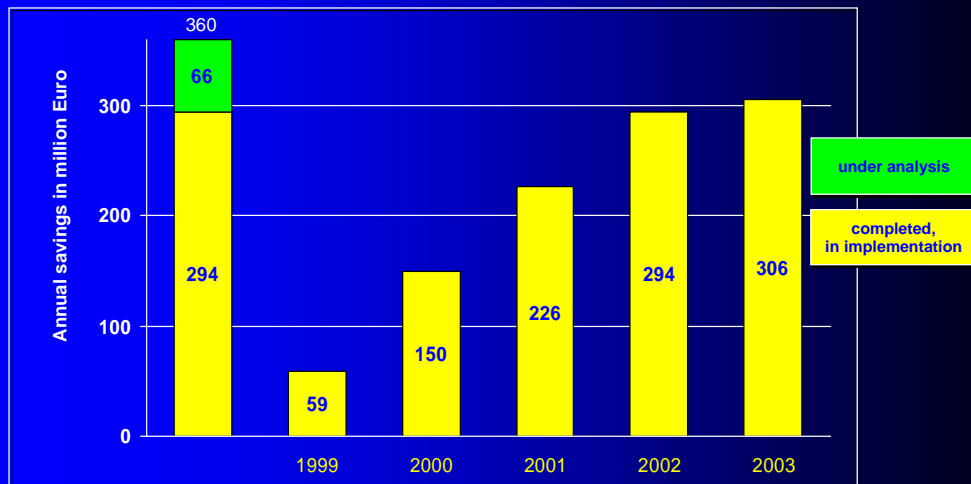


Restructuring Program Target:

improving profitability by DM 700 million (Euro 360 million) through operational excellence



Operational Excellence - Status of restructuring program - end 99



Bayer 

Bayer Pharma 2000: Addressing the challenges of the Pharmaceutical Industry

■ Strategies to ensure profitable growth

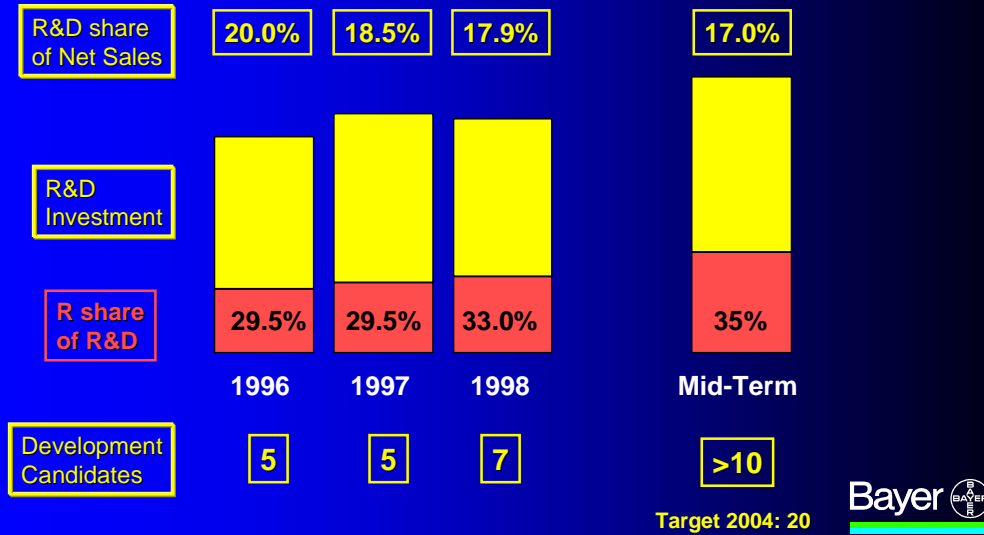
■ Invest in new technologies and capabilities for future business growth

- Co-operations to improve Bayer's technological platform
- Active portfolio management for effective product development and marketing
- Developing new skills and capabilities

Bayer 

On track for the target

Increased R&D productivity at reduced R&D share of net sales



Increasing R&D productivity

Cardiovascular Diseases
 Coronary Heart Disease
 Atherosclerosis / Hyperlipidemia
 Hematology / Coagulation

Metabolic Diseases
 Diabetes Mellitus
 Obesity

Respiratory Diseases
 Asthma
 Chronic Obstructive Pulmonary Disease

Focus on
15
 Segments

Infectious Diseases
 Bacterial Infections
 Viral Infections

Cancer
 Liver Fibrosis
 Osteoporosis

Central Nervous System
 Dementia (Alzheimer)
 Acute Neurology / Stroke
 Chronic Pain



Increasing R&D productivity

| | |
|------|---|
| 1994 | Onyx Axyx |
| 1995 | Myriad |
| 1996 | Pharmacopeia |
| 1997 | Genome Therapeutics Genetics Institute Genzyme Corp. |
| 1998 | Oxford Asymmetry Novalon Amphioxus Cell Technologies Receptron NovaDX ComGenex Fuisz Technologies Abbott Alza Millennium |
| 1999 | Lion Bioscience ArQule Morphosys Cybio Incyte |

Co-operations

Cancer therapy
Anti-inflammatory therapy
Genomics
Combinatorial chemistry
Microbial genomes
Protein library
Chemical libraries
Chemical libraries
Assay technology
Cell culture technologies
Screening technology
cDNA library
Synthesis technology
Formulation technology
Formulation technology
Formulation technology
Enabling technologies
Bioinformatics
Substance library
Target characterization
Screening technology
Bioinformatics



Major new collaborations in Genomics and Bioinformatics



(1998)

Deliverables:

- Identification of 225 therapeutically relevant drug targets (qualified targets)

over 5 years

100% of 99 goals have been achieved: 26 targets, 1 advanced research project.



(1999)

Deliverables:

- 500 new "Silico Targets",
- 70 new annotations on existing Bayer-owned gene targets
- Gene expression markers / SNPs

over 5 years

Collaboration in plan. First version of bioinformatics software and first targets delivered.



Active Portfolio Management

- **Life cycle management**
 - Cipro once daily
 - Lipobay > 10 % market share
 - Avelox i.v.
- **In-licensing**
 - Faropenem
- **Accelerated development opportunities**
 - IL- 2 selective agonist
 - Camptothecin glycoconjugate
 - anti HCMV
- **Focus on high value opportunities**



Faropenem Daloxate

- Inlicensed from Suntory 7/99
- First oral penem
First in a new class of antibiotics for community acquired infection in adults & children
- Excellent antibiotic spectrum, superior safety profile
Potential for development of less resistance than standard β -Lactams
 - Start of Phase II in March 2000
 - Accelerated development program (950 days from IND to NDA)
 - Launch scheduled for end of 2003



PDE-IV Inhibitor *for COPD and Asthma*

- Strong anti-inflammatory
- Innovative therapeutic approach due to novel method of action
- Does not share the side-effect driven limitations of steroids
- High level of convenience by once daily oral dosing
 - Start Phase IIb Asthma: Feb 2000, COPD: Mar 2000
 - Phase III decision early 2001
 - Launch planned for mid 2004



PDE V inhibitor *to treat sexual dysfunction*

- Highly potent and selective phosphodiesterase-V-inhibitor
- 7 to 10 times more potent than Sildenafil (Viagra) in animal experiments
- Improved isoenzyme selectivity suggests lower incidence of side effects than Sildenafil
- Opportunities in female sexual dysfunction and alternative formulations
 - Phase II: significant improvements vs placebo, well tolerated
 - Phase III decision February 2000
 - Launch scheduled for November 2002



Summary: High Priority Projects Focused for rapid development

| <u>Project</u> | <u>Status</u> | <u>Launch</u> |
|------------------------------|--|---------------|
| Avelox i.v. (Bact. Infect.) | Phase III | Jun 2001 |
| PDE-V Inh. (Sexual Dysf.) | Phase II, Start Phase III in April 2000 | Nov 2002 |
| Cipro OD (Bact. Infect.) | Phase I | Mar 2003 |
| Faropenem D. (Bact. Infect.) | Phase I, Start Phase II in March 2000 | Dec 2003 |
| MTP-Inh. (Hyperlipidemia) | Phase II, extended exploratory trial in 2000 | Aug 2004 |
| PDE IV Inh. (COPD + Asthma) | Phase II | Aug 2004 |
| Camptothecin glyco. (Cancer) | Released for clinical development | Sep 2004 |
| IL-4 dm (Severe Asthma) | Phase I in patients. Go/no go decision in March 2001 | Dec 2004 |
| Guanylate CS (HT + AP) | Preclinical dev., start clinical in Jan. 2000 | HT: Mar 2006 |
| cGMP Enhancer (SAP) | Preclinical development started in Sept. 1999 | Aug 2006 |
| Dipeptid Antibiotic | Preclinical | Aug 2006 |



Developing new skills & capabilities

- Research to Development Transition Project
- “Redirecting Medical“
- Strategic Marketing



R2DT

"Research to Development Transition Project"

Objective

- Prepare Development functions for increased output of Research

Key steps

- Benchmarking exercise with Quintiles and other CROs
- Internal project for evaluation of development strategies, development processes and the resulting capacity needs

Results

- Positive technical and scientific evaluation, high efficiency and productivity confirmed
- Organizational and process changes defined for smoothing the Research-to-Development transition process
- Capacity model developed for calculation of resource needs
- Strategic outsourcing proposed as a supportive measure



Redirecting Medical

Objective

- Create an efficient and effective global Bayer Medical Organization prepared for future challenges

Focus

- Design, analysis, interpretation and communication of clinical programs
- Efficiency of clinical trial operations
- Drug safety capabilities

Deliverables

Efficiency improvement and cost savings through

- Newly designed global processes
- Definition of respective skills and capabilities
- Development of adequate structure



Marketing led organization

Strategic Drug Development

- Project organization based on business priorities
- Claim driven clinical development
- High flexibility for resource allocation: support the potential blockbuster

Strategic Product Marketing

- Marketing integrated into Product Development
- Early evaluation of commercial potential of products
- Commercial focus of phase III development
 - Team led by business experts
- Product launch committee formed to track commercialization process from start of phase II



Bayer Pharma 2000 : Actions and implications

■ Strategies to ensure profitable growth

- Development of Cipro OD
- In-license Faropenem
- 1000 day development of Avelox
- Investment in large scale 'intervention' trials (RESPECT, LDS)
- Leading position: HT / IHD with Guanyl.Cyclase; Faropenem; Dipeptid Antibiotic
- Operational excellence program
- Portfolio focus on high value projects

■ Invest in new technologies and capabilities for future business growth

- Millennium - 'Genomics deal of the Century' / Lion
- Early development portfolio
- Building new development & marketing capabilities

■ Strengths of integration

- Convergence of technologies serves as a foundation for the release of synergies of an integrated Healthcare Company

