

# Report on 2009

Zurich

March 19, 2010



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## Agenda

- Introduction and highlights 2009 Mauro Ajani, CEO
- Financial review 2009 Chris Tanner, CFO
- Pipeline update Luigi Moro, CSO
- Outlook 2010 Mauro Ajani, CEO
- Questions & Answers All

## 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 US 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 EUR 12.5 m

## Key financial highlights 2009

- Revenue decreased by 21.9% to € 26.7 m
  - Last year € 10.4 m of € 34.2 m were milestones
- Costs decreased by 3.2% to € 22.2 m reflecting excellent cost control
- EBITDA of € 6.1 m
- Net profit of € 4.0 m
- Cash and financial assets available for sale € 36.4 m

## Income statement and statement of comprehensive income

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>

## Discussion of income statement and statement of comprehensive income

- **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**
  - Cost of sales declined by 3.2%
  - 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
- **EBITDA declined from € 12.8 m to € 6.1 m**
- **Net profit declined to € 4.0 m but total comprehensive income increased from € 7.8 m to € 16.1 m**

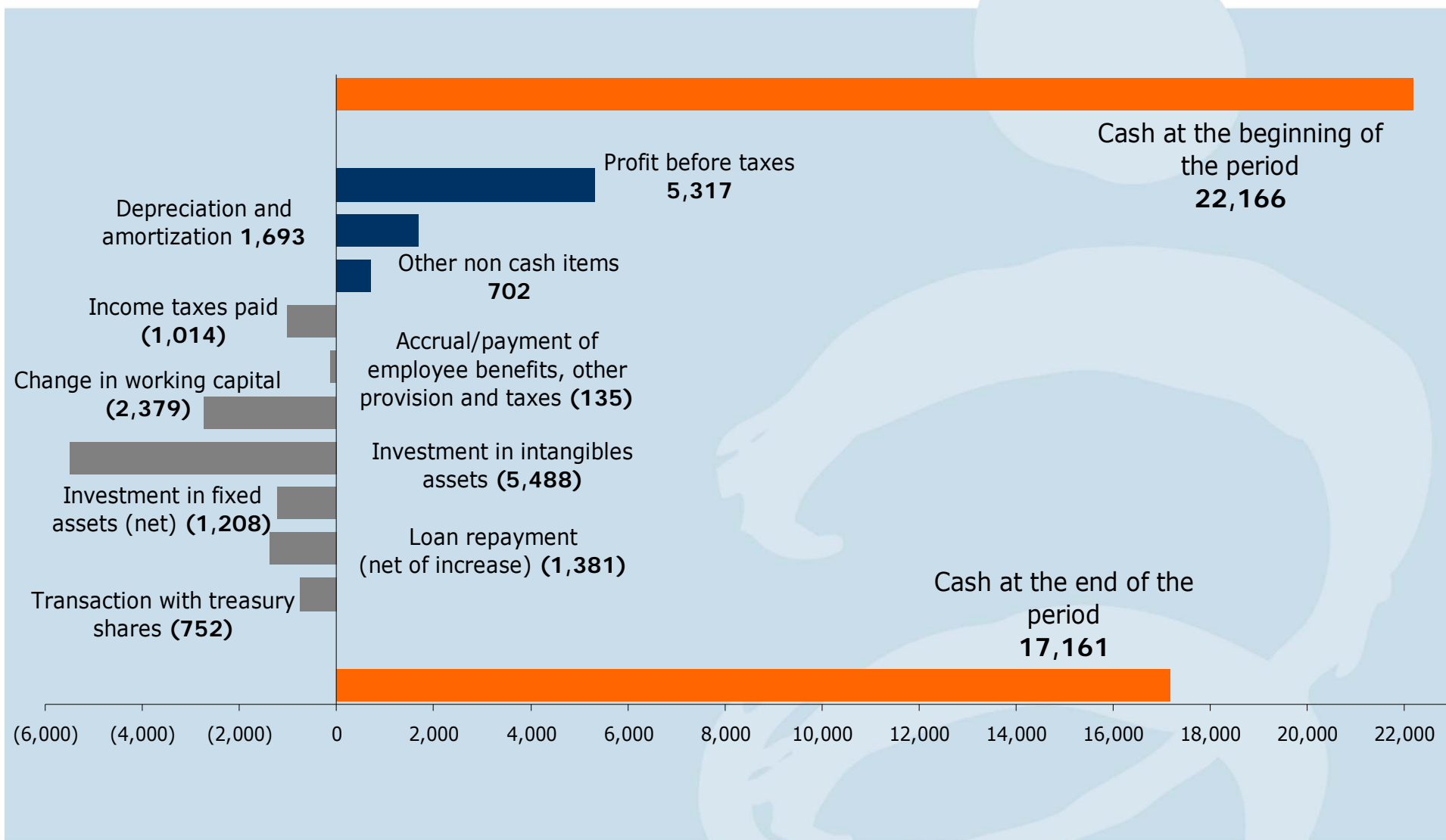
## Statement of financial position

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>

## Discussion of 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**

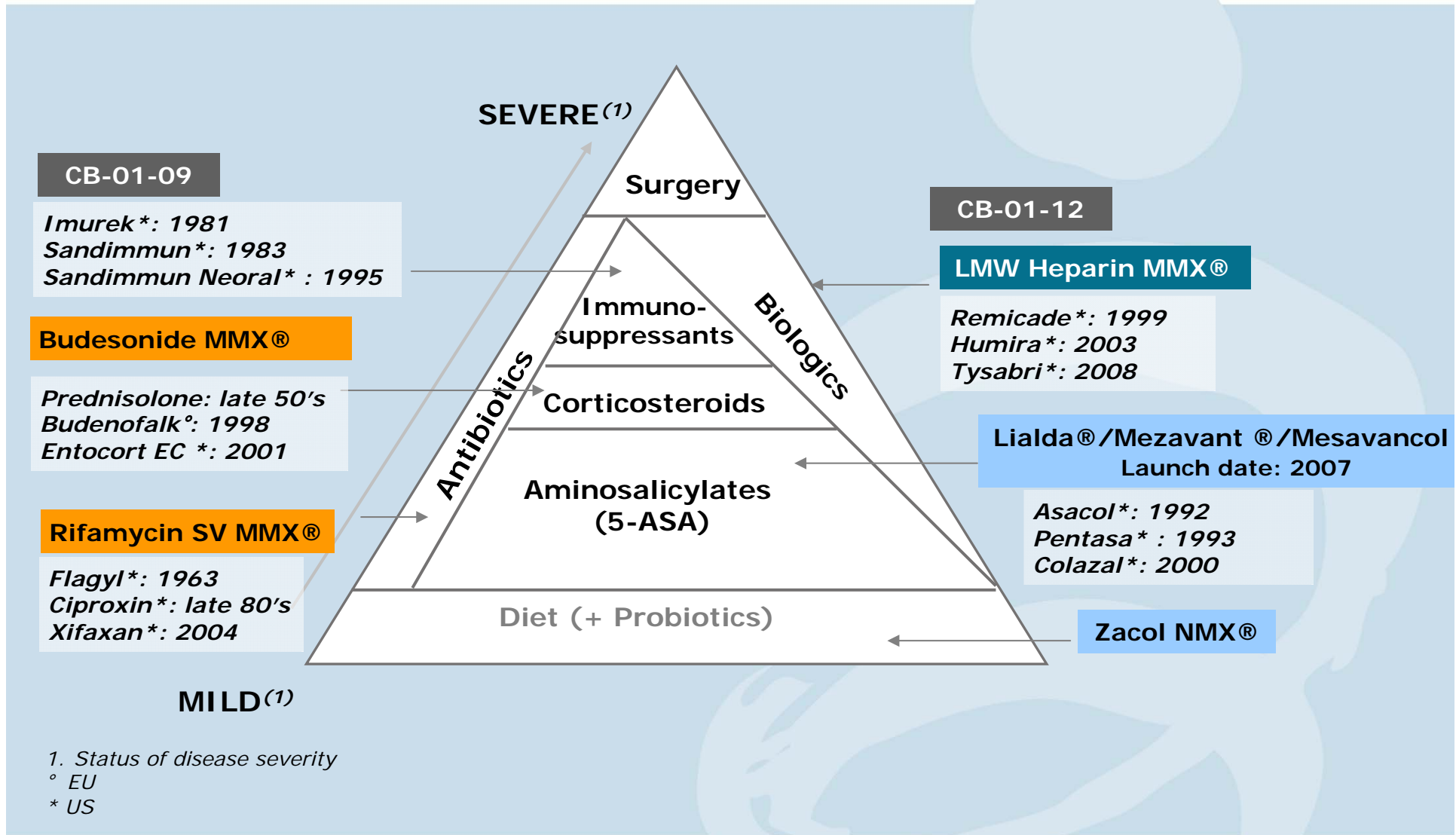
# Cash flow



## Rationale for the BioXell transaction

- **No focus on technology or clinical developments**
  - Nothing paid for this
- **At closing BioXell has around EUR 27 m net assets**
  - Primarily cash, claims for tax refunds and claims for grants
- **Cost to Cosmo**
  - EUR 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 pS between 1.7.2011 and 31.12.2011
- **Next steps**
  - Board has resigned; General Assembly will approve appointment of two persons to delist the Company; put it in liquidation process
  - Company may be continued; purchase assets and activities from other Cosmo companies being considered

# Extensive portfolio in IBD, a disease with very little recent innovation



# Product pipeline: Progress in all projects; no project failures

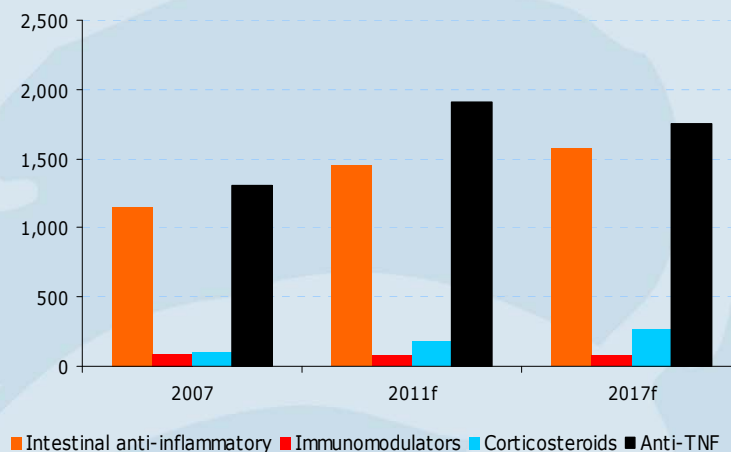
Product	Drug type	Indication	PC	Ph I	Ph II	Ph III	MA Launch	Partner
Lialda®/Mezavant®/Mesavancol®	5-ASA	Mild to moderate Ulcerative Colitis					03/07 USA 10/07 UK 01/10 ITA	Shire/Giuliani
Zacol NMX®	Dietary supplement	Intestinal Disorders (nutraceutical)					12/05 ITA	
Budesonide MMX®	Corticosteroid	Mild to moderate Ulcerative Colitis				Q2/3 10		Santarus - USA Ferring – Worldwide (excluding Japan & USA)
Rifamycin SV MMX®	Antibiotic	Traveller's Diarrhoea				H2 10 EU H2 11 US		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 Toxicologic Study Sensitivity Study	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						

# IBD market size

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>



## Lialda®

- **Indication**
  - Patients with Ulcerative Colitis of mild to moderate severity
- **Analyst projections of net sales**
  - 2009: \$ 215 m in reality \$ 237 m were achieved
  - 2010: \$ 323 m (Europe will come on stream)
  - 2011: \$ 392 m

## Budesonide MMX®

- **Indication**
  - Patients with Ulcerative Colitis of mild to moderate severity
- **Market size**
  - Targeted first at the 64% of all patients that have mild to moderate disease but do not respond to 5-ASA treatments and also at the entire 5-ASA market because corticosteroids are more effective
  - In the US Crohn's Disease market, which is smaller than the UC market, Entocort achieved sales of \$ 189 m in 2008
- **Market need**
  - A corticosteroid tablet with the efficacy of a corticosteroid and the few side effects of salicylates

## Budesonide MMX®: Status and opportunities

- **Status**

- Phase III clinical trials patient enrolment completed in EU and USA
  - 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 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®

- **Indication**
  - Travellers and Infectious Diarrhoea
- **Market size**
  - Worldwide Travellers Diarrhoea market estimated at \$ 2 bn
- **Market need**
  - Most available drugs only address symptoms not the cause
  - Need for a non-absorbable antibiotic that does not sterilize bacteria in upper gut districts and does not promote bacterial resistance

## Rifamycin SV MMX®: Status and opportunities

- **Status**

- Positioned as New Chemical Entity in USA
- Patient recruiting for phase III trials in EU & US to start in Q2

- **Opportunities**

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

## LMW Heparin MMX®

- **Presented LMW Heparin MMX® at DDW in Chicago**
- **Step forward in understanding mechanism of action**
  - Wide range of immunomodulating activity inhibiting pro inflammatory cytokines TNF  $\alpha$  , Interferon  $\gamma$  , IL 2
- **Endogenous substance, very safe**
- **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

- 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
- **Indication**
  - Topical treatment of Acne (currently under clinical development)
  - Hirsutism, Androgenetic Alopecia (future developments)
- **Market size**
  - 16% of 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

# 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

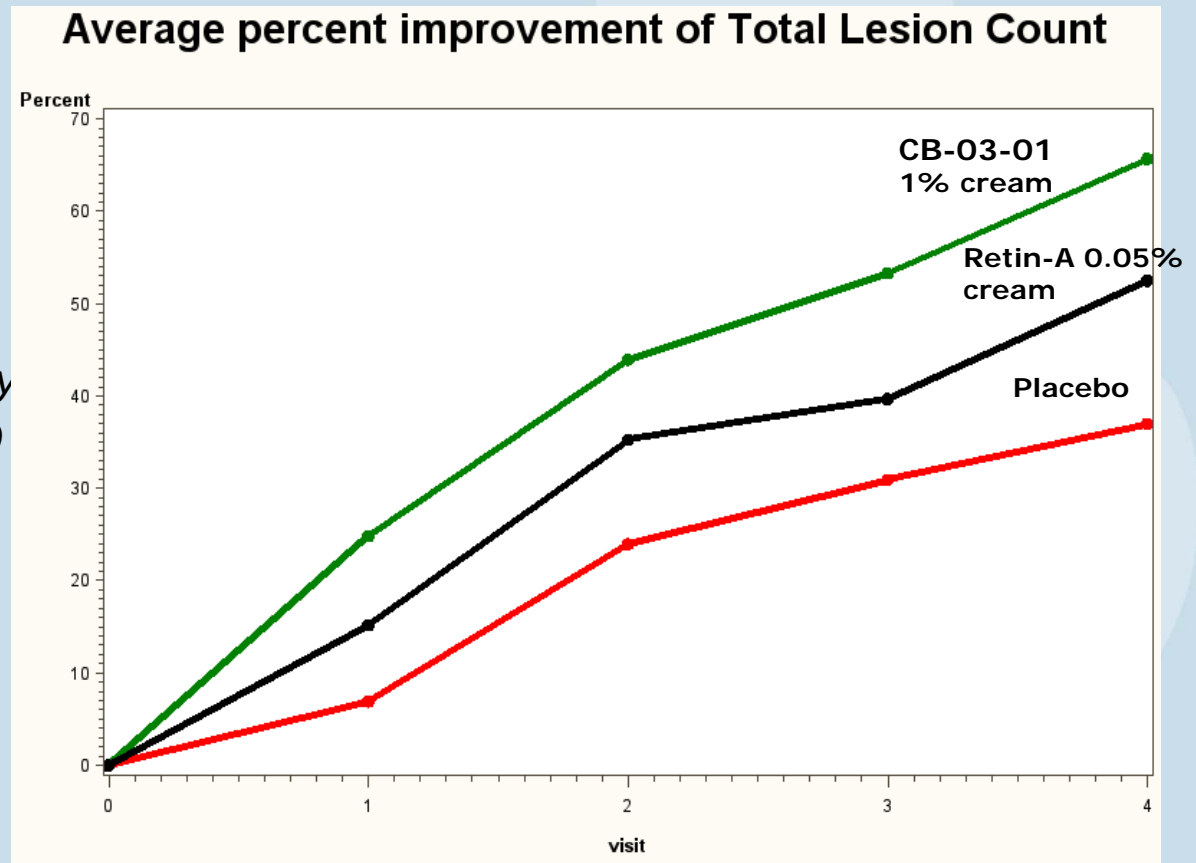
} **Efficacy**

- Local Tolerability
- Sistemic 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 ( $p=0.0015$ )

# CB-03-01 1% cream Phase II study clinical results – summary

## Overall efficacy of CB-03-01 1% cream in acne vulgaris

Parameter	Placebo cream (n=14)	Standard of care comparator 0.05% cream (n=30)	CB-03-01 1% cream (n=28)
<b>Total Lesion Count (TLC)</b> - % reduction vs. baseline, at weeks 8 - median time (days) to reach improvement 50%	37.1 58	52.5 57	65.7 <sup>(a)</sup> 43 <sup>(d)</sup>
<b>Inflammatory Lesion Count (ILC)</b> - % reduction vs. baseline, at weeks 8 - median time (days) to reach improvement 50%	38.9 58	50.7 44	67.2 <sup>(b)</sup> 36 <sup>(e)</sup>
<b>Acne Severity Index (ASI)</b> - % reduction vs. baseline, at weeks 8 - median time (days) to reach improvement 50%	39.5 57	53.0 44	68.3 <sup>(c)</sup> 42 <sup>(f)</sup>
<b>Investigator Global Assessment (IGA)</b> - % of success at weeks 8	7.1	11.5	22.2

<sup>(a)</sup> statistically significant vs. Placebo ( $p=0.0009$ ), and vs. comparator ( $p=0.0265$ )

<sup>(b)</sup> statistically significant vs. Placebo ( $p=0.0134$ ); <sup>(e)</sup> statistically significant vs. Placebo ( $p=0.0217$ )

<sup>(c)</sup> statistically significant vs. Placebo ( $p=0.0090$ ); <sup>(f)</sup> statistically significant vs. Placebo ( $p=0.0134$ )

<sup>(d)</sup> statistically significant vs. Placebo ( $p=0.0125$ )

## Outlook for 2010: Recurring revenue growth, continued profitability, pipeline expansion

- Revenues projected at around € 29.5 m (+10%)
  - Analysts project Lialda® sales to increase to \$ 323 m i.e. by 36%. Royalties and manufacturing income are expected to increase accordingly.
  - Contract drug manufacturing revenue should increase by > 10%
  - License fees of € 2 m budgeted; no assumptions for CB-03-01 licensing agreement(s)
- Stable COGS
- Positive EBITDA, PAT and no cash consumption
- Data from phase III trials for Budesonide MMX® and possibly for Rifamycin SV MMX®
- At least one new product to move from preclinic to clinic
- Cash position maintained; no external financing required

## 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
- Announcement of repositioning of BioXell in H2 2010
- Possible CB-03-01 Acne licensing agreements in H2 2010

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