COSMO Pharmaceuticals

Jefferies 2011 Global Healthcare Conference

New York

June 9, 2011

Safe harbor

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The dilemma of entrepreneurs in pharma companies: high costs of developing a NCE, low probabilities of success

	Biology		Chemistry	HTS	Preclinical		Clinical		FDA
Value Chain	**Target ID/val1**	**Target Val II**	**Screening**	**Optimization**	**Phase 0**	**Phase I**	**Phase II**	**Phase III**	
Terminology									
Activity/output	Circumstantial val	Functional val	Leads	Drug candidates	IND			NDA	
Probability to pass		**5.0%**	**0.00021%**	**50.0%**	**40.0%**	**70.0%**	**52.0%**	**65.0%**	**91.0%**
# IDval1 exp. run	333								
# pot. tgts/IDval1 exp.	3								
# targets input		1,000	50.0						
# compounds input		625,000	31,250,000	64.4					
# candidates input					32.2	12.9	9.0	4.7	3.0
Running total $ m	**25,5**	**231,3**	**271,4**	**390,2**	**484,5**	**531,2**	**616,0**	**716,6**	**742,3**
% of total	3.4%	27.7%	5.4%	16.0%	12.7%	6.3%	11.4%	13.6%	3.5%
Subtotal %		31.2%		21.4%	12.7%			31.3%	3.5%

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The Cosmo approach

- **Use skills in complex manufacturing as starting point and USP**
  - Find applications for MMX technology
  - Focus on complex new generics against total cost coverage and profit share

- **Focus on growth markets with little big pharma competition**
  - The 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 cost
  - Cosmo has made a profit every year since the IPO

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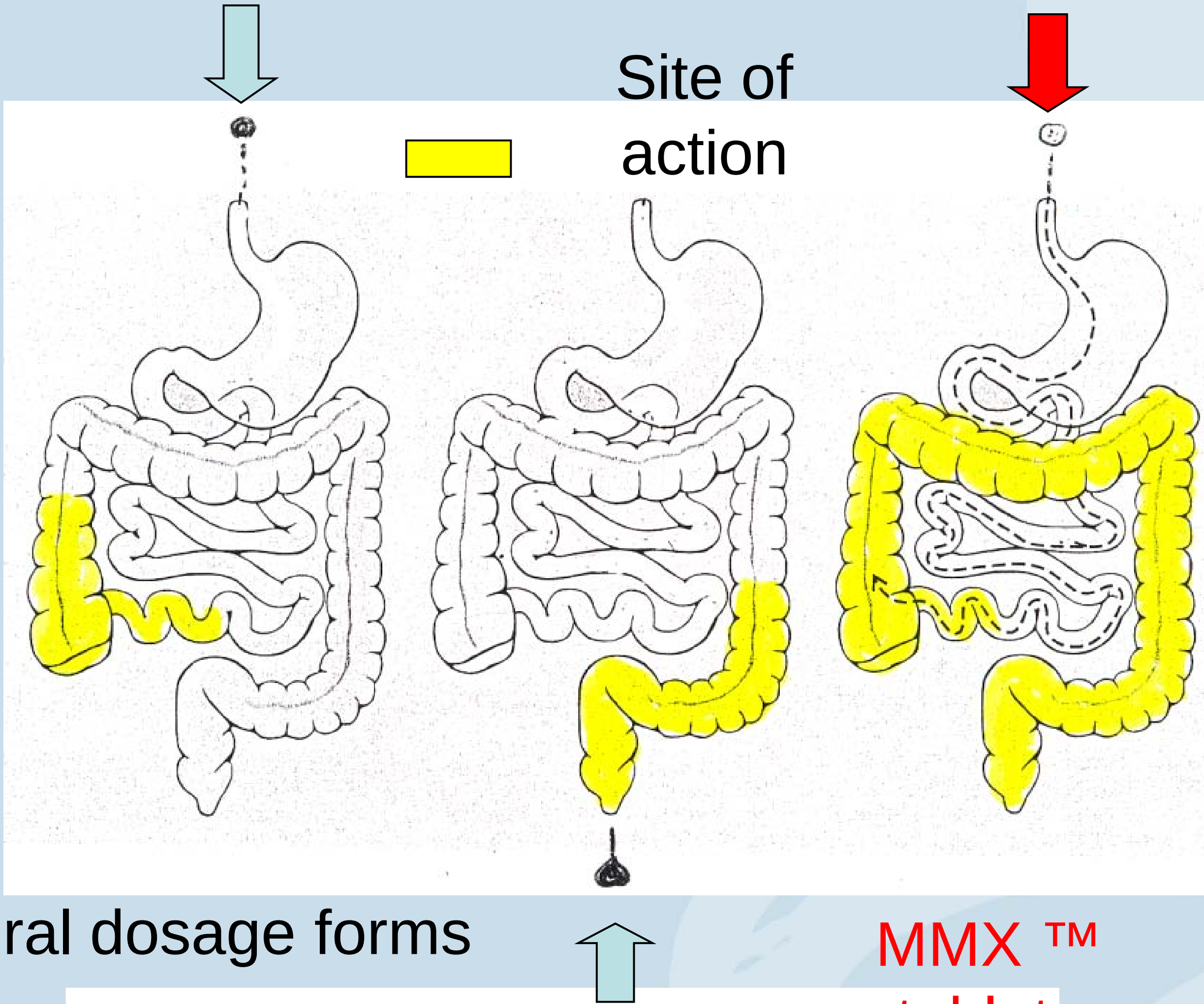
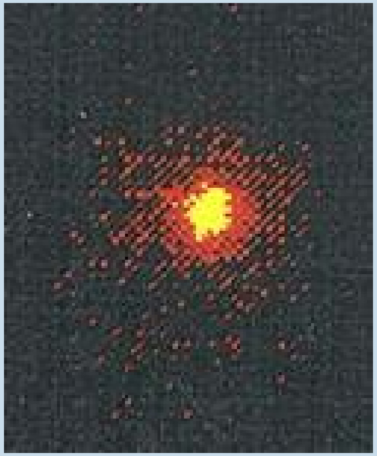
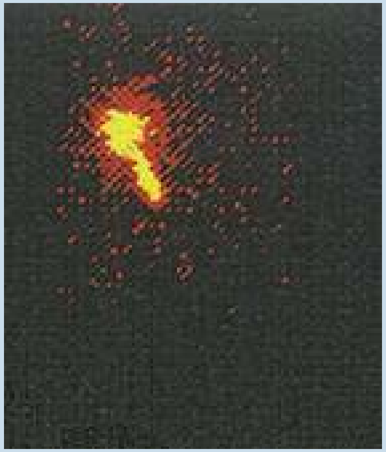
IBD medications: sites of action
MMX™ tablets vs. other dosage forms



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



1h 30’ duodenum



4h 30’ ascending colon

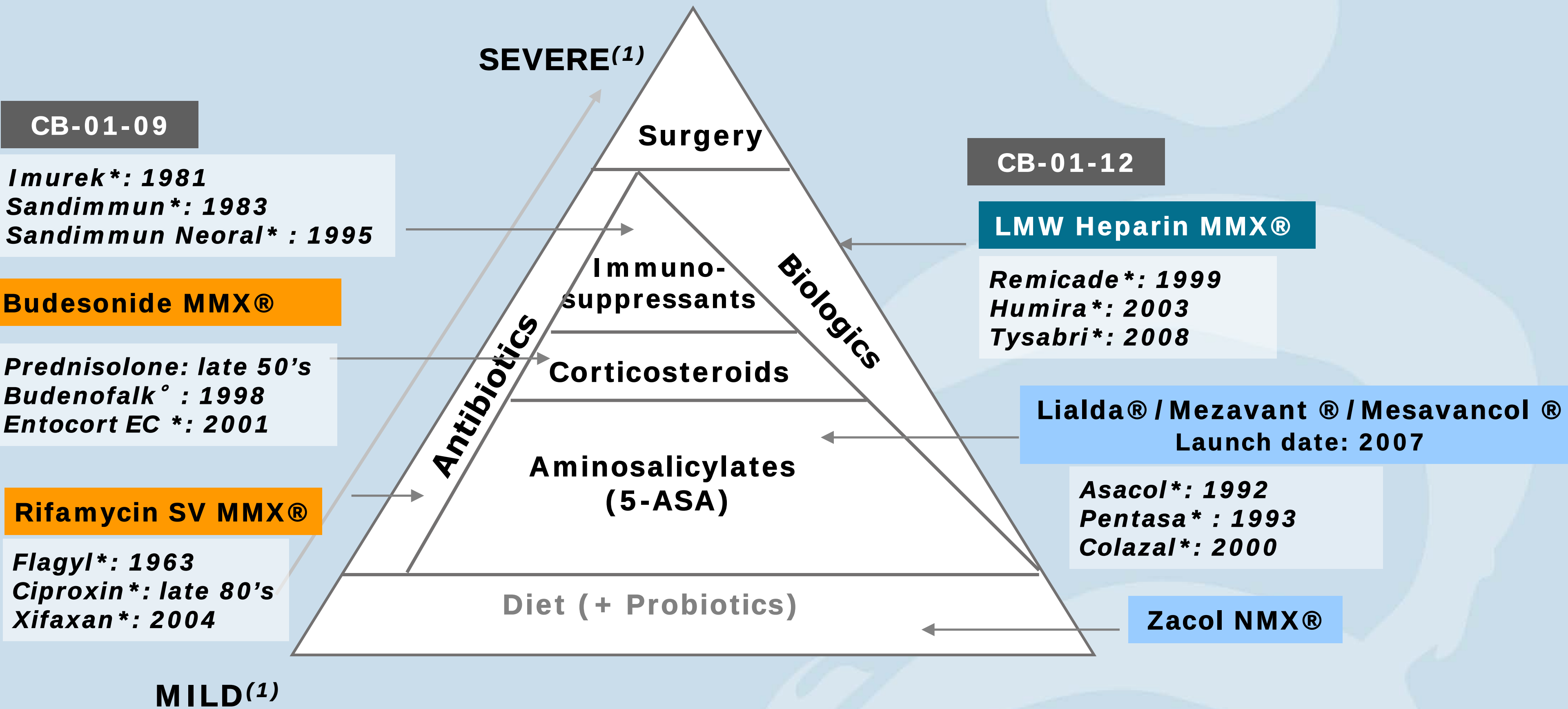
7h 30’ trasverse colon

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

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Cosmo key numbers: safe, continuous development

key numbers in EUR m	2007	2008	2009	2010
total revenue	21.9	34.1	26.7	32.0
of which non recurring fees	3.5	10.4	2.1	2.6
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
Products in market	2	2	2	2
Products in phase III	-	1	2	2

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**	Cortico-steroid		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**	Biologic		2009 2010	H2/12 EU			
- Maintenance treatment for UC of all severities	Biologic	2009	H2/12				
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 H1/12				
CB-03-01 (NCE) **Alopecia**	Steroid ester, androgen antagonist	2009	2010 Dose ranging H1/13				

2009 2010

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The first product: Lialda®

- The Chemical entity mesalamine is an off-patent 5-ASA (amino salicylic acid)
- Indicated for Patients with Ulcerative Colitis of mild to moderate severity
- Market entry in March 2007. 2010 revenue reached $ 293.4 m
- 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
- 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**
  - Attained primary clinical endpoints in both the US and EU trials
- **Projected filing**
  - MAA filed in EU end May; NDA for USA H2 2011
- **Market entry**
  - Around 1 year later
- **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)
- **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: unpartnered
  - Projected value to Cosmo: $ 130 m NPV per $100 m peak sales

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

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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 trail is for non inferiority to Cipro. Start delayed in India, ~200 out of 776 patients recruited.
    - US trial is for superiority against placebo. 2 pivotal trials planned. 100 out of first 262 patients recruited. Recruitment slow because student language courses in Mexico have suffered
- **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
  - Projected value to Cosmo: NPV 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 tissue
- **Indication:**
  - Non invasive staining of cellular structures will make it easier and more likely to visually diagnose colon cancer and ulcerative colitis
- **Market size:**
  - ~20 million colonoscopies performed p.a. in USA and EU. Market potential is the ~ 364 m persons in USA, Cda, EU, Australia and Japan that are >50
- **Competition:**
  - No tablets, local non approved liquid application sprayed via endoscope

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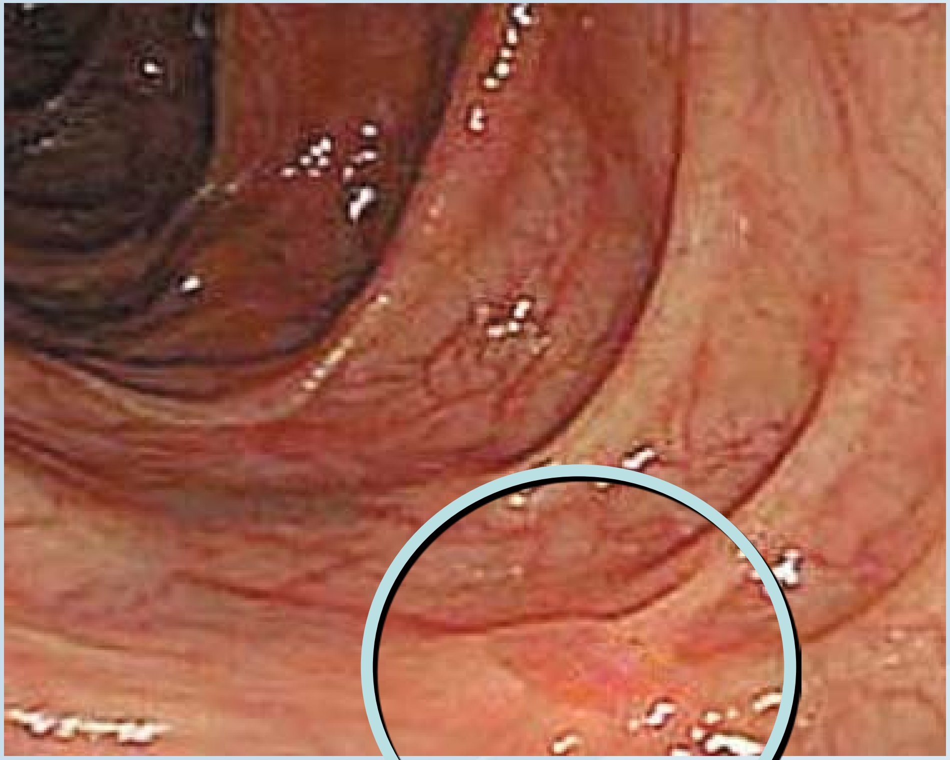
CB -17-01 Methylene Blue MMX: status and way forward

- **Status:**
  - Supply of a new formulation industrial grade methylene blue assured
  - Galenic development completed
  - Proof of concept attained

- **Next steps:**
  - Phase II dose ranging study to optimize staining procedure initiated in late April
    - 100-120 patients
    - Cost ~ EUR 150’000
    - Completion expected Q3 2011
  - Phase III planned for 2012 in US and EU
  - Licensing in late 2011
  - Market entry planned for late 2013

Flat and Depressed Lesions are difficult to see



The Paris endoscopic classification of superficial neoplastic lesions
Gastrointest Endosc 2003

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Chromoendoscopy

Old Technique ('70s)
Developed by Japanese Authors

Methylene Blue MMX objective

- **Methylene Blue MMX can improve the yield on identifying mucosal lesions by a factor 3-8 according to leading gastroenterologists**
  - see more because all parts of colon are stained
  - see better because flat lesions can be detected
  - Distinguish between neoplastic/non-neoplastic lesions
  - Distinguish between advanced/early lesions

- **Work faster so at less cost**
  - because stain is applied before colonoscopy by patient swallowing a tablet
  - No cumbersome stain preparation is necessary
  - No cumbersome spraying is necessary
  - Average time of colonoscopy can be reduced

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**

CB-01-16: opioid antagonist MMX

- **Market size**
  - In the US there are 12 m persons that are chronic opioid users and more than 4.5 m persons that suffer from chronic opioid induced constipation
  - Targeted at home use
- **Mechanism of action**
  - Naloxone is a powerful, off patent, opioid antagonist that displaces opioids from the cell receptor
    - In case of opioid overdoses (heroin), Naloxone is injected
    - Works within minutes when given parenterally
    - Penetrates the Brain Blood Barrier
    - Has a plasma half life of 1 hour when administered parenterally
    - When taken orally has a very high first pass effect being practically totally metabolized in the liver
- **MMX application**
  - MMX technology brings Naloxone to the colon only where it displaces the opioid from the gut receptor thus reactivating peristaltic movements
  - Given the first pass effect and short half life, little pain management conflicts should occur

CB-01-16: opioid antagonist MMX

- **Status**
  - Phase I step up (dose escalation) PK study to start in Q1 2011
  - Phase II dose ranging trial on ~patients per group planned for end 2011

- **Market need; competition**
  - Currently there is no product approved for home use and no tablet is approved for use
  - NKTR 119 uses Naloxol and delivers this through pegilation technology. Was licensed to AZ. Is in phase II
    - Pegilation adds complex polymers to the Naloxone that stops it from going through the Brain Blood Barrier

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 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

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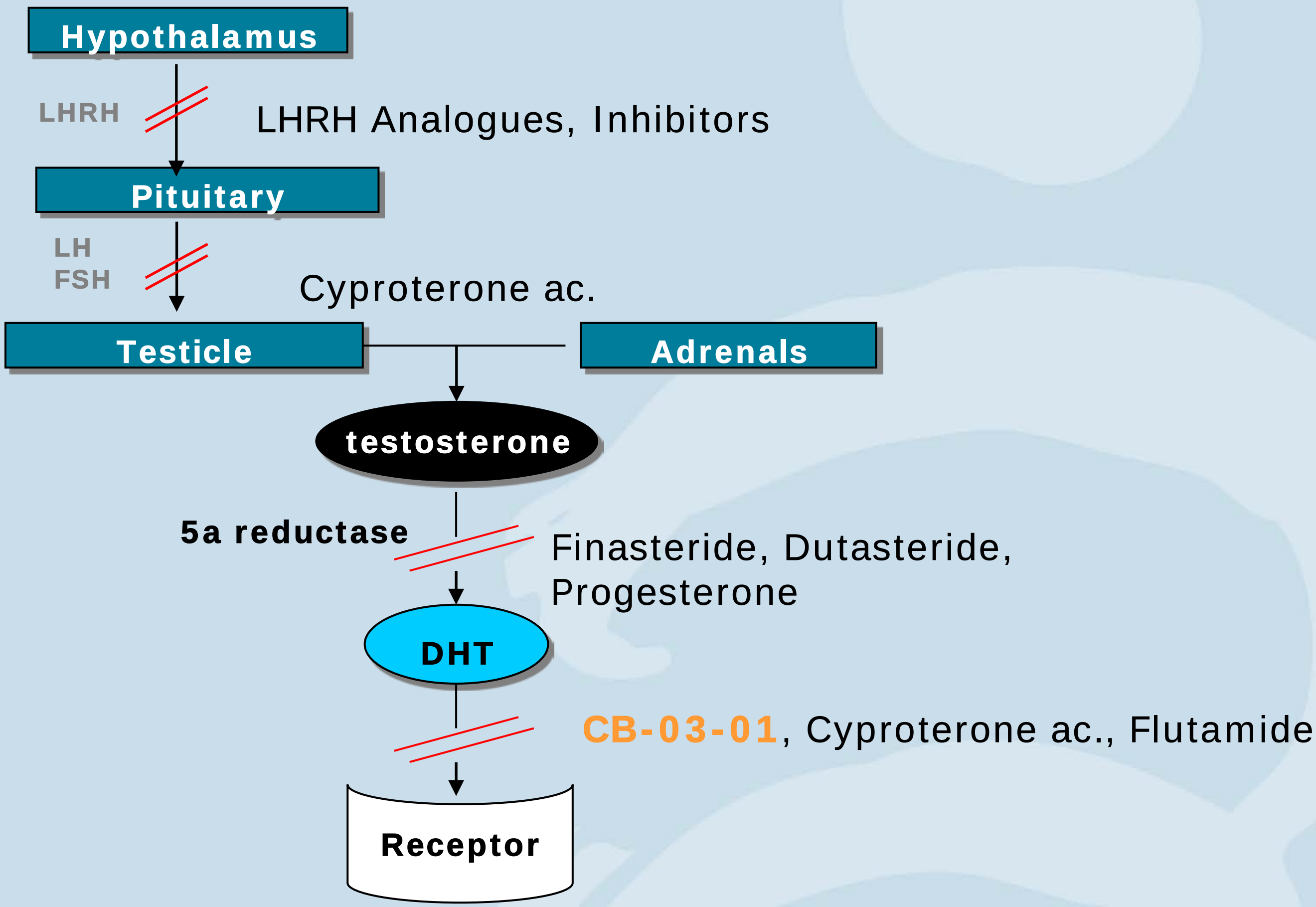
The market in acne and alopecia

- **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

CB-03-01: anti androgen for topical applications

- **Market need**
  - A treatment that is effective and does not affect hormonal balance
- **Mechanism of action**
  - Blocks binding of testosterone and de-hydrotestosterone to the androgen receptor
    - Does not change hormonal balance
    - Blockage impedes androgens from unchaining uncontrolled activity of the sebaceous gland
    - Has no side effects
- **Indication**
  - Topical treatment of Acne and Alopecia, and potentially Hirsutism
- **Status**
  - Preclinical work completed
  - Proof of concept attained in acne and alopecia
  - Established data room and considering options for best partnership structure for development in US
  - Pre IND meeting with FDA scheduled for end July

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



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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)
- Minoxidil/Regaine/Rogaine are vasodilators and are off patent

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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

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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, then there would be a cash outflow of EUR 17.4 m (at CHF 1.35 p EUR)
- **No external financing required**

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Cosmo strategy: go for great cost benefit ratios

product	Total projected cost to Cosmo $ m	NPV p $100 m peak sales[1]
Lialda	3 m	~38[2] /19[3] m
Budesonide	23 m	~130 m[4]
Rifamycin SV	4 m	~110 m[5]
LMW Heparin	45 m	~150 m[6]
CB 17-01	19 m	~150 m[6]
CB 03-01 acne	34 m	~150 m[6]

(1) Discount rate 10%, 10 years product life
(2) Royalties, milestones & net manufacturing income 7%
(3) Royalties, milestones & net manufacturing income 3.5%
(4) Royalties, milestones & net manufacturing income 25%
(5) Royalties, milestones & net manufacturing income 22%
(6) Royalties, milestones & net manufacturing income 28%

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Long term feasibility of Cosmo philosophy: internal financing and product generation plan

R&D cost coverage case in EUR m	2010	2011	2012	2013	2014	2015
R&D internal	2.7	2.8	3.0	3.1	3.3	3.4
total external R&D costs	3.4	5.8	22.0	10.1	11.8	11.3
total R&D costs	**6.1**	**8.7**	**24.9**	**16.6**	**15.1**	**14.7**
Lialda revenue	**15.6**	**19.2**	**23.6**	**26.6**	**30.1**	**16.6**
Products in market	2	2	3	5	5	7
In registration	-	1	1	-	1	2
Phase III	2	1	2	4	3	-
Phase II	1	4	3	-	-	

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COPN has outperformed the SIX indeces

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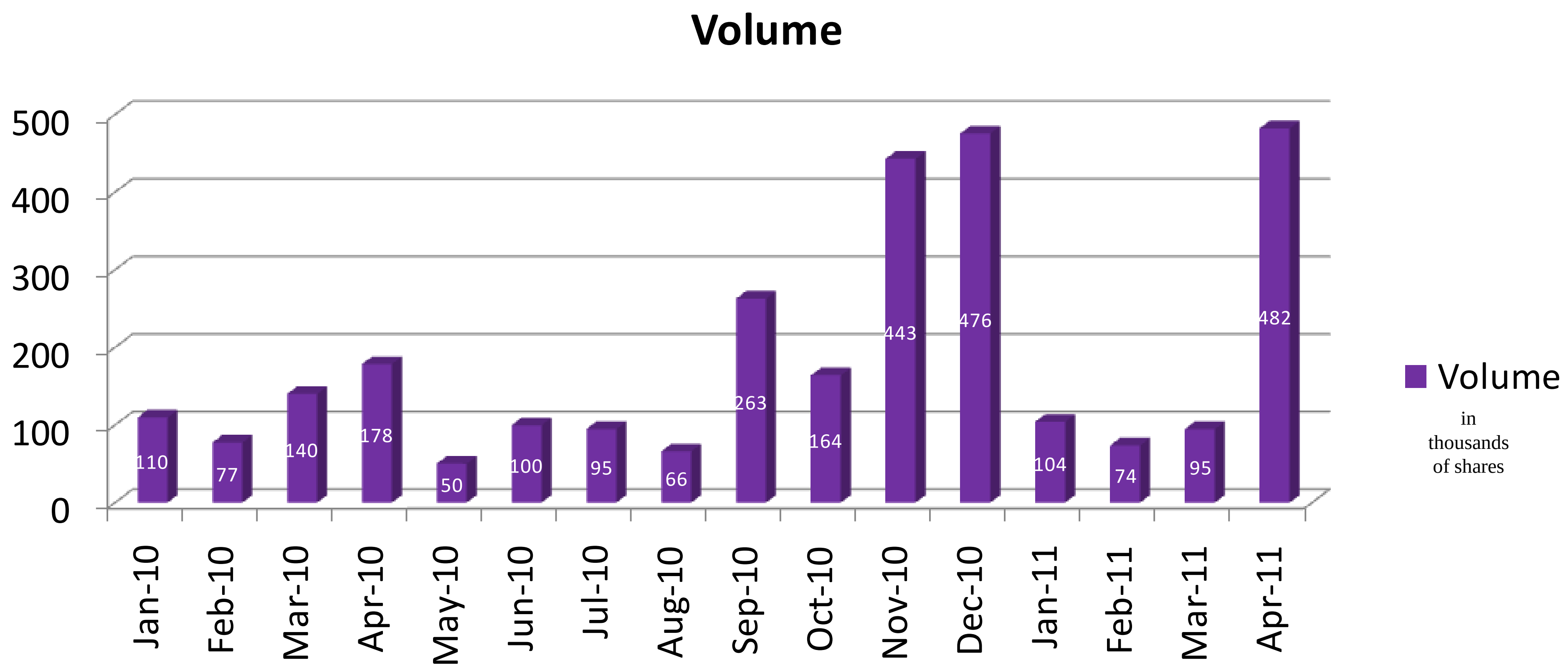
SHARE VOLUME CHART: 01/01/2010 – 30/04/2011



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News events in 2011

H1

-determination of way forward for CB 03-01

-phase I data for Blue Methylene MMX

-filing of Budesonide MMX NDA in the EU

-presentation of various posters at DDW Chicago

H2

-IND approval CB 03-01 in the USA

-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 Blue Methylene MMX

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