

# Report on first half 2011

Lainate

July 29, 2011



# Safe Harbor

*This presentation may include forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management.*

*The inclusion of forward-looking statements should not be regarded as a representation by Cosmo that any of its plans will be achieved. Actual results may differ materially from those set forth in this presentation due to the risks and uncertainties inherent in Cosmo's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), the market for drugs to treat IBD diseases, Cosmo's anticipated future revenues, capital expenditures and financial resources and other similar statements, may be "forward-looking" and as such involve risks and uncertainties and risks related to the collaboration between Partners and Cosmo, including the potential for delays in the development programs for Budesonide MMX® and Rifamycin SV MMX®. No assurance can be given that the results anticipated in such forward looking statements will occur. Actual events or results may differ materially from Cosmo's expectations due to factors which include, but are not limited to, increased competition, Cosmo's ability to finance expansion plans, the results of Cosmo's research and development activities, the success of Cosmo's products, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Cosmo assumes no responsibility to update forward-looking statements or to adapt them to future events or developments.*

*You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Cosmo undertakes no obligation to revise or update this presentation.*

# Agenda

- Introduction and H1 2011 highlights Mauro Ajani, CEO
- H1 2011 Financial review Chris Tanner, CFO
- Pipeline update Luigi Moro, CSO
- 2011 Outlook Mauro Ajani, CEO
- Questions & Answers All

# H1 2011 Highlights

- Higher than expected revenue growth and profitability
- Good market performance of Lialda®. Fastest growing UC tablet. Additional growth to come from maintenance approval
- Budesonide MMX® field in EU, extension study completed, NDA filing in US in coming months
- Rifamycin SV MMX® phase III trials ongoing
- CB-03-01 preclinical work completed, pre IND meeting scheduled
- CB-17-01 proof of concept in colon diagnosis attained

# Key Financial Highlights for H1 2011

- Revenue increased by 14% to € 16.3 million
- Net Operating Expenses contained at € 12.2 million
- EBITDA increased by 75% to € 5.1 million
- Net profit increased by 111.9% to € 3.6 million
- Net working capital increased by 64.5% to EUR 10.3 million
- Cash and financial assets available for sale decreased by 9.1% to € 42.3 million

# Income Statement and Statement of Comprehensive Income

EUR/1,000	30.06.2011	30.06.2010
<b>Revenues</b>	<b>16,338</b>	<b>14,326</b>
Other Income	168	19
Cost of sales	(7,079)	(6,760)
Research and development costs	(2,448)	(2,447)
Selling, general and administrative costs	(2,881)	(3,056)
<b>Net Operating expenses</b>	<b>(12,240)</b>	<b>(12,244)</b>
<b>Operating Result</b>	<b>4,098</b>	<b>2,082</b>
Financial income	719	467
Financial expenses	(545)	(306)
<b>Profit Before Taxes</b>	<b>4,272</b>	<b>2,243</b>
Income tax expenses	(683)	(549)
<b>Profit For The Year</b>	<b>3,589</b>	<b>1,649</b>
EUR/1,000	30.06.2010	30.06.2010
<b>Profit (loss) for the year (A)</b>	<b>3,589</b>	<b>1,694</b>
Gains/(Losses) on fair value of available for sale financial assets	(813)	(7,116)
Gains/(Losses) on cash flow hedge reclassified to profit or loss	(78)	0
Income tax relating to components of other comprehensive income	12	0
<b>Total other comprehensive income, net of tax (B)</b>	<b>(879)</b>	<b>(7,116)</b>
<b>Total comprehensive income (A) + (B)</b>	<b>2,710</b>	<b>(5,422)</b>

# Discussion of Income Statement and Statement of Comprehensive Income

- **Overall revenue increased by 14% to € 16.3 million**
  - Royalties increased by 15.7% to € 4.6 million
  - Manufacturing of MMX based products increased by 39.7% to € 4.9 million
  - Other contract drug manufacturing increased by 5.1% to € 6.1 million
- **Net Operating Expenses remained constant at € 12.2 million**
  - Cost of sales increased by 4.7% to EUR 7.1 million
  - SG&A decreased by 5.7% to € 2.9 m
  - Overall R&D spend remained flat at € 2.4 million but € 1.0 m Budesonide MMX® costs were capitalized
- **Net profit increased by 111.9% to € 3.6 million or EUR 0.244 per share**

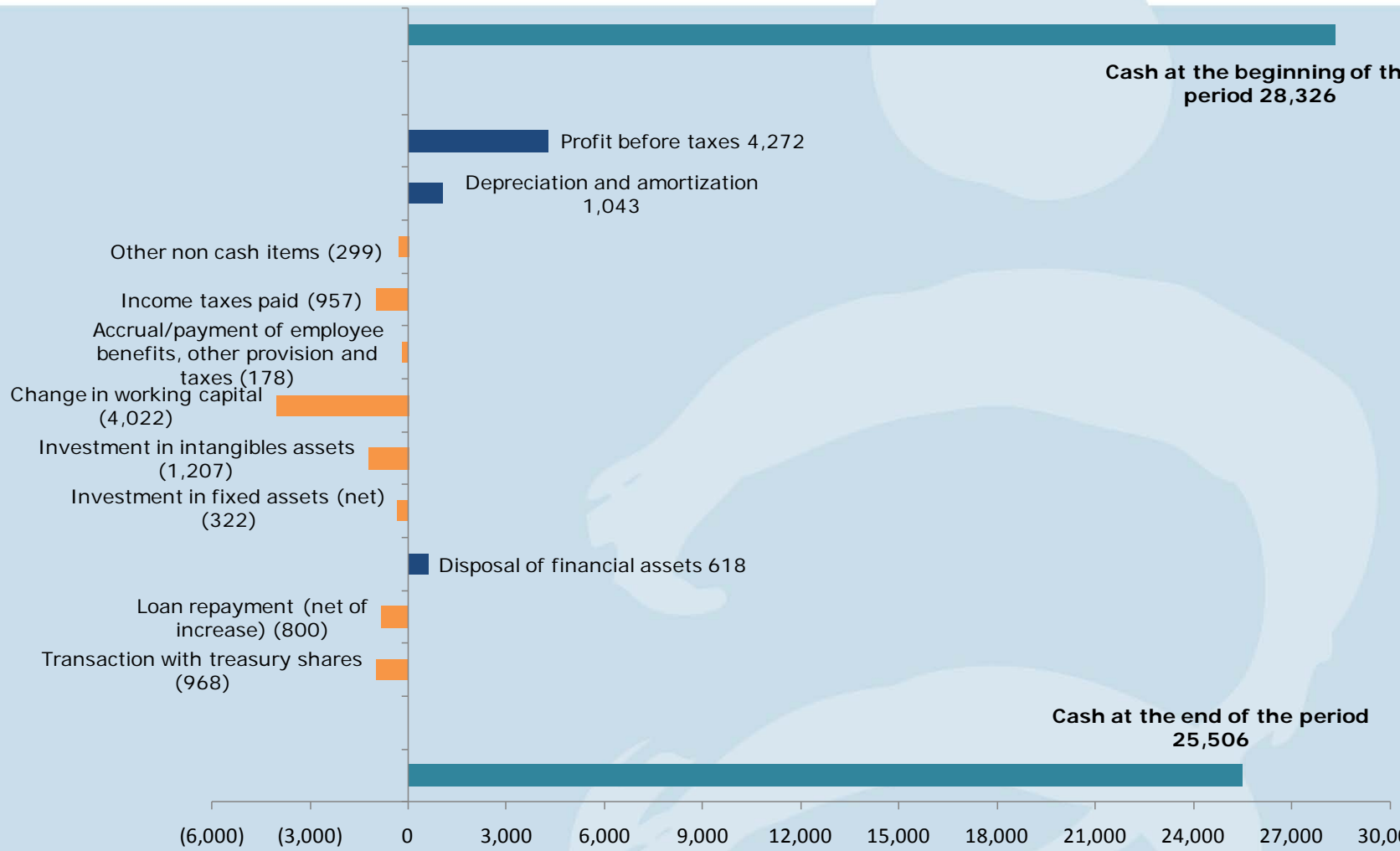
## Consolidated Statement of Financial Position

EUR/1,000	30.06.2011	31.12.2010
Financial assets available for sale	16,749	18,180
Other non current assets	30,586	30,205
Cash and cash equivalents	25,544	28,351
Other current assets	18,805	15,089
<b>Total assets</b>	<b>91,684</b>	<b>91,825</b>
Medium-to long-term interest-bearing loans and borrowings	1,777	2,176
Other non-current liabilities	4,109	4,072
Short-term interest-bearing loans and borrowings	954	1,321
Other current financial liabilities	19,203	18,254
Other current liabilities	6,234	7,636
<b>Equity attributable to owners of the company</b>	<b>59,105</b>	<b>58,065</b>
Non controlling interest	302	301
<b>Total equity and liabilities</b>	<b>91,684</b>	<b>91,825</b>

## Discussion of Statement of Financial Position

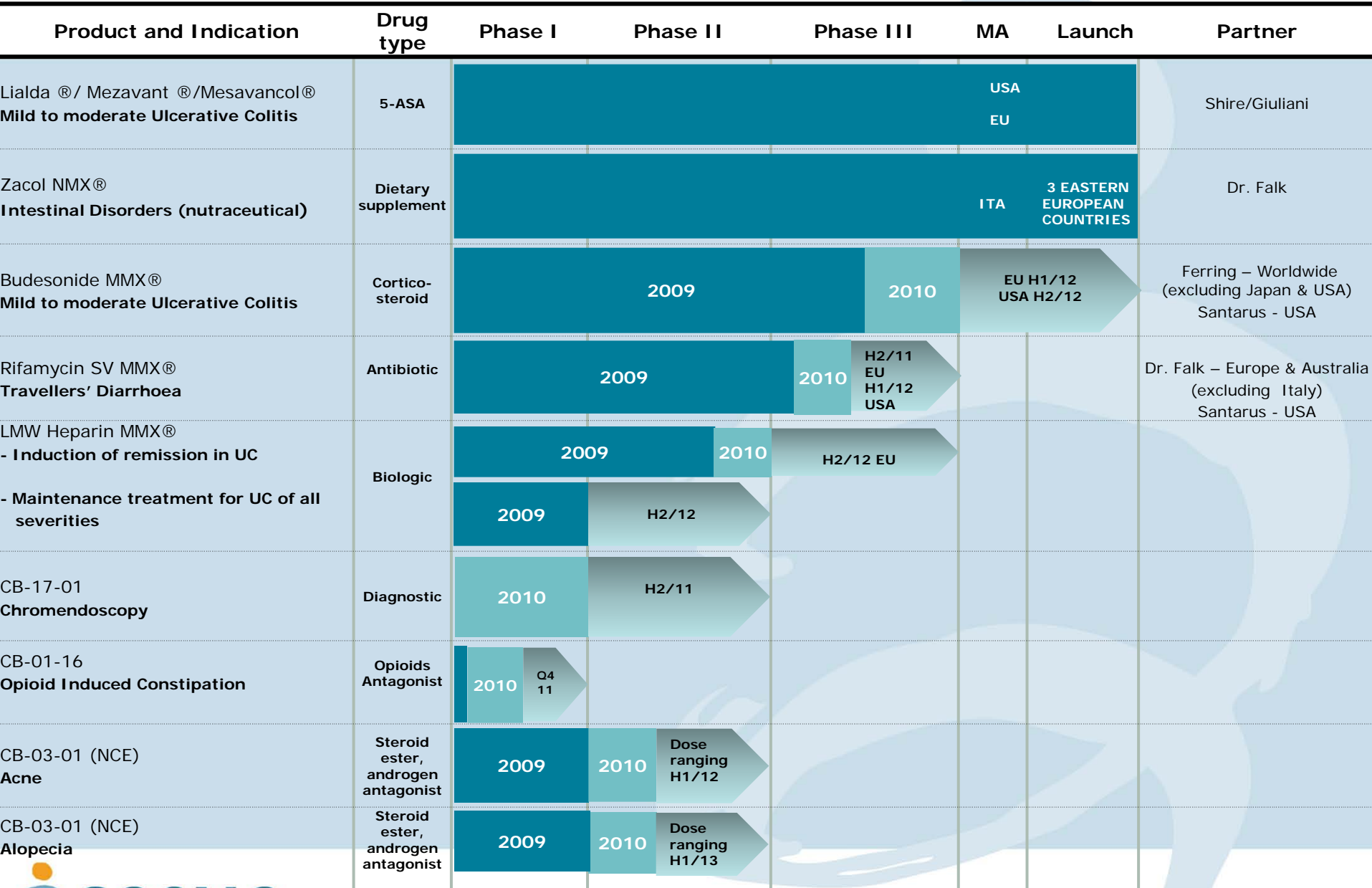
- **Cash and Cash equivalents declined by € 2.8 m to € 25.5 m but net working capital increased by € 4.0 m**
- **Intangible assets increased by 4.6% to € 21.3 m due to capitalization of development cost of Budesonide MMX®**
- **Other current financial liabilities of € 19.2 m were due to accounting for put option exercisable from 1.7. to 31.12.11**
- **Tangible Net Worth increased slightly by 0.3% to € 38 million**
- **64.5% of total Assets financed by Equity**

# H1 2011 Cash flow



# Pipeline Update

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



# Lialda®

- **Indication**
  - Patients with Ulcerative Colitis of mild to moderate severity
- **Net Sales**
  - 2011: \$ 384 m (+31.1%) analysts projections
- **Cosmo Income**
  - 2010: EUR 16.2 m (EUR 8.5 m royalties, EUR 7.7 m manufacturing)
  - 2011 e: EUR 20 m (EUR 10 m royalties, EUR 10 m manufacturing)
- **Additional indications**
  - Shire has received approval for maintenance of ulcerative colitis
  - Phase III trials for uncomplicated diverticulitis are underway

# Budesonide MMX®

- **Indication**

- Induction of remission for patients with mild to moderate UC

- **Market Size**

- In US Crohns Disease market, affecting less patients than in UC, Entocort, an “old Budesonide” had sales of \$ 337 m in 2010
- Santarus is projecting peak sales of \$ 300 m

- **Market need**

- A drug with the efficacy of a corticosteroid and the few side effects of salicylates

- **Status**

- Extension study completed
- EU MAA filing with Dutch Regulator for 15 EU countries in May
- Filing of NDA in US FDA scheduled for Q4 2011

# Rifamycin SV MMX®: Status and Opportunities

- **Indication**
  - Travellers and Infectious Diarrhoea
- **Status**
  - Positioned as New Chemical Entity in USA
  - Patient recruiting for Phase III trials in EU & US ongoing
    - EU trial is for non inferiority to Ciprofloxacin. 244 out of 776 patients recruited. Interim analysis in Q4 foreseen.
    - US trial is for superiority against placebo. 2 pivotal trials planned. 144 out of first 262 patients recruited. Recruitment slow because student language courses in Mexico & Guatemala have suffered
  - Patent in China granted
- **Opportunities**
  - Very effective against Hepatic Encephalopathy
  - Could be used for Diverticulitis
    - More than 60% of people over the age of 60 have diverticulae
      - In 10-20% of cases the diverticula get infected and inflamed
    - No drug is currently approved for this disease
  - Second indication will be selected this year

# CB-17-01 Methylene Blue MMX

- **Indication**
  - Diagnosis of colon diseases
- **Mechanism of action**
  - Non invasive staining of cellular structures in colon through new methylene blue delivered by tablet with MMX technology
- **Market size**
  - Around 20 m colonoscopies are performed per year in US and EU
- **Status**
  - Phase II dose ranging study to optimize staining procedure on up to 140 patients ongoing: 38 patients treated

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

- **Indication**

- Topical treatment of Acne and Alopecia, and potentially Hirsutism

- **Status**

- Ongoing tests deemed necessary for IND application in USA
  - 13 weeks toxicology tests in rat by subcutaneous administration
  - 13 weeks test on mini-pigs by dermal application
  - Micronucleus test of genotoxicity
  - Ocular irritation test in rabbit
- Pre IND discussion with FDA in August
- Corporate structure with external expertise being set up to design and manage clinical trials in the US
- Established data room and considering options for best partnership structure for development in US

# Financial Outlook for 2011: Recurring Revenue growth, continued profitability, sufficient cash

- **Revenues projected at around € 32 million**
  - Lialda® royalties and manufacturing income are expected to increase by ~23% or EUR 3.8 m to € 20 m
  - Contract Drug Manufacturing revenue should increase slightly
  - No milestones nor license fees budgeted (-EUR 2 m)
- **COGS up around 5%**
- **External R&D expenditures of ~EUR 3 m**
- **SG&A around € 6 m**
- **Positive EBITDA and net profits**
- **Cash and financial assets can bear all operating requirements plus the eventual exercise of the put options**
  - If all 1,120,743 shares and options are put, then cash per year end is budgeted at EUR 10 m
- **No external financing required**

# News events in 2011

## H2

- IND approval CB 03-01 in the USA
- announcement of corporate structure for CB 03-01 in USA
- filing of Budesonide MMX NDA in the US
- start work on new indication for Rifamycin SV
- phase I proof of concept data for Naloxon MMX
- phase II data for Blue Methylene MMX

## Contacts

Mauro Ajani; CEO

[majani@cosmopharma.com](mailto:majani@cosmopharma.com)

ph: +39-02-9333'7506

Dr. Chris Tanner; CFO and Head of Investor Relations;

[ctanner@cosmopharma.com](mailto:ctanner@cosmopharma.com)

ph: +39-02-9333'7617

Dr. Luigi Moro; CSO

[lmoro@cosmopharma.com](mailto:lmoro@cosmopharma.com)

ph: +39-02-9333'7276

[www.cosmopharma.com](http://www.cosmopharma.com)