

3rd Berlin Conference on IP in Life Sciences



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Overview: development steps of Cosmo Pharmaceuticals

- **The original plan**
- **Identifying an opportunity**
- **Building on strengths; creating innovative solutions**
- **From a one time shot to further applications; creating a franchise**
- **Securing transformation from drug delivery to drug ownership company with effective patents**
- **Extending the foot-print: beyond IBD**
- **Necessary investments**

The original plan

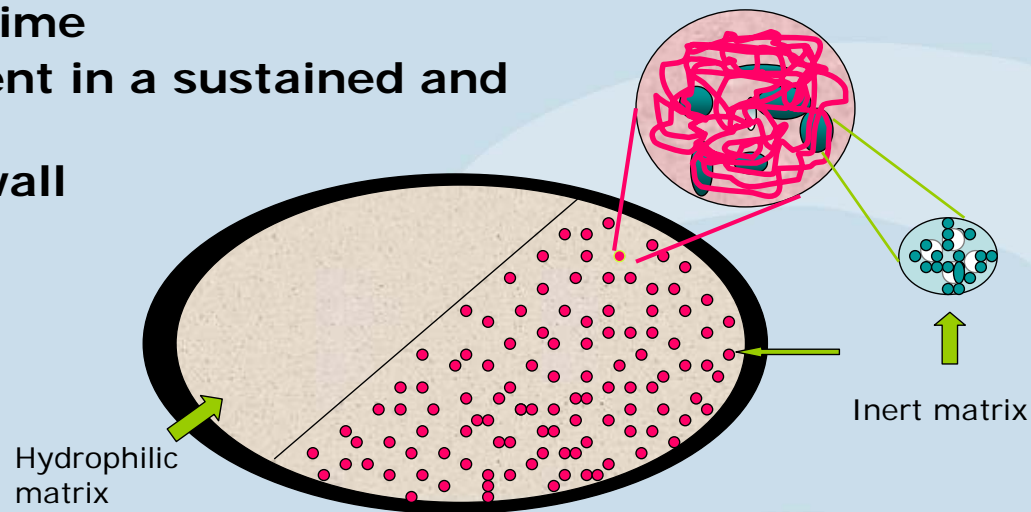
- **Leverage the existing distribution strength of Farmajani**
- **Hypothesis of growing generics market in Italy**
- **Purchase of manufacturing capacity and skills**
- **Identification of manufacturing capacity of Warner Lambert**
 - About to be sold
 - Long dated experience in manufacturing complicated drugs such as Lopid (Genfibrozil), Torvast (Atorvastatin), Neurontin (Gabapentin)
- **Establishment of Cosmo Pharmaceuticals and purchase of plant from Warner Lambert in 1996**

From a problem to an opportunity

- **Generics enabling legislation in Italy is delayed**
- **Contract to manufacture Asacol 250 mg for Giuliani for Italian market**
 - Awareness of problems IBD patients have
 - Chronic relapsing-remitting disease
 - Necessity of bringing 4.8-6 grams to the colon per day during flare
 - 16-24 tablets in regular intervals mean that compliance becomes the main issue
- **Identification of superb formulation skill in acquired team**
 - Bring together expertise from all areas
 - Seek to increase tablet load
 - Seek to identify a reliable mechanism to
 - Release active ingredient where required
 - In a gradual form that is reliable
 - And spreads internally like an ointment

The innovative solution: the MMX® Concept

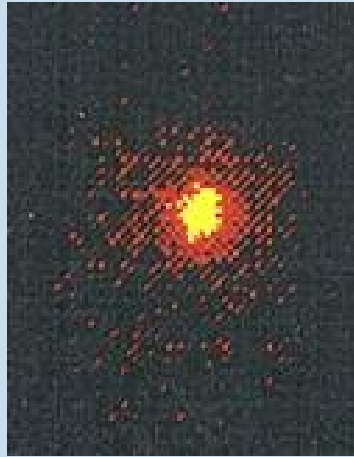
- Structure allows more active ingredient in same space than before ie 1200 mg instead of 250 mg
- Gastroprotectant layer protects drug from gastric degradation
- Erode gradually over time
- Deliver active ingredient in a sustained and progressive mode
- Attach drug to colon wall



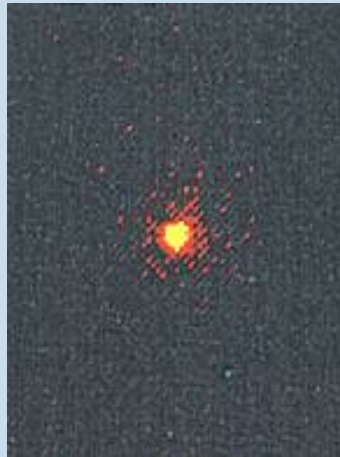
- Gastroprotectant layer
- LV hydrophilic - amphipatic polymer matrix
- HV hydrophilic polym. matrix
- inert matrix material
- drug (+ excipient)



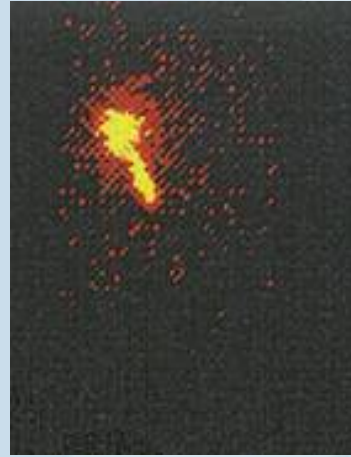
MMX[®] dissolution proof



1h 30' small intestine



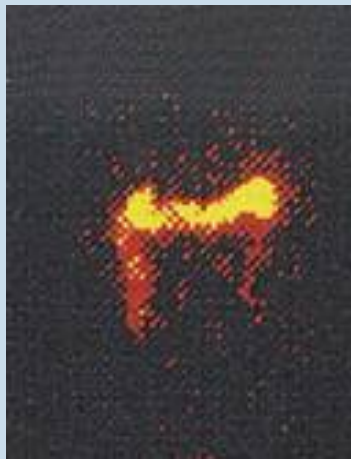
3h 30' ileum



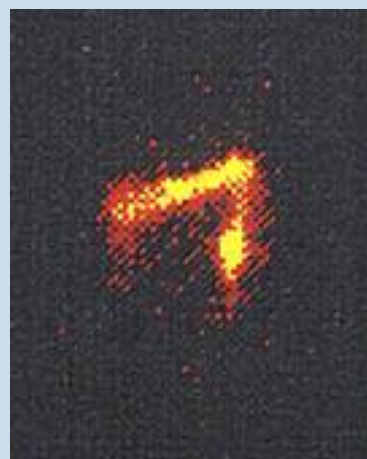
4h 30' ascending colon



7h 30' transverse colon



10h transverse colon



15h descending colon

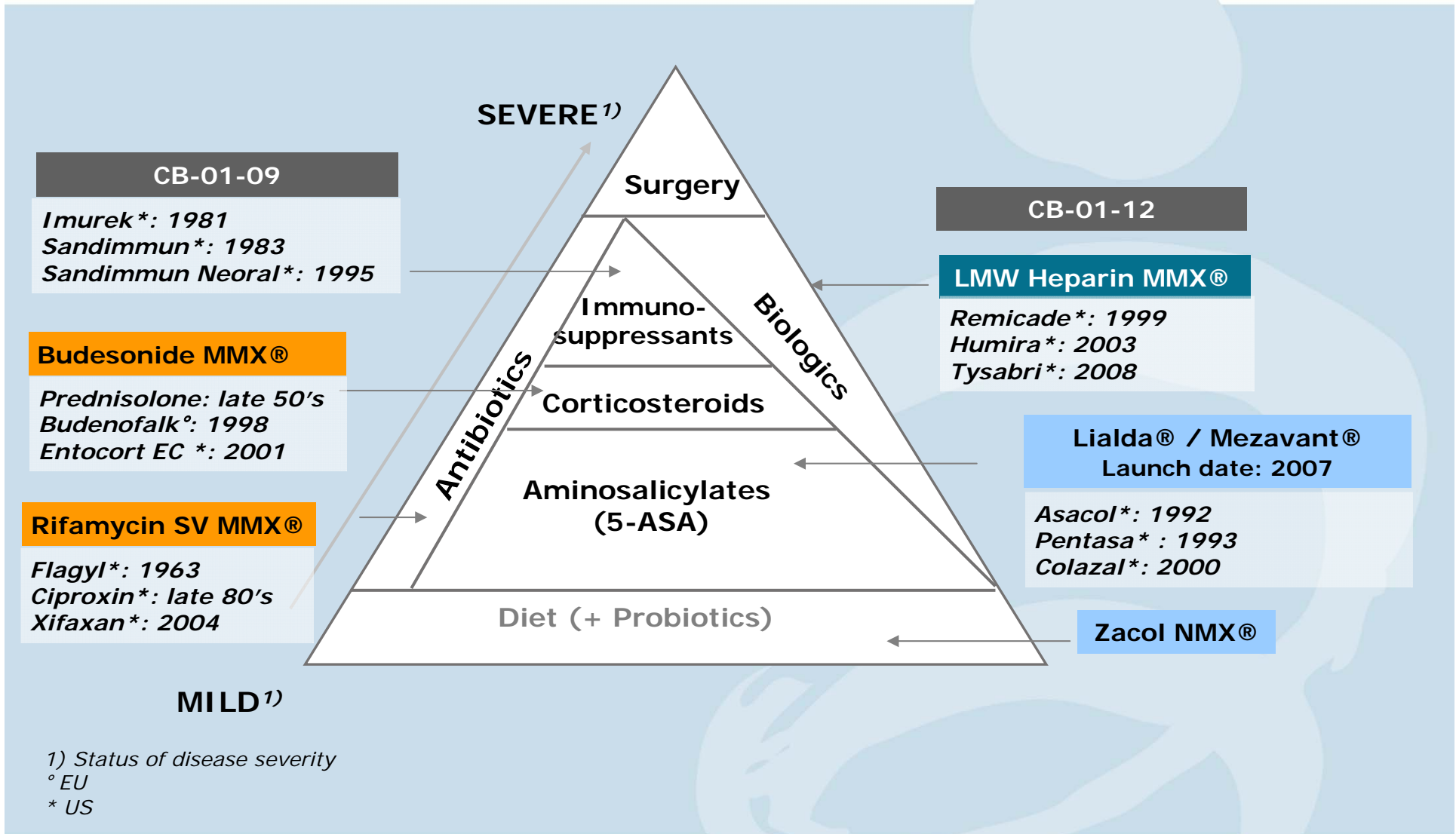


16h descending colon



24h
rectum

The market: Inflammatory Bowel Disease (IBD), a disease with very little recent innovation



From single opportunity to Product Pipeline: Progress in all projects; no project failures

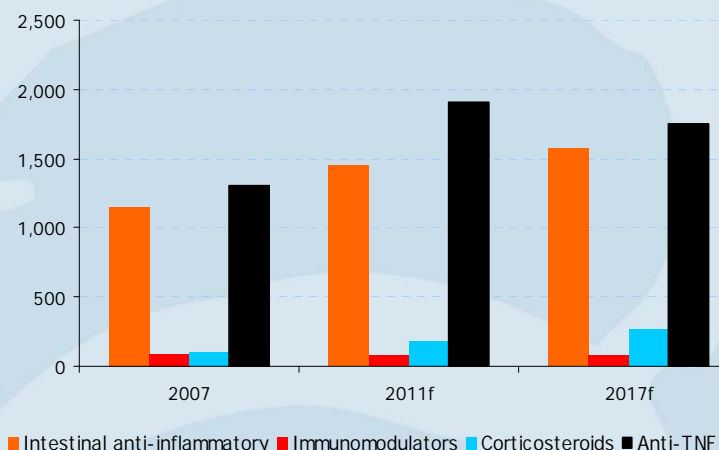
Product	Drug type	Indication	PC	Ph I	Ph II	Ph III	MA Launch	Partner
Lialda®/Mezavant®	5-ASA	Mild to moderate Ulcerative Colitis					03/07 USA 10/07 UK	Shire
Zacol NMX®	Dietary supplement	Intestinal Disorders (nutraceutical)					12/05 ITA	
Budesonide MMX®	Corticosteroid	Mild to moderate Ulcerative Colitis				Q2/3 10		Santarus - USA Ferring – Worldwide (excluding Japan & USA)
Rifamycin SV MMX®	Antibiotic	Traveller's Diarrhoea				H1/2 11		Santarus - USA Dr. Falk – Europe & Australia (excluding Italy)
LMW Heparin MMX®	Biologic	Mild to moderate Ulcerative Colitis				Q4 11 EU		
CB-03-01 (NCE)	Steroid ester, androgen antagonist	Acne		PK Study	POC		Q3 10 Toxicologic Study Sensitivity Study	
CB-01-16	Opioids antagonist	Opioid Induced Constipation				Q4 10		
CB-03-01	Steroid ester, androgen antagonist	Alopecia				Q4 11		
CB-01-12	Protein delivery	IBD/IBS/Parasitic Infections						
CB-01-14	Antibiotic	Crohn's Disease						

IBD markets: Continuous double-digit growth

Main Brand products	2007 Sales	2009f	2011f	2017f
Anti-TNF				
Remicade	1.2 b	1.3 b	1.2 m	483 m
Humira	149 m	348 m	604 m	636 m
Golimumab	0	0	33	222
Cimzia	0	21 m	87 m	97 m
Other	0	0	0	315
Total	1,306	1,628	1,906	1,754
Intestinal anti-inflammatory				
Lialda	27 m	161 m	237 m	334 m
Salofalk	47 m	89 m	152 m	235 m
Pentasa	321 m	343 m	260 m	222 m
Asacol	457 m	447 m	383 m	142 m
Claversal	29 m	28 m	26 m	27 m
Canasa	30 m	29 m	26 m	26 m
Azulfidine	26 m	26 m	26 m	25 m
Colazal	97 m	27 m	27 m	30 m
Other	118 m	198 m	313 m	540 m
Total	1,152	1,348	1,450	1,581
Corticosteroids				
Entocort	85 m	96 m	77 m	30 m
Budesonide MMX	0	0	54 m	134 m
Other	19 m	20 m	42 m	103 m
Total	104	116	173	267
Immunomodulators				
Sandimmune/Neoral	19 m	17 m	15 m	14 m
Purinethol	4 m	5 m	5 m	6 m
Other	64 m	62 m	61 m	61 m
Total	87	84	81	78
Other				
Tysabri	0	46 m	99 m	62 m
CCX-282	0	0	0	298 m
Ustekinumab	0	0	0	78 m
Generic	0	0	0	22 m
Total	0	46	99	460
TOTAL IBD MARKET	2,649	3,222	3,709	4,140
Growth rate	0	22%	15%	12%

IBD Market Sales 2006-2007 (US\$)

Region	2006	2007	Growth rate
7 Major markets	1,956	2,399	23%
Rest of Europe	160	209	31%
Canada	74	96	30%
Asia-Pacific	29	41	41%
South America	7	9	29%
Others	5	7	
Total	2,231	2,761	24%



Source: Datamonitor Report 09/2008 based on MIDAS Sales Data and IMS Prescribing Insights Data, IMS Health, February 2009

The first break through: Lialda®

- **Indication**
 - Patients with Ulcerative Colitis of mild to moderate severity
- **Market positioning**
 - Entire differentiation is in delivery (all necessary tablets can be taken at once) of well known active principle
- **Great acceptance in markets**
 - Launch in March 2007, at end H1 2009 15.8% of entire US oral 5 ASA market as per Shire reports
 - 73% growth over the market share at H1 2008 (10.8%)
 - 2009 proj sales: \$ 240 m; est 2010: \$323 m; 2011:\$392 m
- **Financial implication for Cosmo**
 - ~3% royalties on revenues capped at cum \$ 90 m
 - ~3% manufacturing profit without cap

Securing the franchise: Intellectual Property & Patent strategy

- **Provide adequate IP protection**
 - to the basic technology
 - the development projects
 - the products deriving from the application of the delivery technology
- **Multiple patent coverage**
 - The principle, chemical composition of the matrices building substances, the specific formulations and the different deriving compositions are protected
 - To cover all the compositions belonging to the indicated dosage form structures, independently of the active ingredient they could contain
 - Once the technology has been applied to a specified API, a new patent is designed to cover the specific field of application and the matrices composition
- **Deriving product patent**
 - focus on starting substances and ratios between the active ingredient and the auxiliary substances

Patent portfolio

- MMX technology patent granted in all major countries (29) with validity until 2020
- Lialda patent granted in all major countries valid until 2020
- Budesonide MMX covered in all major countries under general patent and with CIP in USA with validity until 2020
- Rifamycin MMX patent granted in 18 countries, pending in 12 and published in Korea and USA. The patent is valid until 2025
- LMW Heparin MMX patent granted in 5 countries , pending in 3 and published in 21. With validity until 2012 in Turkey and 2021 in Italy. Valid until 2022 in the rest of the countries
- CB-03-01 patent granted in 29 countries and pending in USA. The patent is valid until 2021 in Slovakia and Mexico. Valid until 2022 in the rest of the countries

Securing the franchise: manufacturing

- Construction of a new plant dedicated to MMX manufacturing started in 2003 and finished at the beginning of 2006 plus 1 year for full equipment, utilities and processes validation
- 2 separate totally insulated, fire proof floors
- The total cost for building, equipment and machinery has been approx EUR 12.5 million.
- FDA approval in 2006
- Manufacturing capacity of 80 batches per floor per month in 3 shifts. Current utilization: 10 batches per week , 1 floor in 1 long shift
- Manpower needed for single shift full capacity utilization: 6/7 per floor

Securing the franchise: Beyond IBD

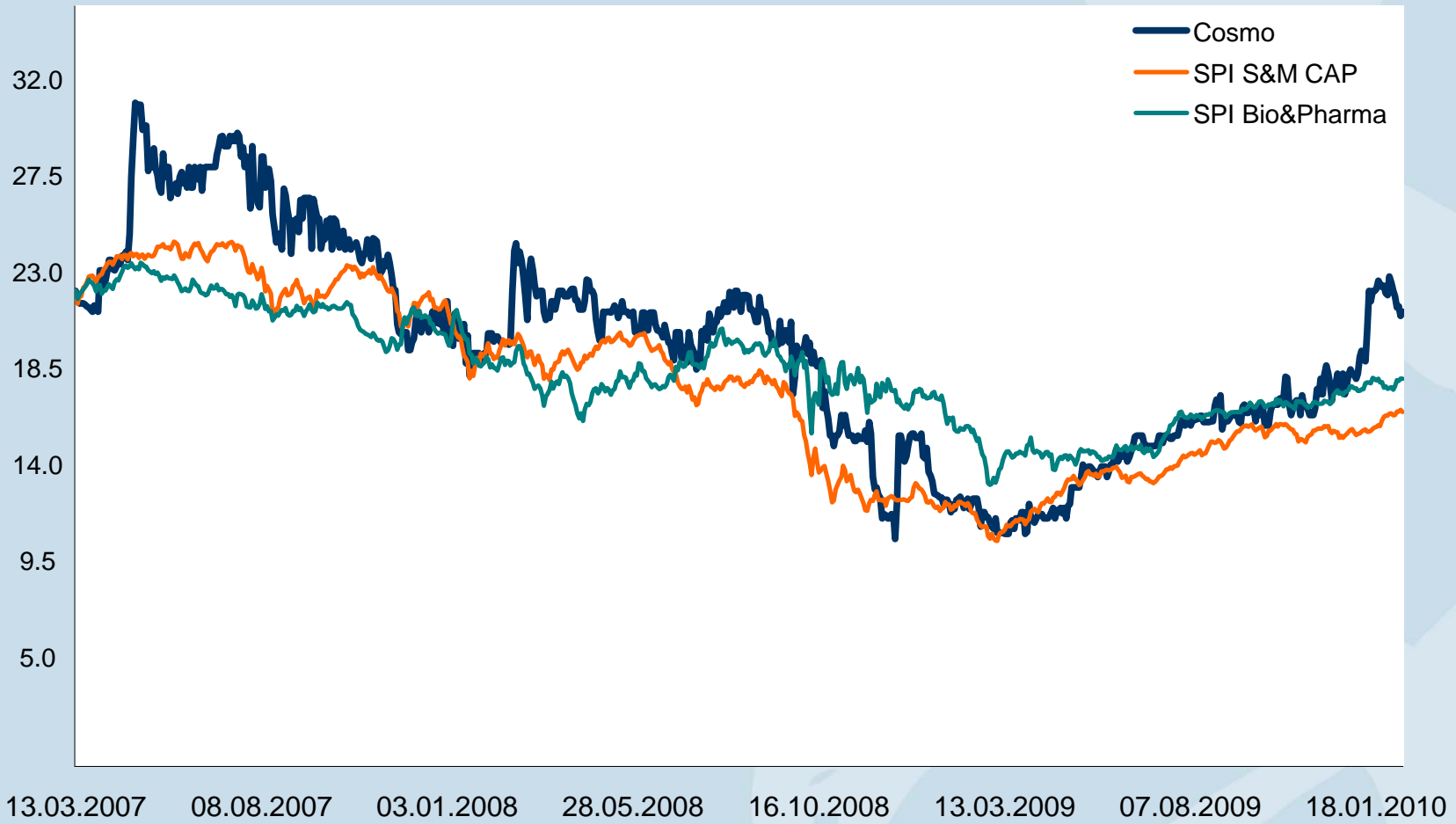
- **Unique characteristics of the patent protected MMX technology**
 - Assembling the active ingredients into the matrices is not a chemical process
 - No heat application is required
- **Ability to tabletise proteins and peptides and bring them to the colon**
- **Additional projects for MMX® application:**
 - CB-01-12 (proteins)
 - CB-01-14 (antibiotic)
 - CB-01-16 (opioid induced constipation)

Key Figures

In EUR million	2007	2008	2009e
Revenues :	21.9	34.2	27.2
- Own products (including MMX)	7.3	21.1	15.1
- Third party products	14.6	13.1	12.1
Cost of sales	(13.2)	(13.2)	(12.7)
R&D costs	(4.8)	(4.3)	(4.4)
Operating Result	(0.2)	11.2	5.3
Net profit after tax	0.1	9.4	4.6
Cash and cash equivalents	25.5	22.2	18.9
Financial assets	-	6.8	13.5
Financial debt	(5.2)	(4.3)	(3.0)
Equity	35.1	43.2	53.3

Share price development

CHF



Looking forwards

- **Confirming the technology**
 - Budesonide and Rifamycin SV are in phase III
 - LMW Heparin is in phase II
- **Improve profitability**
 - New license agreements move the company from a 6.5% return on revenue to 25-30% return on revenue company
- **Replenish pipeline**
 - Seek new MMX applications
 - CB 01-12 for Proteins
 - CB 01-16 for anti opioids
- **Diversify into other areas**
 - Topical treatments of skin diseases
 - CB 03-01 proof of concept attained