

Cosmo Pharmaceuticals update

Sachs Conference, Zurich, 11.2.2010



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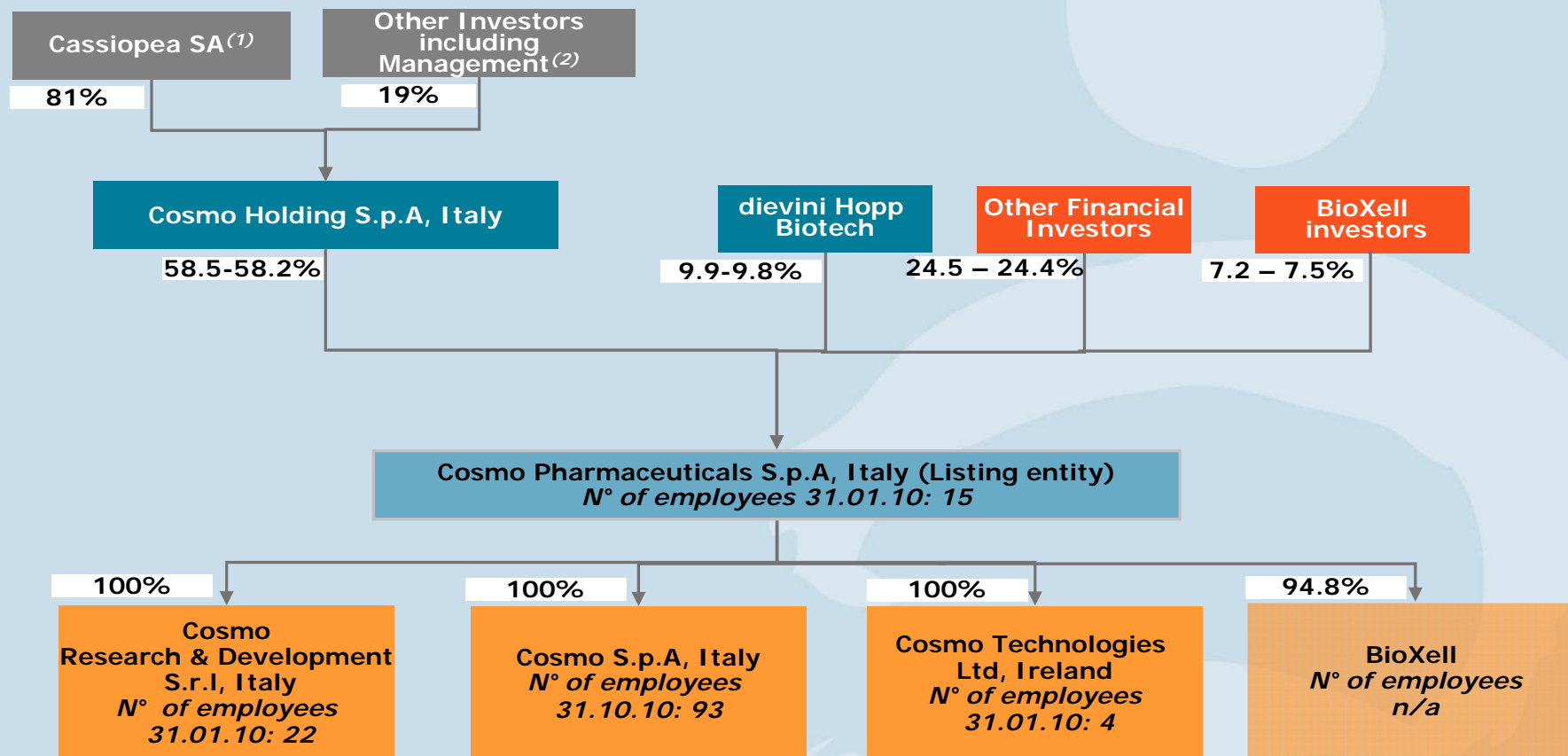
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Cosmo profile

- **CEO is an entrepreneur and the major shareholder**
- **Focus on Inflammatory Bowel Diseases (IBD)**
- **Proven, proprietary, patented MMX® technology that is platform for low risk new product development**
- **Large, deep pipeline with 2 phase III and 2 phase II products**
- **Increasing recurrent revenues, cash flow positive**
- **Sufficient cash to finance entire planned clinical program, no further financings needed**

Prospective Organisation and Shareholding Structure after BioXell transaction



Source: Company information
 1. Controlled by the Ajani family
 2. Management holds 10%

Corporate strategy

Positioning

- From a contract drug manufacturer to a drug developer
- First proof with Lialda®

Technology

- Confirm MMX® technology
- Develop further reformulations with Budesonide and Rifamycin

Pipeline

- Developments with high potential – LMW Heparin MMX® and CB-03-01 on track
- Enter into joint development dialogue with major pharmas, protein / peptide delivery to the colon discussions started

Process

- Increase quality of clinical trial and regulatory approval process with the assistance of Santarus, Falk and Ferring

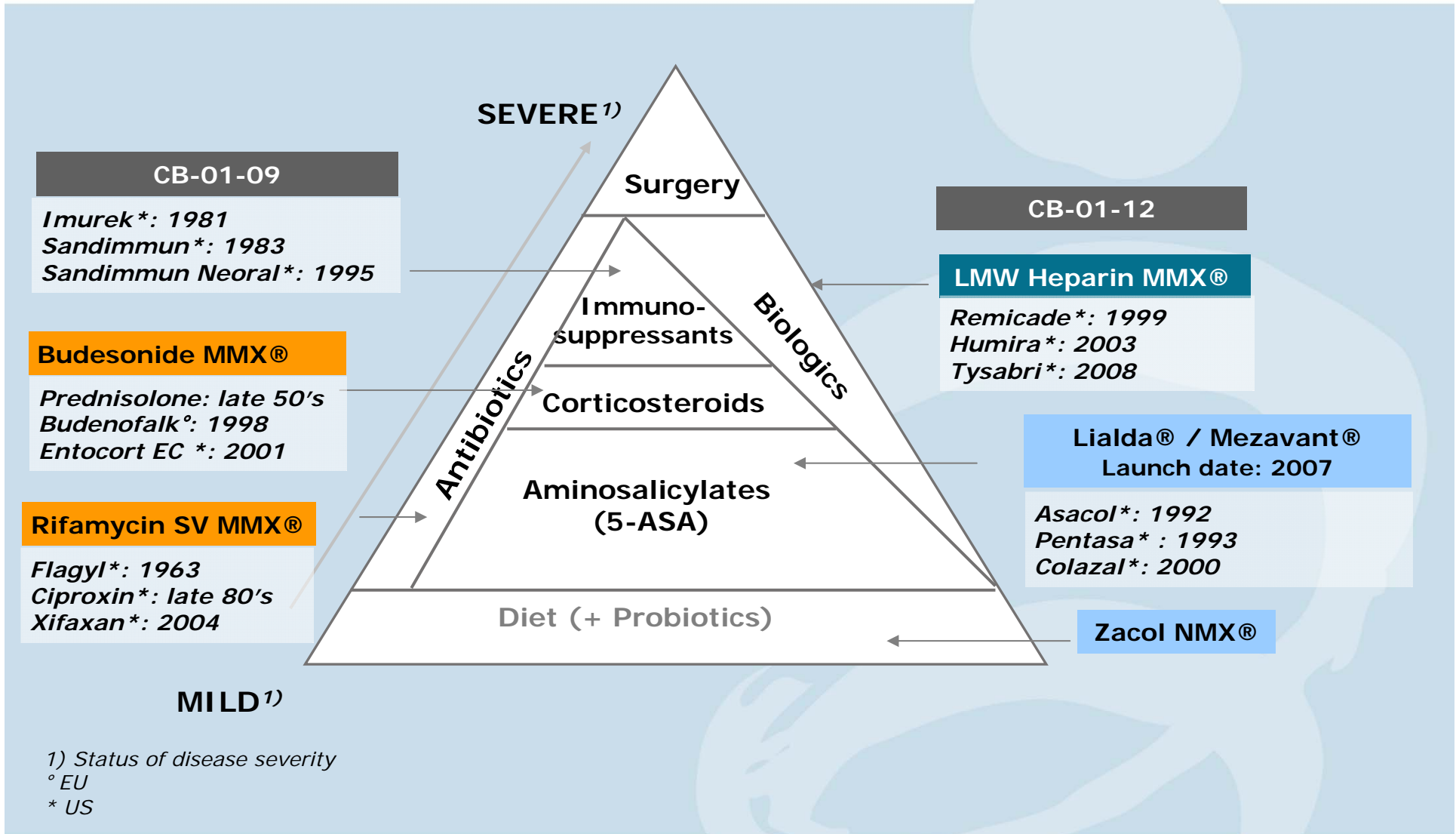
Distribution

- Implement US distribution strategy through Santarus

Financials

- Improve return from licensing agreements from 6% to 25-30%
- Improve cost management in phase III via partnering deals

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

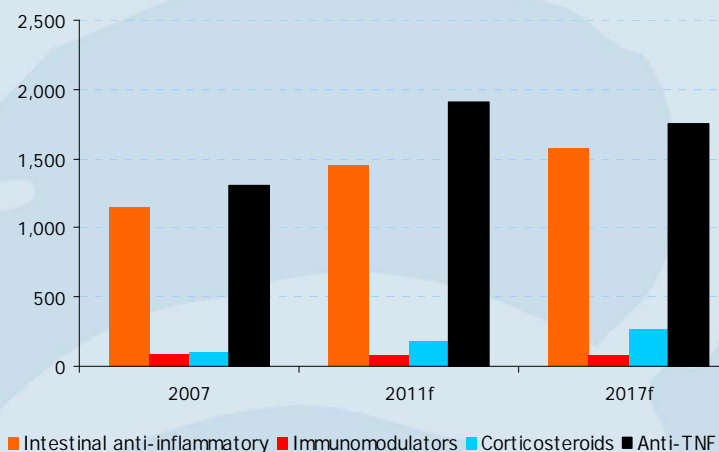


IBD markets: Continuous double-digit growth

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

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			
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							

Lialda®

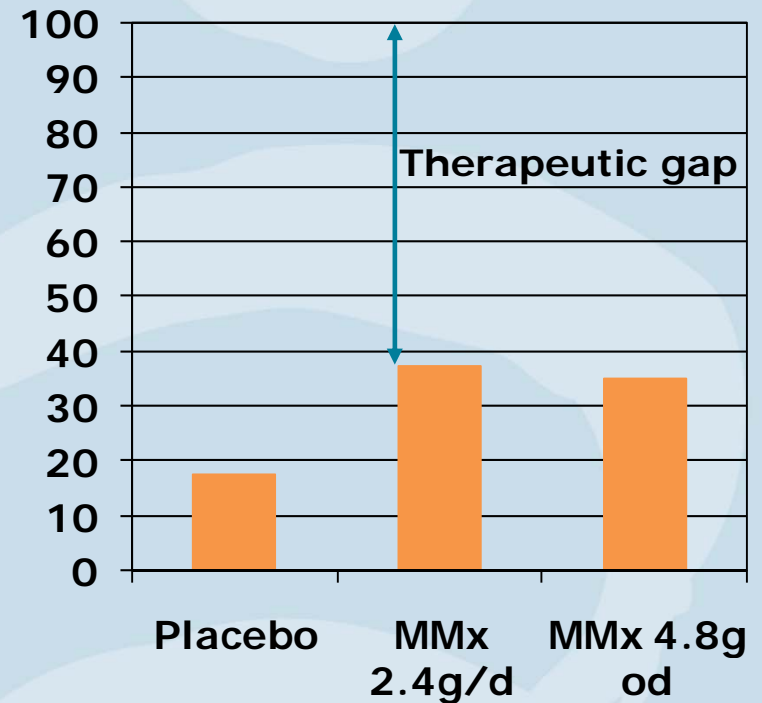
- **Indication**
 - Patients with Ulcerative Colitis of mild to moderate severity
- **Market positioning**
 - Entire differentiation is in delivery (all necessary tablets can be taken at once) of well known active principle
- **Great acceptance in markets**
 - Launch in March 2007, at end 2009 18.1% of entire US oral 5 ASA market as per Shire reports
 - 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

The therapeutic gap in conventional therapy: from Lialda® to corticosteroids like Prednisolone or Budesonide MMX®

Lialda® for active Ulcerative Colitis

- Remission rates @ 8 weeks
- Remission definition: DAI <1
- 517 patients, mild-moderate UC
- Placebo vs 2.4g/d vs 4.8g once daily

Sandborn et al APT 2007;26:205



Common side-effects of Prednisolone, Budesonide MMX®'s most important steroid competitor

System	Long-term and short-term therapy	Long-term therapy
Central nervous	Sleep disturbance Psychosis	Headache
Musculoskeletal	Myopathy Aseptic necrosis	Osteoporosis
Ocular	Glaucoma	Cataracts
Gastrointestinal	Ulcer, pancreatitis	
Cardiovascular	Hypertension Fluid retention	
Endocrinological	Adrenal suppression	Permanent adrenal suppression Growth failure
Metabolic	Hyperglycemia Hyperlipemia	Fatty liver Hypokalemia
Skin	Acne, easy bruising	Striae, atrophy, wound infection, Cushingoid fat distribution
Immune suppression	Infection	Opportunistic infection



Rutgeerts Rev Gastroenterol Disord 2004; 4(Suppl. 3): S3-9

Budesonide MMX®

- **Indication**

- Patients with Ulcerative Colitis of mild to moderate severity, mainly that are refractory to 5-ASAs

- **Status**

- Phase III clinical trials underway in the USA and EU
 - Efficacy and safety of new oral Budesonide MMX® 9mg and 6mg, multicenter, randomized, double-blind, double-dummy comparative study versus placebo, with an additional reference arm evaluating Asacol® 2400 mg (in the USA) or Entocort® EC capsules (in EU)
 - Two times 480 patients; Per December 2009 enrolment completed in EU, >90% enrolled in the USA; Data for EU in April/May 2010

- **Market need**

- A tablet with the efficacy of a corticosteroid and the few side effects of 5-ASAs

- **Opportunity**

- First steroid drug approved worldwide for patients with mild to moderate Ulcerative Colitis
- Use as first line treatment

Rifamycin SV MMX[®] product description

- **Description**

- Broad spectrum, low toxicity, semi-synthetic, orally poorly absorbable antibiotic with activity against Gram-positive and Gram-negative microorganisms and mycobacteria
- Rifamycin SV is an ansamycin
- No cross-resistances have been observed between Rifamycin SV and other antibiotics
- Pre-clinical studies have also demonstrated anti-inflammatory activity when administered directly in the gastrointestinal tract

- **Mechanism of action**

- Bactericidal activity interfering with the synthesis of nucleic acids by inhibiting DNA-dependent RNA polymerase

- **Status**

- Used in Europe as intramuscular or intravenous application since 20 years but considered new chemical entity in USA

Rifamycin SV MMX®: Status and opportunities

- **Status**

- Additional preclinical data required by FDA presented. IND approved in USA.
- Phase III trials starting Q1 2010
 - USA: 2 subsequent Randomized, double-blind, multi-centre trials of Rifamycin SV MMX® 800 mg against placebo, total 400-700 patients
 - EU: 1 Randomized, double-blind, multi-centre trial of Rifamycin SV MMX® 800mg against Ciprofloxacin 1000 mg, 300-400 patients

- **Positioning strategy**

- First indication for Travellers' Diarrhoea which strikes 20-50% of the 80 m persons that travel to the tropics p.a.
- Then move on to:
 - IBD supportive therapy
 - Diverticulitis, a chronic disease that affects more than 60% of people over the age of 60
 - Clostridium Difficile associated disease (CDAD)
 - Hepatic Encephalopathy

LMW Heparin MMX®: Status and opportunities

- **Status**

- Completed phase IIb clinical trials; demonstrated that LMW Heparin MMX®, when associated to 5-ASAs
 - Has no side effects
 - Stops bleeding and is substantially more effective than 5-ASAs
 - Has disease modifying properties
- Mechanism of action work on joint therapy with salicylates, corticosteroids, immunosuppressants and anti-TNFs completed
- FDA meeting in Q3 to determine requirements for trials in US
 - Pre clinical analyses including carcinogenesis tests required
- Advisor meeting with EU Agencies pending to determine requirements for phase III in EU

- **Opportunities**

- Become the maintenance drug of choice for mild to moderate to severe patients

CB-03-01 to treat Acne and Seborrhoea

- **Activity**

- Acts on the skin androgen receptor
- Blocks the binding of androgen hormones to the sebaceous gland receptor, preventing the stimulating effect of androgens on the sebaceous gland
- Has moderate anti-inflammatory activity, similar to hydrocortisone/HC

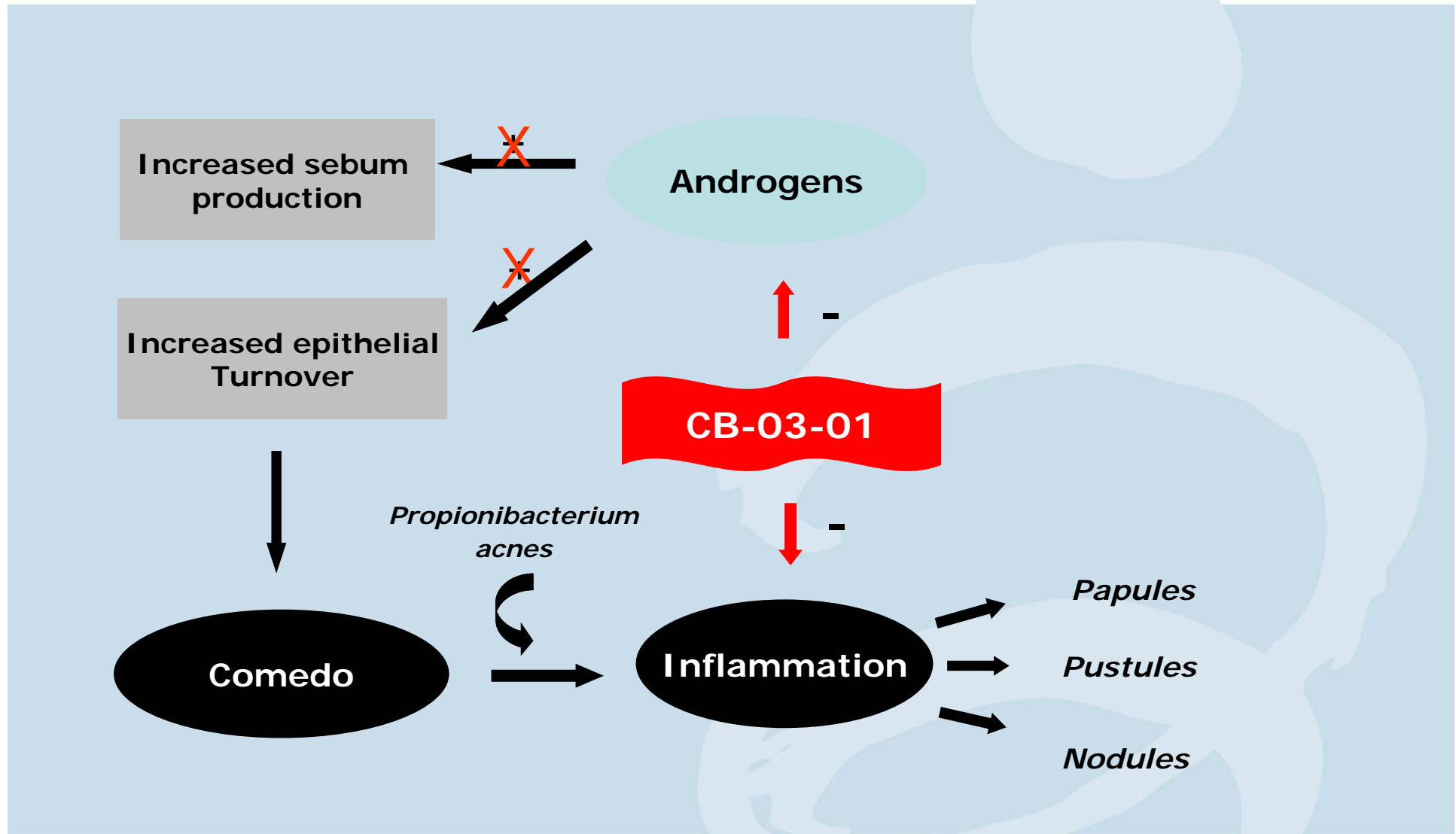
- **Market size**

- 16% of the US population suffer from acne
- 10% of all women have Hirsutism
- 12% of all men have Alopecia

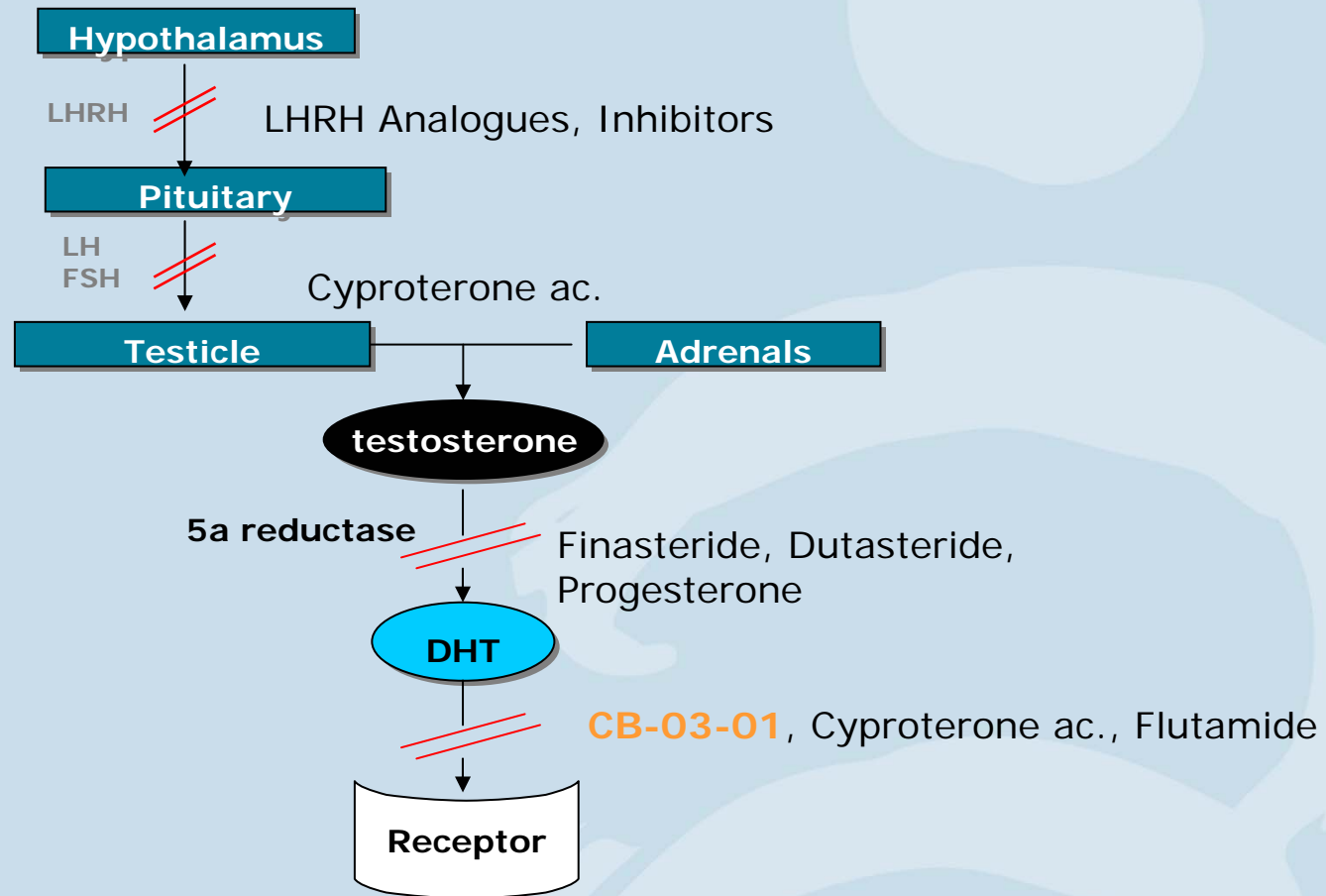
- **Market need**

- A treatment that is effective by topical application and does not cause hormonal imbalance

Pathogenesis of Acne and mechanisms of action of CB-03-01



Endocrine control of androgen-dependent organs, and mechanism of action



CB 03-01: Phase II proof of concept trial

Design:

- 3 arms, randomized, double blind, parallel-groups, control versus placebo and versus Retin A 0.05% cream in facial acne vulgaris in males
- Treatment: single daily topical application for 8 weeks + 2 weeks follow up
- 77 males (18-45 years of age) randomized, 72 evaluated (ITT population) and 67 (PP population)

Clinical end points:

- Total lesion count (TLC), Inflammatory lesion count (ILC), acne severity index (ASI), Investigators global assessment (IGA) assessed at baseline, plus Local Irritancy Score (IS) all assessed after 2,4,6,8 weeks

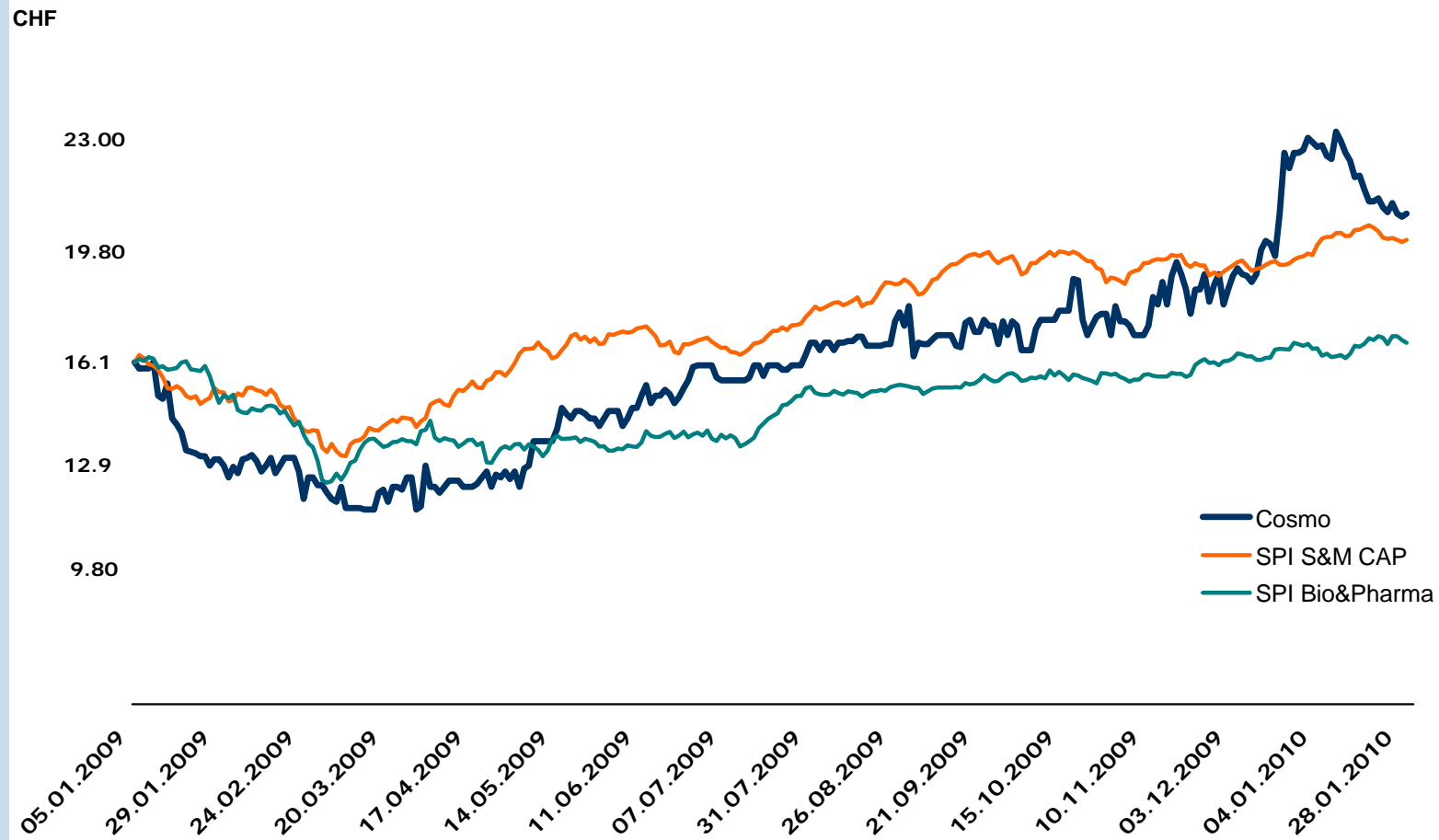
Results:

- Clinically and statistically superior to placebo on all scores and to retin A on all scores except for IGA

MMX® early stage projects

- **CB 01-16 for opioid induced constipation**
 - Brings a well known anti opioid directly to the colon
 - Galenic development concluded
 - Phase I to start Q409
- **Assessment of MMX® application to antibodies, proteins and peptides to treat colonic diseases by oral delivery**
 - IL 10
 - IFN α

Cosmo's share at a glance



2009 Full Year Outlook

- Revenues EUR 27.2 million
- Operating Result EUR 5.3 million
- Net profit EUR 4.6 million
- Financial Debt EUR 3.0 million
- Cash EUR 18.9 million

Milestones and news events 2010

- **Budesonide**
 - Results EU phase III trial Q1/2
 - Results and milestones US phase III trial Q4
- **Rifamycin**
 - Results EU & NA phase III trial in late Q4
- **LMW Heparin**
 - License Agreement 2H
- **CB 03-01**
 - Proof of concept alopecia
- **Opioid constipation**
 - Results phase I

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