

UBS Global Life Sciences Conference

New York

September 22, 2010



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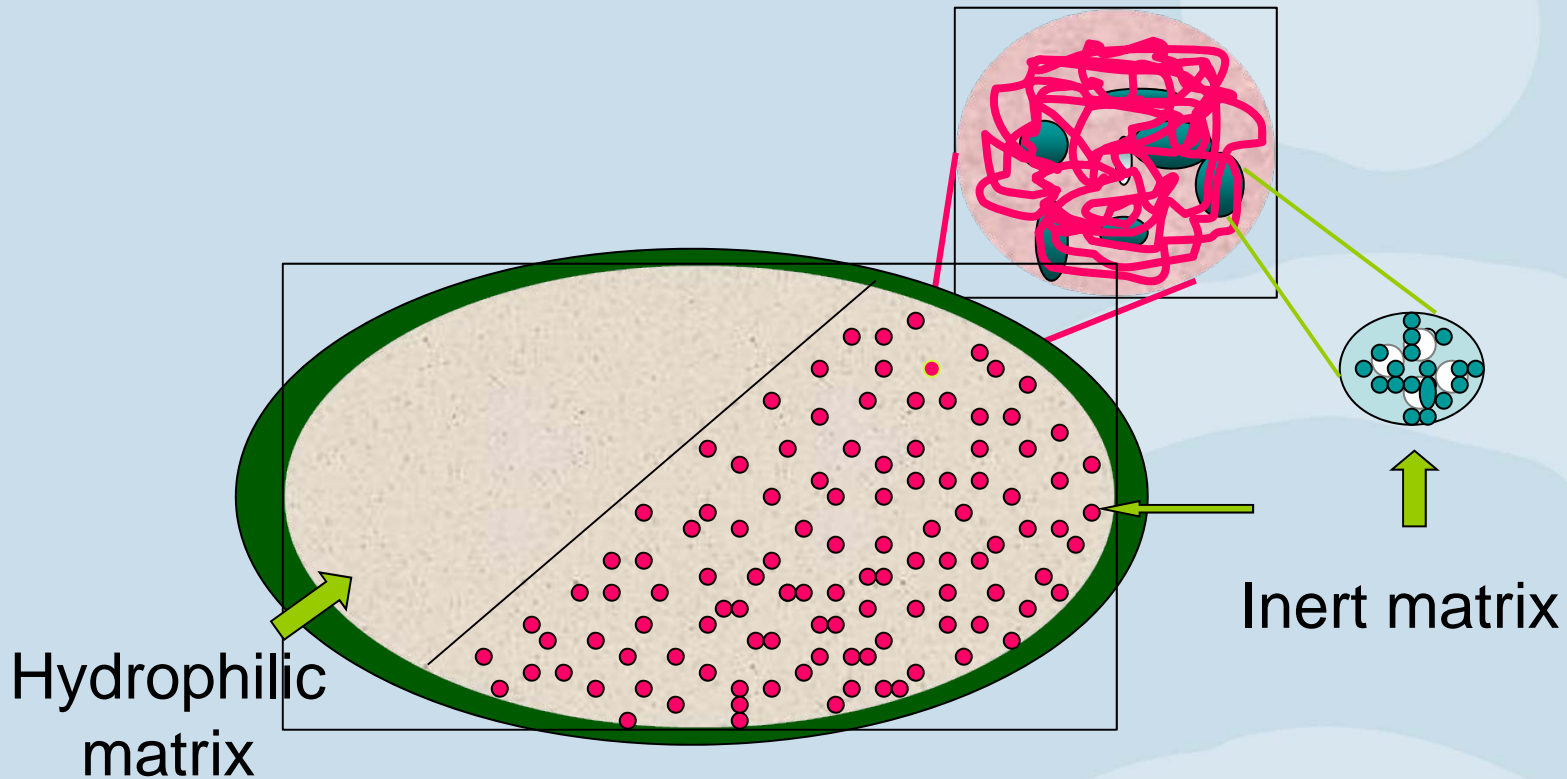
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What makes Cosmo different: the approach

- Entrepreneurial and not science driven approach
- Product development strategy focused on improvements and re-indications assures a much higher success rate than classical biotechs
- Far lower costs per project than classical biotechs
- Contract manufacturing is being focused on more profitable new generics projects requiring specialized delivery competences against total cost coverage and profit share
- Cosmo continues generating at least one new development product per year
- Focus on strongly growing markets:
 - The IBD market is growing at >12% p.a. ; limited big pharma competition
 - Effective topical products for Acne and Alopecia market could make those into very large markets

The basis: the Multi Matrix System™ (MMX™)



Gastroprotectant layer



LV hydrophilic - amphipatic polymer matrix



HV hydrophilic polym. matrix



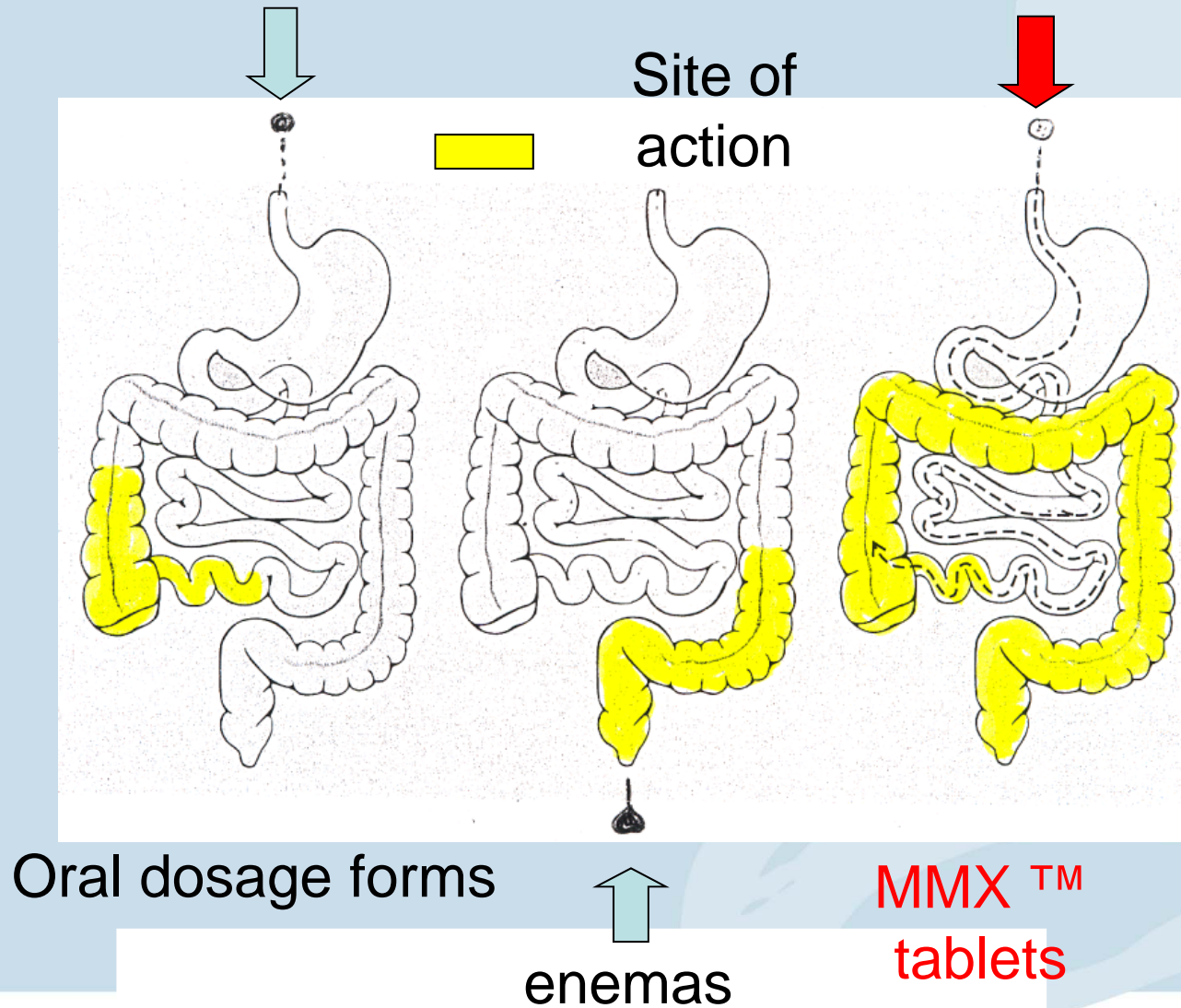
inert matrix material

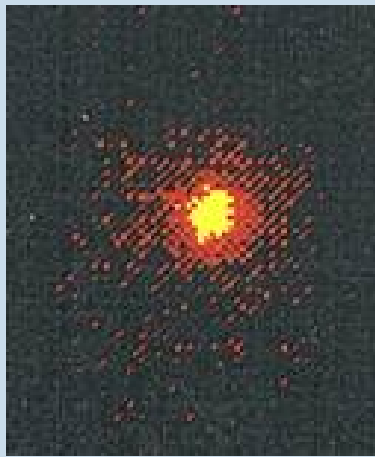


drug (+ excipient)

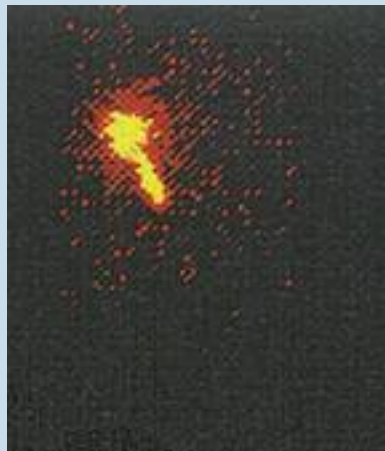
IBD medications: sites of action

MMX™ tablets vs. other dosage forms

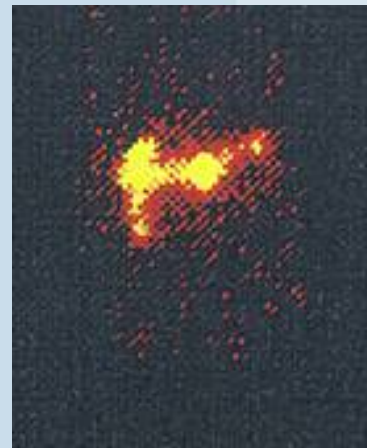




1h 30' duodenum



4h 30' ascending colon



7h 30' transverse colon



10h transverse colon



16h descending colon

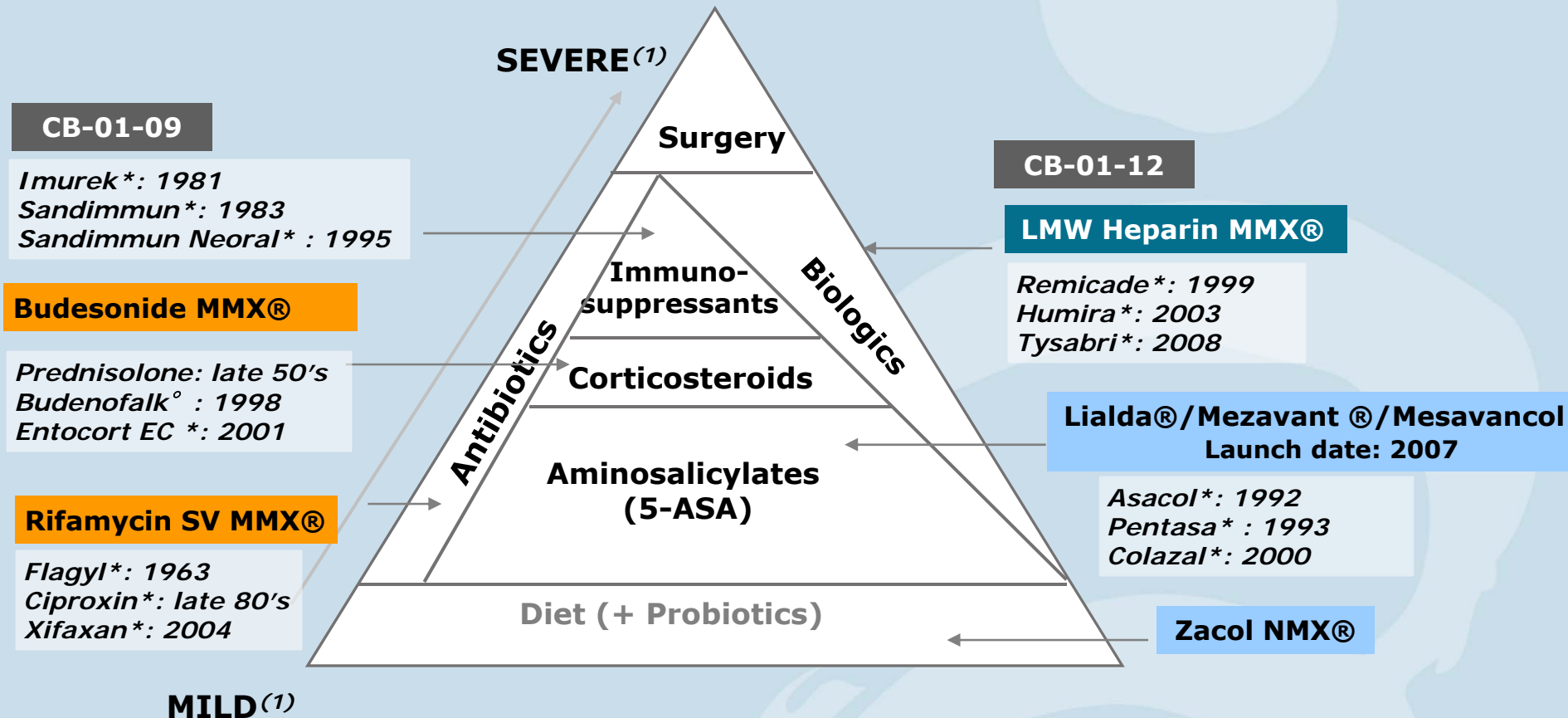


24h rectum

What makes Cosmo different: Results

- Since the IPO in 2007 Cosmo has made money
- Lialda® / Mezavant® / Mesavancol® pre tax income is projected to rise from ~ € 15 m to ~ € 27 m p.a. until end 2014 assuming 100% production:
 - From 2016 on they are projected to stabilize above € 13 m
 - Total development cost for Cosmo was € 1 m
- 6 products in the clinic, each with market potentials of > € 100 m; market entries scheduled for each of the coming years until 2015
- Economic terms in new agreements are 4-5 times better for Cosmo than with Lialda®
- The CEO and 44% shareholder has a total compensation of € EUR 220,000
 - Interests that are totally aligned to outside shareholders

Focus on IBD, a disease with little recent innovation



1. Status of disease severity
 ° EU
 * US

But strong growth and little competition outside anti-TNFs

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

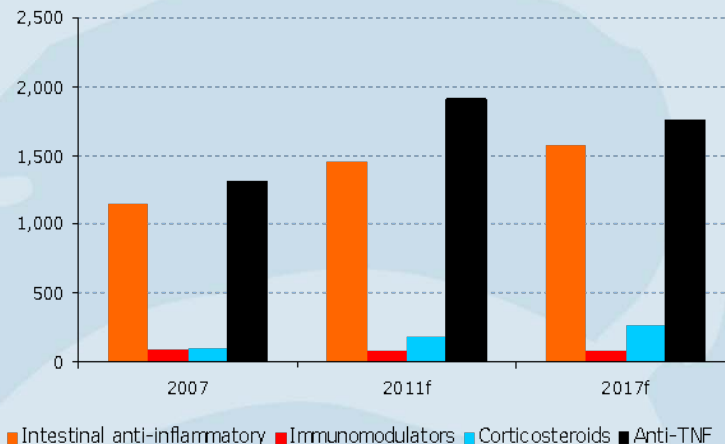
Immunomodulators				
Sandimmune/Neoral	19 m	17 m	15 m	14 m
Purinethol	4 m	5 m	5 m	6 m
Other	64 m	62 m	61 m	61 m
Total	87	84	81	78

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 2008

Cosmo's pipeline

Product and Indication	Drug type	Phase I	Phase II	Phase III	MA	Launch	Partner
Lialda ®/ Mezavant ®/Mesavancol® Mild to moderate Ulcerative Colitis	5-ASA					USA UK ITA	Shire/Giuliani
Zacol NMX® Intestinal Disorders (nutraceutical)	Dietary supplement					ITA	
Budesonide MMX® Mild to moderate Ulcerative Colitis	Cortico-steroid					EU Q4 11/Q1 12 USA Q2 12	Ferring – Worldwide (excluding Japan & USA) Santarus - USA
Rifaximin SV MMX® Travellers' Diarrhoea	Antibiotic				H1/11 EU H2/11 USA		Dr. Falk – Europe & Australia (excluding Italy) Santarus - USA
- Clostridium Dificile			Dose ranging Q4/11				
LMW Heparin MMX® - Induction of remission in M2M UC	Biologic				Q4/11 EU		
- Maintenance treatment for UC of all severities							
CB-03-01 (NCE) Acne	Steroid ester, androgen antagonist	POC					
		Pk & Irrit. Q4/10	Dose ranging Q1/12				
CB-03-01 (NCE) Alopecia	Steroid ester, androgen antagonist						
		Pk Study Q3/11	Dose ranging Q3/12				
CB-01-16 Opioid Induced Constipation	Opioids Antagonist		Q2/11				

An excellent first product: Lialda®

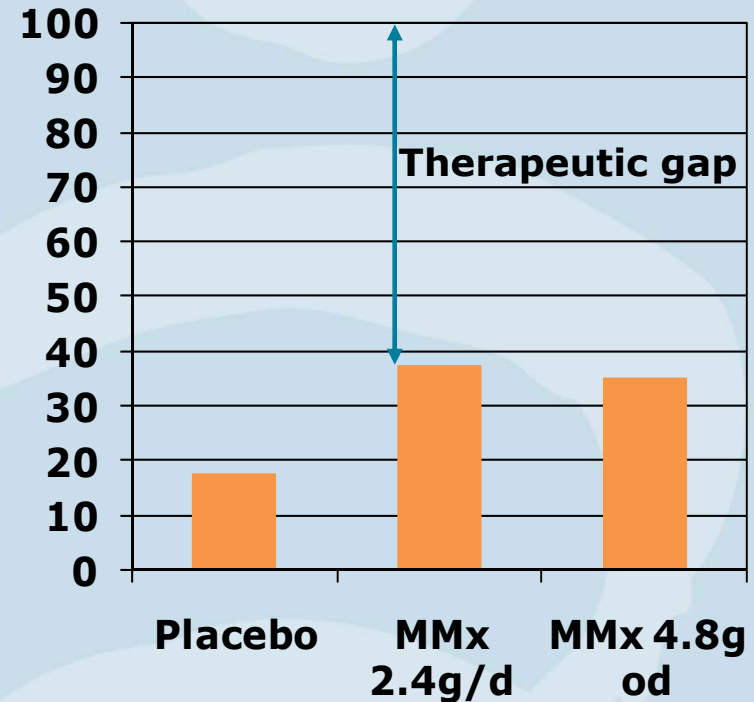
- **Chemical entity mesalamine**
 - An off-patent 5-ASA (amino salicylic acid)
- **Indication**
 - Patients with Ulcerative Colitis of mild to moderate severity
- **Net sales**
 - 2007: Market entry
 - 2009: \$ 237 m
 - 2010: \$ 323 m (Europe will come on-stream) (analysts projections)
 - 2011: \$ 392 m (analysts projections)
- **Competing products (2009)**
 - Asacol \$ 684 m; Pentasa \$236 m; Canasa \$ 95 m all with increased sales but decreasing TRX
 - Zydus filed ANDA for 1200 mg Mesalamine tablets in May 2010; Shire has filed law suit for patent infringement

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



Budesonide MMX®

- **Chemical entity budesonide**
 - A non-halogenated glucocorticoid
 - Greater topical anti-inflammatory activity with less systemic absorption than other glucocorticoids due to high first pass metabolism
 - Approved for use in Entocort for Crohn's Disease
- **Indication**
 - Patients with Ulcerative Colitis of mild to moderate severity
- **Competing drugs**
 - More effective than all 5-ASAs
 - Entry target are patients that do not react to 5-ASAs, i.e. around 30% of patients
 - Subsequently the entire 5-ASA market because corticosteroids are more effective
- **Market**
 - 2009 Entocort sales at \$ 237 m equal to Lialda® for a patient base 2/3 that of Lialda®

Budesonide MMX®: Status and opportunities

• Status

- Patient enrolment completed in EU and the USA for two pivotal phase III clinical trials
 - 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 440 patients; patient eligibility based on UCDAI 4-10. Remission defined as UCDAI ≤ 1
 - Stool frequency score: 0
 - Rectal bleeding score: 0
 - Mucosal appearance score: 0
 - Physician rating score: max 1
 - US Data base locked, EU data base lock in the next 2 weeks
 - Extension study on first 100-150 patients that go into remission (only has exploratory purposes for FDA)

Budesonide MMX®: Business case

- **Market entry**

- USA: H2 2012 expected
- EU: H2 2011 expected

- **Projected peak sales**

- USA: \$150-250 million
- RoW: EUR 100 million

- **Licensing revenue**

- USA: 12-14% royalties; 10% COGS
- RoW: 25-33% total return
- Japan: unpartnered

Rifamycin SV MMX®

- **Chemical entity rifamycin**

- Off-patent, broad-spectrum antibiotic belonging to the ansamycin family, practically not absorbed when taken as a tablet

- **Market need**

- Need for a non-absorbable antibiotic that does not sterilize bacteria in upper gut
- Does not promote bacterial resistance

- **Competing products**

- Xifaxan \$ 110 m in USA projected to grow to \$ 1 billion including various other indications
- Ciprofloxacin € 331 m

- **Partnerings**

- In USA and EU
- Not partnered in Latin America, Asia nor Africa

Rifamycin SV MMX®: Status and opportunities

• Status

- Positioned as new chemical entity in the USA
- Patient recruiting for phase III trials in the US ongoing and in the EU pending
 - Primary clinical endpoint: time to last unformed stool
 - EU trial is a single phase III trial on around 700 patients 400 mg b.i.d. X 72 hours non inferiority vs Ciprofloxacin 500 mg b.i.d
 - US trials are two consecutive phase III studies on 300 patients each 400 mg b.i.d. X 72 hours superiority vs. placebo

• Opportunities

- Highly effective against Clostridium Dificile Assoc Disease (CDAD)
- Very effective against Hepatic Encephalopathy
- Given its anti-inflammatory properties, Rifamycin SV MMX®
 - Could also be used for IBD supportive therapies
 - Could be the drug of choice for the treatment of Diverticulitis, a chronic disease that affects more than 60% of people over the age of 60

LMW Heparin MMX®

- **Completed phase IIb clinical trials; demonstrated that LMW Heparin MMX®, when associated to 5-ASAs**
 - Endogenous substance: has no side effects
 - Stops bleeding and is substantially more effective than 5-ASAs
 - Has disease modifying properties
- **Presented LMW Heparin MMX® at DDW 2009 in Chicago**
 - Wide range of immunomodulating activity inhibiting pro inflammatory cytokines TNF α , Interferon γ , IL2
- **Possible target indication expanded to maintenance of remission for UC patients of all severity**
- **FDA meeting for phase III preparation**
 - LMW Heparin presently not approved in the USA, i.e. it is a new chemical entity
 - Full preclinical tests required including carcinogenicity tests
- **EU partnering discussions and discussions for phase III trial design planned in Q4 2010**

CB-03-01: Anti-androgen for topical applications

- **Mechanism of action**

- Acts at the level on the skin androgen receptor only; blocking the binding of androgen hormones to the sebaceous gland preventing their stimulating effect; has moderate anti inflammatory activity similar to hydrocortisone

- **Potential indications**

- Topical treatment of Acne and Androgenetic Alopecia (currently under clinical development)
- Hirsutism (future developments)

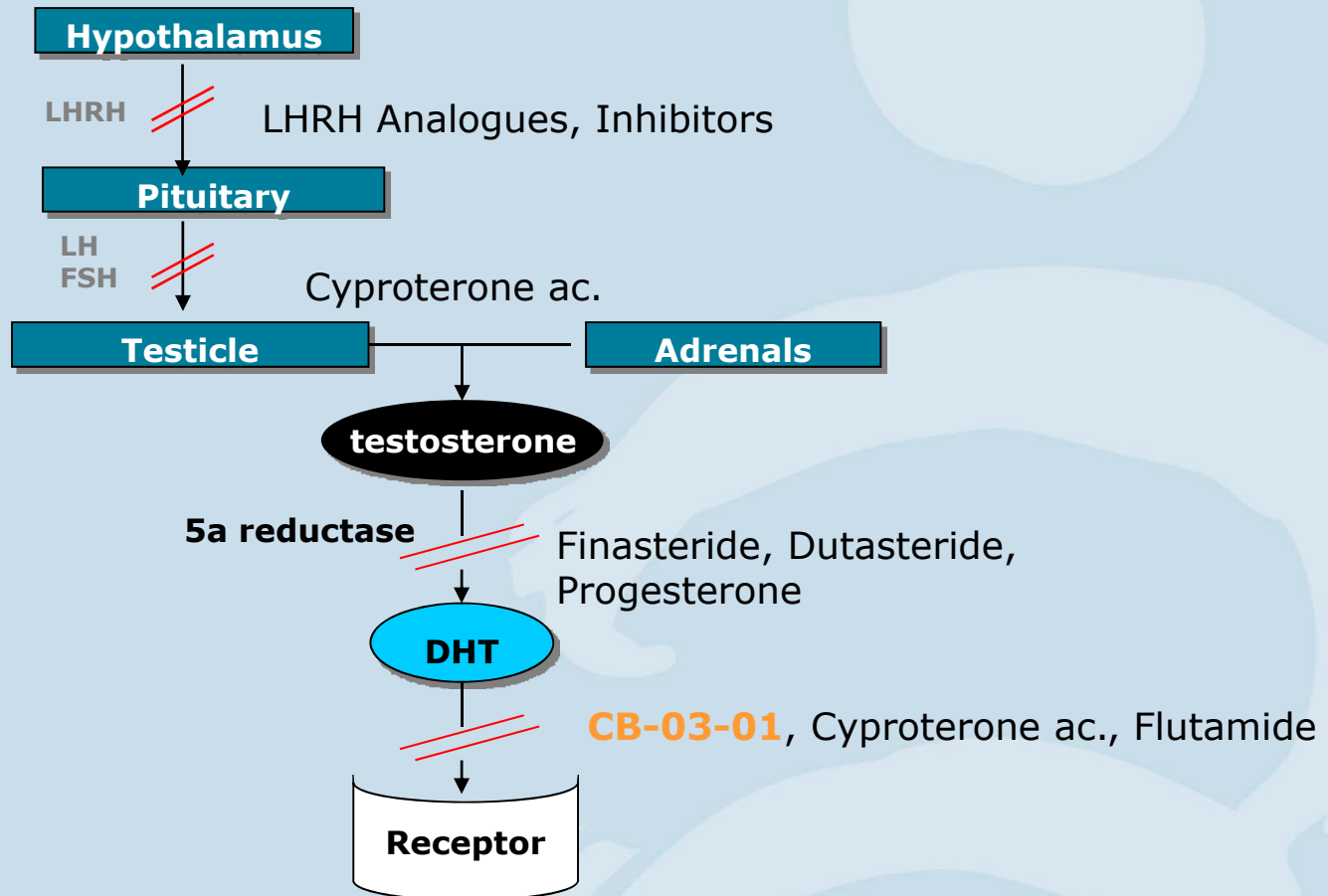
- **Market size**

- 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
- Is not a skin irritant
- Does not cause hormonal imbalance

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



CB-03-01: acne formulation; next steps

- **Completion of Phase I study**
 - Reprotox study in pregnant female rats and rabbits
 - Repeated doses PK study on 12 volunteers
 - Irritability and sensitivity study on 24 males and 12 females
 - Completion by December 2010
- **Determine partner**
- **Dose finding study and phase II study**
 - Position drug in moderate to severe acne
 - 120-150 males and women, treatment for 8-12 weeks, duration likely 9-12 months, start possible Q1 2011
- **Phase III**
 - 2 times >500 patients, start possible Q1 2012
- **Earliest market entry**
 - 2014

Androgenetic Alopecia

Basis

- In the anagen phase cells continuously split and create the hair shaft. This phase lasts for 2-6 years. In the catagen phase the hair-root cells die and the hair stops growing. In the telogen phase the hair shaft stays in the hair channel and then falls out.
- Normally grown ups have 85'000 to 150'000 hairs of which 80-90% are in the growth phase

Incidence of Androgenetic Alopecia

- In the US up to 50 m persons suffer hair loss, in the EU up to 90 m persons, around 40% seek treatment, between 10% and 20% use prescription drugs, the rest cosmetics

Causes

- Androgenetic alopecia is caused by testosterone which is produced as a body own substance and is converted into di-hydrotestosterone by the enzyme 5 α reductase. Di-hydrotestosterone binds to androgen receptors of the hair follicle and it is presumed that it reduces the blood circulation necessary to keep the follicle alive. Growth processes in the anagen are blocked which induces the catagen phase, causing a miniaturization of the hair shaft, causing hair to fall out quicker

CB-03-01: alopecia formulation; phase II proof of concept study

- **Study size**

- 70 volunteers (40 men (Hamilton); 30 post menopausal women (Ludwig))

- **Treatment**

- 5 treatments via ionophoresis. This reduces compliance risks
- Two concentrations of CB 03-01 (1% and 5%) for men and women
- Comparators are ciproterone acetate 1% (women) and 17 α estradiol 1% (men)

- **Evaluation criteria**

- Hair thickness
- Follicle density (1 cm²)
- Pull test
- Dimension of sebaceous gland
- Diameter of hair

- **Time line**

- Study started in March 2010; data available October 2010

Preliminary results of proof of concept analysis

1 week after treatment	base	CB 03-01; n=50	Ciproterone Acetate n= 10	17 α estradiol n= 10
Shaft diameter in mm	0.41	0.66	0.51	0.53
improvement	=	79%	59%	61%
Pull test	3	70%	43%	46%
1 month after treatment	base	CB 03-01	Ciproterone Acetate	17 α estradiol
Shaft diameter in mm	0.41	0.86	0.66	.65
improvement	=	88%	64%	61%
Pull test	3	70%	58%	56%

Market opportunity

Market potential

- **It is presumed that around 40% of men between 20 and 65 suffer hair loss**
 - up to 40% of these try to do something about it
 - Around 20% of these are willing to use drugs
- **Up to 50% of all women after menopause suffer hair loss**
 - Up to 60% of these try to do something about it
 - Around 33% of these are willing to use drugs

FDA approved drugs

- **No topical anti androgen approved**
- **Propecia**; an alpha 5 reductase inhibitor, taken as a tablet, had revenues of \$ 429 m (2008)
- **Minoxidil/Regaine/Rogaine** are vasodilators and are off patent

CB-03-01: alopecia, next steps

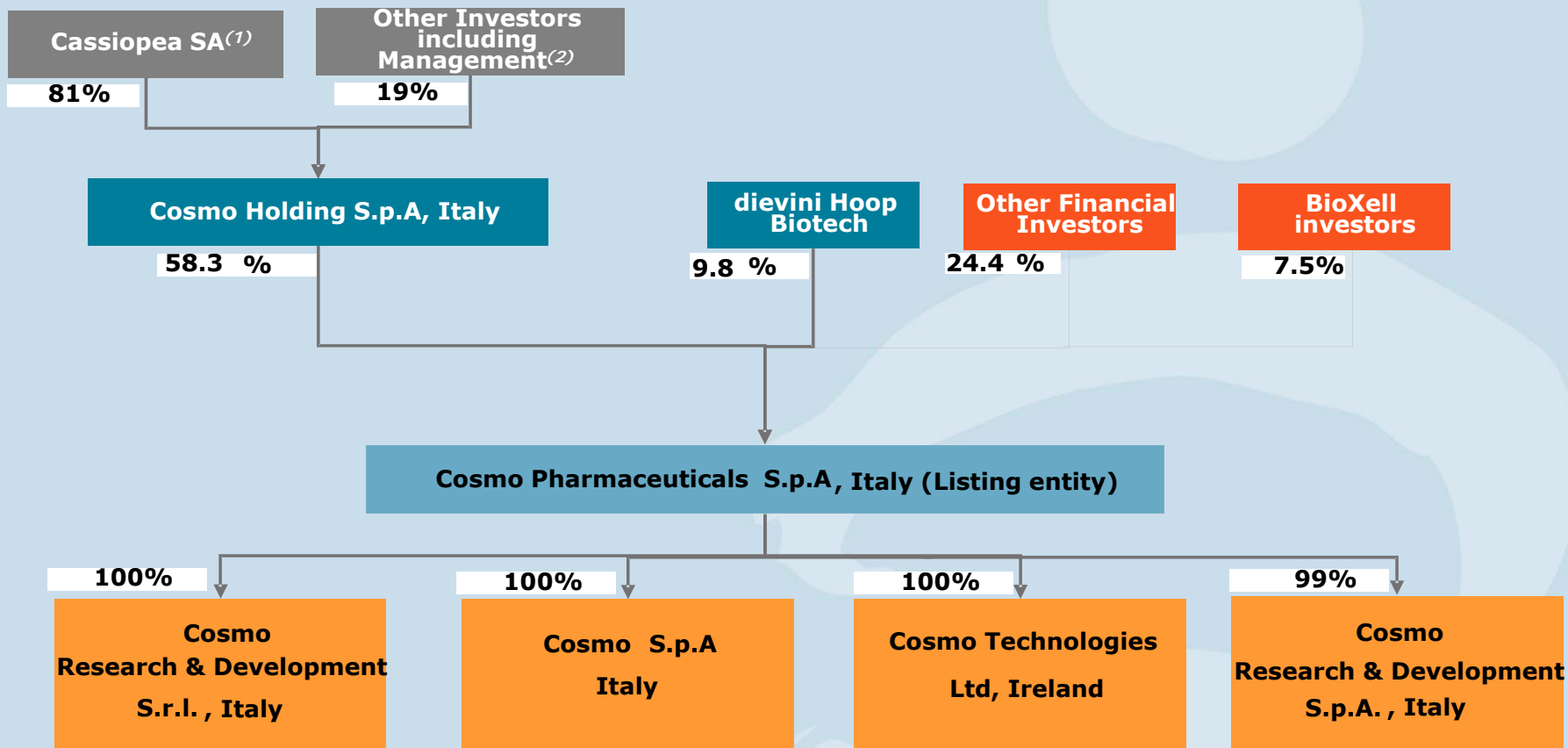
- **Development of formulation**
 - To be completed by the end of 2010
- **PK study and irritability and sensitivity study**
- **Determine partner**
- **Dose finding study and phase II study**
 - Requires 6-12 months treatment
 - Probably against Minoxidil
- **Phase III**
 - 2 pivotal trials of >500 subjects each
- **Earliest market entry:**
 - 2015

CB-01-16: opioid antagonist MMX

- **Chemical entity: Naloxone**
- **Mechanism of action**
 - Naloxone is a powerful, off patent, opioid antagonist that displaces opioids from the cell receptor
- **MMX application**
 - MMX technology brings Naloxone to the colon only where it displaces the opioid from the MU receptor thus freeing peristaltic movements
- **Market size**
 - Around 230 m prescriptions are written for opioids in the US, around 400 m in the world. Between 40% and 90% develop constipation, practically all that need to use opioids chronically
- **Status**
 - Phase I with dose escalation to start in September
- **Market need; competition**
 - Currently no tablet is approved for use
 - NKTR 119 uses Naloxol and delivers this through pegylation technology. Was licensed to AZ. Is in phase II

Organisation and Shareholding Structure

(as of 17-09-2010)



TOTAL N. OF EMPLOYEES 141

Source: Company information

1. Controlled by the Ajani family

2. Management holds 10%

A whole range of projected launches

	2011	2012	2013	2014	2015
Budesonide MMX®	EU	USA			
Rifamycin SV MMX®		EU	USA		
LMW Heparin MMX®			EU		USA
CB-03-01 Acne				EU&USA	
CB-03-01 Alopecia					EU&USA
CB-01-16					EU&USA

Outlook for 2010: Recurring Revenue growth, continued profitability, pipeline expansion

- Revenues projected at around € 30.5 million (+10%)
 - Analysts project Lialda® sales to increase to \$ 323 m ie by 36%. Royalties and manufacturing income are expected to increase accordingly.
 - Contract Drug Manufacturing revenue should increase by > 10%
 - License fees of € 2 million budgeted; no assumptions for CB-03-01 licensing agreement(s)
- Stable COGS ratio
- Positive EBITDA, PAT and no cash consumption
- Possible data from first trial of Rifamycin SV MMX®
- Cash position maintained; no external financing required

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