## Jefferies 2010 Global Life Sciences Conference, New York





## **COMPANY PROFILE AND STRATEGY**

#### **Company Profile**

- Mid sized pharmaceutical company with a European focus (2800 employees, of which 1400 field force)
- R&D in the cardiovascular and urology fields and in treatments for rare diseases
- Marketing operations in the main Western European markets and in Russia, CEE and Turkey
- Proprietary drugs sold worldwide through licensees
- Expanding through organic development and through acquisitions

# 

OE – Orphan Europe subsidiaries

#### Develop product portfolio by

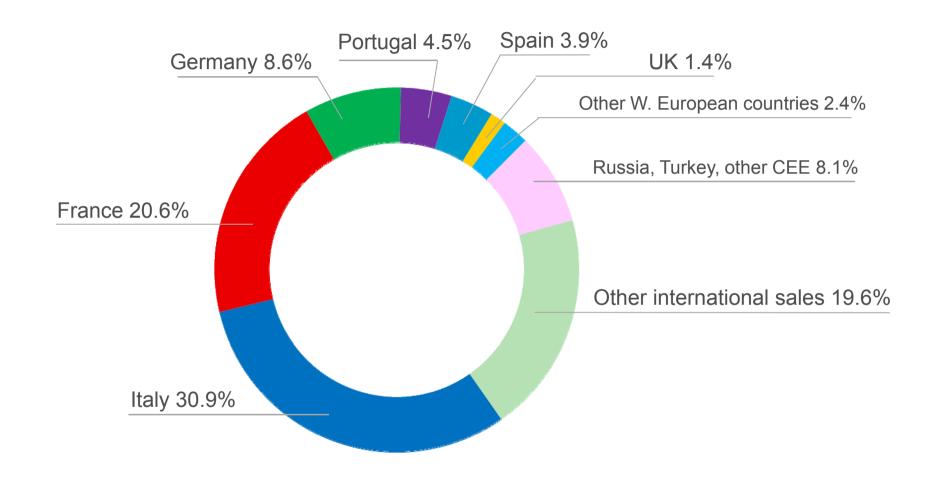
- High focus on new corporate products
- Maximizing existing products
- Acquiring new product rights
- Prioritizing specialty care products
- Enriching pipeline of products in development

#### Pursue further geographical expansion by

- Entering new markets characterized by high growth in CEE
- Launching new corporate products and existing proprietary products in these markets
- Taking the opportunity of establishing a direct presence in the U.S, for the marketing of treatments for rare diseases



## GEOGRAPHICAL BREAKDOWN OF PHARMACEUTICAL REVENUE

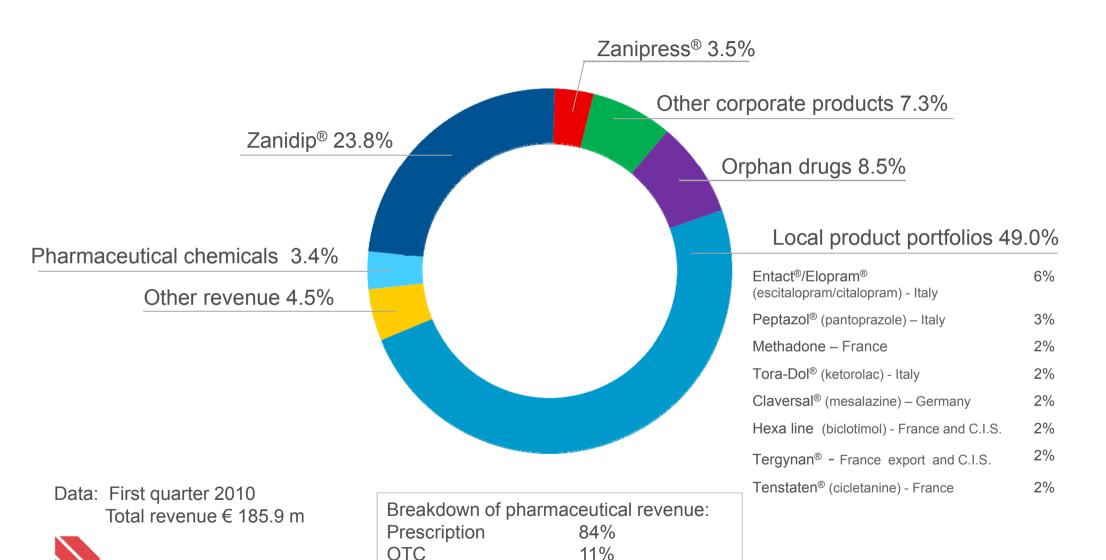




Data: First quarter 2010

Pharmaceutical revenue € 179.6 m

## **COMPOSITION OF REVENUE BY BUSINESS**



5%

Other revenue



3

## **CORPORATE PRODUCTS**

# ZANIDIP® (lercanidipine)

- Calcium channel blocker indicated for the treatment of hypertension. Lipophilic dihydropiridine discovered and developed by Recordati. Efficacy as best in class, superior tolerability.
- On the market in 95 countries.
- Patent expired end January 2010 in main markets. Generic competition expected in France, Italy, UK, Germany, Spain, and other European countries
- Strategy will be to match, or nearly match, the generic price to keep sales volumes
- In most markets, at the same price, the branded drug is preferred
- Promotion to continue in these markets where brands maintain their value
- In some markets where brands are more likely to lose their value, an own generic of lercanidipine will be sold



## **CORPORATE PRODUCTS**

# ZANIPRESS® (lercanidipine+enalapril)

- Fixed combination of lercanidipine (a CCB) and enalapril (an ACE-I) indicated for the treatment of hypertension. Two strengths:
   10mg lercanidipine/10mg enalapril, and
   10mg lercanidipine/20mg enalapril.
- Clinical data exclusivity until 2016
- Approved in Germany in July 2006.
   Approval recognition in EU, Norway and Iceland granted in March 2008. Approved in Australia in February 2008 and subsequently in other ex-EU countries.
- On the market in sixteen countries, further launches expected in 2010.
- To be approved and launched in all lercanidipine markets

- Fixed combinations will play a significant role in the future hypertension market
- New aggressive targets for blood pressure control.
   Combination of drugs needed for most patients
- Increased patient compliance
- Large clinical outcome trials show that cardiovascular events are drastically reduced by using modern antihypertensive drug combinations (CCB, ACE-I, ARB) as opposed to using older treatments.
- The NICE (National Institute for Clinical Excellence, UK) guideline for the treatment of hypertension in primary care was updated to incorporate new evidence (1)
- "In hypertensive patients aged 55 or over, or black patients of any age, the first choice for initial therapy should be either a CCB or a thiazide-type diuretic." (1)
- "If initial treatment was with a CCB or a thiazide-type diuretic and a second drug is required, add an ACE inhibitor. If initial therapy was with an ACE inhibitor, add a CCB or a thiazidetype diuretic." (1)
  - (1) National Collaborating Centre for Chronic Conditions. Hypertension: management in adults in primary care: pharmacological update. London: Royal College of Physicians, 2006.



## **CORPORATE PRODUCTS**

#### DRUGS FOR THE TREATMENT OF RARE DISEASES

- Recordati acquired Orphan Europe, a European pharmaceutical company dedicated to treatments for rare diseases, in December 2007
- Orphan Europe operates in a niche market. It has a cash generating portfolio of 9 products with strong growth potential and a promising pipeline
- A unique distribution network from a centralized unit in Paris serves patients worldwide
- Orphan Europe employs about 120 personnel and has subsidiaries in nine European countries and in the United Arab Emirates as well as representative offices in seven countries
- Well trained orphan drug specialists and scientific product support team collaborate with healthcare professionals and patient groups to improve knowledge and awareness of rare diseases

#### **Product**

Adagen®
Carbaglu®
Cystadane®

Cystagon<sup>®</sup> Normosang<sup>®</sup>

Pedea® Sucraid®

Vedrop®

Wilzin®

#### Compound

Pegademase bovine Carglumic acid

Betaine anhydrous

Cysteamine bitartrate

Human haemin

Ibuprofen iv

Sacrosidase

Water soluble

vitamin E

Zinc acetate

#### Indication

SCID-ADA deficiency

NAGS deficiency

Homocystinuria

Nephropathic cystinosis

Porphyria

Patent Ductus Arteriosus

Sucrase isomaltase deficiency

Vitamin E deficiency due to

CC and CF

Wilson's disease

#### **Geographical presence**

Belgium Austria

France Czech Rep.
Germany Denmark
Italy Finland

Portugal Netherlands

Spain Poland Sweden Turkey

Switzerland U.A. Emirates United Kingdom



#### **NEW CORPORATE PRODUCTS**

# UROREC®/SILODYX™ (silodosin)

- Highly selective α<sub>1A</sub> receptor antagonist indicated for the treatment of symptoms associated with benign prostatic hyperplasia (BPH)
- Originator Kissei Pharmaceutical Co., Ltd., Japan. Developed by Recordati for Europe (45 countries) and other 18 countries (Middle East and Africa). Patented in Europe until 2018 (inc. SPC), clinical data exclusivity until 2020
- Approved by European Commission end January 2010
- Main launches to take place September 2010 through March 2011
- Silodosin to be sold directly by Recordati in 8 EU markets, in Russia and other C.I.S. countries, and in Turkey. Co-marketing planned in most countries
- License granted to Algorithm for the Middle East (except Israel), to Almirall for Spain, to Nycomed for Italy and Portugal, to Pharmaplan for South Africa, to Zambon for France and further licenses planned for all territories where we are not present directly

- BPH market in 19 major European markets approx. €
   1.0 billion
- In-market peak sales expected: € 100-150 million

#### positioning

- The symptoms associated with BPH (urination frequency and urgency, hesitancy and weak urinary flow) interfere with daily activities and sleeping. BPH occurs mainly in elderly patients.
- Silodosin is the first alpha blocker with very high selectivity for α<sub>1A</sub> adrenergic receptors showing
  - Fast onset of action. Significant improvements in the maximum urinary flow rate within 2-6 hours after the first dose, continuing through 12 weeks of therapy
  - High efficacy on bothersome symptoms (nocturia) and obstructive signs (Q<sub>max</sub>)
  - Very good cardiovascular safety, no symptomatic effects on blood pressure or heart rate when administered in combination with antihypertensive medications
- Early and sustained benefit to patients, improving their daily quality of life and nocturnal rest



## **NEW CORPORATE PRODUCTS**

# LIVAZO® (pitavastatin)

- Highly effective HMG-CoA reductase inhibitor indicated for the treatment of hypercholesterolaemia
- Semi-exclusive license granted by Kowa Pharmaceutical Europe (KPE) for marketing and sales in Italy, France, Spain, Portugal, Greece, Ireland, Cyprus, Turkey, Russia and other C.I.S. countries
- MAA submitted by KPE for the 7 EU territories in the Recordati license. Decentralized procedure. Russia, Turkey and CIS territories: submission up to Recordati
- Foreseen approval time: third quarter 2010
- To be launched progressively during 2011
- Statins market in the 8 largest of the 21 countries covered by the agreement was € 3 billion in 2009
- In-market peak sales expected: € 100-150 million

#### positioning

- Similar LDL-C reduction of market leading best-in-class statins
- Broad-spectrum effects on secondary lipid parameters
- Any time of day dosing allows prescribing flexibility
- Similar safety to other statins
- Low risk of drug-drug interactions due to metabolic pathway
- Appropriate for multi-medicated patients
- In high-risk difficult-to-treat patients with dyslipidemia only pitavastatin allows thorough control due to its dual action both on LDL and HDL. It offers high reduction of aggressive factors (LDL) as well as good increase of protective ones (HDL).



# **R&D Pipeline**

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
Urorec®/Silodyx™	Kissei	Benign prostatic hyperplasia (BPH)	Approved
Carbaglu <sup>®</sup>	Orphan Europe (Recordati)	NAGS deficiency	Approved in EU and in the U.S.
lercanidipine 8/16 mg	Pharmathen	Essential hypertension	Approved
pitavastatin	Kowa	Dyslipidemia	Filed in EU
Carbaglu <sup>®</sup>	Orphan Europe (Recordati)	Organic acidemias (OA)	Pre-registration in EU
Normosang <sup>®</sup>	Orphan Europe (Recordati)	Hepatic porphyria	Approved in EU Pre-registration in U.S.
Infasurf <sup>®</sup>	Ony	Respiratory Distress Syndrome (RDS)	Phase II-III
Stanate <sup>®</sup>	Rockefeller U. /InfaCare	Neonatal jaundice, hyperbilirubinemia	Phase II-III
Cystagon <sup>®</sup>	Mylan	Other indication unrelated to nephropathic cystinosis	Phase II-III
new lercanidipine combinations	Recordati	Essential hypertension	Phase II
Cystadrops®	Orphan Europe (Recordati)	Ocular cystinosis	Phase II
REC 0422	Recordati	Overactive bladder and Incontinence	Phase I-II
REC 1819	Recordati	Overactive bladder and Incontinence	Preclinical
REC 0436	Recordati/UFPeptides	Overactive bladder in patients with spinal lesions	Preclinical
RECORDATI			· · · · · · · · · · · · · · · · · · ·

#### New developments for the Lower Urinary Tract Symptoms (LUTS) and incontinence

- Irritative symptoms of the lower urinary tract (mainly urgency and frequency with or without incontinence) are frequent, mainly in women and the elderly. This condition, known as Overactive Bladder (OAB) is either idiopathic or due to known conditions (interstitial cystitis, neurogenic causes, etc.). Only 7 million of the estimated 65 million OAB sufferers in the U.S. and the EU are treated at any time. Under-diagnosis and under-treatment are the main reasons.
- Unmet medical and market needs are significant. Under-treatment is often due to lack
  of satisfactory efficacy and tolerability of existing drugs. All existing drugs have the
  same mechanism of action and the older ones are cheap. Therefore, reimbursement
  issues in Europe make newer drugs less accessible.
- Recordati is taking into development three innovative products:
  - REC 0422 is a combination of two existing drugs, indicated for other conditions, which has displayed a significant synergistic effect in pharmacological models of OAB
  - REC 1819 has a completely new mechanism of action at the CNS level
  - REC 0436 represents a structurally different class of compounds and is being studied for the treatment of OAB in patients with spinal lesions



## **Development of drugs for rare diseases**

- Carbaglu® (carglumic acid), a drug developed by Orphan Europe for the treatment of NAGS deficiency, was approved in the EU in 2003 and by the FDA in 2010. Carbaglu® is also in pre-registration phase in Europe for additional indications in organic acidaemias.
- Infasurf® is a calf derived surfactant for the prevention and treatment of neonatal respiratory distress syndrome (RDS) originated by Ony. Neonatal RDS is a life-threatening disease which affects mainly premature infants and surfactants are well established in the treatment of this condition. Exclusive marketing rights for 27 European countries.
- Stanate® (stannsoporfin) Inhibits the production of bilirubin in cases of hyperbilirubinemia of different origin. Originated by Rockefeller University, it is under development by InfaCare for the treatment of neonatal hyperbilirubinemia (jaundice). Severe hyperbilirubinemia, if untreated, can lead to severe brain damage. If approved, stannsoporfin could be used immediately in infants not responding to phototherapy.

- Orphan Europe will complete the clinical development of stannsoporfin in Europe.
- Cystagon<sup>®</sup> (cysteamine bitartrate), a drug indicated for the treatment of nephropathic cystinosis, is being studied for a new and promising unrelated indication.
- Cystadrops® (cysteamine chlorhydrate) are eye drops developed for "ocular manifestations of cystinosis" which cannot be controlled by orally administered cysteamine and specially formulated in a patient-friendly gel form. A phase II clinical study is currently ongoing.
- Normosang® (human haemin) is indicated for the treatment of acute attacks of hepatic porphyria. It is an emergency medicine that is recognized as the gold standard therapy to stop the attack and prevent neuropathic complications. Normosang® is approved in the 27 EU countries and Orphan Europe is in contact with the FDA to pursue its approval in the USA.



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### FIRST QUARTER 2010 HIGHLIGHTS

- Revenue € 185.9 million, up 1.2%, international sales grow by 1.0%
- Operating income (EBIT) € 43.1 million, up 6.0%
- Net Income € 30.0 million, up 8.5%
- Urorec<sup>®</sup>/Silodyx<sup>™</sup> (silodosin) approved in Europe
- Carbaglu<sup>®</sup> (carglumic acid) approved by the FDA in the U.S.
- Licensing-out agreements signed with Leespharm for Zanidip<sup>®</sup> in China and with Esteve for pitavastatin in Spain



# **COMPOSITION OF REVENUE**

(million Euro)	1Q 2010	1Q 2009	Change %
Italy	55.6	54.9	1.3
France	36.9	38.1	(3.1)
Germany	15.5	14.7	5.7
Portugal	8.1	11.1	(26.7)
Spain	6.9	7.4	(6.7)
United Kingdom	2.5	3.5	(29.7)
Other Western European countries	4.3	3.7	15.8
Russia, Turkey, other CEE countries	14.6	12.3	19.0
Other international sales	35.2	31.2	12.8
TOTAL PHARMACEUTICALS	179.6	176.8	1.6
PHARMACEUTICAL CHEMICALS	6.2	6.9	(9.5)



# **MAIN PRODUCT SALES**

(million Euro)	1Q 2010	1Q 2009	Change %
Zanidip® (lercanidipine)	44.2	51.2	(13.7%)
Zanipress® (lercanidipine+enalapril)	6.4	3.1	110.4
Other corporate products	13.5	7.6	78.0
Orphan drugs	15.7	11.9	31.6



# **FIRST QUARTER 2010 RESULTS**

(million Euro)	1Q 2010	1Q 2009	Change %
Revenue	185.9	183.7	1.2
Gross Profit as % of revenue	126.2 67.9%	123.5 67.2%	2.1
SG&A Expenses as % of revenue	65.8 35.4%	65.8 35.8%	0.0
R&D Expenses as % of revenue	16.4 8.8%	15.3 8.3%	7.4
Other Income (Expense), net as % of revenue	(0.9) (0.5%)	(1.8)	(50.6)
Operating Income as % of revenue	43.1 23.2%	40.6 22.1%	6.0
Net Income as % of revenue	30.0 16.1%	<b>27.6</b> 15.0%	8.5



# NET FINANCIAL POSITION AND SHAREHOLDER'S EQUITY

(million Euro)	31 Mar 2010	31 Dec 2009	Change
Cash and short-term financial investments	87.6	93.8	(6.2)
Bank overdrafts and short-term loans	(6.3)	(28.9)	22.6
Loans – due within one year	(1.8)	(2.4)	0.6
Loans – due after one year	(82.1)	(82.2)	0.1
NET FINANCIAL POSITION	(2.6)	(19.7)	17.1
SHAREHOLDERS' EQUITY	542.0	509.0	33.0



#### 2010 - 2012 BUSINESS OBJECTIVES

#### **SALES DEVELOPMENT ASSUMPTIONS: lercanidipine franchise**

- Zanidip® (lercanidipine) sales will diminish progressively over the 2010-2012 period to approx. € 100 million and remain relatively stable thereafter
- Zanipress® (lercanidipine + enalapril):
  - Will grow in line with expectations in the countries where already launched
  - Will be launched in Italy at the beginning of 2011
  - Will be launched progressively in all other countries
  - Sales of approx. € 70 million targeted in 2012 with further growth expected thereafter



#### 2010 - 2012 BUSINESS OBJECTIVES

#### **FINANCIAL PROJECTIONS: Assumptions**

- Gross profit is expected to decrease to approx. 65-66% of sales over the period
- SG&A expenses:
  - Sales force restructuring already completed. Now around 1,400 strong.
  - Promotional activity to increase in 2011-2012 to support launch of new corporate products
  - SG&A will remain at around 35-36% of sales over the period
- R&D expenses estimated at around 10% of sales over the period



## 2010 - 2012 BUSINESS OBJECTIVES

#### FINANCIAL PROJECTIONS

(million Euro)	2009 Actual	2010 Targets	2011 Plan	2012 Plan
Revenue	747.5	>700	730-740	780-800
Operating income (EBIT)	162.2	>140	145-150	155-160
Net Income	110.6	>95	100-102	110-112

- Based on existing business, no new acquisitions included.
- Targets for 2010 and 2011 are substantially in line with those announced previously and are improved in some cases.

# Company declarations, disclaimers and profile

DECLARATION BY THE MANAGER RESPONSIBLE FOR PREPARING THE COMPANY'S FINANCIAL REPORTS

The manager responsible for preparing the company's financial reports Fritz Squindo declares, pursuant to paragraph 2 of Article 154-bis of the Consolidated Law on Finance, that the accounting information contained in this presentation corresponds to the document results, books and accounting records.

Statements contained in this presentation, other than historical facts, are "forward-looking statements" (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are based on currently available information, on current best estimates, and on assumptions believed to be reasonable. This information, these estimates and assumptions may prove to be incomplete or erroneous, and involve numerous risks and uncertainties, beyond the Company's control. Hence, actual results may differ materially from those expressed or implied by such forward-looking statements.

All mentions and descriptions of Recordati products are intended solely as information on the general nature of the company's activities and are not intended to indicate the advisability of administering any product in any particular instance.

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271) with a total staff of over 2,800, dedicated to the research, development, manufacturing and marketing of pharmaceuticals, with headquarters in Milan, Italy, operations in the main European countries, and a growing presence in the new markets of Central and Eastern Europe. A European field force of around 1,400 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati's current and growing coverage of the European pharmaceutical market makes it a partner of choice for new product licenses from companies which do not have European marketing organizations. Recordati is committed to the research of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2009 was € 747.5 million, operating income was € 162.2 million and net income was € 110.6 million.

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