

# Report on 2010

Zurich

March 25, 2011



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# Agenda

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

## 2010 Highlights

- Good revenue growth, continued profitability
- Excellent market performance of Lialda® in USA. Fastest growing UC tablet, 20.2% share in 5-ASA market
- Budesonide MMX® attained phase III primary clinical end point in USA and EU. Filing in preparation
- Rifamycin SV MMX® phase III trials ongoing
- CB-03-01 proof of concept in alopecia attained
- CB-17-01 proof of concept in colon diagnosis attained
- Acquisition of BioXell executed

## Key Financial Highlights for 2010

- Revenue increased by 20.1% to € 32.05 m
- Costs increased by 22.5% to € 27.2 million
- EBITDA increased by 11% to € 6.8 million
- Net profit decreased by 10.9% to € 3.6 million
- Cash and financial assets available for sale increased by 27.8% to € 46.5 million

# Income Statement and Statement of Comprehensive Income

EUR/1,000	31.12.2010	31.12.2009
<b>Revenues</b>	<b>32,050</b>	<b>26,685</b>
Other Income	75	315
Cost of sales	(14,326)	(12,774)
Research and development costs	(6,779)	(4,454)
Selling, general and administrative costs	(6,218)	(5,329)
<b>Net Operating expenses</b>	<b>(27,248)</b>	<b>(22,242)</b>
<b>Operating Result</b>	<b>4,802</b>	<b>4,443</b>
Financial income	611	1,290
Financial expenses	(954)	(416)
<b>Profit Before Taxes</b>	<b>4,459</b>	<b>5,317</b>
Income tax expenses	(852)	(1,267)
<b>Profit For The Year</b>	<b>3,607</b>	<b>4,050</b>
EUR/1,000	31.12.2009	31.12.2008
<b>Profit (loss) for the year (A)</b>	<b>3,607</b>	<b>4,050</b>
Gains/(Losses) on fair value of available for sale financial assets	(4,333)	12,473
Gains/(Losses) on cash flow hedge	78	-
Income tax relating to components of other comprehensive income	(9)	(439)
<b>Total other comprehensive income, net of tax (B)</b>	<b>(4,264)</b>	<b>12,034</b>
<b>Total comprehensive income (A)+(B)</b>	<b>(657)</b>	<b>16,084</b>

# Discussion of Income Statement and Statement of Comprehensive Income

- **Overall revenue increased by 20.1% to € 32.0 million**
  - Recurring revenues increased by 19.7% to € 29.4 million
    - Royalties increased by 41.0% to € 8.5 million
    - Manufacturing of MMX based products increased by 13.6% to € 7.7 million
    - Other contract drug manufacturing increased by 11.2% to € 11.7 million
  - One time license fees and milestones increased by 25.1% to € 2.6 million
- **Operating costs increased by 22.5% to € 27.2 million**
  - Cost of sales increased by 12.1%
  - SG&A increased by 16.7% to € 6.2 m; one time costs related to the BioXell transaction primarily drove this increase
  - Overall R&D spend increased by 19% to € 16.3 million but € 4.2 m Budesonide MMX® costs reimbursed by Santarus and € 5.4 m Budesonide MMX® costs were capitalized
- **Net profit declined by 10.9% to € 3.6 million**

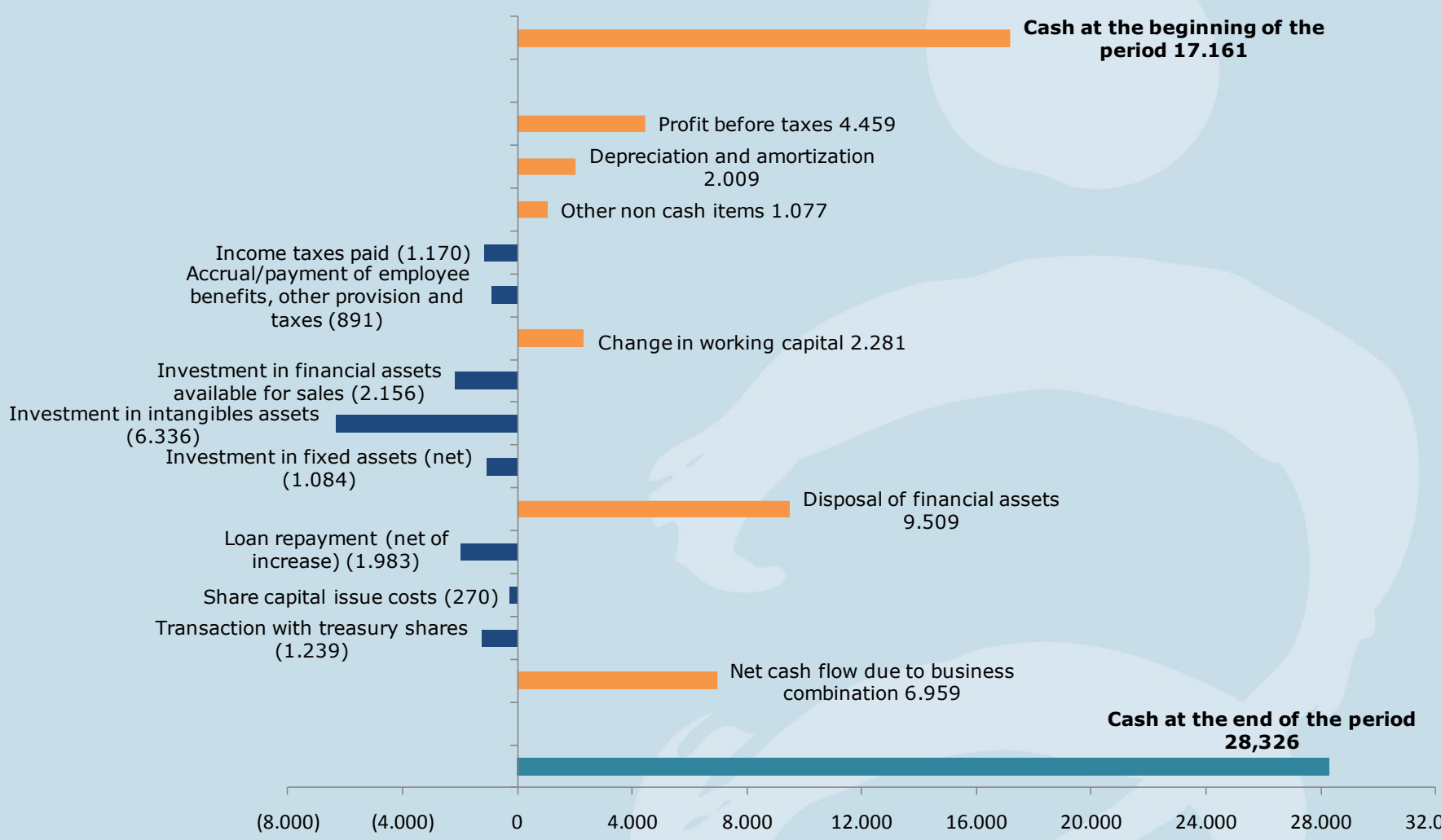
## Consolidated Statement of Financial Position

EUR/1,000	31.12.2010	31.12.2009
Financial assets available for sale	18,180	19,242
Other non current assets	30,205	22,396
Cash and cash equivalents	28,351	17,161
Other current assets	15,089	12,665
<b>Total assets</b>	<b>91,825</b>	<b>71,464</b>
Medium-to long-term interest-bearing loans and borrowings	2,176	1,642
Other non-current liabilities	4,072	2,739
Short-term interest-bearing loans and borrowings	1,321	1,334
Other current liabilities	25,890	5,954
<b>Equity attributable to owners of the company</b>	<b>58,065</b>	<b>59,795</b>
Non controlling interest	301	-
<b>Total equity and liabilities</b>	<b>91,825</b>	<b>71,464</b>

## Discussion of Statement of Financial Position

- **Cash and Cash equivalents up 65.2% to € 28.4 m**
  - Due to BioXell transaction
- **Intangible assets up 69.4% to € 20.4 m due to capitalization of development cost of Budesonide MMX®**
- **Other current financial liabilities of € 18.3 m were due to accounting for put option exercisable from 1.7. to 31.12.11**
- **Tangible Net Worth decreased by 19.5% to € 38.3 million**
- **64.1% of total Assets financed by Equity**

# 2010 Cash flow

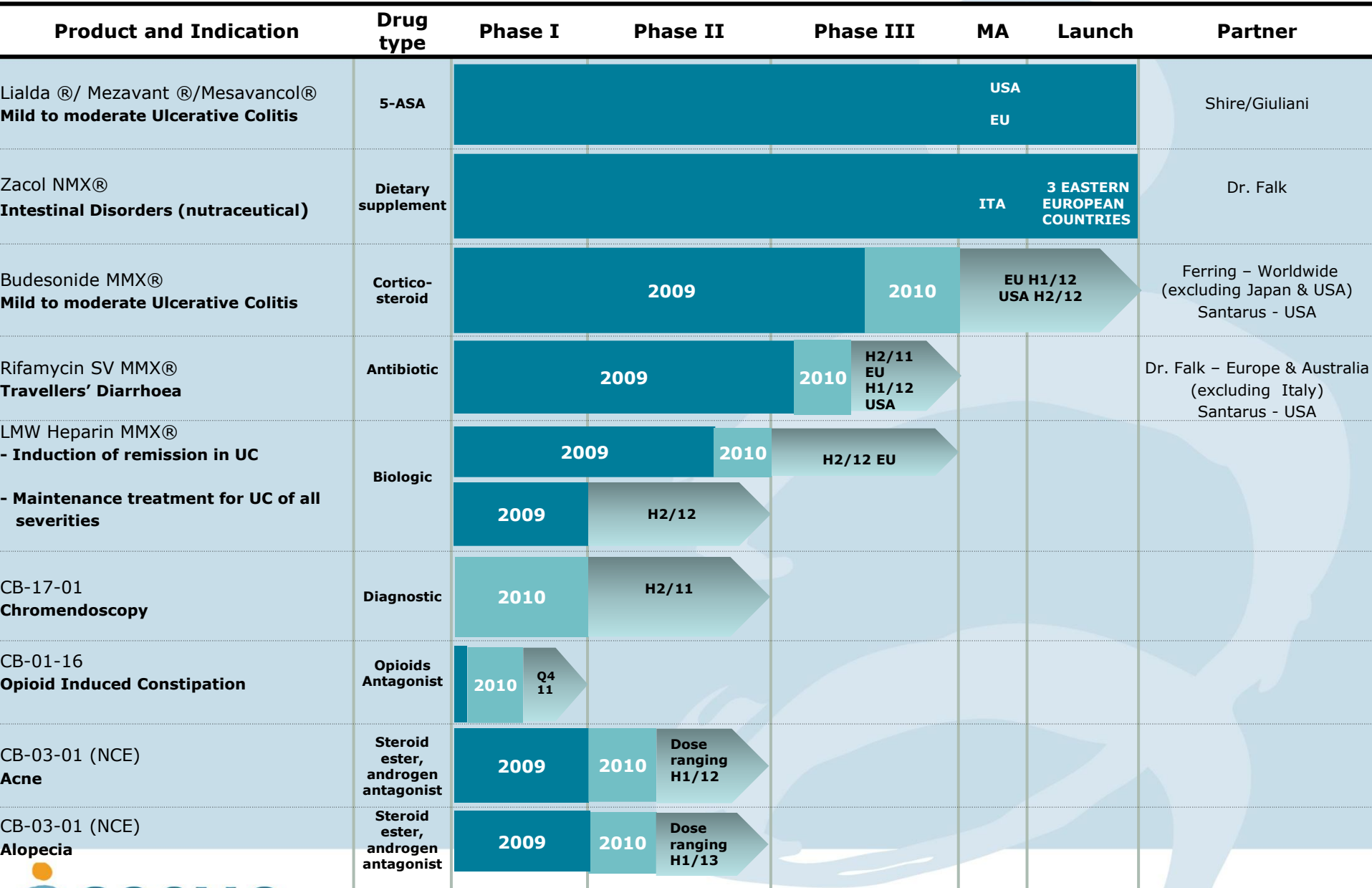


## BioXell transaction

- **98.96% of all shares tendered**
- **Cost to Cosmo**
  - EUR 10.7 m in cash
  - Issuance of 1'120'743 shares ie 8.1% increase respectively increase of free float by 31% to 32%
  - Issuance of 1'120'743 options to put shares to Cosmo for CHF 21 pS between 1.7.2011 to 31.12.2011
  - Sufficient cash to purchase all shares and either place these in the market of hold for ESOP program
- **Got EUR 26.9 m cash**
  - Primarily cash, claims for tax refunds and claims for grants
- **Renamed Cosmo Research & Development SpA**

# Pipeline Update

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



# The IBD market according to Datamonitor

- **Strong growth**
  - 7 major market revenues reached \$ 3.9 b in 2009 and are projected to climb by 4.4% p.a. to 5.6 b in 2019
  - 5 ASAs increased revenues by 18% and TRX by 4% in 2010
- **Key disease treatment objectives**
  - Key in the treatment of chronic IBD is getting a quick remission and maintaining this as long as possible
- **Many old products**
  - Asacol, the largest 5 ASA with revenues of \$ 728 m (2010) is scheduled to go off patent shortly. Pentasa (\$ 255 m) is off patent. There will be increased market gains by generics
- **Few drugs approved for maintaining remission**
- **Few new drugs in late development**
  - Budesonide, LMW Heparin,
  - CCX (for Crohns)
  - Vedolizumab (immunosuppressant)
  - Golimumab (antirheumatic)

- **Indication**

- Patients with Ulcerative Colitis of mild to moderate severity

- **Net Sales**

- 2009: \$ 237 m
- 2010: \$ 293 m (+23.6%); increase of TRX by 19%
- 2011: \$ 384 m (+31.1%) analysts projections

- **Cosmo Income**

- 2009: EUR 12.8 m (EUR 6 m royalties, EUR 6.8 m manufacturing)
- 2010: EUR 15.6 m (EUR 8 m royalties, EUR 7.6 m manufacturing)

# 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**

- Attained primary clinical endpoints in both the US and EU trials
- Filing to EU scheduled for Q2 2011
- Filing for 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 Cipro. Start delayed in India,  $\geq 150$  out of 776 patients recruited. Recruitment could go into 2012.
  - US trial is for superiority against placebo. 2 pivotal trials planned. 100 out of first 262 patients recruited. Recruitment slow because student language courses in Mexico have suffered

- **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

## LMW Heparin MMX®

- **The market for maintaining remission could be as large as the market for inducing remission**
  - Objective is to prolong remission until next relapse
  - Inhibitors hamper new inflammation thus prolong remission
  - Best inhibitors are biologics such as anti TNF  $\alpha$ 's
    - None are approved, very expensive, may have serious side effects
  - Decision to target LMW Heparin in maintenance of remission for all levels of severity
    - LMW Heparin inhibits human intestinal epithelial cell inflammatory responses to TNF  $\alpha$ , IL 6 and IL 1b
    - It inhibits CD 4+T cells inducing Th1 and Th2 polarization
    - All analyses point to a very safe product
- **Decision to launch phase II proof of concept trial for maintenance of remission**
  - >150 patients with documented history of UC, in remission, normal stools, absence of rectal bleeding, normal mucosa
  - Number of patients maintaining remission 1,3,6,9,12 months vs placebo
- **US activities to be developed together with a strong US partner**

## 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**

- Galenic development made
- Secured supply of industrial grade methylene blue
- Patents application filed and internationally extended
- Proof of concept attained
- Phase II dose ranging study to optimize staining procedure filed

# IBD Market position

- **Cosmo has one of the most comprehensive IBD portfolios in the industry**
  - all ranges of products from colon health products, to 5 ASA's, steroids, biologics, anti-infectives and diagnostics
  - To date there has not been a product failure
  - Cosmo has a very low cost in developing products
  - Cosmo is the only developing company that manufactures. This reduces generic risks
- **The IBD market value grew by >20% p.a. in the last 2 years**
- **There are very few new products in sight, two of which are from Cosmo**
- **Cosmo is increasingly recognized as an innovator in colon diseases and will present 3 different papers at the coming DDW in Chicago in May**
  - Prof Dr. W. Sandborn: Budesonide 9 mg clinical trial in US and India
  - Prof Dr. S.Travis: Budesonide 9 mg clinical trial in EU,RU,Isr and AU
  - Prof Dr. A.Repici: A new tool for pre-colonoscopy dying of colonic mucosa with oral MMX technology

# The market in acne and alopecia

- **Very high unmet needs**
  - 16% of US population suffer from acne
  - 12% of all men have Alopecia
  - 10% of all women have Hirsutism
- **Old concepts**
  - Acne
    - 157 approved products, heavily genericized market
    - 60% of non generic WW revenue by drugs launched before 1996
    - Hormonal tablets frequently contraceptive linked
    - Topical applications are retinoids or anti-microbials
  - Alopecia
    - Only one proprietary alopecia treatment, Propecia \$ 440 m launched 1998
    - Vasodilators (Rogaine) off patent
- **Thin pipeline**
  - 2 anti acne agents in phase III, 12 in phase II
  - Only two products in clinical development for alopecia

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

- **Market need**
  - A treatment that is effective and does not affect hormonal balance
- **Mechanism of action**
  - Blocks binding of testosterone and de-hydrotestosterone to the androgen receptor
    - Does not change hormonal balance
    - Blockage impedes androgens from unchaining uncontrolled activity of the sebaceous gland
    - Has no side effects
- **Indication**
  - Topical treatment of Acne and Alopecia, and potentially Hirsutism
- **Status**
  - Preclinical work completed
  - Proof of concept attained in acne and alopecia
  - 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 ~20% or EUR 3.5 m to € 19 m
  - Contract Drug Manufacturing revenue should increase slightly
  - No milestones nor license fees budgeted (-EUR 2 m)
- **Stable COGS**
- **External R&D expenditures of ~EUR 5.4 m, EUR 2 m over 2010**
- **Overall costs are likely to decrease by ~EUR 2 m** (less onetime costs)
- **Positive EBITDA and net profits**
- **Cash and financial assets unchanged at EUR 46 m**
  - If all 1,120,743 shares and options are put, then there would be a cash outflow of EUR 17.4 m (at CHF 1.35 p EUR)
- **No external financing required**

# News events in 2011

## H1

- determination of way forward for CB 03-01
- phase I data for Blue Methylene MMX
- filing of Budesonide MMX NDA in the EU
- presentation of various posters at DDW Chicago

## H2

- IND approval CB 03-01 in the 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

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