

Jefferies 2011 Global Healthcare Conference

London

September 28, 2011



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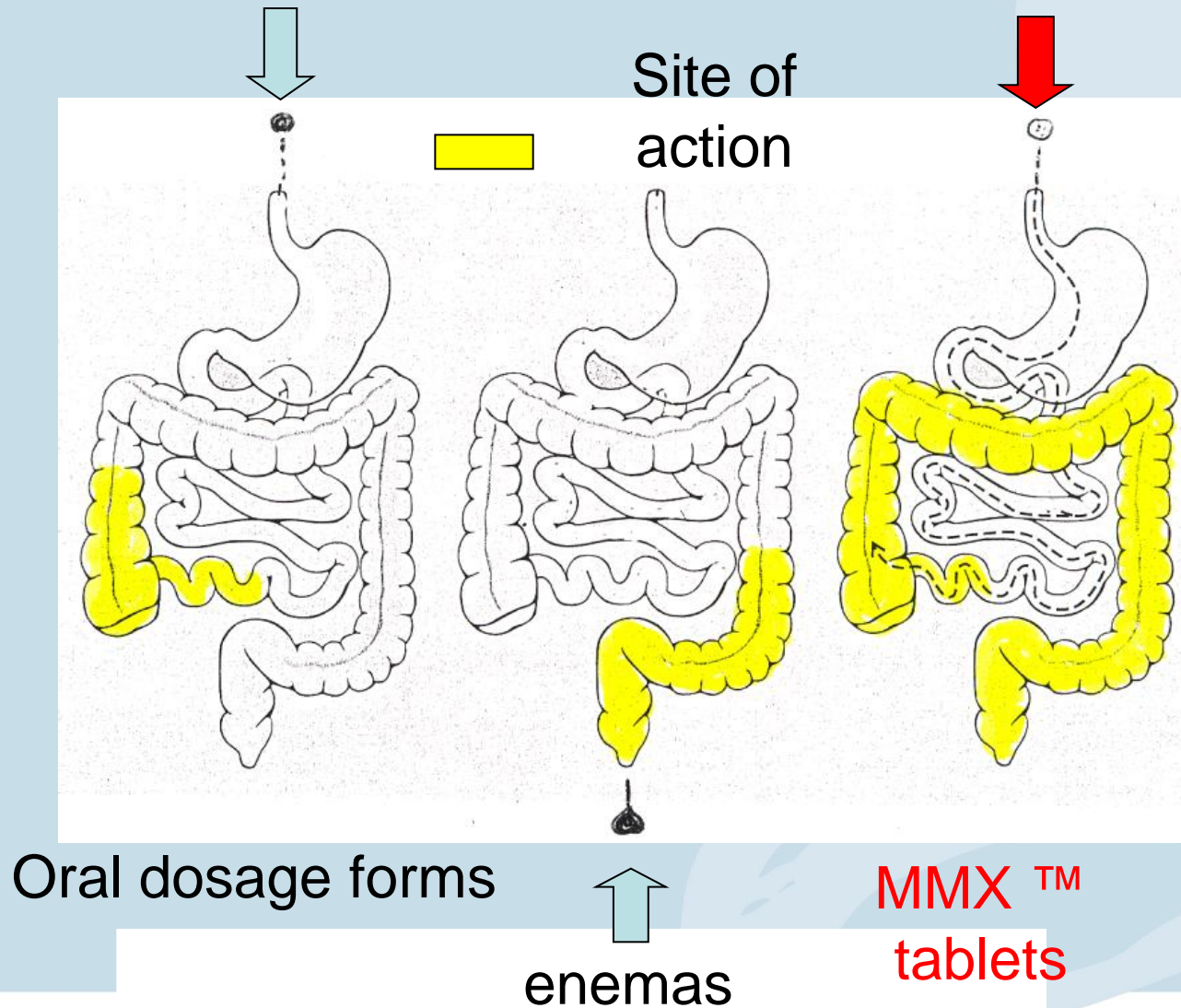
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Cosmo's entrepreneurial approach

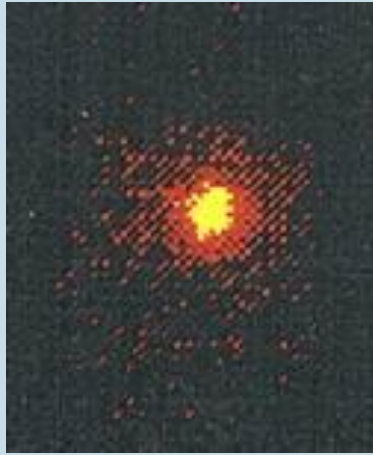
- **Use skills in complex manufacturing as starting point and USP**
 - Key manufacturing skills came with the team of specialists acquired with the main plant of Warner Lambert/ Parke Davis in Italy
 - This led to the development of the MMX technology
 - Business model is to identify applications for the MMX technology
 - **Focus on growth markets with little big pharma competition**
 - The Inflammatory Bowel Disease (IBD) market is growing at >12% p.a.
 - Skin is an area of enormous interest to consumers but few new products
 - Colon diagnostics and constipation
 - **Product development strategy primarily focused on improvements and re-indications**
 - Seek to develop one new product per year
 - Keep project costs low
 - Develop low risk projects with higher success rates than NCEs
- Be entrepreneurial**
- Only spend cash you have, keep costs low
 - Establish proof of concept before incurring high costs

IBD medications: sites of action

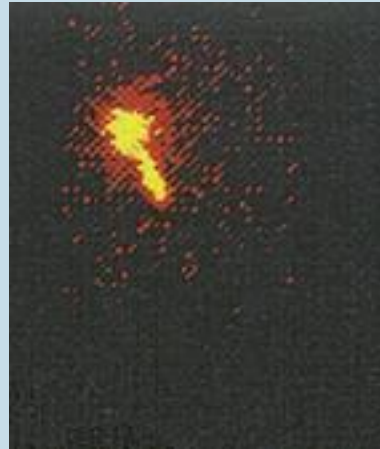
MMX™ tablets vs. other dosage forms



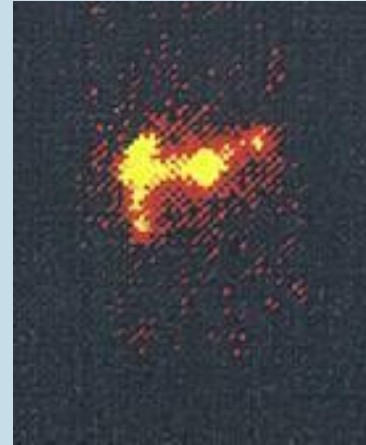
MMX: Proving extended release and persistence of radioactive traces released by MMX in gut



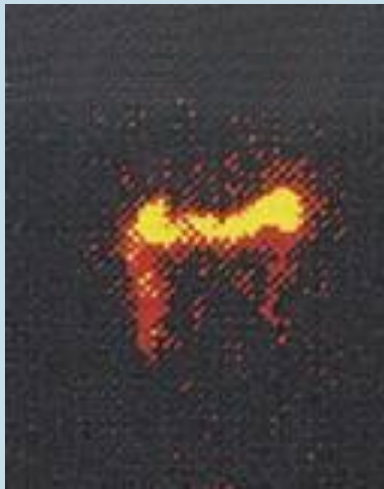
1h 30' duodenum



4h 30' ascending colon



7h 30' trasverse colon



10h trasverse colon

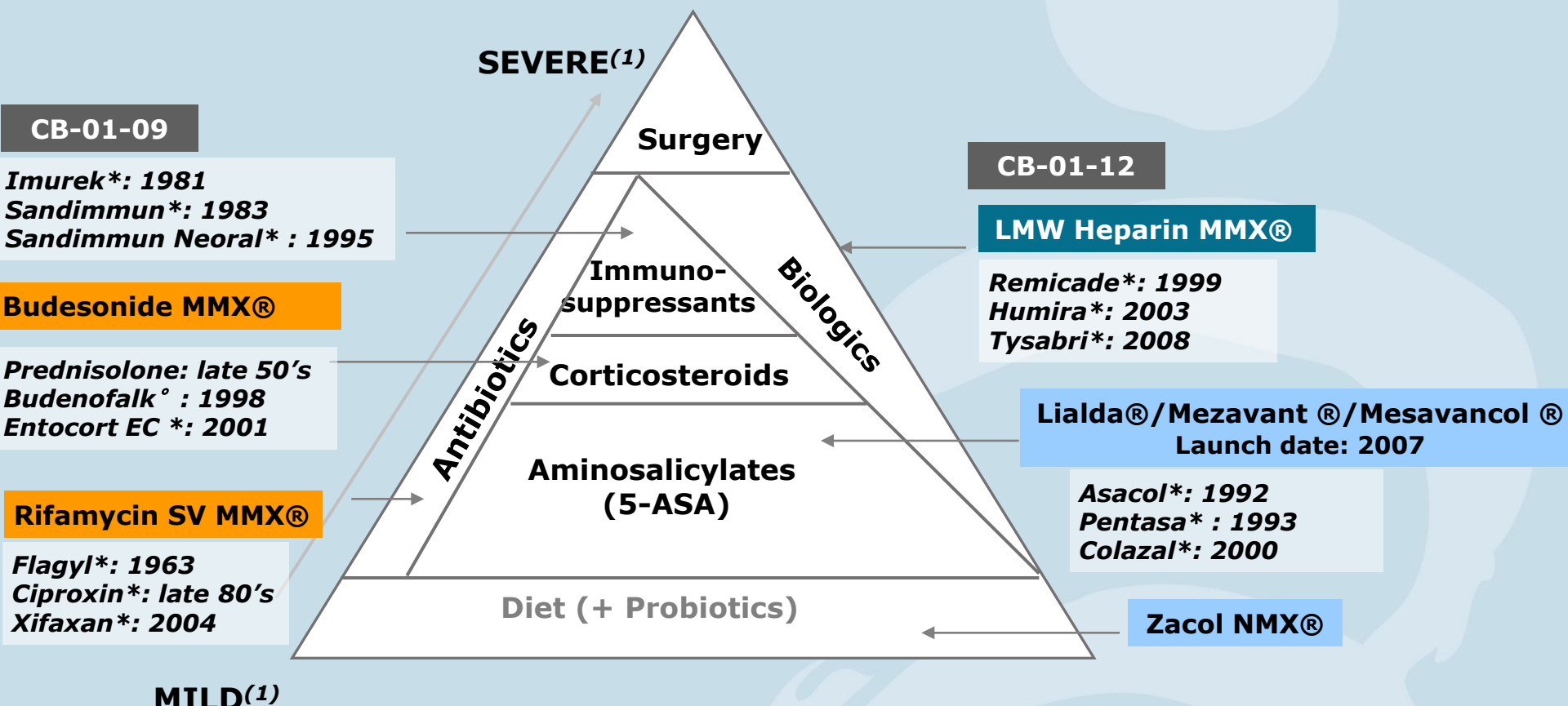


16h descending colon



24h rectum

Focus on IBD, a disease with little recent innovation, has made Cosmo one of the most complete IBD companies



1. Status of disease severity
 ° EU
 * US

Cosmo's safe, continuous development

key numbers in EUR m	2007	2008	2009	2010
Total recurring revenue	18.4	23.7	24.6	29.4
Non recurring revenue	3.5	10.4	2.1	2.6
total revenue	21.9	34.1	26.7	32.0
operating result	-0.2	11.2	4.4	4.8
PAT	0.1	9.4	4.0	3.6
Cash	25.5	22.2	17.2	28.4
Investments	0	6.8	19.2	18.2
total assets	47.2	57.8	71.5	91.8
total equity	35.1	43.2	59.8	58.4

Product pipeline: Progress in all projects; no project failures

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 EU		Shire/Giuliani
Zacol NMX® Intestinal Disorders (nutraceutical)	Dietary supplement					ITA	3 EASTERN EUROPEAN COUNTRIES	Dr. Falk
Budesonide MMX® Mild to moderate Ulcerative Colitis	Corticosteroid	2009		2010		EU H1/12 USA H2/12	Ferring – Worldwide (excluding Japan & USA) Santarus - USA	
Rifamycin SV MMX® Travellers' Diarrhoea	Antibiotic	2009		2010	H2/11 EU H1/12 USA		Dr. Falk – Europe & Australia (excluding Italy) Santarus - USA	
LMW Heparin MMX® - Induction of remission in UC - Maintenance treatment for UC of all severities	Biologic	2009		2010	H2/12 EU			
CB-17-01 Chromendoscopy	Diagnostic	2010	H2/11					
CB-01-16 Opioid Induced Constipation	Opioids Antagonist	2010	Q4 11					
CB-03-01 (NCE) Acne	Steroid ester, androgen antagonist	2009	2010	Dose ranging H2/12				
CB-03-01 (NCE) Alopecia	Steroid ester, androgen antagonist	2009	2010	Dose ranging H2/13				

The first product: Lialda®

- **Basics**

- Mesalamine is an off-patent 5-ASA (amino salicylic acid).
- Licensed to Giuliani/Shire.
- Market entry in March 2007 for induction of remission in mild to moderate UC. 2010 revenue reached \$ 293.4 m. 2011 analyst projections \$ 350 m.
- July 2011 additional indication for maintenance. 2011 announcement of phase III diverticulitis trials expected.

- **Economics**

- Royalties of ~4% capped, manufacturing income of ~3%. Cosmo product pre tax income is projected to rise from € 15.6 m (2010) 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 € 2 m

- **Competition**

- Competing products in 2010 were Asacol \$ 728 m; Pentasa \$255 m; Canasa \$ 104 m all with increased sales but decreasing TRX
 - Zydus filed ANDA for 1200 mg Mesalamine tablets in May 2010; Shire has filed a law suit for patent infringement

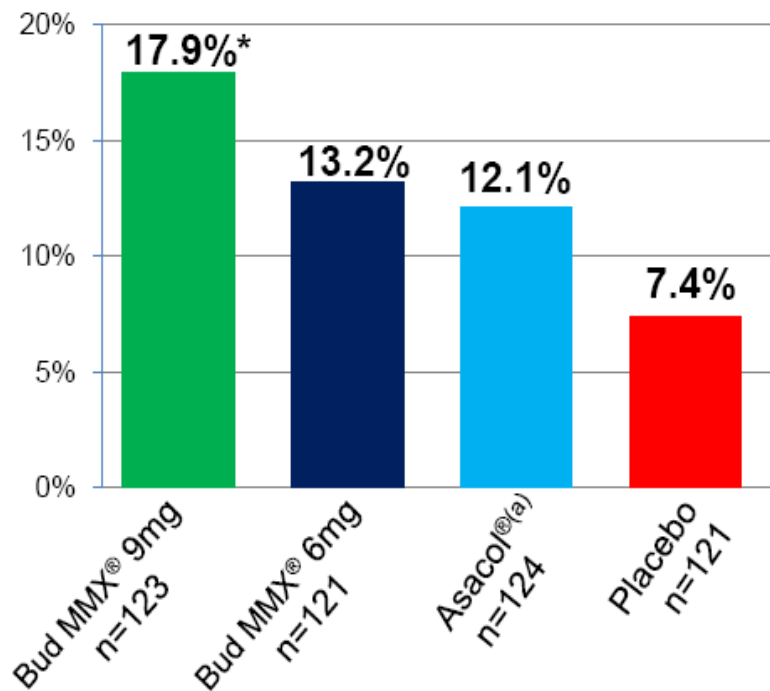
Budesonide MMX®: Status and Opportunities

- **Status**
 - MAA filed in EU end May;
 - US extension study endpoints attained; NDA filing in USA H2 2011 expected
- **Market entry**
 - Around 1 year later

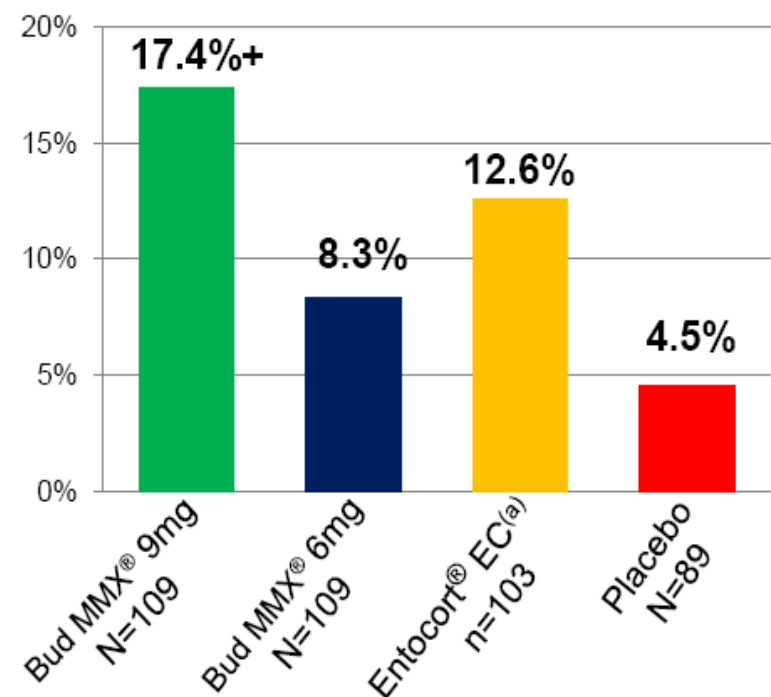
Budesonide MMX[®] 9 mg - Positive Results in Induction of Remission of Active Ulcerative Colitis

Remission rates after 8 weeks of treatment

U.S. Phase III Clinical Study



E.U. Phase III Clinical Study



Statistical analysis plan intent to treat population excludes patients who had normal histology at baseline, GCP violations or major entry criteria violations. A total of 20 patients in US study and 101 patients in EU study were excluded.

*Statistically significant vs placebo at $p=0.0143$

+Statistically significant vs placebo at $p=0.0047$

Statistically significant vs placebo at $p=0.05$

Budesonide MMX[®] Generally Well Tolerated

Treatment related AE data from U.S. and E.U. studies

Treatment Arm	Treatment Related AEs U.S. Study	Treatment Related AEs E.U. Study
Budesonide MMX [®] 9 mg	28.3%	25.8%
Budesonide MMX [®] 6 mg	27.8%	21.9%
Asacol [®] (mesalamine)	24.4%	-
Entocort [®] EC (budesonide)	-	23.0%
Placebo	26.4%	24.0%

Top-line study results indicate that budesonide MMX[®] 9 mg and 6 mg were generally well tolerated and the frequency of treatment related adverse events was similar across all treatment groups.

Budesonide MMX 6 mg Extended Use Study

Top-line study results will be provided in support of NDA for induction of remission planned for December 2011

- 12-month extended use study undertaken to evaluate the long-term safety and tolerability of budesonide MMX 6 mg
- Frequency of treatment related adverse events for budesonide MMX 6 mg (21.0%) was similar to placebo (21.3%)
- Mean plasma cortisol levels for budesonide MMX 6 mg and placebo remained within normal limits at all visits
- No clinically meaningful differences in the numbers of patients with abnormal bone mineral density scans at end-of-study between budesonide MMX 6 mg and placebo
- Exploratory efficacy data
 - Primary endpoint of maintenance of remission was not statistically different between budesonide MMX 6 mg and placebo
 - Positive trends for secondary endpoint of clinical relapse

Budesonide MMX®: Status and Opportunities

- **Market**

- In USA there is no steroid approved for mild to moderate UC
- 2010 Entocort sales in US reached \$ 337 m for Crohns (patient base 2/3 the size of UC)

- **Product USP**

- More effective than Asacol and minimal side effects
- One tablet a day

- **Projected peak sales**

- USA \$ 300 million (Santarus projection); RoW EUR 100 million
 - targeted at the ~30% of patients that do not react to 5 ASA's
 - After assessing safety data the entire 5 ASA market could be targeted

- **Licensing revenue**

- USA: licensed to Santarus; 12-14% royalties; plus ~10% COGS for US
- RoW: 25-33% total return
- Japan: un-partnered
- Projected value to Cosmo: \$ 134 m pre tax PV per \$100 m peak sales

(1)Discount rate 10%, 10 years product life

Rifamycin SV MMX®: Status and Opportunities

- **Indication**

- Travellers and Infectious Diarrhoea

- **Status**

- Positioned as New Chemical Entity in USA
- Patient recruiting for Phase III trials in EU & US ongoing
 - EU trial is for non inferiority to Cipro in infectious colitis. ~279 out of 776 patients recruited. Interim Analysis expected Q4 2011/Q1 2012
 - US trial is for superiority against placebo. 2 pivotal trials planned. 169 out of first 262 patients recruited. Recruitment slow because student language courses in Mexico have suffered because of violence risk

- **Opportunities**

- Sister molecule of Rifaximin (Xifaxan/Salix; 2010 revenues \$ 340 m)
- Very effective against Hepatic Encephalopathy
- Could be used for Diverticulitis
 - More than 60% of people over the age of 60 have diverticulae
 - In 10-20% of cases the diverticula get infected and inflamed
 - No drug is currently approved for this disease
- Second indication will be determined by Falk and Santarus this year
- Proj. value to Cosmo: pre tax PV of \$ 110 m per \$ 100 m peak sales

CB -17-01 Methylene Blue MMX: opportunity for colon diagnosis

- **Chemical entity**
 - new formulation of Methylene Blue
- **Mechanism of action**
 - depicts cellular structures in the mucosal (gut) tissue
- **Indication**
 - IBD and colon cancer diagnostic
- **Advantages**
 - Taken pre colonoscopy, stains the entire colon, increases yield on identifying mucosal lesion by a factor 3-8
- **Cost of colon cancer**
 - Colon cancer strikes 47.2 out of 100'000 persons. Cost is \$ 38'000 to \$ 85'000 p.a. per patient
- **Market size**
 - ~20 million colonoscopies performed p.a. in USA and EU. Market potential is the ~ 364 m persons that are >50 in 7 major markets
- **Competition**
 - local non approved liquid applications sprayed via endoscope

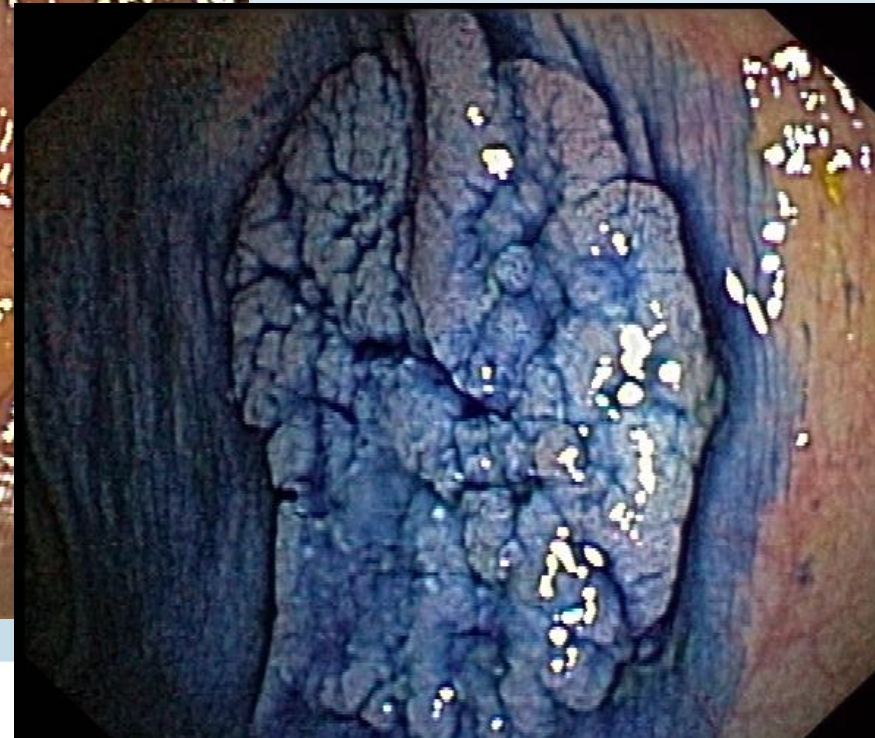
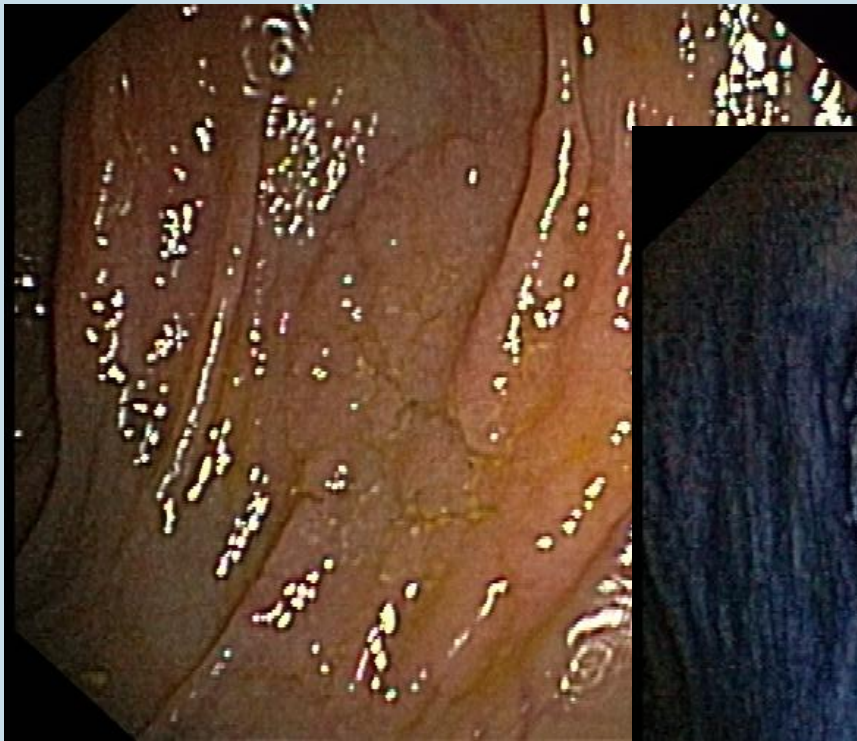
Flat and Depressed Lesions are difficult to see



*The Paris endoscopic classification of superficial neoplastic lesions
Gastrointest Endosc 2003*

Chromoendoscopy

**Old Technique ('70s)
Developed by Japanese Authors**



CB -17-01 Methylene Blue MMX: status and way forward

- **Status:**

- Supply agreement for a new formulation industrial grade methylene blue signed
- Galenic development completed
- Proof of concept attained
- Phase II dose ranging study to optimize staining procedure initiated in late April
 - 100-120 patients
 - Cost ~ EUR 150'000
 - Completion expected Q4 2011

- **Way forward**

- Phase III planned for 2012
- Market entry possible late 2013

LMW Heparin MMX®

- **The market for maintaining remission could be as large as the market for inducing remission**
 - Objective is to prolong remission until next relapse
 - Inhibitors hamper new inflammation thus prolong remission
 - Best inhibitors are biologics such as anti TNF α 's
 - None are approved, very expensive, may have serious side effects
 - Decision to target LMW Heparin in maintenance of remission for all levels of severity
 - LMW Heparin inhibits human intestinal epithelial cell inflammatory responses to TNF α , IL 6 and IL 1b
 - It inhibits CD 4+T cells inducing Th1 and Th2 polarization
- **Decision to launch phase II proof of concept trial for maintenance of remission**
 - >150 patients with documented history of UC, in remission, normal stools, absence of rectal bleeding, normal mucosa
 - Number of patients maintaining remission 1,3,6,9,12 months vs placebo
- **US activities to be developed together with a strong US partner**

IBD Market position

- **Cosmo has one of the most comprehensive IBD portfolios in the industry**
 - all ranges of products from colon health products, to 5 ASA's, steroids, biologics, anti-infectives and diagnostics
 - To date there has not been a product failure
 - Cosmo has a very low cost in developing products
 - Cosmo is one of very few developing companies that manufactures. This reduces generic risks and gives additional opportunities
- **The IBD market value grew by >20% p.a. in the last 2 years**
- **There are very few new products in sight, two of which are from Cosmo**
- **Cosmo is increasingly recognized as an innovator in colon diseases and presented 3 different papers at DDW in Chicago in May**
 - Prof Dr. W. Sandborn: Budesonide 9 mg clinical trial in US and India
 - Prof Dr. S.Travis: Budesonide 9 mg clinical trial in EU,RU,Isr and AU
 - Prof Dr. A.Repici: A new tool for pre-colonoscopy dying of colonic mucosa with oral MMX technology

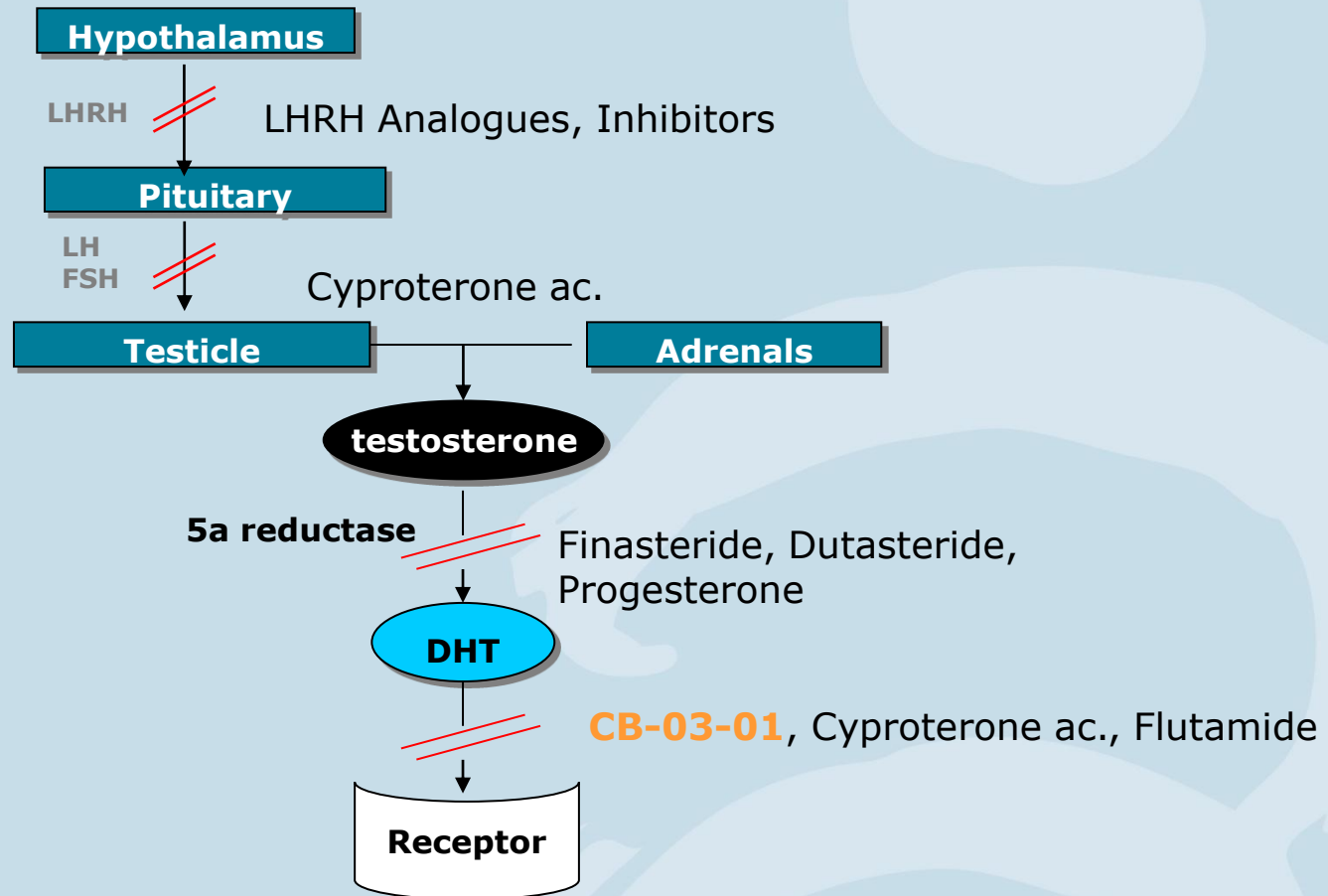
CB-03-01: Anti-androgen for topical applications

- **Chemical name**
 - *Cortexolone 17a-propionate*
- **Therapeutic Area** *Antiandrogenic (ATC D11 AX)*
 - New Chemical Entity (NCE) with anti-androgen properties, under development for topical treatment
 - Anti-androgen without systemic effects
 - Acts on the skin androgen receptor (AR) only, blocking the binding of androgens to the AR located in the sebaceous glands and in the hair follicles; has moderate anti-inflammatory activity similar to hydrocortisone
- **Medical need**
 - A treatment for acne, seborrhoea, alopecia and hirsutism that is effective by topical application
 - A topical treatment for acne that provides a reliable alternative to retinoids (poorly tolerated and presence of side-effects) and antibiotics/anti-infectives
 - Is not a skin irritant
 - Does not cause hormonal imbalance

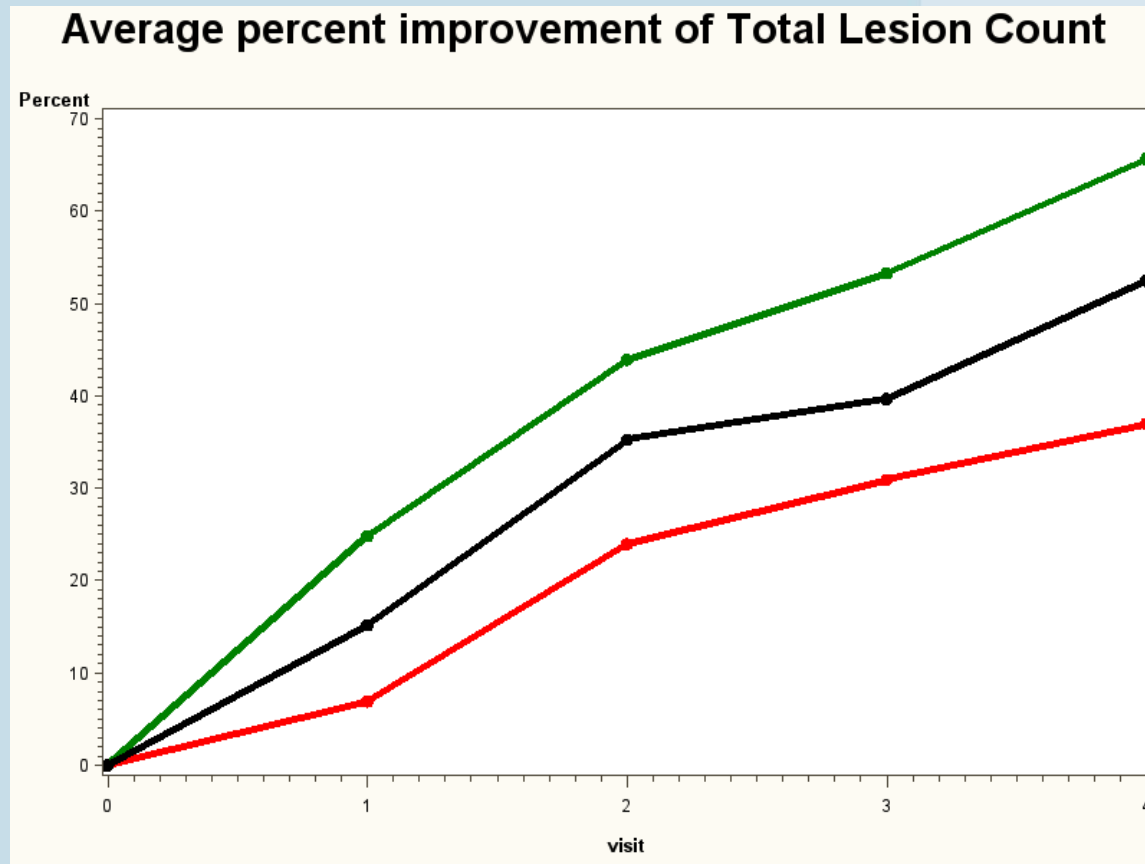
The market in acne and alopecia

- **Very high unmet needs**
 - 16% of US population suffer from acne
 - 12% of all men have Alopecia
 - 10% of all women have Hirsutism
- **Old concepts**
 - Acne
 - 157 approved products, heavily genericized market
 - 60% of non generic WW revenue by drugs launched before 1996
 - Hormonal tablets frequently contraceptive linked
 - Topical applications are retinoids or anti-microbials
 - Alopecia
 - Only one proprietary alopecia treatment, Propecia \$ 440 m launched 1998
 - Vasodilators (Rogaine) off patent
- **Thin pipeline**
 - 2 anti acne agents in phase III, 12 in phase II
 - Only two products in clinical development for alopecia

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



CB-03-01 1% cream Phase II Study – Clinical Results

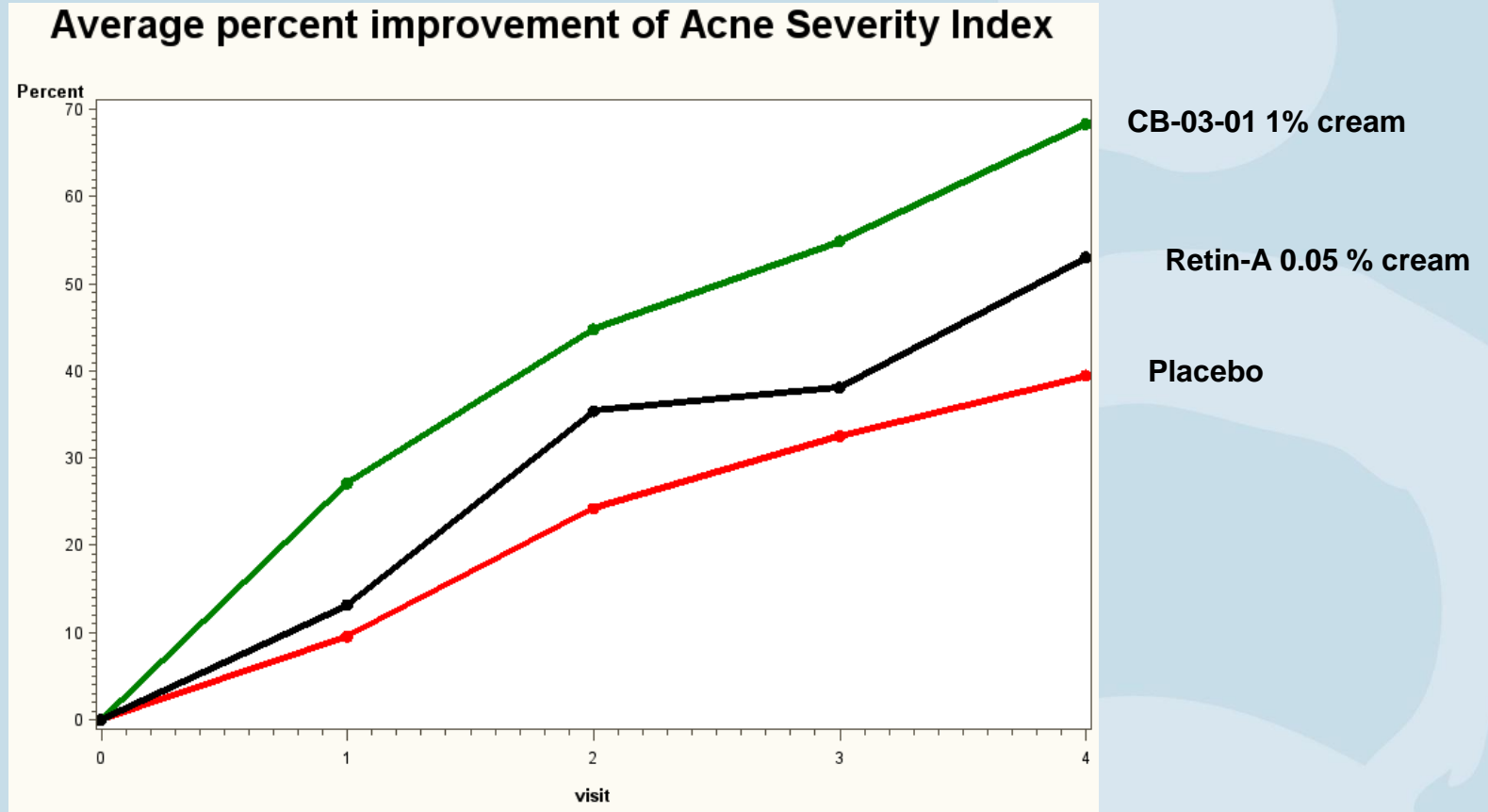


CB-03-01 1% cream

Retin-A 0.05 % cream

Placebo

CB-03-01 1% cream Phase II Study – Clinical Results



CB-03-01 First publication on BJD 2011

Br J Dermatol. 2011 Mar 24. doi: 10.1111/j.1365-2133.2011.10332.x. [Epub ahead of print]

Cortexolone 17 α -propionate 1% cream, a new potent anti-androgen for topical treatment of acne vulgaris. A pilot randomized, double-blind comparative study versus placebo and tretinoin (Retin-A(®) 0.05% cream).

Trifu V, Tiplica GS, Naumescu E, Zalupca L, Moro L, Celasco G.

Central Emergency Clinical Military Hospital "Dr. Carol Davila"- Clinic of Dermatology, Bucharest, Romania. Clinical Hospital Colentina-Clinic II of Dermatology, Bucharest, Romania. Clinical Hospital of Dermato-Venerology "Prof. Dr. Scarlat Longhin"- Clinic of Dermatology, Bucharest, Romania. Outpatient Centre of Diagnosis and Treatment "Dr. N. Kretzulescu", Bucharest, Romania Cosmo S.p.A., Lainate (MI), Italy. Cosmo Research & Development S.p.A., Lainate (MI), Italy.

Abstract

Background: Acne vulgaris is a disorder of the pilo-sebaceous unit in which the androgens contribute to its onset and persistence. The use of anti-androgens is therefore potentially effective, however anti-androgens for topical use are not available in the market. Cortexolone 17 α -propionate (CB-03-01) is a new potent topical anti-androgen potentially useful in acne vulgaris. **Objectives:** To evaluate the safety and the topical efficacy of cortexolone 17 α -propionate 1% cream in acne vulgaris as compared to placebo and to tretinoin (Retin-A(®) 0.05% cream). **Patients/Methods:** Seventy-seven adult males with facial acne scored 2-3 according to Investigator's Global Assessment (IGA), were randomly subdivided to receive placebo cream (n=15), or CB-03-01 1% cream (n=30), or Retin-A(®) 0.05% cream (n=32) once a day at bed-time for 8 weeks. Clinical efficacy was evaluated every 2 weeks including total lesion count (TLC), inflammatory lesion count (ILC), acne severity index (ASI) and IGA. Safety assessment included local irritancy score (IS), laboratory tests, physical examination, vital signs and recording of adverse events. **Results:** CB-03-01 1% cream resulted very well tolerated, significantly better than placebo on TLC (P = 0.0017), ILC (P = 0.0134) and ASI (P = 0.0090), and also clinically more effective than comparator. The product induced also a faster attainment of 50% of improvement in all above parameters. **Conclusions:** This pilot study supports the rationale for the use of topical anti-androgens in the treatment of acne vulgaris. CB-03-01 1% cream seems to fit with the profile of an ideal anti-androgen for topical use.

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CB-03-01: Development Status

- **Preclinical work completed**
- **Proof of concept attained in acne and alopecia**
- **Pre IND meeting with FDA in August 2011:**
 - Drug Substance: proposed release specifications and analytical methods are adequate. Two small additional test are required
 - Drug product: no material issues since all material excipients have been approved by FDA in other products
 - Non clinical issues: save for carcinogenicity tests most test have been done or are underway; no unexpected issues
 - Clinical: FDA recommends co-primary endpoints as per updated disease guidelines. The population is to include teenagers
 - IND is scheduled to be filed in December 2011
 - A single Phase II dose ranging trial, including additional PK and HPA tests on a trial subpopulation, to take place in 2012
 - Phase III with two concurrent trials planned for 2013

Acne Planned Clinical Study Summary

Study Name	Timing	Pts on Drug	Study n
P1: PK/HPA suppression	Nov 2012-Oct 2013	20 + 20	40
P2: Dose Ranging Trial	Jan-Dec 2012	288	360
P3: Pivotal Trial	Apr 2013-Oct 2014	300	600
P3: Pivotal Confirmatory Trial	Apr 2013-Oct 2014	300	600
<i>P3b: Open Label Safety Study (if required)</i>	<i>Apr 2013-Oct 2015</i>	<i>500</i>	<i>500</i>
TOTAL		1428*	2100*

* Does not include patients from P1 and P2 coming from EU experience

Acne Non-Clinical Studies (eventually required)

Study Name	Timing
Non-Clinical Evaluation	April 2011-Dec 2012
Carcinogenicity/CRC study	Nov 2011-Nov 2014
Segment I and III Repro Tox studies (if required)	May 2012-Feb 2014
6 month rat tox sub-Q (if required)	May 2013-Apr 2014

CB 03-01: Market opportunity in alopecia

- **Market potential**

- It is presumed that around 40% of men between 20 and 65 suffer hair loss and up to 40% of these try to do something about it
 - Around 20% of these are willing to use drugs ie around 3% of all men
- Up to 50% of all women after menopause suffer hair loss and up to 60% of these try to do something about it
 - Around 33% of these are willing to use drugs , ie around 10% of all women >50

- **FDA approved drugs**

- No topical anti androgen approved
- Propecia; an alpha 5 reductase inhibitor, taken as a tablet, had revenues of \$ 440 m (2009). June 2011 FDA issued prostate cancer warning for alpha reductase inhibitors
- Minoxidil/Regaine/Rogaine are vasodilators and are off patent

Alopecia Program Key Activity Timing

Activity plan

Mfr/test/release toxicity formulations	
Pre-IND Meeting with FDA	2012
Conduct Animal Dermal Irritation Study	
Conduct Animal Ocular Irritation Study	
Pilot toxicity studies in animals	
9 months Repeat Dose animal toxicity Study	
File IND	2012
Conduct POC Study	2012-2013
Conduct phase III pivotal trials	2014-2015

Summary of Cosmo patent structure

	Compound	Basic Technology	Composition & Use	Process
Lialda		2020		
Budesonide		2020		
Rifamycin SV		2020	2025	
LMW Heparin		2020	2022	
Opioid Constipation		2020/2030		
Blue Methylene	2028*	2020	2030	
Anti Androgen	2022/2028			2028

* Licensed in

Financial Outlook for 2011: Recurring Revenue growth, continued profitability, sufficient cash

- **Revenues projected at around € 32 million**
 - Lialda® royalties and manufacturing income are expected to increase by ~20% or EUR 3.5 m to € 19 m
 - Stable classical Contract Drug Manufacturing revenue
 - No milestones nor license fees budgeted (-EUR 2 m)
- **Stable COGS**
- **External R&D expenditures of ~EUR 5.4 m** (EUR 2 m > 2010)
- **Overall costs are likely to decrease by ~EUR 2 m** (less onetime costs)
- **Positive EBITDA and net profits**
- **Cash and financial assets unchanged at EUR 46 m**
 - If all 1,120,743 shares and options are put, (with remaining 645'239 shares put at exchange rate of CHF 1.20 p EUR, and all shares are destroyed) then net cash position is projected at EUR 8 m
- **No external financing required**

COPN has outperformed the SIX indeces



COPN in CHF, EURO, USD, GBP



News events in 2011

H2

- results of Budesonide extension trial in September
- strategic decision on CB 03-01 partnering
- filing of Budesonide MMX NDA in the US
- end of phase III for Rifamycin SV MMX in the EU and first trial in US
- start work on new indication for Rifamycin SV
- phase I proof of concept data for Naloxon MMX
- phase II data for Methylene Blue MMX

Contacts

Mauro Ajani; CEO

majani@cosmopharma.com

Dr. Chris Tanner; CFO and Head of Investor Relations;

ctanner@cosmopharma.com

Phone: 0039-02-9333'7453

Giuseppe Cipriano; COO

gqipriano@cosmopharma.com

Dr. Luigi Moro; CSO

lmoro@cosmopharma.com

www.cosmopharma.com

