

# Swiss Equity Biotech Day

Zurich

13 April 2010



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## Highlights 2009

- Continued profitability even though there were no milestone events
- Excellent market performance of Lialda® in the USA: fastest growing UC tablet, 18% share in 5-ASA market
- Phase III of Budesonide MMX® EU completed, last patient in for the US trial and extension study progressing
- Positioning of Rifamycin SV MMX® as a new chemical entity in the USA
  - Additional preclinical requirement for start of phase III for Rifamycin SV MMX® in the USA fulfilled, SPA obtained, trials about to start
- CB-03-01 proof of concept in Acne attained
- Acquisition of BioXell increases liquidity of shares, generates additional cash reserves and increases strategic options for Cosmo
- Financial value of investment in Santarus increases by € 12.5 m

## Income statement

EUR 1,000	31.12.2009	31.12.2008
<b>Revenues</b>	<b>26,685</b>	<b>34,173</b>
Other income	315	47
Cost of sales	(12,774)	(13,203)
Research and development costs	(4,454)	(4,287)
Selling, general and administrative costs	(5,329)	(5,546)
<b>Net operating expenses</b>	<b>(22,242)</b>	<b>(22,989)</b>
<b><i>Operating result</i></b>	<b><i>4,443</i></b>	<b><i>11,184</i></b>
Financial income	1,290	1,369
Financial expenses	(416)	(940)
<b><i>Profit before taxes</i></b>	<b><i>5,317</i></b>	<b><i>11,613</i></b>
Income tax expenses	(1,267)	(2,212)
<b><i>Profit for the year</i></b>	<b><i>4,050</i></b>	<b><i>9,401</i></b>

EUR 1,000	31.12.2009	31.12.2008
<b><i>Profit for the year (A)</i></b>	<b><i>4,050</i></b>	<b><i>9,401</i></b>
Gains (/Losses) on fair value of available for sale financial assets	12,473	(1,996)
Income tax relating to components of other comprehensive income	(439)	439
<b><i>Total other comprehensive income, net of tax (B)</i></b>	<b><i>12,034</i></b>	<b><i>(1,557)</i></b>
<b>Total comprehensive income (A) + (B)</b>	<b>16,084</b>	<b>7,844</b>

## Key points on income statement

- **Overall revenue decreased by 21.9% to € 26.7 m**
  - Recurring revenues increased by 3.4% to € 24.6 m
    - Royalties increased by 69.8% to € 6.0 m
    - Manufacturing of MMX® based products decreased by 5% to € 6.8 m
    - Other contract drug manufacturing decreased by 15.2% to € 10.5 m
  - One time licence fees and milestones decreased by 79.8% to € 2.1 m
- **Operating costs decreased by 3.2% to € 22.2 m**
  - Personnel increased to 134 persons
  - Overall R&D spend increased by 24.5% to € 13.7 m but € 4.0 m Budesonide MMX® costs reimbursed by Santarus and € 5.3 m Budesonide MMX® costs were capitalized
- **Net profit according to IFRS declined to € 4.0 m but total comprehensive income increased from € 7.8 m to € 16.1 m**
  - 6 m shares in Santarus were recorded as income in 2008 at \$ 1.58
  - In 2009, these reached a value of \$ 4.84, an increase of € 12.5 m

## Statement of financial position

EUR 1,000	31.12.2009	31.12.2008
Financial assets available for sale	19,242	6,769
Other non-current assets	22,396	17,303
Cash and cash equivalents	17,161	22,166
Other current assets	12,665	11,527
<b>Total assets</b>	<b>71,464</b>	<b>57,765</b>
Medium- to long-term interest-bearing loans and borrowings	1,642	2,903
Other non-current liabilities	2,739	2,242
Short-term interest-bearing loans and borrowings	1,334	1,391
Other current liabilities	5,954	7,993
<b>Equity</b>	<b>59,795</b>	<b>43,236</b>
<b>Total equity and liabilities</b>	<b>71,464</b>	<b>57,765</b>

## Key points on statement of financial position

- **Cash and cash equivalents down 22.6% to € 17.2 m, however:**
  - Additional financial assets available for sale of € 19.2 m (lock up on Santarus shares expired 15 March 2010)
- **Intangible assets up 75.5% to € 12.0 m due to capitalization of development cost of Budesonide MMX®**
- **Bank debt decreased by 30.7% to € 3.0 m**
  - 76.1% are bank loans
  - 23.9% are leasing obligations
- **Tangible net worth increased by 31.4% to € 47.7 m**
- **83.7% of total assets financed by equity**

## What makes Cosmo different: the approach

- Product development strategy focused on improvements 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%; limited big pharma competition
  - Effective topical products for Acne and Alopecia market could make those into very large markets

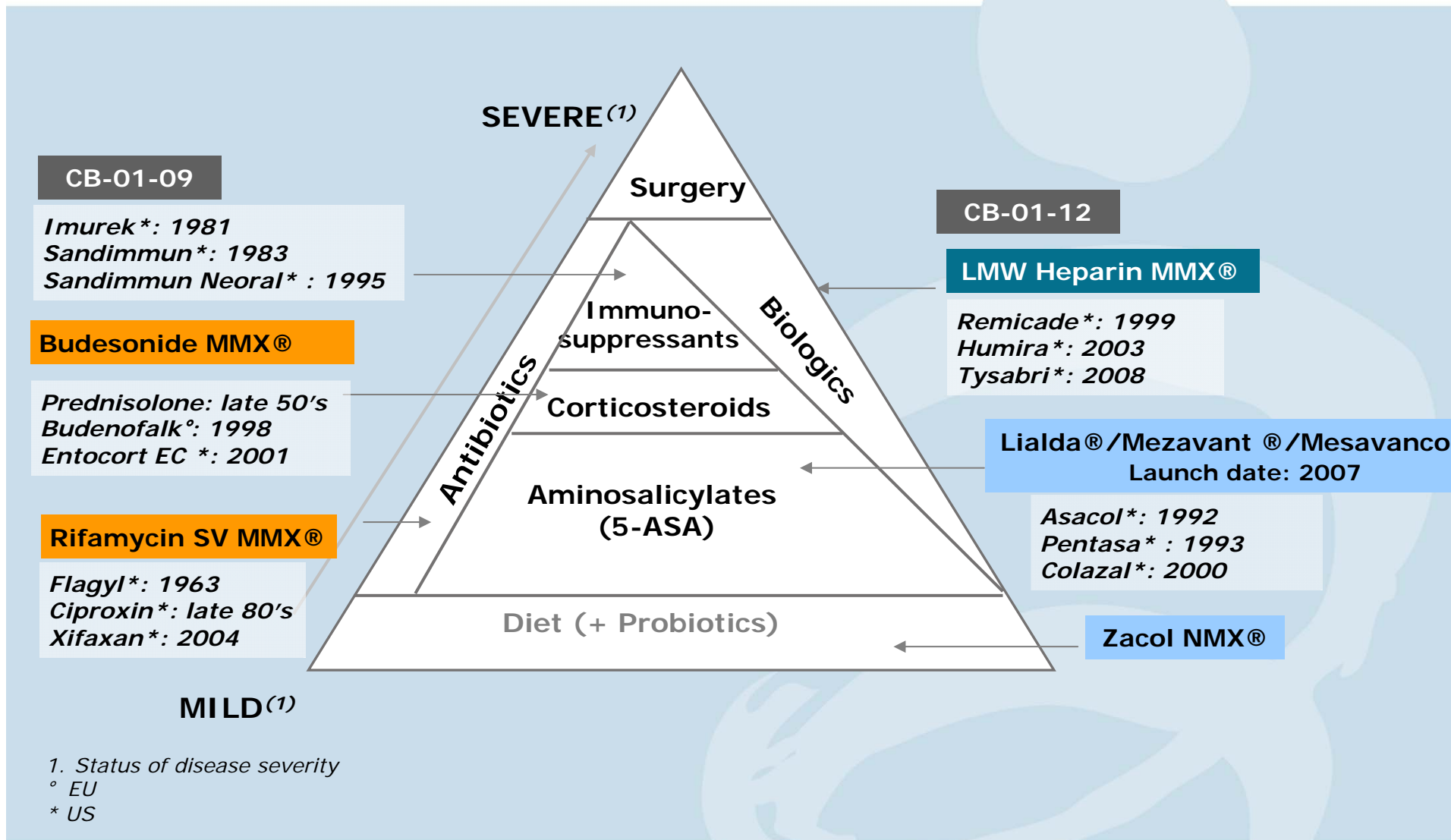
## What makes Cosmo different: Results

- Since the IPO in 2007 Cosmo has made money
- Lialda® / Mezavant® / Mesavancol® income at >6% of revenues until end 2014:
  - From 2016 on they will stabilize above € 5 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 50% shareholder has a total compensation of € 220,000
  - Interests that are totally aligned to outside shareholders

## Delivering on business strategy

- **Focus on low competition markets that show good growth**
- **Focus on low risk, low cost development processes**
  - Off-patent chemical entities that can be improved
  - Re-indications
  - Moderate yearly treatment costs to patient
- **Focus on what we do best and find best partners for the rest**
- **No frills, low-cost organisation**
- **Fully align management interests with shareholders' interests**

# Focus on IBD, a disease with little recent innovation

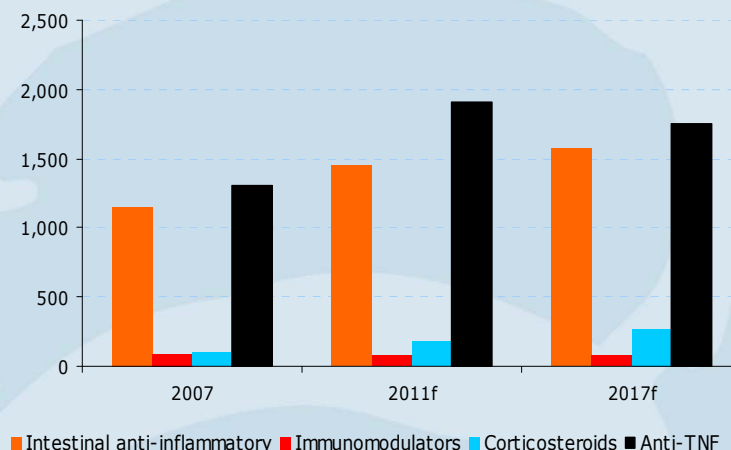


## But strong growth and little competition outside anti-TNFs

Main Brand products	2007 Sales	2009f	2011f	2017f
<b>Anti-TNF</b>				
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
<b>Total</b>	<b>1,306</b>	<b>1,628</b>	<b>1,906</b>	<b>1,754</b>
<b>Intestinal anti-inflammatory</b>				
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
<b>Total</b>	<b>1,152</b>	<b>1,348</b>	<b>1,450</b>	<b>1,581</b>
<b>Corticosteroids</b>				
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
<b>Total</b>	<b>104</b>	<b>116</b>	<b>173</b>	<b>267</b>
<b>Immunomodulators</b>				
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
<b>Total</b>	<b>87</b>	<b>84</b>	<b>81</b>	<b>78</b>
<b>Other</b>				
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
<b>Total</b>	<b>0</b>	<b>46</b>	<b>99</b>	<b>460</b>
<b>TOTAL IBD MARKET</b>	<b>2,649</b>	<b>3,222</b>	<b>3,709</b>	<b>4,140</b>
<b>Growth rate</b>	<b>0</b>	<b>22%</b>	<b>15%</b>	<b>12%</b>

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	
<b>Total</b>	<b>2,231</b>	<b>2,761</b>	<b>24%</b>



# Develop a full range of low risk products with higher probability of success

Product	Drug type	Indication	Ph I	Ph II	Ph III	MA	Launch	Partner
Lialda®/Mezavant®/ Mesavancol®	5-ASA	Mild to moderate Ulcerative Colitis	[Progress bar]				03/07 USA 10/07 UK 01/10 ITA	Shire/Giuliani
Zacol NMX®	Dietary supplement	Intestinal Disorders (nutraceutical)	[Progress bar]				12/05 ITA	
Budesonide MMX®	Corticosteroid	Mild to moderate Ulcerative Colitis	[Progress bar]				Q2/3 10	Santarus - USA Ferring – Worldwide (excluding Japan & USA)
Rifamycin SV MMX®	Antibiotic	Traveller's Diarrhoea	[Progress bar]				H2 10 EU H2 11 US	Santarus - USA Dr. Falk – Europe & Australia (excluding Italy)
LMW Heparin MMX®	Biologic	Mild to moderate Ulcerative Colitis	[Progress bar]				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	[Progress bar]				Q4 10	

## With low total development costs to licencing out

	Cosmo carries cost up to Phase II	Cosmo carries cost up to Phase III	Cosmo carries cost up to Approval
Mesalamine MMX®	€ 1 m		
Budesonide MMX®			€ 23 m
Rifamycin SV MMX®		€ 4 m	
LMW Heparin MMX®		€ 8 m	
CB-03-01 Acne		€ 3.5 m	
CB-03-01 Alopecia		€ 1.8 m	
CB-01-16		€ 3 m	

## 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

## 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  $\leq 1$ 
    - Stool frequency score: 0
    - Rectal bleeding score: 0
    - Mucosal appearance score: 0
    - Physician rating score: max 1
  - Extension study on first 100-150 patients that go into remission (only has exploratory purposes for FDA)

## 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, Ciprofloxacin € 331 m

## Rifamycin SV MMX®: Status and opportunities

- **Status**

- Positioned as new chemical entity in the USA
- Patient recruiting for phase III trials in EU and the US to start in Q2
  - 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

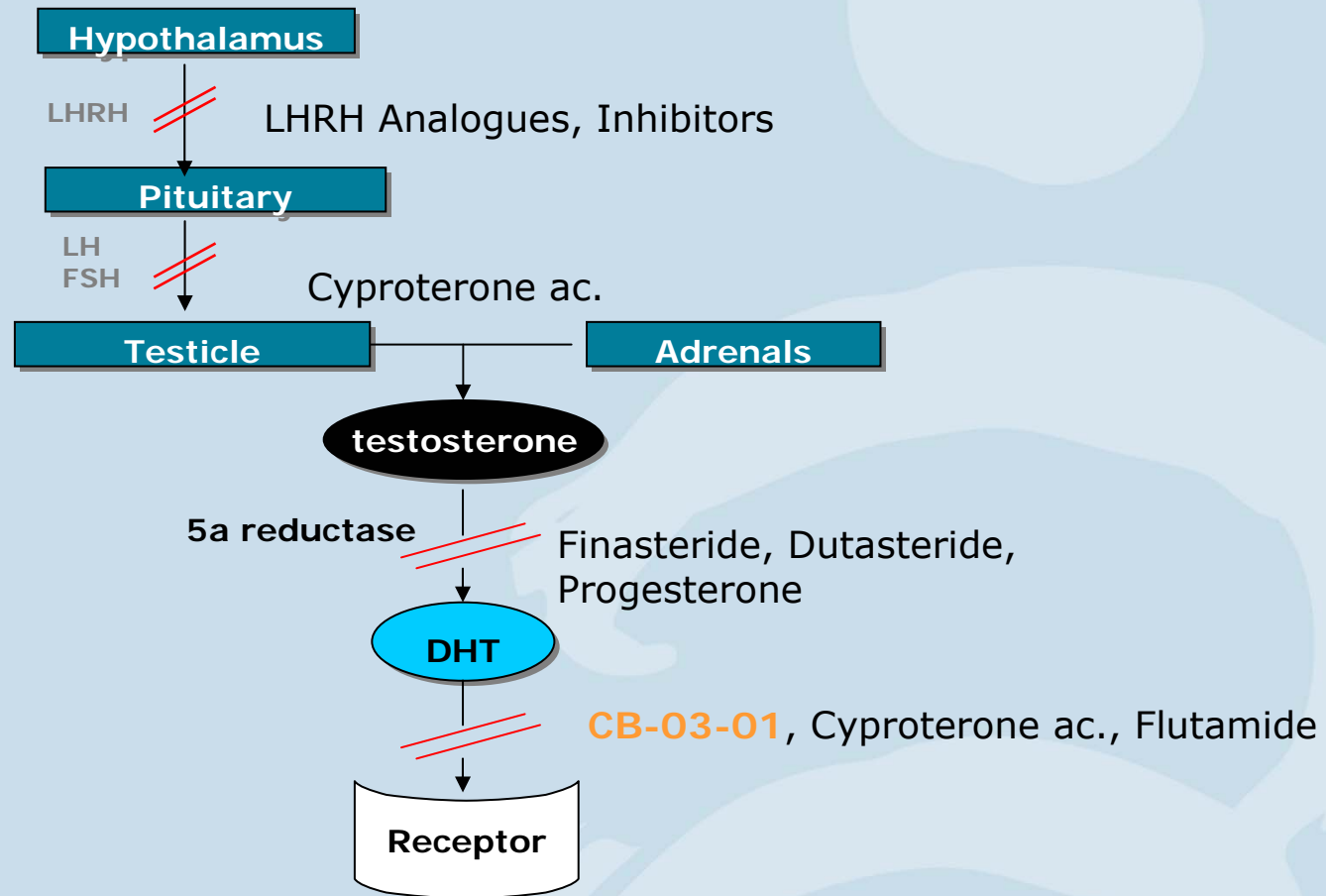
## LMW Heparin MMX®

- **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 $\alpha$ , Interferon  $\gamma$ , IL2
- **Possible target indication expanded to maintenance of remission for UC patients of all severity**
- **FDA meeting for phase III preparation**
  - LMW Heparin MMX® presently not approved in the USA, i.e. it is a new chemical entity
    - Full preclinical tests required including carcinogenicity tests
    - Analyses have started
- **EU meetings for discussions of phase III trial design planned in Q2 2010**

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

- **Chemical entity cortexolone 17a propionate**
- **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 (currently under clinical development)
  - Hirsutism, Androgenetic Alopecia (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 1% cream Pilot phase II study

- **Patients:**
  - Screened 83
  - Randomized 77
  - Evaluated 72
- **Inclusion criteria:**
  - Facial Acne
  - Mild to moderate severity
  - IGA (Investigator Global Assessment) SCORE: 2-3
  - TLC (Total Lesion Count): 20-100
  - ILC (Inflammatory Lesion Count): 10-50
- **Criteria Of Evaluation**
  - TLC
  - ILC
  - ASI (Acne Severity Index)
  - IGA

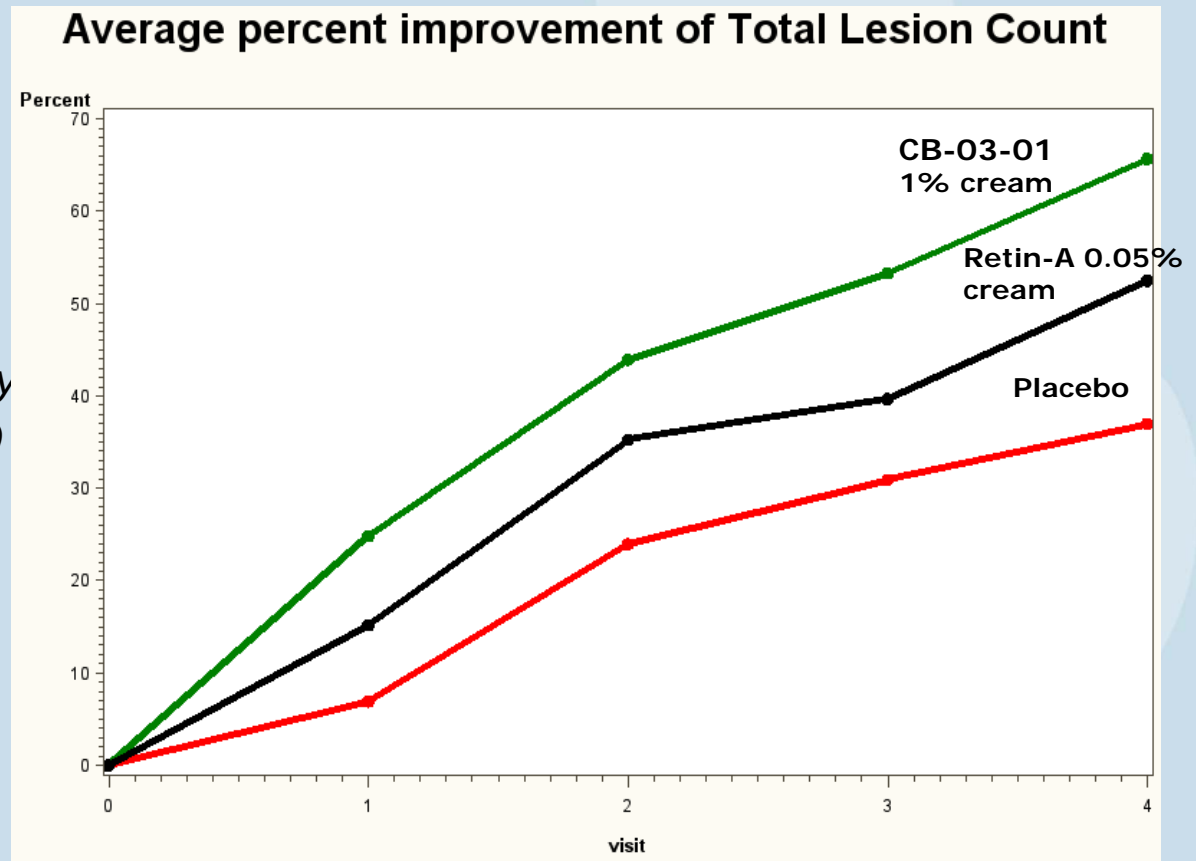
} **Efficacy**

  - Local tolerability
  - Systemic tolerability

} **Safety**

## CB-03-01 1% cream Phase II study

- Very well tolerated at local and systemic level
- Not irritant
- Rapid onset of activity (*50% improvement of lesions count and severity between 36 and 43 days*)
- Highly effective (*number and severity of lesions reduced by >65%*)
- Excellent cosmetic acceptance



Overall comparison: CB-03-01 1% cream vs Placebo ( $p=0.0006$ )  
CB-03-01 1% cream vs Retin-A 0.05% cream ( $p=0.0015$ )

## 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
Others			EU&USA		

## Rationale for the BioXell transaction

- **No focus on technology or clinical developments**
  - No payment for this; includes an asset we may continue developing
- **At closing BioXell had around € 27 m net assets**
  - Primarily cash, claims for VAT refunds and claims for grants
  - Accumulated losses of € 94.8 m
- **Cost to Cosmo**
  - € 10.7 m in cash
  - Issuance of 1,120,743 shares i.e. 8.1% increase, respectively increase of free float by 31% to 32%
  - Issuance of 1,120,743 options to put shares into Cosmo for CHF 21 per share between 1.7.2011 and 31.12.2011
- **Next steps**
  - The General Assembly has approved the appointment of two persons to delist BioXell; put it in liquidation process
  - Company may be continued; purchase of assets and activities from other Cosmo companies being considered

## Operating outlook for 2010

- **Analysts project Lialda® sales to increase to \$ 323 m i.e. by 36%. Royalties and manufacturing income are expected to increase accordingly**
- **Data from phase III trials for Budesonide MMX® and possibly for Rifamycin SV MMX®**
- **Proof of concept data for CB-03-01 for Alopecia**
- **Contract drug manufacturing revenue should increase by > 10%**
- **Licence fees of € 2 m budgeted; no assumptions for CB-03-01 licencing agreement(s)**
- **At least one new product to move from preclinic to clinic**
- **No external financing required**

## Full-year financial outlook 2010

- Revenues € 30.6 m (+14.7%)
- Outsourced clinical costs € 4.4 m (+127.8%)
- Operating result € 7.0 m (+7.2%)
- Net profit € 4.2 m (+5.0%)
- Total debt € 18.7 m
  - Commercial debt € 3.6 m
  - Put option contingency CHF 23.5 m
- Cash and investments € 53.0 m

## Anticipated news events 2010

- Top line data EU Budesonide MMX® phase III trial in May
- Top line data US Budesonide MMX® phase III trial in Q3 2010
- CB-03-01 Alopecia proof of concept trial to start in H2 2010
- Decision on repositioning of BioXell in H2 2010
- Possible CB-03-01 Acne licencing agreements in H2 2010

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