



# RECORDATI

**A European specialty pharmaceutical company**

JP Morgan 27<sup>th</sup> Annual Healthcare Conference  
San Francisco, 14 January 2009

# COMPANY PROFILE

- Mid sized pharmaceutical company with a European focus
- 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, CIS and Turkey
- Expanding through organic development and through acquisitions
- Proprietary drugs sold worldwide through licensees



# STRATEGY

- Recordati will continue to develop its business in Europe, both Western and in the new growing CEE (Central and Eastern Europe) markets, which together represent the second largest pharmaceutical market in the world,
- by growing its existing product portfolio,
- acquiring new product rights,
- enriching its pipeline of products in development
- and enlarging its geographical footprint

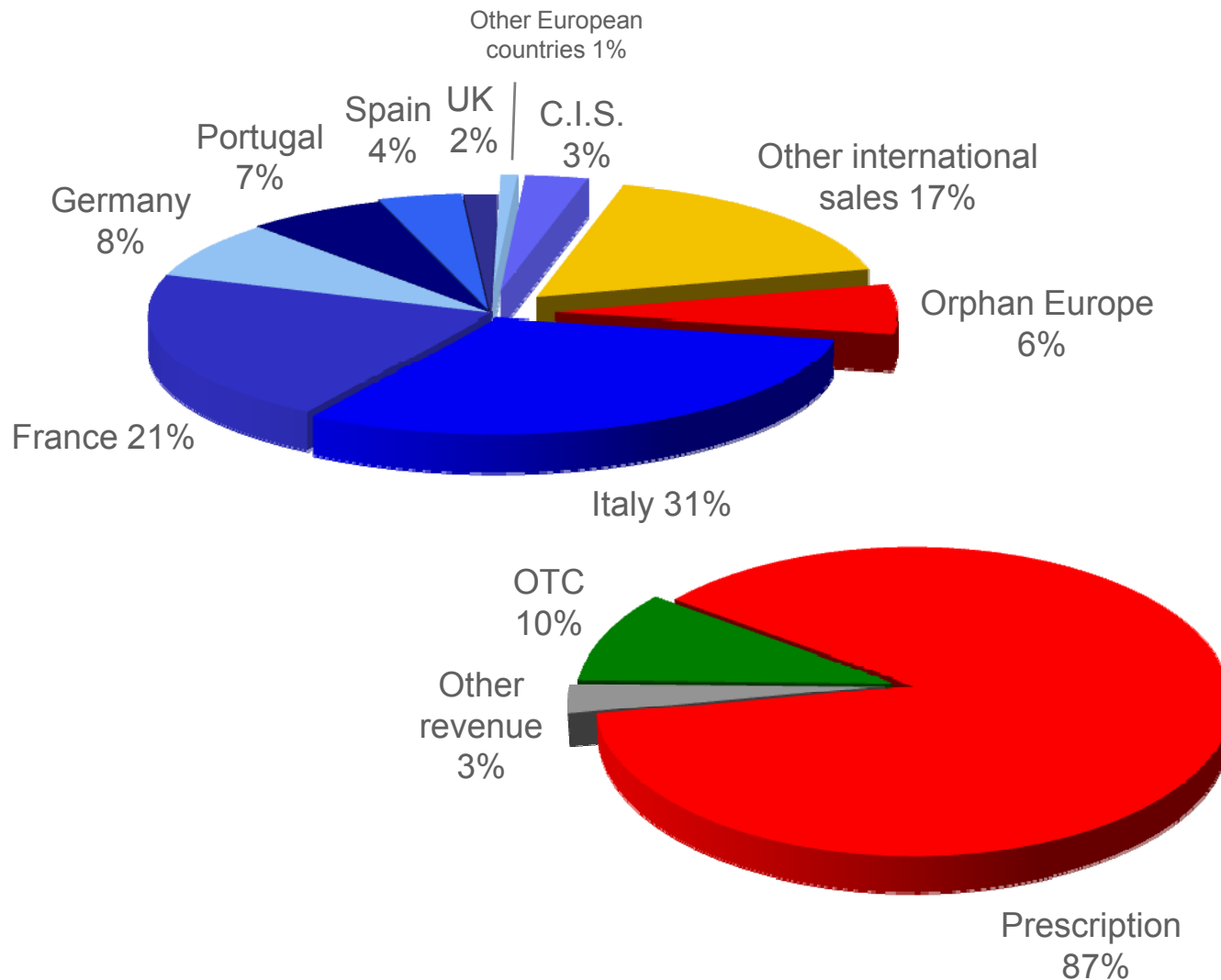
## Portfolio development

- High focus on new corporate products
- Maximization of existing products
- Prioritize development of specialty care products

## Geographical expansion

- Enter new markets characterized by high growth in CEE
- Launch new corporate products and existing proprietary products in these markets

# CURRENT BREAKDOWN OF PHARMACEUTICAL REVENUE



	% of pharmaceutical revenue
Zanidip®/Zanipress® (lercanidipine/lercanidipine+enalapril)	32%
Elopram® /Entact® (citalopram/escitalopram)	6%
Peptazol® (pantoprazole)	3%
Tora-Dol® (ketorolac)	3%
Claversal® (mesalazine)	2%
Methadone	2%
Adagen® (pegademase bovine)	2%
Tenstaten® (cicletanine)	2%
Hexa line (biclotimol)	2%
Tergynan®	2%
Nitrocor® (nitroglycerine T.P.)	2%
Cidine® (cinitapride)	2%

Data: First nine months 2008  
 Total revenue € 508 m  
 Pharmaceutical revenue € 485 m

# ZANIDIP<sup>®</sup> (lercanidipine)

- Calcium channel blocker indicated for the treatment of hypertension. Lipophilic dihydropyridine discovered and developed by Recordati. **Efficacy as best in class, superior tolerability.**
- **On the market in 90 countries. Second largest CCB in the 16 main markets. Leader in its class in France**
- Patent expires 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
- Sales in 2008 expected to reach € 200 million
- Sales in 2009 expected to be around € 200 million
- Following appearance of generic competition in main markets sales in 2010 expected to be around € 105 million
- Further price erosion in 2011 expected to be of around 20%

# R&D PIPELINE

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
Zanipress®/Zanitek®	Recordati	Hypertension (lercanidipine+enalapril)	Launched in Germany , Australia and Ireland MRP in Europe completed
rupatadine	Uriach	Rhinitis, allergic, seasonal / perennial urticaria	Approved
prulifloxacin	Nippon Shinyaku /Angelini	Infection, respiratory tract Infection, urinary tract	Filed
pitavastatin	Kowa	Hyperlipidemia, general	Filed
silodosin	Kissei	Benign prostatic hyperplasia	Filed
lercanidipine MR	Diff. technology platforms	Hypertension, general	Formulation/Phase II/Phase III
2 new lercanidipine combinations	Recordati	Hypertension	Phase II
REC 0422	Recordati	Overactive bladder and Incontinence	Preclinical
REC 1819	Recordati	Overactive bladder and Incontinence	Preclinical

MRP – Mutual Recognition Process



# NEW CORPORATE PRODUCTS

- ZANIPRESS® (lercanidipine+enalapril)
- SILODOSIN
- PITAVASTATIN
- KENTERA® (oxybutynin TDS), RUPATADINE,  
FROVATRIPTAN

# NEW 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.
- On the market in Germany (three brands, Recordati, Berlin Chemie and Meda), in Australia (Solvay Biosciences) and in Ireland (Recordati).
- Further launches early 2009
- 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 <sup>(1)</sup>
- “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.” <sup>(1)</sup>
- “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 thiazide-type diuretic.” <sup>(1)</sup>

(1) National Collaborating Centre for Chronic Conditions.

*Hypertension: management in adults in primary care: pharmacological update.* London: Royal College of Physicians, 2006.



# NEW CORPORATE PRODUCTS

## SILODOSIN

- Highly selective  $\alpha_{1A}$  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
- MAA filed with EMEA November 2008. Foreseen approval time: Early 2010
- Launches to be initiated second half 2010 following local country by country pricing and reimbursement negotiations
- 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) 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  $\alpha_{1A}$  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 ( $Q_{max}$ )
  - **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

## 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: November 2009
- Launches expected to take place as from second half 2010
- Statins market in the 8 largest of the 21 countries covered by the agreement was € 2.8 billion in 2007
- 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)**.

# NEW CORPORATE PRODUCTS

## KENTERA<sup>®</sup> (oxybutynin TDS)

- Bi-weekly oxybutynin transdermal patch indicated for the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with unstable bladder (or otherwise referred to as overactive bladder, OAB)
- Approved through the centralized procedure by the EMEA in 2004
- Exclusive license granted by a subsidiary of Watson Pharmaceuticals, Inc. for marketing and sales in 29 European countries
- Kentera<sup>®</sup> currently re-launched in Germany, UK, Greece and Ireland by Recordati and in other European countries by sub-licensees
- License granted to Orion for the Scandinavian countries and Switzerland, and to EuroCept BV for Belgium, the Netherlands and Luxembourg

## RUPATADINE

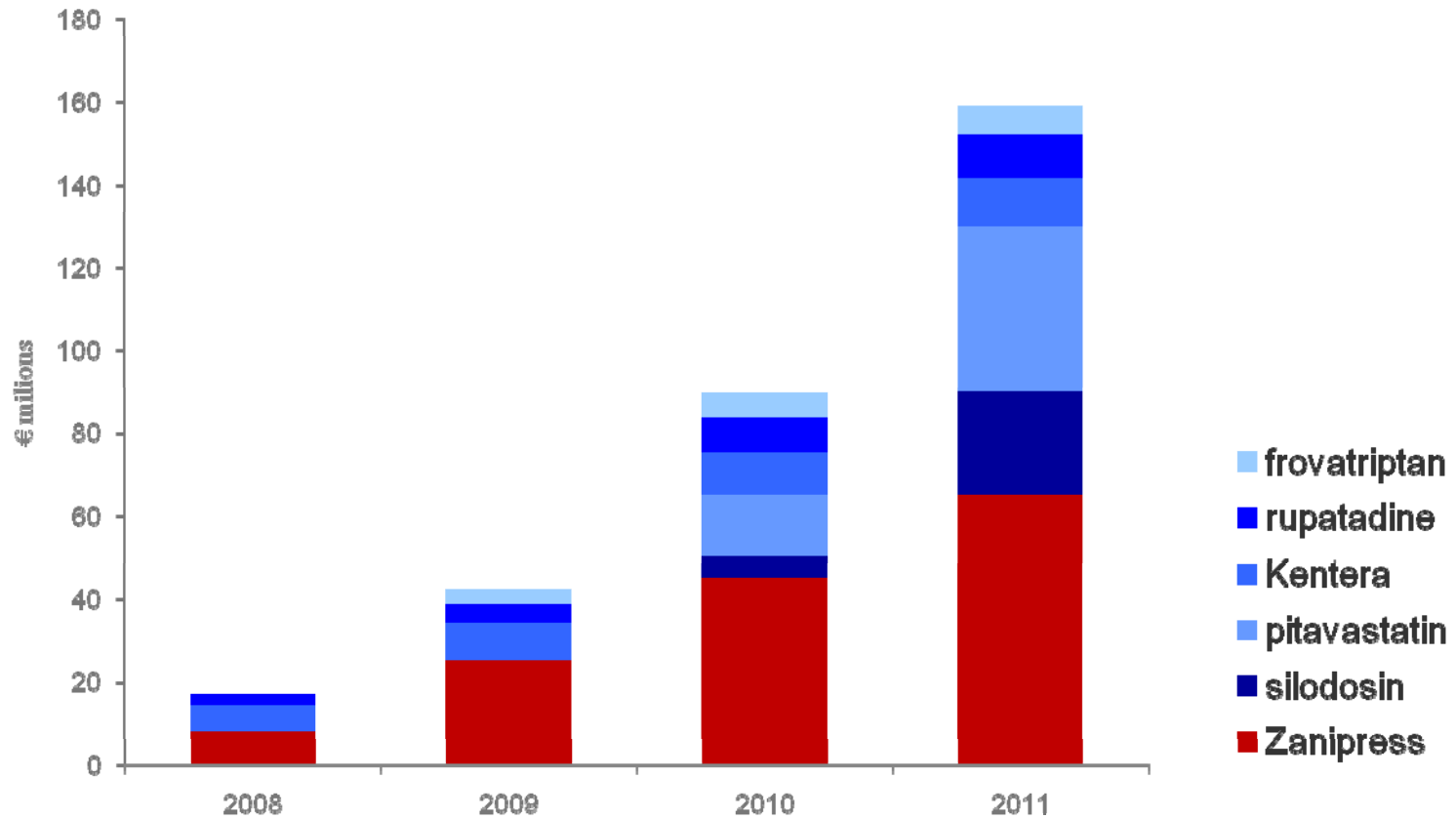
- Latest generation systemic antihistamine drug indicated for the treatment of allergies and in particular allergic rhinitis
- Rupatadine does not cause sleepiness, an undesired side effect of previous generation drugs
- License granted by Uriach for marketing and sales in Spain (Alergoliber<sup>®</sup> on the market since beginning 2004), Italy and Germany (launched in 2008 as Rupafin<sup>®</sup>) and France (to be launched in 2009 as Wystamm<sup>®</sup>)

## FROVATRIPTAN

- New selective 5HT<sub>1B/1D</sub> receptor agonist indicated for the acute treatment of migraine attacks with or without aura
- Frovatriptan distinguished from other triptans by its long half-life (26 hours) ensuring long-lasting clinical efficacy and reduction of the recurrence rate of migraine attacks
- Semi-exclusive license granted by Menarini for marketing and sales in France and Greece where it has been launched as Isimig<sup>®</sup> and Pitunal<sup>®</sup> respectively

# NEW CORPORATE PRODUCTS

## EXPECTED SALES



Includes direct sales and sales to licensees

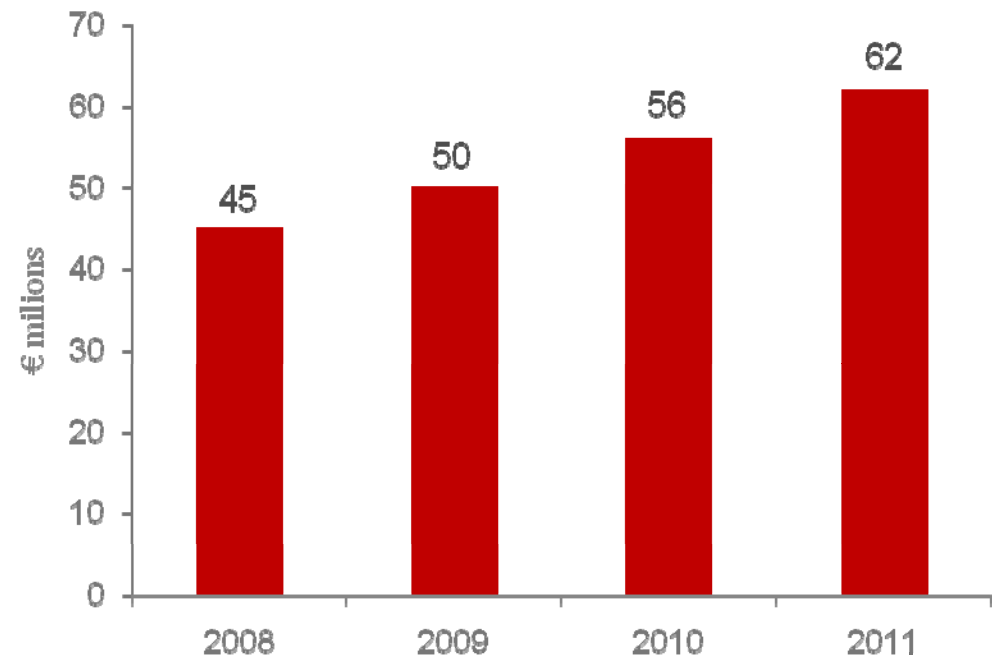
# New developments for the Lower Urinary Tract Symptoms (LUTS) and incontinence

- 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 two 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

# ORPHAN EUROPE

- Recordati completed the acquisition of Orphan Europe, a European pharmaceutical company dedicated to treatments for rare diseases, in December 2007
- Well balanced, cash generating portfolio of 9 products with strong growth potential and a promising pipeline
- Current product portfolio CAGR of 10% over the period
- Stanate® (stannsoporfin), under development for the treatment of neonatal hyperbilirubinemia caused by G6PD deficiency and ABO incompatibility, to be approved by end 2011
- Upside: Approval of Carbaglu® (carglumic acid) in the United States for the treatment of NAGS deficiency could be received within the period and would represent an opportunity for a direct presence of Recordati in the U.S. for the sale of orphan drugs

## Expected sales



Based on existing product portfolio



# R&D PIPELINE – drugs for rare diseases

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
Carbaglu®	Orphan Europe (Recordati)	NAGS deficiency	Approved in EU Filed in U.S.
Carbaglu®	Orphan Europe (Recordati)	Organic acidemias	Pre-registration in EU
Vedrop®	Orphan Europe (Recordati)	Vitamin E deficiency in cystic fibrosis and chronic cholestasis	Filed with EMEA
Infasurf®	Ony	Calf derived surfactant for RDS	Phase II-III
Stanate®	Rockefeller U. /InfaCare	Neonatal jaundice, hyperbilirubinemia	Phase II-III
Cystagon®	Mylan	Other indication unrelated to nephropathic cystinosis	Phase II-III
Cystadrops®	Orphan Europe (Recordati)	Ocular cystinosis	Phase II
Normosang®	Orphan Europe (Recordati)	Hepatic porphyria	Approved in EU Pre-registration in U.S.



# Development of drugs for rare diseases

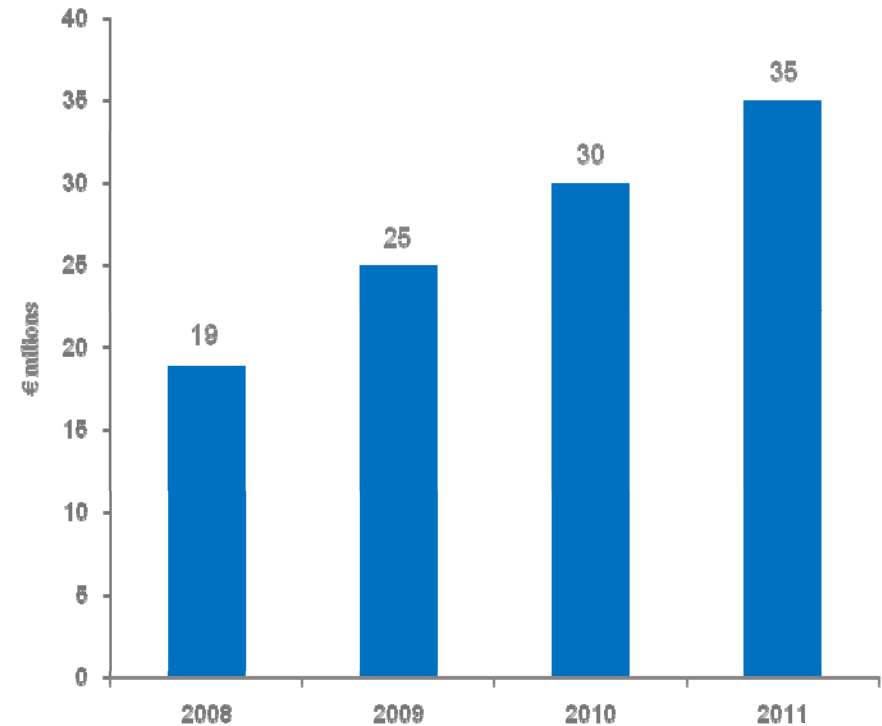
- **Carbaglu®** (carglumic acid), a drug developed by Orphan Europe for the treatment of NAGS deficiency, approved in the EU in 2003 and filed recently for approval with the FDA. Carbaglu® is also in pre-registration phase in Europe for additional indications in organic acidaemias.
  - **Vedrop®** (tocofersolan), a drug developed by Orphan Europe indicated for vitamin E deficiency in patients with cystic fibrosis or chronic cholestasis, is a water-soluble vitamin E which is easily absorbed in such patients. The drug was filed for EMEA approval in 2007.
  - **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®** (stannosporfin) Inhibits the production of bilirubin in cases of hyperbilirubinemia of different origin. Originated by Rockefeller University, is under development by InfaCare for the treatment of neonatal hyperbilirubinemia (jaundice). Severe hyperbilirubinemia, if untreated, can lead to severe brain damage. If approved, stannosporfin could be used immediately in infants not responding to phototherapy.
- Orphan Europe will complete the clinical development of stannosporfin in Europe in accordance with the relevant regulatory bodies' scientific advice. The plan addresses hyperbilirubinemia caused by G6PD deficiency and ABO incompatibility.
- **Cystagon®** (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 cystinosis" which cannot be treated 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 discussing with the FDA its registration in the USA.



## COMMONWEALTH OF INDEPENDENT STATES (CIS)

- In March Recordati acquired the French companies FIC and FIC Médical which are dedicated to the registration and the promotion of pharmaceutical products on behalf of third party companies in Russia and other C.I.S. countries.
- In 2007 Recordati's sales in the C.I.S. countries through the services of FIC Médical were € 13.7 million
- New and existing corporate products to be added to the current portfolio of promoted products.
- Launches of corporate products expected as from 2010

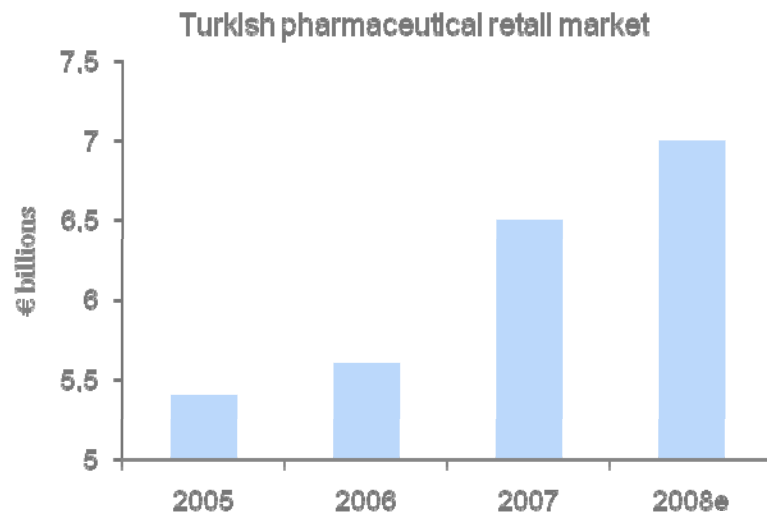
### Expected sales



Excludes other income

## TURKEY

- Acquisition of Yeni İlaç in Turkey end 2008
- Current product portfolio expected to generate sales of over € 17 million in 2008
- Sales of lercanidipine, fenticonazole and flavoxate (total of € 7 million p.a.) currently licensed out will be sold directly by the new Turkish subsidiary as from mid 2009
- Launch of new corporate products as from 2010

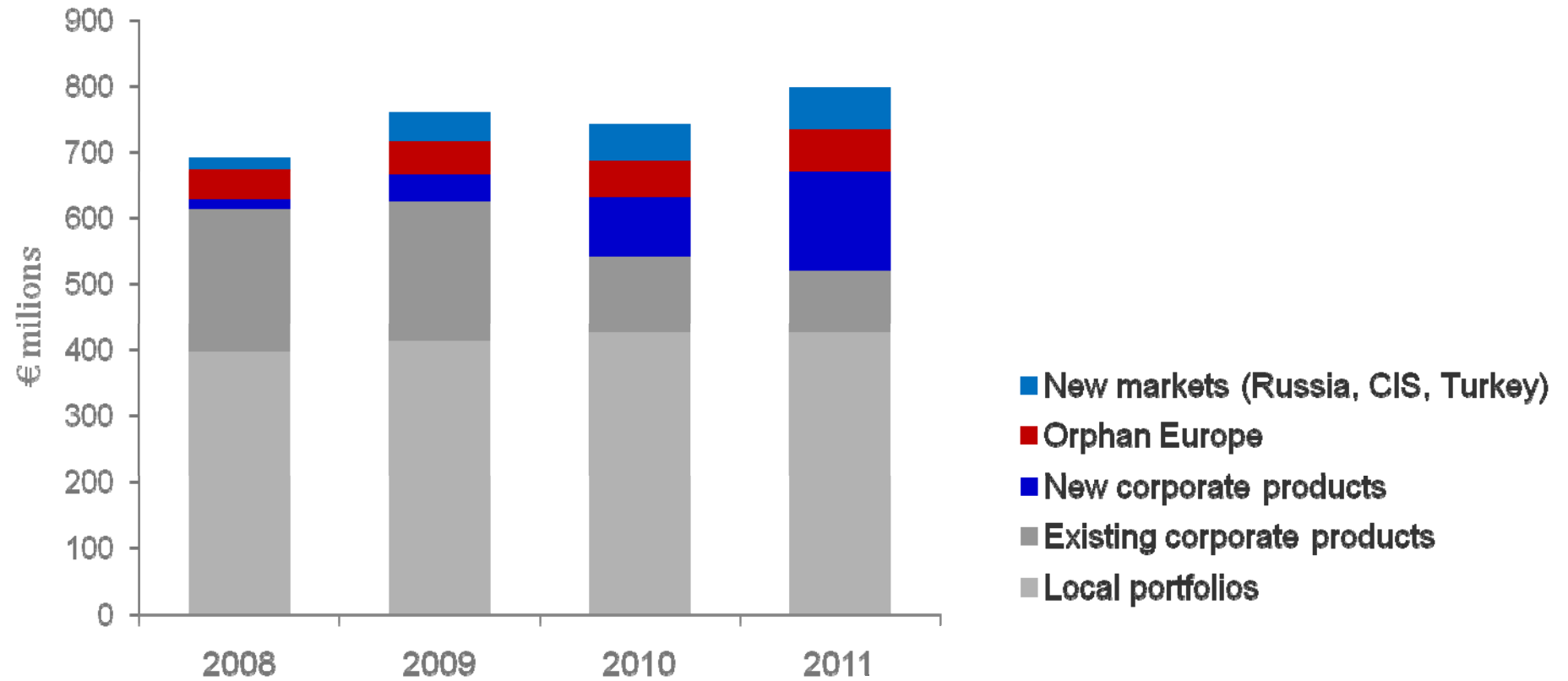


## Expected sales



# FINANCIAL PROJECTIONS

## SALES DEVELOPMENT



Based on existing business, no new acquisitions included

# FINANCIAL PROJECTIONS

## 2008 TARGETS, 2009 - 2011 PLAN

(million Euro)	2008 Targets	2009 Plan	2010 Plan	2011 Plan
Revenue	~ 690	~750	700-720	780-800
R&D expenses	~ 60	~75	~70	~75
Operating income (EBIT)	~ 144	~155	135-140	145-150
Net Income	~ 100	~105	95-98	102-105

Based on existing business, no new acquisitions included

# NET FINANCIAL POSITION

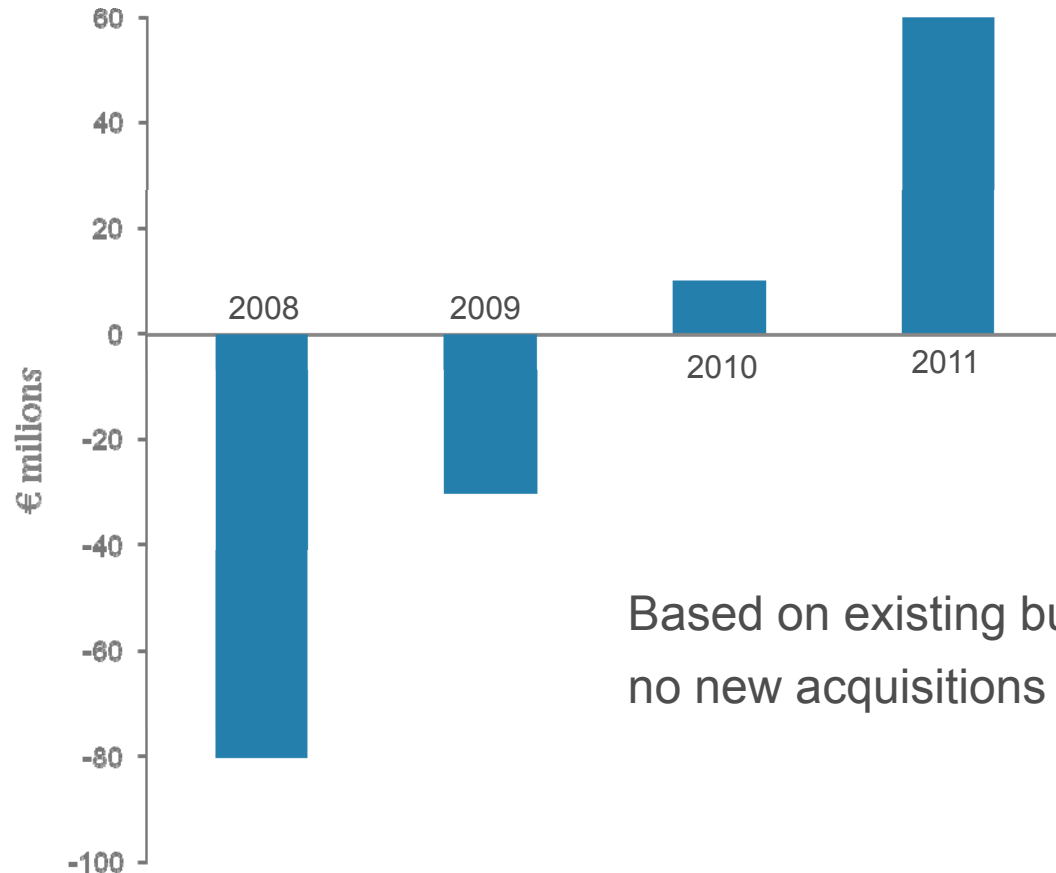
## Expected cash flow generation

(million Euro)	2009 Plan	2010 Plan	2011 Plan
Cash flow	~135	~125	~130
CAPEX (tangible assets)	~10	~10	~10
Investment in intangible assets	~20	~20	~20
Expected free cash flow generation	~105	~95	~100
Dividend pay-out ratio maintained as % of net income	50%	50%	50%

Based on existing business, no new acquisitions included

# NET FINANCIAL POSITION

## Expected net financial position



Based on existing business,  
no new acquisitions included

# STRATEGIC OBJECTIVE

- Strategic objective for the 2009-2011 period is to grow sales and profits every year by adding to organic development new business acquisitions in growing markets
- Solid acquisition track record
- Since 1999 approx. € 375 million invested in acquisitions to expand geographical presence
- Operating return generated in 2008 approx. 15%

# 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), dedicated to the research, development, manufacturing and marketing of pharmaceuticals, with headquarters in Milan, Italy, operations in the main European countries, and a total staff of over 2,400. A European field force of over 1,300 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 in which its research team has proven scientific competence and a track record of discovery and development of original drugs, the most recent of which, lercanidipine, a latest generation calcium channel blocker for the treatment of hypertension, is the company's leading product. Consolidated revenue for 2007 was € 628.4 million, operating income was € 131.5 million and net income was € 84.9 million.**

### Contact Information

#### **Offices:**

**Recordati S.p.A.**

**Via M. Civitali 1**

**20148 Milano, Italy**

#### **Investor Relations:**

**Marianne Tatschke**

**+39 02 48787393**

**tatschke.m@recordati.it**

#### **Website:**

**[www.recordati.com](http://www.recordati.com)**