



COSMO

Pharmaceuticals

Biotech in Europe 2007

Sachs Associates

October 2, 2007 Zurich



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Cosmo Profile

➔ **INNOVATIVE TREATMENTS FOR IBD**

- ◆ Focus on IBD and GI infections
- ◆ Addresses key unmet medical needs of many patient segments in IBD and GI

➔ **POSITIONED TO CAPTURE ALL PARTS OF THE VALUE CHAIN**

- ◆ Comprehensive, focused product portfolio
- ◆ Manufacturing skills and capacity
- ◆ Commercialisation strategy

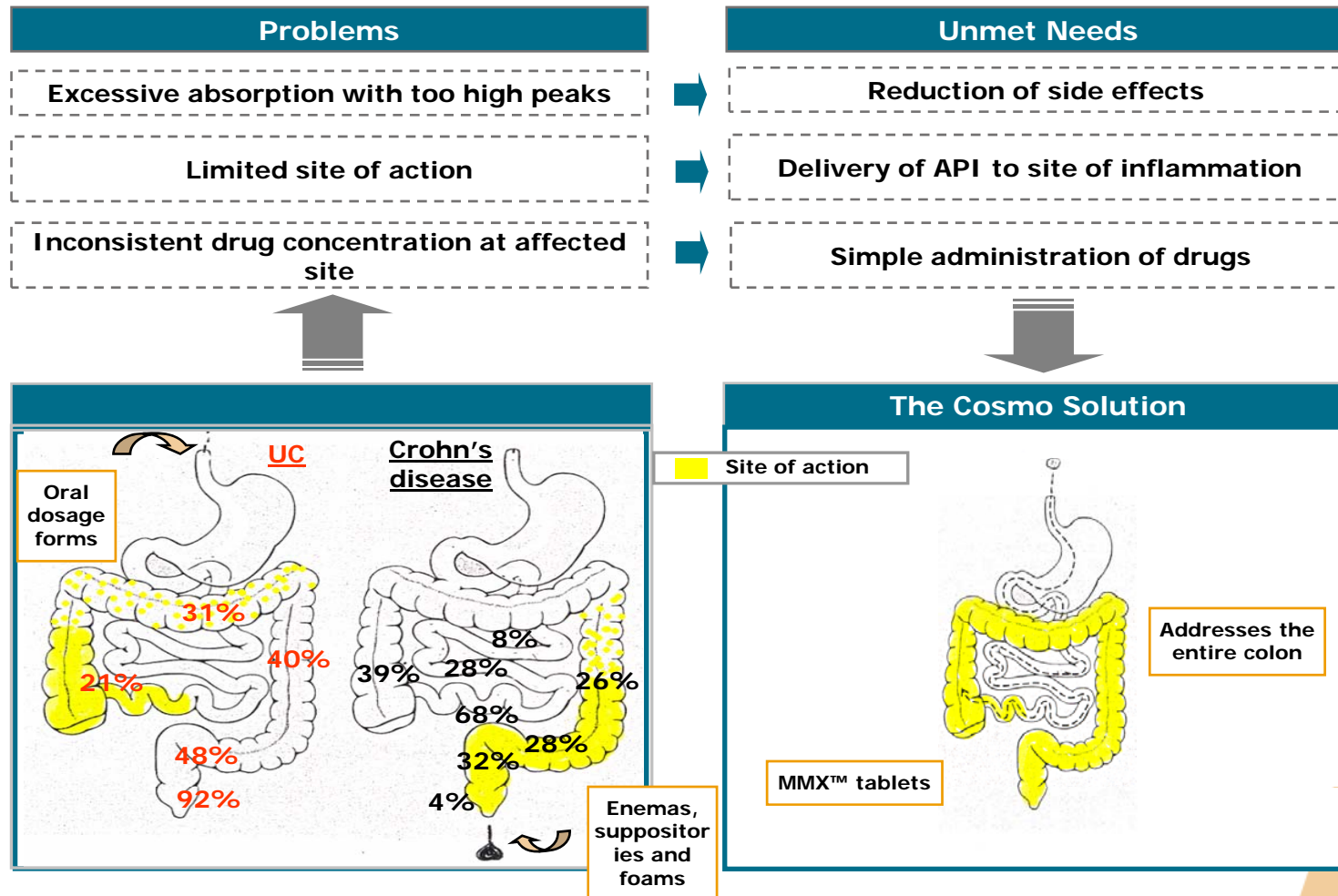
➔ **LARGE, DEEP PIPELINE – LOW RISK APPROACH**

- ◆ 2 Marketed products
- ◆ 1 Product in phase III, two ending phase II
- ◆ 3 Pre-clinical products, one which is approaching first in man clinical trials

➔ **PROVEN, PROPRIETARY, PATENTED MMX™ TECHNOLOGY**

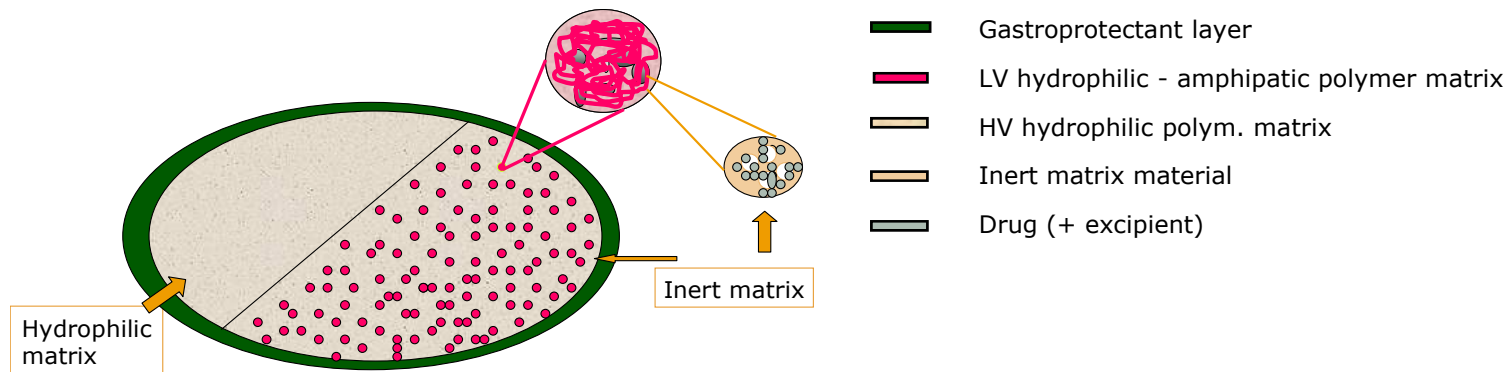
- ◆ Proof of concept achieved
- ◆ Base for further product development and replenishment of pipeline

Cosmo's focus: addressing unmet medical needs in IBD



The Multi Matrix System (MMX™)

Key benefits



Compliance

Once daily administration improves convenience

Efficacy

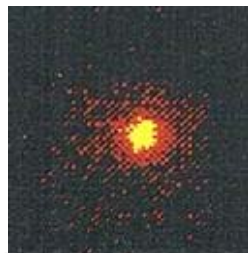
Active substance brought to all parts of the colon

Safety

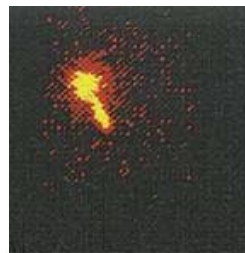
Topical application. Toxicity/ **side effects reduced**

MMX addresses the entire colon

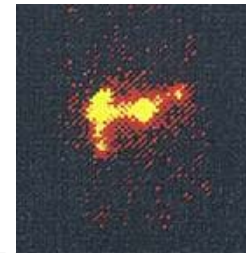
Greatly Improves the Pharmacological Activity and Disposition Characteristics of Existing Drugs



1h 30m
duodenum



4h 30m
ascending colon



7h 30m
transverse colon



10h
transverse colon



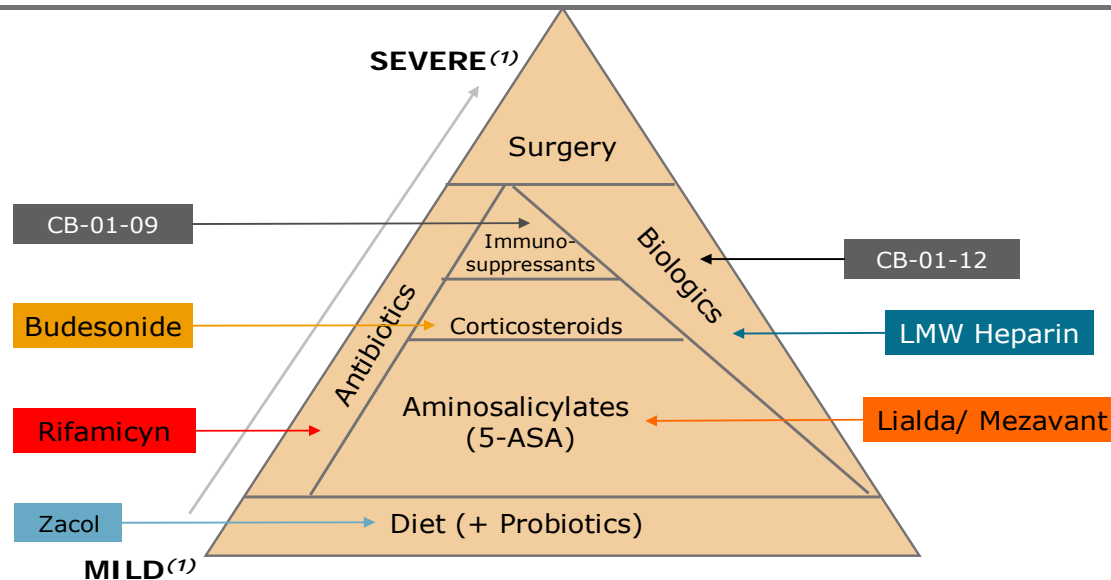
16h
descending colon



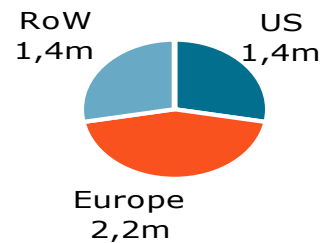
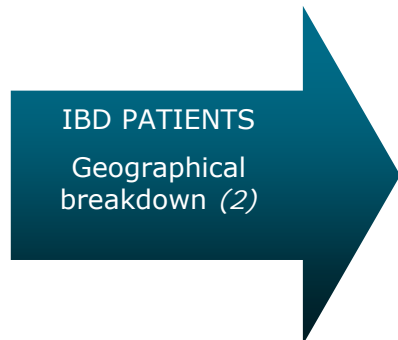
24h
rectum

MMX™ is a unique technology with clear differentiation from existing IBD therapies

Extensive Portfolio Covering IBD



1. Status of disease severity



Severity

- 70-80% are mild to moderate sufferers
 - 30-40% of these are salicylate non responders
- Moderate and severe 20-30%

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 MMX™ / Mezavant MMX™ <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				Q4 08		2010 e	
Rifamycin SV MMX™ <i>Infectious diarrhoea</i>	Antibiotic				Q4 08		2010 e	
LMW Heparin MMX™ <i>Mild to moderate Ulcerative Colitis</i>	Biologic				Q1 08		2012 e	
Zacol NMX <i>Intestinal disorders (nutraceutical)</i>	Dietary supplement						December 2005 Italy	
CB-01-12 <i>IBD</i>	Anti-TNF α							
CB-01-09 <i>IBD</i>	Immuno-suppressant							
CB-03-01 (NCE) <i>Male pattern baldness, acne and seborrhoea</i>	Steroid ester, androgen antagonist							
CB-01-13 <i>CDAD</i>	Antibiotic						2011 e	

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

- ◆ EU market entry expected in Q4 2007 for induction of remission and maintenance of mild to moderate Ulcerative Colitis.
- ◆ H1 2008 market launch Lialda in US for maintenance of UC

Business Case

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

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 Ulcerative Colitis

Market Opportunity

- ◆ Targeting 28% of all patients with mild to moderate Ulcerative Colitis to switch to Budesonide MMX for their treatment in acute phase

Development

- ◆ Phase III clinical trials in EU and USA for induction of remission of Ulcerative Colitis
- ◆ New decision to attach a trial for maintenance of remission following end of clinical trial in 2008.
- ◆ Market introduction in USA and EU expected 2010.

Business Case

- ◆ NPV for Cosmo in agreement currently being assessed is approximately 110% of peak sales
- ◆ If approval can be obtained for maintenance treatment, a doubling of peak sales could be expected

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
- ◆ Potential for eventual application in Clostridium Difficile Associated Diarrhoea (CDAC) and 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 CDAC. 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**
- ◆ Dose ranging for IND in Jan 08. First patient of phase III for colon infections in Mexico to start in Q3 2008
- ◆ Decision on proof of concept trial for CDAD in October 2007

Business Case

- ◆ Three opportunities of achieving peak sales > \$ 200 m each with an NPV multiplier in excess of 1.2

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 IBD and the only biological drug with virtually no side effects and could be used by all IBD patients

Development

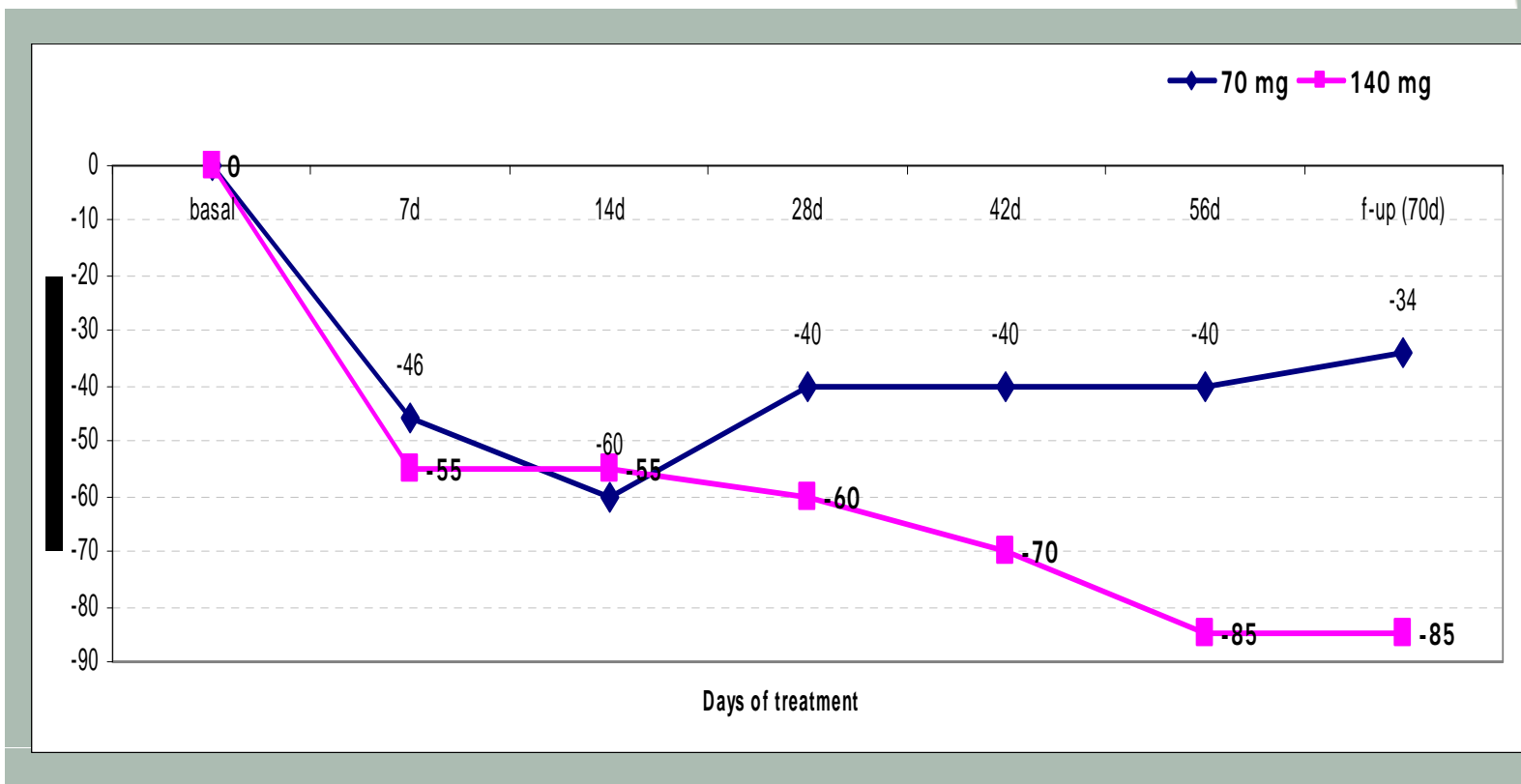
- ◆ Phase II 120 patients proof of concept trial in EU against placebo will be completed at the end of October 2007; data report IQ 2008
- ◆ **Mechanism of action:** sodium parnaparin inhibits pro inflammatory cytokines (TNF α , IFN γ and IL-2) and has a wider activity profile than Monoclonal Antibodies.

Business case

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

LMW Heparin MMX™

Clinical efficacy (as CAI % reduction) after oral administration as MMX™ formulation on small ph IIa trial study



Pre-clinical Products

CB-03-01



- ◆ CB-03-01 to be the first topically effective anti-androgen on world wide market
- ◆ In pre-clinical tests product shows to have an antiandrogenic potency at least comparable with flutamide and finasteride
- ◆ Devoid of systemic activity
- ◆ In vivo metabolized to a physiological substance, that has virtually no side effects
- ◆ CTA has been filed; phase I clinical trial (first in man PK and safety) to be started by year end 2007
- ◆ Licensing out opportunity in 2008

CB-01-12



- ◆ Successful redesign of anti TNF α monoclonal antibody injection into a MMX™ tablet
- ◆ Approach may have general application for topical colonic treatment of
 - Biologic drugs (proteins and peptides)
 - Monoclonal antibodies

Focused but Broad and evenly timed Product Pipeline

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

Product	Drug type	Clinical status	USP	Market entry	Market	Status
Lialda MMX™ / Mezavant MMX™ <i>Mild to moderate Ulcerative Colitis</i>	5-ASA	Market	Once a day	2007	5 ASA	Licensed out
Budesonide MMX™ <i>Mild to moderate Ulcerative Colitis</i>	Corticosteroid	Phase III	Much shorter treatment time	2010	Corticosteroid and 5 ASA	Licensing negotiations in EU
Rifamycin SV MMX™ <i>Infectious diarrhoea</i>	Antibiotic	Data report phase II	Long term treatments possible	2008/2010	30% of IBD and Diverticulitis	Licensing negotiations in EU
LMW Heparin MMX™ <i>Mild to moderate Ulcerative Colitis</i>	Biologic	Phase II b	High efficacy, no side effects	2012	All IBD	No negotiations until data report phase II
Zacol NMX <i>Intestinal disorders (nutraceutical)</i>	Dietary supplement	Market	Only combination product plus site specific delivery	2007	All IBD	Licensing negotiations in EU
CB-01-12 <i>IBD</i>	Anti-TNF α	Pre clinical	Oral anti tnf	Open	Anti tnfs	Open
CB-01-09 <i>IBD</i>	Immuno-suppressant	Pre clinical	Less side effects	Open	Immuno-suppressants	Open
CB-03-01 (NCE) <i>Male pattern baldness, acne and seborrhoea</i>	Steroid ester, androgen antagonist	Pre clinical	Only topical antiandrogen	Open	Acne, baldness, hirsutism	Licensing negotiations initiated
CB-01-13 <i>CDAD</i>	Antibiotic	Pre clinical	Most effective application	Open	Nosocomial intestinal infections	Open

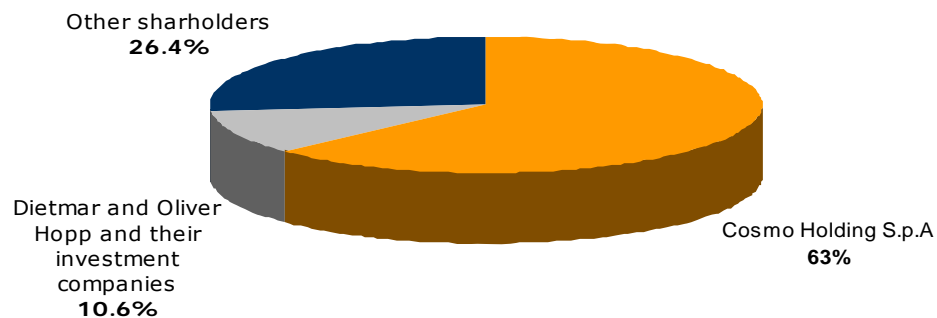
Key Financial Parameters

- ◆ **Cash and Equivalents:** € 24 million per September 30
- ◆ No cash burn for remainder **2007**
- ◆ **2008:**
 - cash from operating activity: € 3.7 m
 - working capital, financing and investing activity: € 5.2 m
 - clinical trials: € 13.1 m
 - milestones: tbn
- ◆ **2009:**
 - cash from operating activity: € 5.3 m
 - working capital, financing and investing activity: € 4.8 m
 - clinical trials: € 7.95 m
 - milestones: tbn

Shareholder Structure

Shareholders	N° of shares
Cosmo Holding S.p.A. (*)	8,740,000
Dietmar and Oliver Hopp and their investment companies	1,476,874
Other shareholders	3,658,126
<i>Total shares outstanding</i>	<i>13,875,000</i>

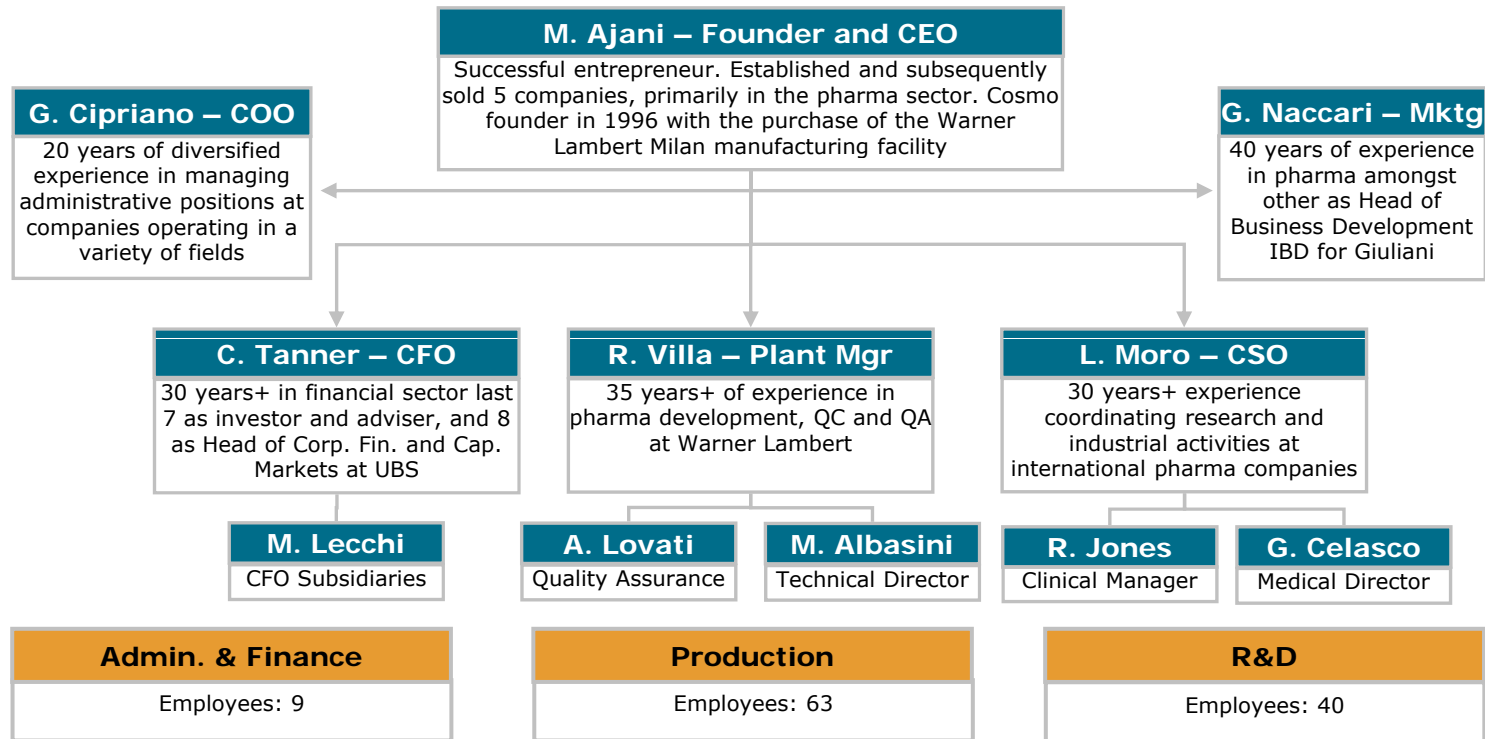
(*) Locked up until 12/03/2008



News Flow

- ◆ **Q4 07:** Budesonide MMX EU licensing agreement
- ◆ **Q4 07:** market launch of Mezavant in Europe for acute and maintenance of UC
- ◆ **Q4 07:** filing of CTA for CB-03-01
- ◆ **Q4 07:** first patient Budesonide phase III
- ◆ **Q1 08:** launch of proof concept trial for Rifamycin for Clostridium difficile
- ◆ **H1 08:** market launch Lialda in US for maintenance of UC
- ◆ **H1 08:** CB-03-01 licensing agreement
- ◆ **H1 08:** data report LMW Heparin MMX phase II clinical trials
- ◆ **H2 08:** first patient in phase III Rifamycin clinical trials for Infectious Colitis in Mexico

Management Team



♦ **Total employees: 123**

- ♦ *Entrepreneur driven company*
- ♦ *Management has significant ownership and will not sell any shares in IPO*
- ♦ *Strong, commercially focused management team encompassing diverse skills:*
 - *Product development, regulatory, manufacturing, sales and marketing*

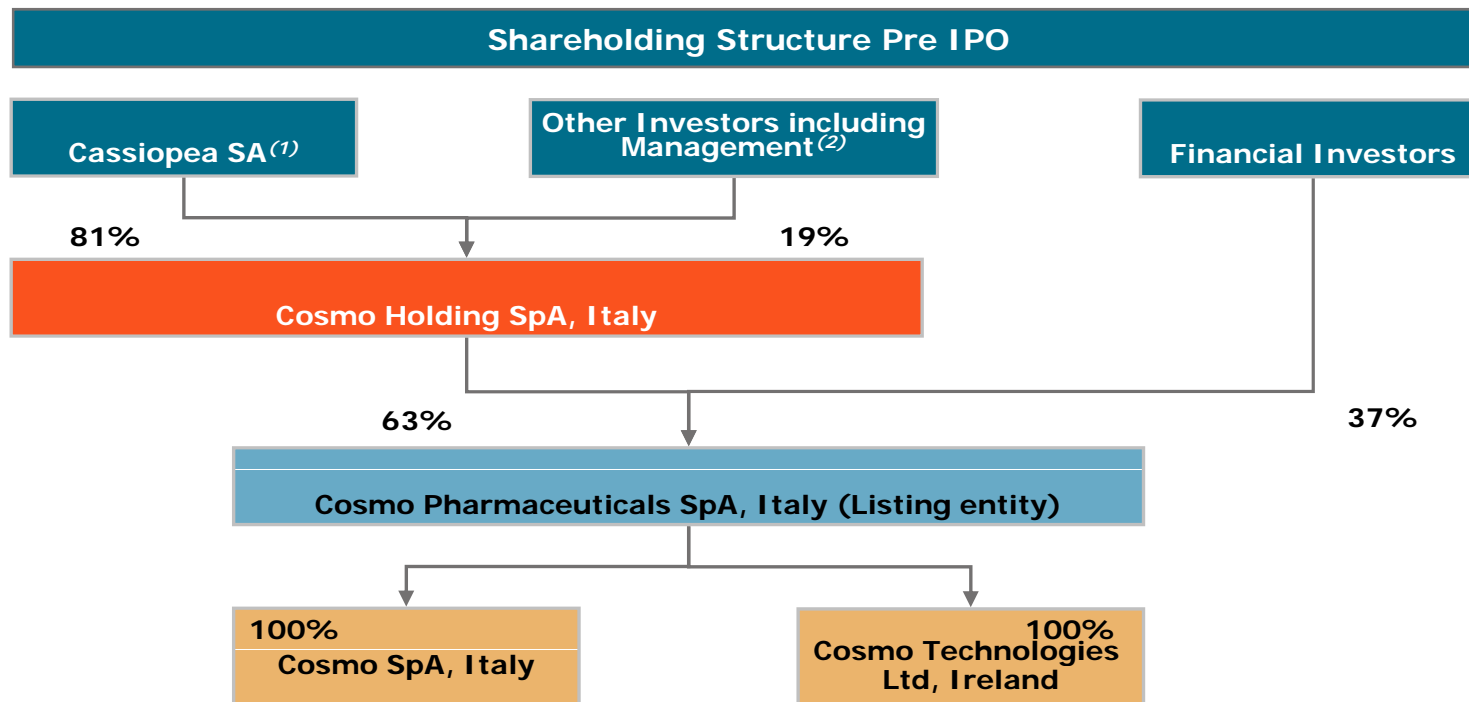
Experienced Board of Directors

Name	Committee	Tenure and Experience
Rolf Stahel (Non-executive Chairman)	– Nomination & Compensation – Audit	<i>Since 2006.</i> Executive Chairman of Chesyl Pharma Ltd and Non-executive Chairman of Newron Pharmaceuticals S.p.A. Former CEO of Shire Pharmaceuticals plc
Mauro Ajani (CEO)		<i>Since 1996.</i> Founder, and through his holdings in Cassiopea SA, main shareholder of Cosmo Holding and Cosmo Bioscience S.p.A., as well as indirectly of Cosmo Pharmaceuticals S.p.A.
Gianluigi Bertolli (Non-executive)	– Audit	<i>Since 2006.</i> Board member of Cosmo Holding since 2005. Owner-manager of Studio Bertolli, a firm specializing in financial and tax advisory
Alessandro Della Chà (Non-executive)		<i>Since 2006.</i> Senior partner of law firm Studio Legale Edoardo Ricci & Associati in Milan where he specializes in company law and mergers and acquisitions
Dieter Enkelmann (Non-executive)	– Audit – Nomination & Compensation	<i>Since 2006.</i> CFO and member of the executive management board of Julius Bär Holding. Formerly CFO of Barry-Callebaut, Head of Financial Services and of Corporate Finance and Investor Relations, Treasury at SwissRe and investment banker at CSFB. Board member of iNNutriGEL
Chris Tanner (CFO)		<i>Since 2006.</i> Board Member of Cosmo Holding since 2005. CFO of Cosmo Pharmaceuticals S.p.A. since 2006. Board member of Joimax and Private Equity Holding. Co-founder of the 20 Minutes Group of newspapers and founder of A&A Active Investor. Former Head of Corporate Finance of UBS in Zurich
Friedrich von Bohlen und Halbach (Non-executive)	– Nomination & Compensation	<i>Since 2005.</i> Managing partner at Dievini GmbH, the company managing the life science investments of Dietmar and Oliver Hopp. Board member of Apogenix, Curacyte, CureVac, Cytonet, Heidelberg Pharma, Lion Bioscience, Life Biosystems and Wylex

Scientific Advisors

Name	Institution
Prof. Jean-Frédéric Colombel	Department of Hepato-gastroenterology, Hôpital Huriez, Lille (France)
Prof. Brian Gordon Feagan	Department of Epidemiology & Biostatistics, University of Western Ontario, London, Ontario (Canada)
Prof. Claudio Fiocchi	Department of Gastroenterology & Hepatology, the Cleveland Clinic Foundation, Cleveland, Ohio (USA)
Prof. Michael Kamm	Chairman of Medicine and Director Inflammatory Bowel Disease and Physiology Units, St. Mark's Hospital, London (UK)
Prof. Robert Löfberg	Professor of Gastroenterology, Karolinska Institutet, Stockholm (Sweden)
Prof. William Sandborn	Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota (USA)
Prof. Maurizio Vecchi	Director Gastroenterology and Gastrointestinal Endoscopy Unit, Policlinico San Donato Milanese (Italy)

Current Shareholding Structure



Contacts

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