

# Sachs Associates 8th Biotech in Europe Investor Forum

Zurich, 23 September 2008



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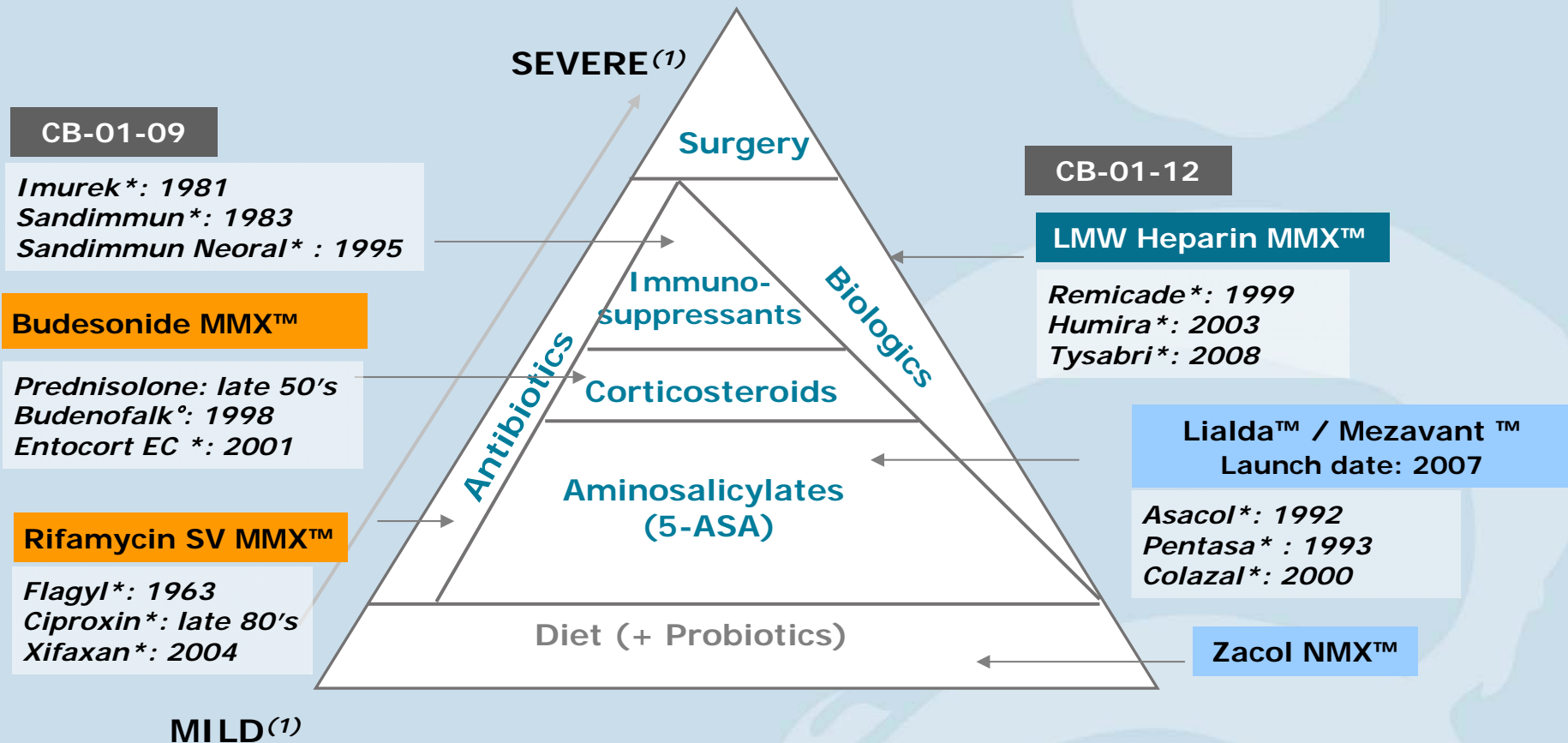
## Cosmo Profile

- Entrepreneur led
- Focus on inflammatory bowel diseases
- Positioned to become an integrated company
- Large, deep pipeline – low risk approach
- Proven, proprietary, patented MMX™ technology that is platform for new product development
- Strongly increasing recurrent revenues, basically cash neutral

## Cosmo Highlights

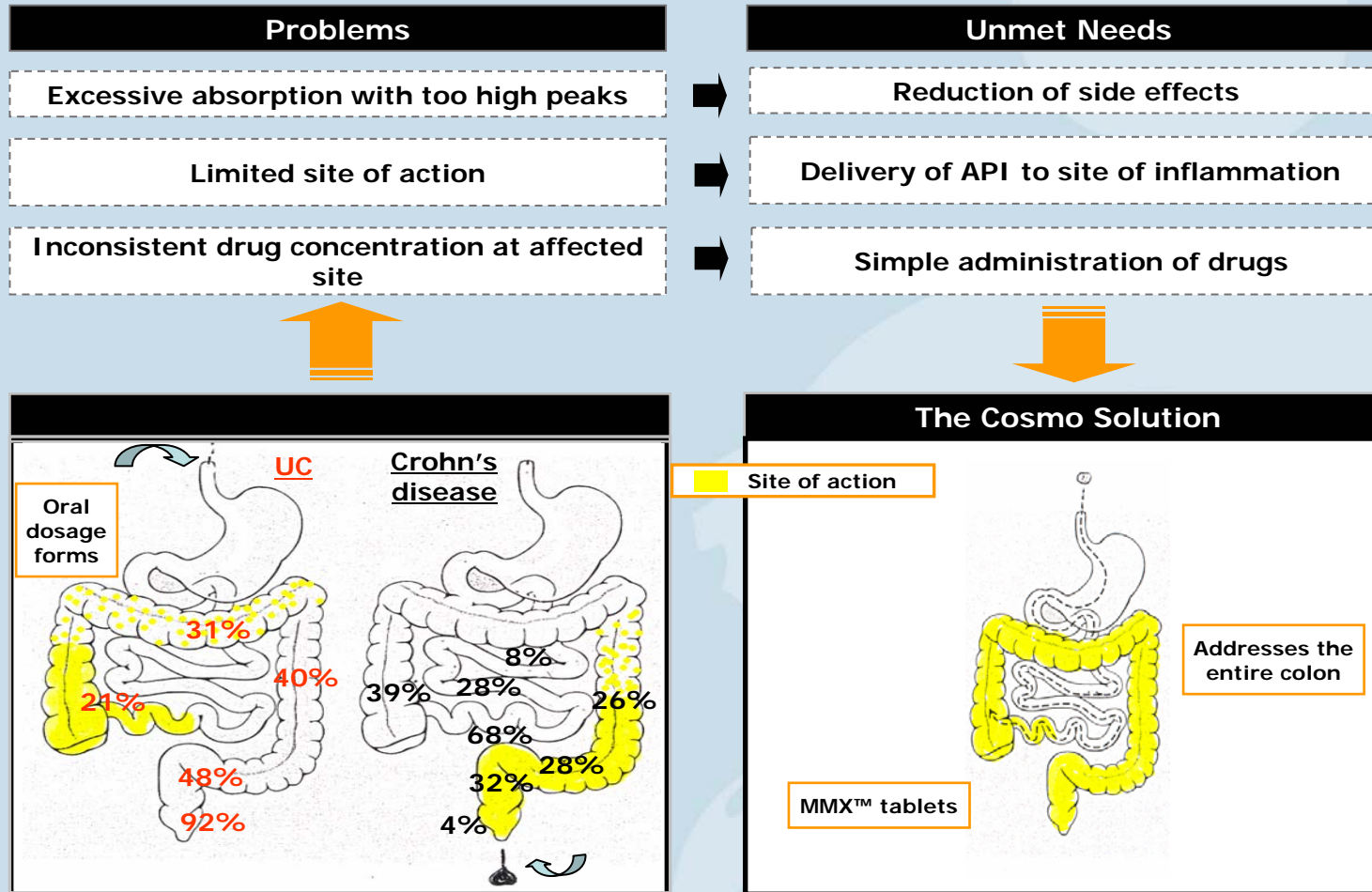
- Start of activities of new FDA approved manufacturing plant in June 2006
- FDA approval of Lialda™ and IPO in March 2007
- Licensing agreement for Budesonide MMX™ for non USA and Japan with Ferring in 2007
- Successful phase II trials for Budesonide MMX™, Rifamycin SV MMX™ and LMW Heparin MMX™
- Lialda™ reaches a market share of 11.3% of all 5-ASA tablets in the US 15 months after market introduction

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

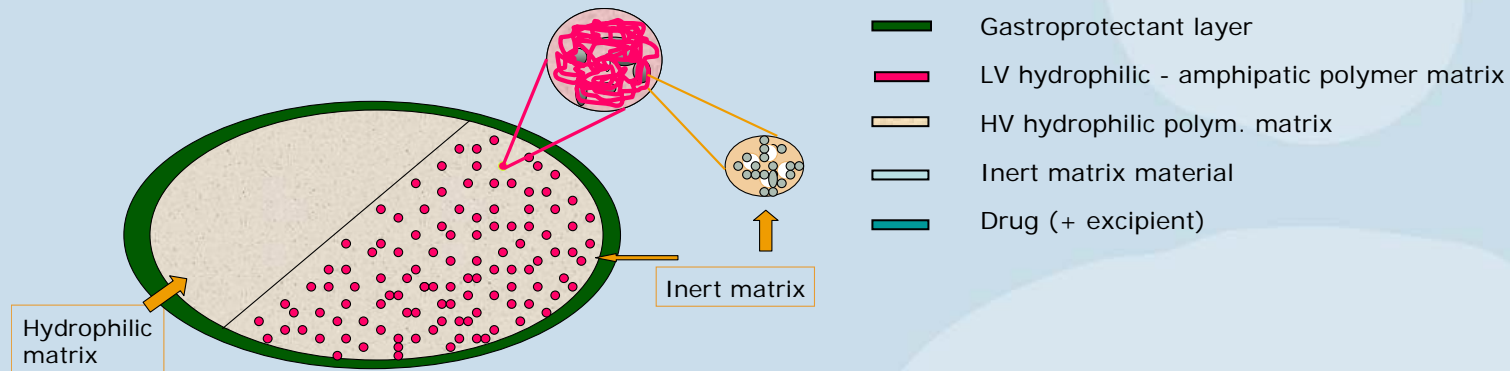


1. Status of disease severity  
° EU  
\* US

# Cosmo's Focus: addressing unmet medical needs in Colon diseases



# The Multi Matrix System (MMX™): Key Benefits



## Compliance

**Once daily** administration improves convenience

## Efficacy

Active substance brought to all parts of the colon

## Safety

Topical application. Toxicity/ **side effects reduced**

# Product Pipeline: Strong Potential to Improve Existing Treatments in Terms of Compliance, Efficacy and Safety

Partner	Drug type	Indication	Ph I	Ph II	Ph III	MA	Launch	
Shire Limited	5-ASA	Mild to moderate Ulcerative Colitis	Lialda™ / Mezavant™					03/07 USA 10/07 UK
	Dietary supplement	Intestinal disorders (nutraceutical)	Zacol NMX™					12/05 ITA
Ferring	Corticosteroid	Mild to moderate Ulcerative Colitis	Budesonide MMX™			4Q 09		2011e
Expected EU Licensing	Antibiotic	Infectious diarrhoea	Rifamycin SV MMX™			4Q 09		2010e
	Biologic	(Mild to moderate) Ulcerative Colitis	LMW Heparin MMX™			2Q 11		2012e
	Antibiotic	CDAD	Rifamycin SV MMX™	1Q 10				
	Steroid ester, androgen antagonist	Acne, male pattern baldness, and hirsutism	CB-03-01 (NCE)	3Q 09				

## Lialda™ / Mezavant™

- **Indication**
  - Mild to moderate Ulcerative Colitis
- **Market size**
  - Approximately 5 m patients worldwide; approx 70% have the disease as mild to moderate in severity
  - Total \$2-2.4 bn 2008 for 5-ASAs; USA \$ 1.1 bn for 5-ASAs
- **Market need**
  - Once a day
  - No side effects
- **Status:**
  - On its way to \$ 400 m peak sales
  - Royalty of 3.5% capped at cumulative \$ 95 m
  - Manufacturing income of approx 3% of revenue

## Budesonide MMX™

- **Indication**

- Patients with Ulcerative Colitis of mild to moderate severity, mainly that are refractory to 5-ASA's

- **Market Size**

- Targeted first at the 21% 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

- **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 underway in USA and EU;
  - 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 480 patients; due to end Q4 2009.

- **Opportunities**

- First steroid drug approved worldwide for patients with mild to moderate Ulcerative Colitis

# 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 stomach and upper gut

# Rifamycin SV MMX™: Status and Opportunities

- **Status**

- Phase II trials completed
- Phase III trials in EU and US currently under design

- **Opportunities**

- Highly effective against Clostridium Difficile (CDAD)
- Given its anti inflammatory properties, Rifamycin SV MMX™ could also 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™

- **Indication**

- Phase II demonstrated efficacy in patients with acute mild to moderate Ulcerative Colitis. Assessments under way to determine drug applicability to patients with acute moderate or moderate to severe Ulcerative Colitis and colonic Crohns Disease

- **Market size**

- At a minimum, the 70% of all patients with mild to moderate disease
- Likely scenario is to go for the 500,000 patients worldwide with moderate to severe disease

- **Market need**

- An effective product for patients with moderate to severe IBD
  - with no side effects
  - Convenience of a once a day tablet

## LMW Heparin MMX™: Status and Opportunities

- **Status**

- Completed phase II clinical trials demonstrated that LMW Heparin MMX™ is substantially more effective than 5-ASA's and has disease modifying properties
- Phase III clinical trials in EU and USA currently being prepared

- **Opportunities**

- Positioning the product in direct competition with immuno-suppressants and potentially anti-TNF's

## CB-03-01

- **Indication**

Topical treatment of

- Acne
- Hirsutism
- Androgen-induced alopecia

- **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: Status and Opportunities

- **Status**
  - First phase I study successfully completed
    - Permeates skin and is quantifiable in plasma
    - Well tolerated
    - No measurable side effects
  - Phase II proof of concept to start at end 2008
- **Opportunities**
  - First topically effective anti-androgen treatment in the market

# Pre clinical Pipeline

Product	Drug type	Indication	Projected start phase I
CB-01-12	Anti-TNF $\alpha$	IBD	Six months after kick off by partner
CB-01-06	Immuno-suppressant	IBD	tbd
CB-01-13	COX-2 inhibitor	Colo rectal cancer prevention	Bound to the API clearance
CB-01-14	Antibiotic	Crohn's Disease	1H 09
CB-01-16	Opioid antagonist	Opioid Induced Constipation (OIC)	1H 09

Focus our search for molecules that are active in the colon and whose efficacy or safety profile can be improved by applying MMX™ technology

## Key Financial Highlights for 1H 2008

In EUR m	1HY 2008	1HY 2007	%
Revenues	11.9	9.9	20
COGS	6.7	6.5	3
R&D expenditures	3.2	2.2	46
EBITDA	(0.7)	(2.5)	72
Net profit after tax	(0.8)	(1.7)	53
	<b>30/6/2008</b>	<b>31/12/2007</b>	
Cash and cash equivalents	23.9	25.5	(6)
Total assets	47.9	47.2	1

## Anticipated upcoming milestones

- EU licensing agreement for Rifamycin SV MMX™
- CB-03-01 phase II clinical trials start
- Start phase III clinical trials for Rifamycin SV MMX™ in EU and North America
- Decision on US market penetration strategy

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