

COSMO

Pharmaceuticals

**Report of
Preliminary Results of 2007
March 4 2008**



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Agenda

- ◆ Introduction and 2007 highlights Mauro Ajani, CEO
- ◆ 2007 Financial review Chris Tanner, CFO
- ◆ Pipeline update Mauro Ajani, CEO
- ◆ 2008 Outlook Chris Tanner, CFO
- ◆ Questions & Answers All

Key Financial Highlights for 2007

- ◆ IPO on SWX Swiss Exchange March 2007, raised net € 30 million
- ◆ Revenue increased by 44.5% to € 21.9 million of which only € 3.5 million is non recurring
- ◆ costs increased by 21.1% to € 22.7 million reflecting increased R&D activities
- ◆ EBITDA of € 1.2 million
- ◆ Net profit of € 0.1 million
- ◆ Cash € 25.5 million

Key Operating Highlights 2007

- ◆ Lialda™ launched in the US in March, gaining an 8% share at year end
- ◆ Budesonide MMX™ began phase III trials in US and EU
- ◆ Rifamycin SV MMX™ successfully completed phase IIb trials
- ◆ Indications for Rifamycin SV MMX™ extended to CDAD
- ◆ Anti Androgen and Anti TNFα project progressed
- ◆ New anti opioid induced constipation and new colo-rectal cancer prevention project
- ◆ Licensing agreement signed with Ferring SA for Budesonide MMX™ for the EU, Latin America and Asia excluding Japan

Income Statement

(Thousands of Euros)

	31.12.2007	31.12.2006
Revenue	21,900	15,158
Other income	516	4,934
Changes in inventories of finished goods and work in progress	380	(110)
Raw material and consumables used	(6,642)	(5,387)
Personnel expenses	(6,629)	(4,910)
Depreciation and amortization	(1,460)	(1,492)
Other operating expenses	(8,313)	(6,818)
OPERATING RESULT	(248)	1,375
Financial income	870	112
Financial expenses	(469)	(983)
PROFIT (LOSS) BEFORE TAXES	153	504
Income tax expenses	(37)	(848)
PROFIT (LOSS) FOR THE PERIOD	116	(344)

Income Statement reclassified

(Thousands of Euros)

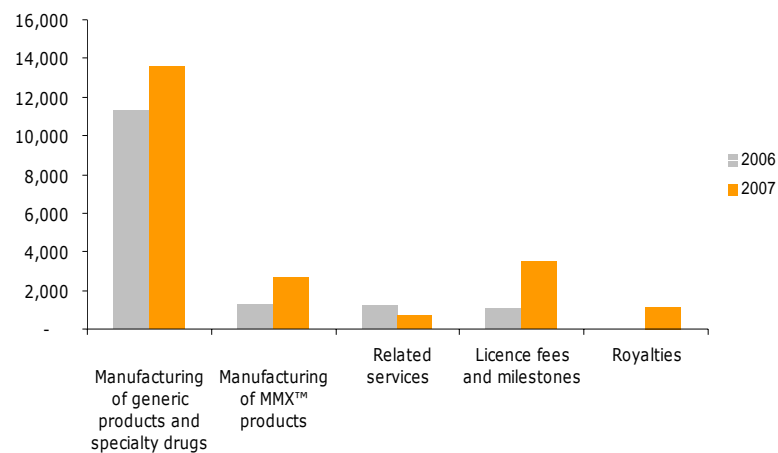
	31.12.2007	31.12.2006
Revenue	21,900	15,158
Other income	516	4,934
Product costs	(12,093)	(9,906)
R&D costs	(4,446)	(3,854)
SG&A costs	(4,665)	(3,465)
Depreciation and amortization	(1,460)	(1,492)
OPERATING RESULT	(248)	1,375
Financial income	870	112
Financial expenses	(469)	(983)
PROFIT (LOSS) BEFORE TAXES	153	504
Income tax expenses	(37)	(848)
PROFIT (LOSS) FOR THE YEAR	116	(344)

	31.12.2007	31.12.2006
BUDESONIDE	435	520
HEPARYN	1,002	556
RIFAMYCIN	421	27
ANTI ANDROGENS	740	237
OTHERS	42	631
Pre-clinical and clinical trials	2,640	1,971

Revenue

(Thousands of Euros)

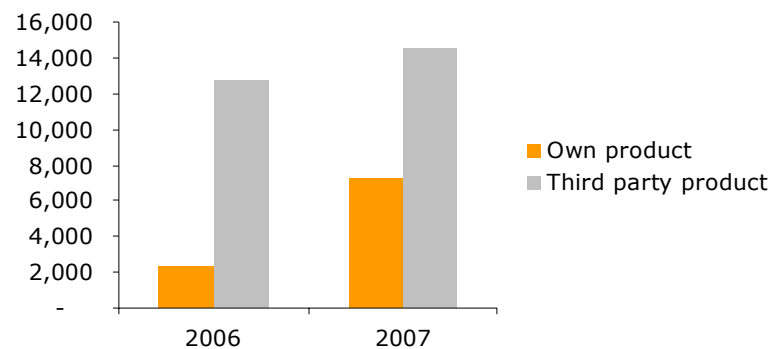
	31.12.2007	31.12.2006
Manufacturing on behalf of third parties:		
Manufacturing of generic products and specialty drugs	13,558	11,308
Manufacturing of MMX™ products	2,670	1,260
Related services	703	1,227
Other revenues from sale	313	264
Licence fees and milestones	3,502	1,077
Royalties	1,154	22
Total revenue	21,900	15,158



Revenue

(Thousands of Euros)

	31.12.2007	31.12.2006
Own product	7,326	2,359
Third party product	14,574	12,799
Total revenue	21,900	15,158



Revenue Growth

- ◆ Overall revenue grew by 44.5% to € 21.9 million
 - MMX™ related revenues grew by 210% to € 7.3 million
 - € 3.5 million was a non recurring milestone payment
 - Contract drug manufacturing revenues grew by 19.9% to € 13.6 million
 - Generics manufacturing grew by 34.6%
 - Specialty pharma manufacturing grew by 5.3%

- ◆ Revenue composition is evolving:
 - 2007 MMX™ related revenue reached 33.5% of total revenues, up from 15.6% in 2006
 - 2007 generics manufacturing reached 52.8% of total contract drug manufacturing, up from 47.0%

Costs

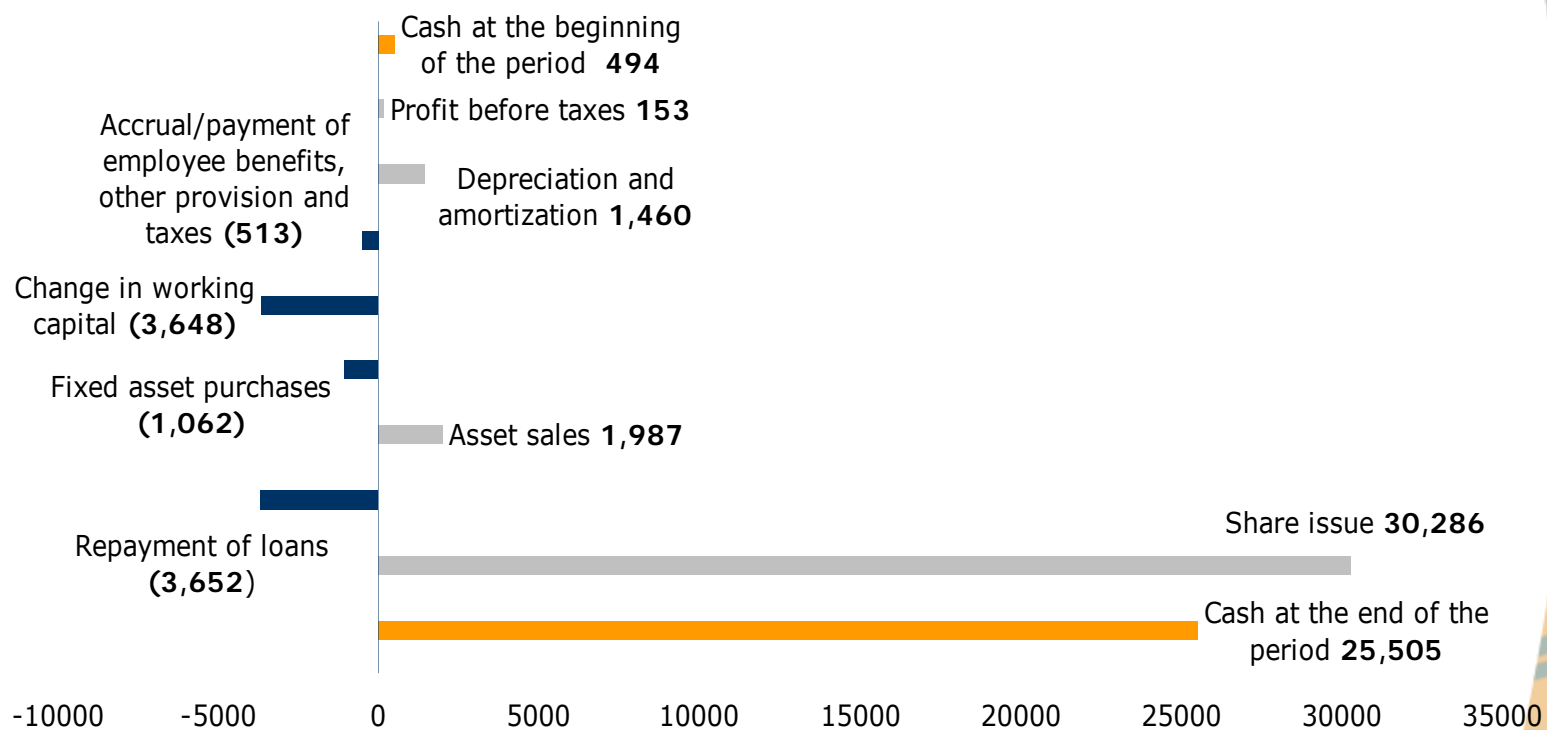
- ◆ Raw materials & consumables costs increased by 23.3% to € 6.6 million
 - But materials and consumables costs to manufacturing revenue went down from 42.8% to 40.9%
- ◆ Personnel costs went up by 35% to € 6.6 million
 - But personnel cost to total revenue dropped from 32.3% to 30.3%
 - Personnel costs include a non recurring € 1 million payment made to all employees
- ◆ External costs for clinical trials rose by 33.4% to € 2.6 million
- ◆ In reclassified terms:
 - R&D cost 20% of total revenue
 - SG&A cost 21% of total revenue
 - Production cost 55% of total revenue

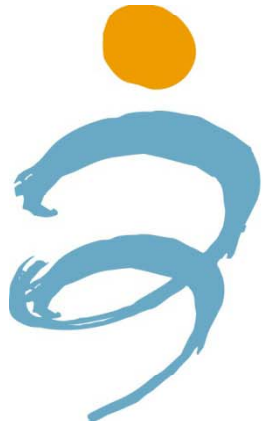
Balance Sheet

(Thousands of Euros)

	31.12.2007	31.12.2006
ASSETS		
Non-current assets		
Property, plant and equipment	6,891	7,096
Goodwill	109	109
Other intangible assets	3,175	3,384
Deferred tax assets	1,434	1,223
Other non-current receivables	1,953	1,906
Total non-current assets	13,562	13,718
Current assets		
Inventories	1,549	966
Trade receivables	3,400	3,168
Current tax assets	273	126
Other receivables	2,939	4,975
Cash and cash equivalents	25,505	2,339
Total current assets	33,666	11,574
TOTAL ASSETS	47,228	25,292
EQUITY		
Share capital	3,469	2,185
Share premium	29,372	-
Other reserves	2,162	2,876
Stock option plan reserve	28	-
Profit/(Loss) for the period	116	(344)
TOTAL EQUITY	35,147	4,717
LIABILITIES		
Non-current liabilities		
Interest-bearing loans and borrowings	3,658	4,783
Employee benefits	630	755
Deferred tax liabilities	1,213	1,160
Other non-current liabilities	2	10
Total non current liabilities	5,503	6,708
Current liabilities		
Interest-bearing loans, borrowings and bank overdraft	1,540	5,912
Trade payables	4,162	4,948
Current tax liabilities	171	190
Other current liabilities	705	2,817
Total current liabilities	6,578	13,867
TOTAL LIABILITIES	12,081	20,575
TOTAL EQUITY AND LIABILITIES	47,228	25,292

Cash Flow





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Pipeline Update

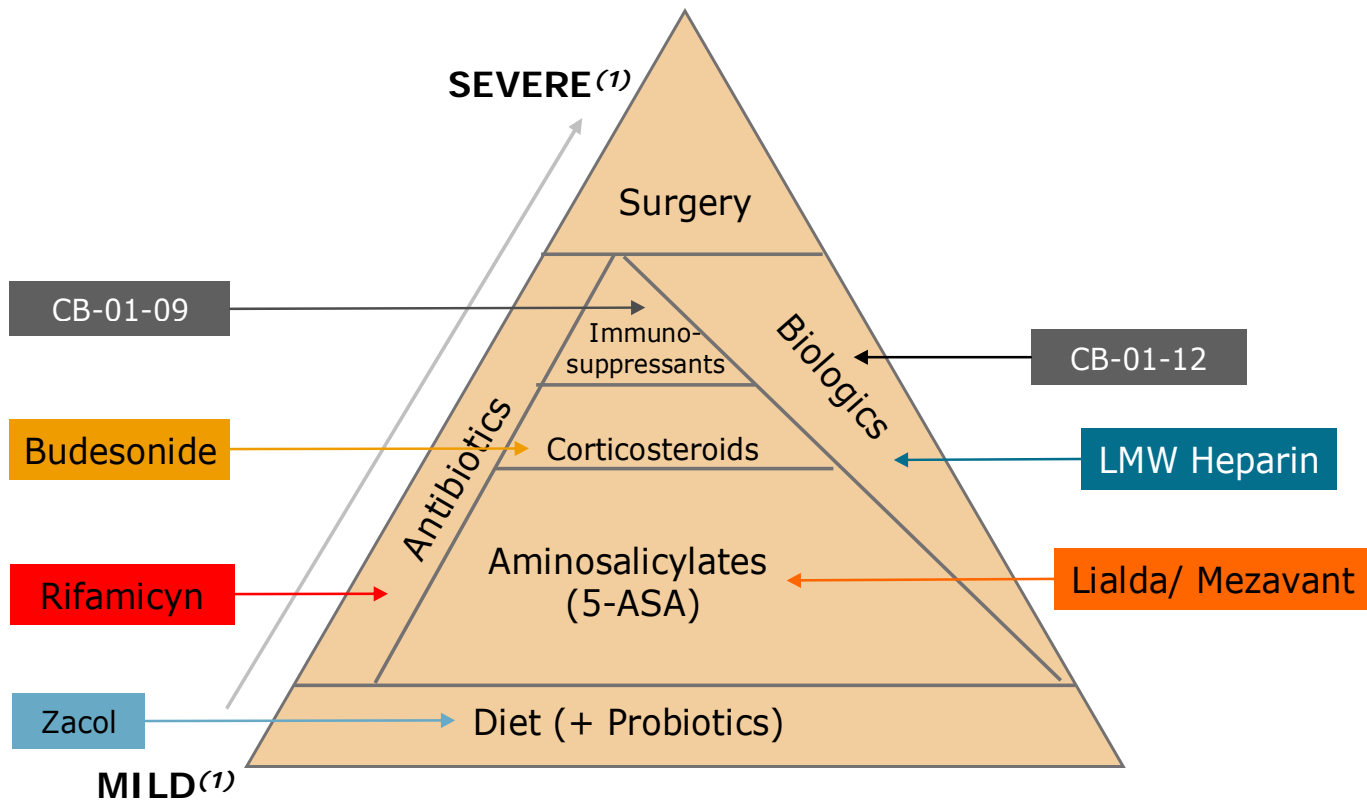


Product Pipeline

Strong Potential to Improve Existing Treatments in Terms of Compliance, Efficacy and Safety

Product	Drug type	Pre-clinical	Ph I	Ph II	Ph III	MA	Launch	
Lialda™/ Mezavant™ <i>Mild to moderate Ulcerative Colitis</i>	5-ASA	Licensed worldwide to Giuliani/ Shire						March 2007 USA
Budesonide MMX™ <i>Mild to moderate Ulcerative Colitis</i>	Corticosteroid				H1 09		2010e	
Rifamycin SV MMX™ <i>Infectious diarrhoea</i>	Antibiotic				Q3 09		2010e	
LMW Heparin MMX™ <i>Mild to moderate Ulcerative Colitis</i>	Biologic			Q1 08			2012e	
Zacol NMX <i>Intestinal disorders (nutraceutical)</i>	Dietary supplement							
Rifamycin SV MMX™ <i>CDAD</i>	Antibiotic			Q1 10			December 2005 Italy	
CB-03-01 (NCE) <i>Acne, male pattern baldness, and hirsutism</i>	Steroid ester, androgen antagonist			Q2 09				
CB-01-12 <i>IBD</i>	Anti-TNF α						2011e	
CB-01-09 <i>IBD</i>	Immuno-suppressant							
CB-01-13 <i>Cancer prevention</i>	Colo rectal cancer prevention							
CB-01-14 <i>Crohn's disease</i>	Antibiotic							
CB-01-16 <i>Opioids Constipation</i>	Opioids antagonist							

Extensive Portfolio Covering IBD



1. Status of disease severity

Overview of Lialda™ / Mezavant™

Key Achievement

- ◆ In US market since March 2007 for induction of remission of UC
- ◆ MMX™ technology now proven
- ◆ Lialda™ / Mezavant™ substantially improves compliance with a once-daily formulation
- ◆ Shire is putting a substantial effort into building the MMX™ brand

Market

- ◆ Market value: \$ 1.3 b ⁽¹⁾
- ◆ N° of patients: around 5 m patients world wide:
 - 91% have mild and moderate disease of which
 - 69% respond to 5-ASA
 - 22% do not respond to 5-ASA
 - 9% severe

(1) 7 major markets include US, Japan, UK, Germany, Italy, France and Spain

Development

- ◆ UK market entry in Q4 2007 for induction of remission and maintenance of mild to moderate Ulcerative Colitis
- ◆ In US 9% of 5-ASA market share for 2007. H1 2008 market launch Lialda™ in US for maintenance of UC

Business Case

- ◆ Analysts are projecting Shire's peak Lialda™ /Mezavant™ sales at >\$400 m p.a.
- ◆ Cosmo's profits from production approximately 3% of revenues
- ◆ 3.5% sales royalties, cap \$ 95 m

Overview of Zacol NMX™

Key Objective

- ◆ Deliver butyric acid and inulin to the colon where these can support the integrity and reconstitution of the gut mucosa

Market Opportunity

- ◆ As a dietetic product suitable to compete against classical probiotics

Development

- ◆ Clinical trials demonstrate reduction of side effects associated with antibiotic therapy
- ◆ Reduction of bloating and diarrhoea
- ◆ Product registered and trial marketed in Italy with gastro intestinal specialists

Business case

- ◆ Available for licensing in the US & Canada
- ◆ Available for licensing in EU and RoW

Overview Budesonide MMX™

Key Objective

- ◆ Maintain steroid efficacy at greatly reduced side effects
- ◆ Reduction in treatment time by 50%
- ◆ Objective to become first oral corticosteroid for mild to moderate Ulcerative Colitis

Market Opportunity

- ◆ 31% of patients with mild to moderate UC are refractory to 5 ASAs
- ◆ Targeted at first line therapy
- ◆ 19% of TRX best case if first line for induction of remission in mild to moderate UC
- ◆ 14% of TRX if first line for steroid therapy

Development

- ◆ Phase III clinical trials in EU and USA for induction of remission of Ulcerative Colitis
- ◆ Trial for maintenance of remission following end of clinical trial in 2009
- ◆ Market introduction in USA and EU expected 2010

Business Case

- ◆ Peak sales potential in USA of \$ 160-390 million
- ◆ If approval can be obtained for maintenance treatment, a substantial increase of peak sales could be expected
- ◆ Licensed to Ferring for EU, Asia and Latin America

Green light for Budesonide MMX™ trial designs by FDA and EMEA

- ◆ **AM trial. CB-01-02/01** - *Efficacy and safety of New Oral Budesonide MMX™ 9mg and 6mg extended release tablet formulations (CB-01-02) in patients with mild or moderate, active Ulcerative Colitis – A multicenter, randomized, double-blind, double-dummy comparative study versus Placebo, with an additional reference arm evaluating Asacol® 2400 mg.*
 - Patients to enroll: 440 in USA, CA, BRA, MEX, ARG, PE
 - To be followed by maintenance trial
- ◆ **EU trial. CB-01-02/02** - *Efficacy and safety of New Oral Budesonide MMX™ 9mg and 6mg extended release tablet (CB-01-02) in patients with mild or moderate, active Ulcerative Colitis – A multicenter, randomized, double-blind, double-dummy comparative study versus Placebo, with an additional reference arm evaluating Entocort® EC capsules.*
 - Patients to enroll: 440 in ND, B, F, CZ, HU, LT, LV, PO, SW, IT, UK, RO, UK, RS
 - To be followed by maintenance trial

Overview Rifamycin SV MMX™

Key Objective

- ◆ First focussed delivery into the colon of a non-absorbable antibiotic
- ◆ Not to affect flora of the stomach and upper small intestine
- ◆ Allow long term treatment of colon infections, reducing risk of resistance
- ◆ Apply to Clostridium Difficile Associated Diarrhoea (CDAD) and potentially Diverticulitis

Market Opportunity

- ◆ Colon infections are concomitant with inflammations in 30-50% of IBD cases of IBD; this is a potential market of up to \$ 2 b
- ◆ Travellers diarrhoea market is around \$ 2 b
- ◆ 0.2% of all Hospital patients get CDAD. Market potential of \$ 500 m

Development

- ◆ Phase II/III trial on 120 patients comparing Rifamycin SV MMX™ to Rifaximin in infectious diarrhoea (non inferiority) completed and clinical endpoints met
- ◆ Dose finding study started Jan 08; IND expected Q2 08. First patient of phase III for colon infections in Mexico to be treated in Q4 2008
- ◆ Dose finding phase II study for CDAD PoC study starting Q1 2008

Business Case

- ◆ Three opportunities of achieving peak sales > \$ 200 m each
- ◆ Intention to market in USA directly
- ◆ Intention to license to partners in EU H1 2008

Rifamycin SV MMX™ potential extension of indications

In addition to Infectious Colitis, IBD concomitant infections and Clostridium Dificile associated Diarrhoea, Rifamycin SV MMX™ could be developed for the following indications:

- ◆ IBD supportive therapy
- ◆ Diverticulitis
- ◆ Hepatic Encephalopathy

Overview of LMW Heparin MMX™

Key Objective

- ◆ Identification of LMW Heparin, an endogenous biologic drug, that retains and maximizes the anti-inflammatory properties found in Heparin

Market Opportunity

- ◆ LMW Heparin MMX™ would be the first oral, topical heparin treatment for UC, the only biological drug with virtually no side effects and could be used by all UC patients

Development

- ◆ Phase II proof of concept trial completed; data report IQ 2008
- ◆ If successful extension to Crohn's Disease will be initiated
- ◆ **Mechanism of action found:** sodium parnaparin inhibits pro inflammatory cytokines (TNF α , IFN γ and IL-2) and has a wider activity profile than MABs

Business case

- ◆ Opportunity to become gold standard of UC with peak sales potential
> \$ 500 m p.a.
- ◆ Or as adjuvant with peak sales potential of
> \$ 200 m p.a.

Detail of LMW Heparin trial designs

- ◆ **Phase II trial** – *Efficacy and tolerability of a new oral extended-release formulation containing Low Molecular Weight Heparin (CB-01-05 MMX™), administered as add-on therapy to oral mesalazine or other 5-ASA derivatives, in patients with active, left-sided, mild to moderate ulcerative colitis. A multicentre, randomised, double-blind, comparative study versus placebo – patient treatment completed, report by 1Q 08.*

5 countries (IT, UK, RO, HU, RS) with 24 investigator sites

- **157** patients screened
- **141** randomised
- **132** completed
- **9** withdrawn

Patient treatment and follow-up ended in November 07

Overview of CB-03-01 (Anti Androgen)

Key Objective

- ◆ Identification of a NCE with anti-androgenic properties that has low systemic effects and can thus be topically used for the treatment of acne, alopecia and hirsutism
- ◆ CB-03-01 is a steroid derivative of Cortisol with strong, local androgen antagonist activity

Market Opportunity

- ◆ 6% of US population suffer from acne vulgaris
- ◆ 10% of all women have hirsutism: no FDA approved drug
- ◆ 6% of all men have alopecia

Development

- ◆ Phase I 24 volunteer trial in Austria started February 2008; Phase II to be completed 2Q 2009
- ◆ **Mechanism of action:**
Blocks the skin and hair follicle androgen receptor and has anti-inflammatory properties

Business case

- ◆ Blockbuster potential
- ◆ Will be licensed out after phase II

Trial design for CB-03-01

- ◆ **Phase I** – *First dose in man of CB-03-01; a new topical anti-androgen drug. First dose in man, randomised, double-blind, placebo controlled, consecutive cohorts, single ascending doses, non occluding, topical administration. – ongoing, to be completed by 2Q 08*

24 volunteers with assessment of safety and tolerability + PK end-points

Overview of CB-01-09 MMX™ (immunosuppressant)

Description

- ◆ Cyclosporine is indicated as an immunosuppressant after organ transplants and has been used for severe cases of IBD
- ◆ Off patent peptide
- ◆ Variable oral absorption makes it unreliable
- ◆ High systemic absorption creates serious immuno related side effects

Development

- ◆ Studies show that Cyclosporine is endowed with topical activity when administered locally
- ◆ 3 clinical studies on volunteers proved efficacy, also in enema delivery

Key Objective

- ◆ Develop an MMX™ application for severe cases of IBD
- ◆ With strong topical activity
- ◆ Greatly reduced side effects

Market Opportunity/Business case

- ◆ Relatively small market

Overview of CB-01-12 MMX™ (anti TNFα)

Key Objective

- ◆ Prove that biologic drugs (peptides and proteins) can be brought into the colon for topical application
- ◆ Transform anti-TNFα injection into an anti-TNFα tablet
- ◆ Increase patient comfort
- ◆ Maintain effectiveness
- ◆ Reduce side-effects

Market Opportunity

- ◆ Currently there are no oral MAb oral dosage forms on the market
- ◆ Cosmo patent could extend the life of the selected MAb to 2026

Development

- ◆ Material transfer agreement with one MAb provider signed
- ◆ Joint research agreement to determine feasibility and bioavailability with a MAb owner being negotiated
- ◆ Data availability in Q4 2008

Business case

- ◆ Dependent on agreement with a MAb owner
- ◆ Opportunity to become the only anti TNF α tablet in the market
- ◆ Cosmo would be paid milestones and a royalty that is to be negotiated

Overview of CB-01-13 MMX™ (colon cancer prevention)

Description

- ◆ Aberrant crypt foci (ACF) are precancerous lesions in the colon predictive for colorectal cancer
- ◆ COX 2 inhibitors are known to reduce the creation of ACFs but many have serious side effects
- ◆ CB 01-13 uses a well know NSAID COX 2 inhibitor with a low absorption in the colon

Development

- ◆ The NSAID COX 2 inhibitor is in the market in a number of countries
- ◆ Animal tests demonstrated reduction in ACFs after topical application
- ◆ Joint Development agreement with NSAID COX 2 owner signed
- ◆ PK study
- ◆ Thereafter dose proposal, MMX™ tablet development and dose ranging study on 12 volunteers to take place in 2008

Objective

- ◆ Creation of an approved COX 2 application for prevention of colorectal cancer
- ◆ By using the MMX™ process the COX 2 inhibitor can be brought directly to the colon thus reducing drastically potential side effects caused by systemic absorption

Market opportunity/Business case

- ◆ 6% of US population are projected to get Colorectal Cancer during their life time
- ◆ Only 39% of cancers are detected at an early stage, cancer prevention is thus crucial
- ◆ Blockbuster potential

Overview of CB-01-14 MMX™

Description

- ◆ Metronidazole is well known molecule, a broad spectrum antibiotic used since 35 years for the treatment of gut and local infections including CDAD
- ◆ Used orally, in creams but also injections
- ◆ Heavy side effects on CNS, blood and liver restrict its use
- ◆ Off patent

Development

- ◆ Still in pre clinical development

Key Objective

- ◆ Creation of an MMX™ application of Metronidazole allowing higher concentration in gut
- ◆ Prove strongly reduced systemic absorption
- ◆ Target it at Crohn's Disease with an adapted MMX technology

Market Opportunity/Business Case

- ◆ Niche application

Overview of CB-01-16 MMX™ (opioid constipation)

Description

- ◆ Long term therapy with opioids is always complicated by severe constipation
- ◆ Opioid antagonists are known to be able to displace opioids from their receptors
- ◆ CB-01-16 uses the MMX™ technology to bring an opioid antagonist to the gut where it can block the opioid receptors of the gut locally without reducing the pain relief activity

Development

- ◆ Product rationale has been developed
- ◆ Phase I in volunteers being prepared following a dose escalating clinical evidence
- ◆ Phase II scheduled for 2009

Objective

- ◆ Develop a pharmaceutical that can be taken at the same time as all opioid products are taken in pain killing therapy in order to
 - reduce constipation
 - maintain opioid efficacy in pain killing

Market Opportunity/Business case

- ◆ Blockbuster potential

Outlook for 2008: Revenue growth, profitability, pipeline expansion

- ◆ Anticipating strong growth in revenues from Lialda™ sales
- ◆ Concluding a licensing agreement for Rifamycin SV MMX™ in Europe
- ◆ Finalising US distribution strategy
- ◆ Further strong growth anticipated in contract drug manufacturing business
- ◆ Phase IIb results of LMW Heparin MMX™ clinical trials
- ◆ Four projects to enter the clinic
- ◆ Identification of two new preclinical projects
- ◆ Maintain cash position and sustain modest profitability

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