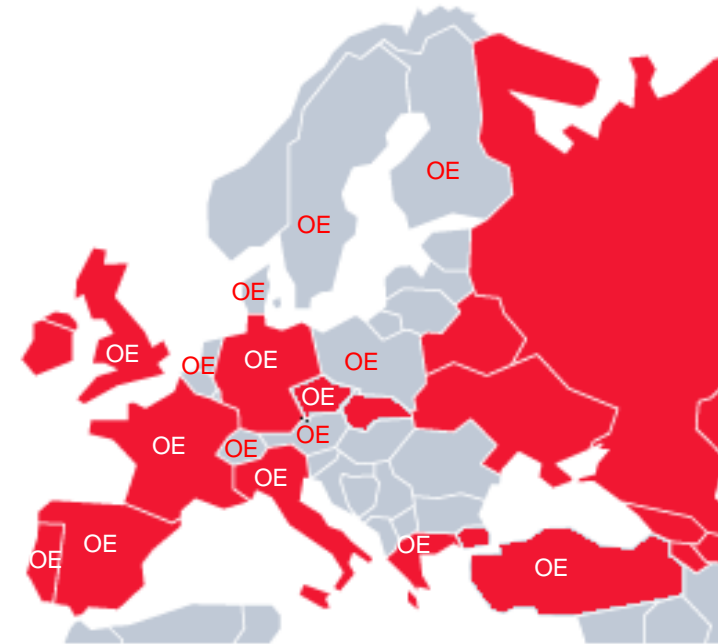


**RECORDATI**

**A European specialty pharmaceutical company**

## Company Profile

- Mid sized pharmaceutical company with a European focus (2950 employees, of which 1450 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

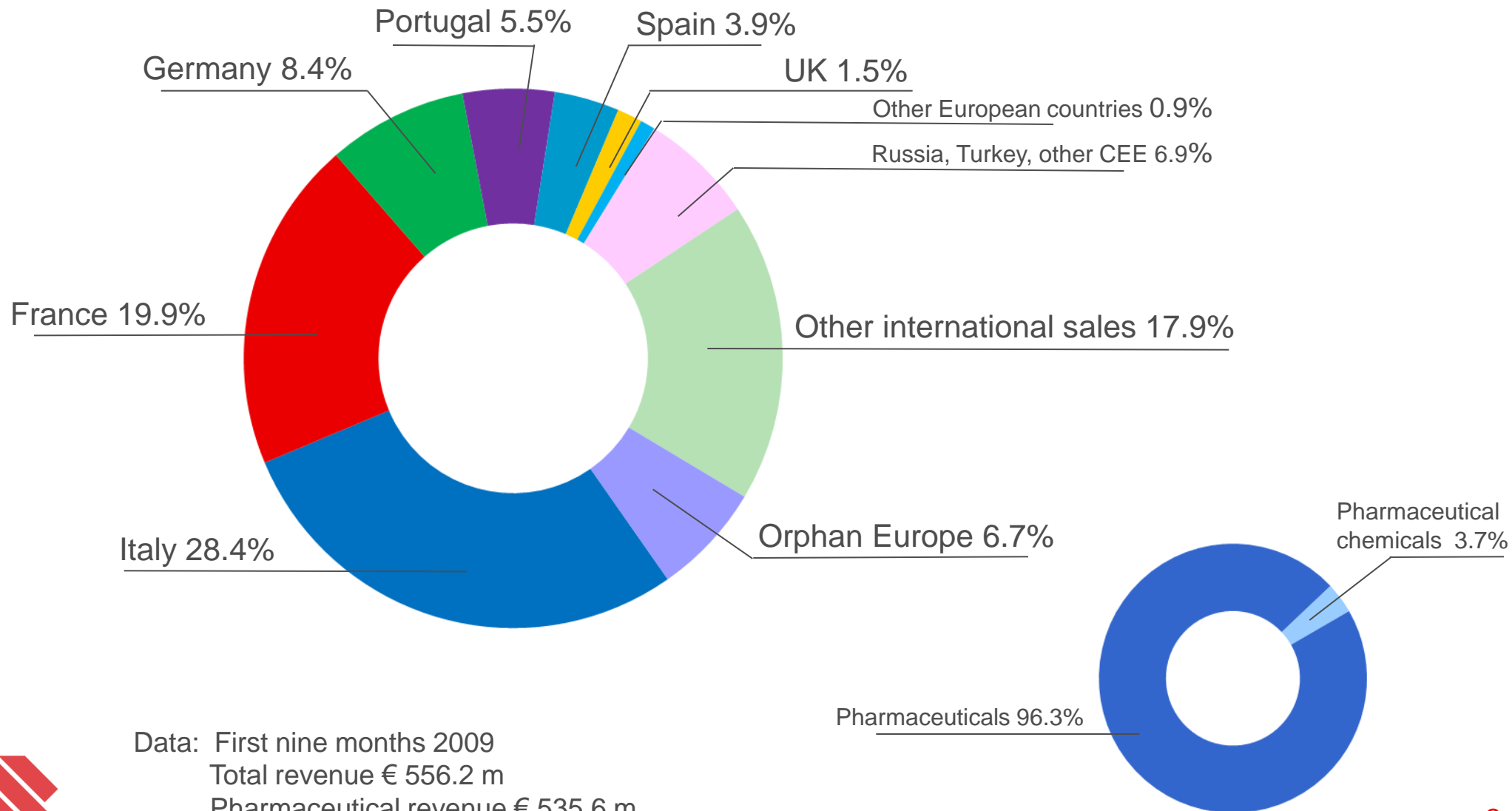
## Develop product portfolio by

- 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

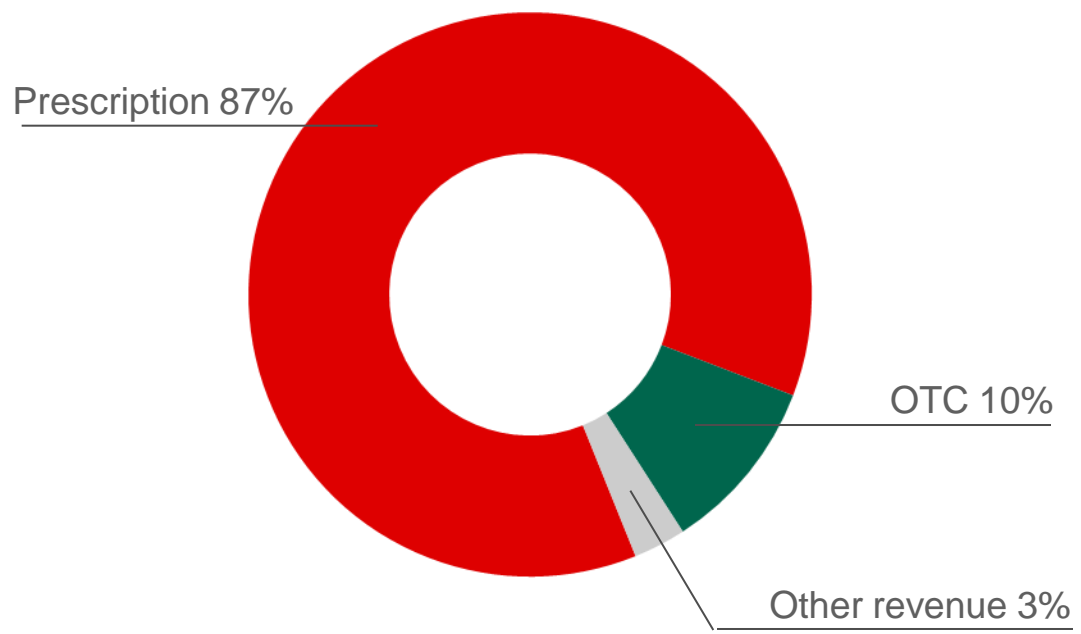
- Establishing new subsidiaries in new markets characterized by high growth in CEE
- Launching new corporate products and existing proprietary products in these markets
- Taking the opportunity of establishing a direct presence in the U.S, for the marketing of treatments for rare diseases

# COMPOSITION OF PHARMACEUTICAL REVENUE



Data: First nine months 2009  
Total revenue € 556.2 m  
Pharmaceutical revenue € 535.6 m

# BREAKDOWN OF PHARMACEUTICAL REVENUE



	% of pharmaceutical revenue
Zanidip®/Zanipress® (lercanidipine/lercanidipine+enalapril)	33%
Elopram® /Entact® (citalopram/escitalopram) - Italy	6%
Peptazol® (pantoprazole) - Italy	3%
Methadone - France	2%
Adagen® (pegademase bovine) -Orphan Europe	2%
Claversal® (mesalazine) - Germany	2%
Tora-Dol® (ketorolac) - Italy	2%
Tergynan® - France export and C.I.S.	2%
Hexa line (biclotimol) - France and C.I.S.	2%
Tenstaten® (cicletanine) - France	2%

Data: First nine months 2009  
 Pharmaceutical revenue € 535.6 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 92 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

# R&D PIPELINE

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
Zanipress®/Zanitek®	Recordati	Hypertension (lercanidipine+enalapril)	Approved. Launched in a number of countries
rupatadine	Uriach	Rhinitis, allergic, seasonal / perennial urticaria	Approved. Launched in a number of countries
silodosin	Kissei	Benign prostatic hyperplasia	Filed
pitavastatin	Kowa	Hyperlipidemia, general	Filed
lercanidipine IR	Pharmathen	Hypertension, general	Filed
new lercanidipine combinations	Recordati	Hypertension, general	Phase II
REC 0422	Recordati	Overactive bladder and Incontinence	Preclinical
REC 1819	Recordati	Overactive bladder and Incontinence	Preclinical

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

## 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 Germany, Australia, Ireland, Finland, Denmark, Greece, the Netherlands, South Africa, France, Spain, Belgium, Norway and Portugal.
- 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 <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.



## 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: first half 2010
- 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)**.

## 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 Almirall for the Middle East (except Israel), to Almirall for Spain 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 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 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®  
Normosang®  
Pedeia®  
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	



# R&D PIPELINE – drugs for rare diseases

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
<b>Carbaglu®</b>	Orphan Europe (Recordati)	NAGS deficiency	Approved in EU Filed in U.S.
<b>Carbaglu®</b>	Orphan Europe (Recordati)	Organic acidemias	Pre-registration in EU
<b>Infasurf®</b>	Ony	Calf derived surfactant for RDS	Phase II-III
<b>Stanate®</b>	Rockefeller U. /InfaCare	Neonatal jaundice, hyperbilirubinemia	Phase II-III
<b>Cystagon®</b>	Mylan	Other indication unrelated to nephropathic cystinosis	Phase II-III
<b>Cystadrops®</b>	Orphan Europe (Recordati)	Ocular cystinosis	Phase II
<b>Normosang®</b>	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.
  - **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 in accordance with the relevant regulatory bodies' scientific advice. The plan addresses hyperbilirubinemia caused by AB0 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.



# FIRST NINE MONTHS 2009 HIGHLIGHTS

- Revenue € 556.2 million, up 9.4%, international sales grow by 13.0%
- Operating income (EBIT) € 121.8 million, up 9.5%
- Net Income € 85.3 million, up 11.3%
- Acquisition of Herbacos-Bofarma in the Czech Republic
- Almirall and Nycomed to co-market silodosin in Spain and Italy respectively. Pharmaplan exclusive licensee for South Africa.
- Zanipress<sup>®</sup> (lercanidipine+enalapril) launched in a number of European countries
- Agreement with Pharmathen (Greece) for a new low dose formulation of lercanidipine.
- TransAct<sup>®</sup> LAT (flurbiprofene patch) licensed from Amdipharm for Italy and Portugal.

# FIRST NINE MONTHS 2009 RESULTS

(million Euro)	Jan-Sep 2009	Jan-Sep 2008	Change %
Revenue	556.2	508.2	9.4
Gross Profit as % of revenue	379.2 68.2	346.6 68.2	9.4
SG&A Expenses as % of revenue	200.8 36.1	190.4 37.5	5.5
R&D Expenses as % of revenue	49.5 8.9	42.3 8.3	17.2
Other Income (Expense), net as % of revenue	(7.0) (1.2)	(2.7) (0.5)	n.s.
Operating Income as % of revenue	121.8 21.9	111.3 21.9	9.5
Net Income as % of revenue	85.3 15.3	76.6 15.1	11.3



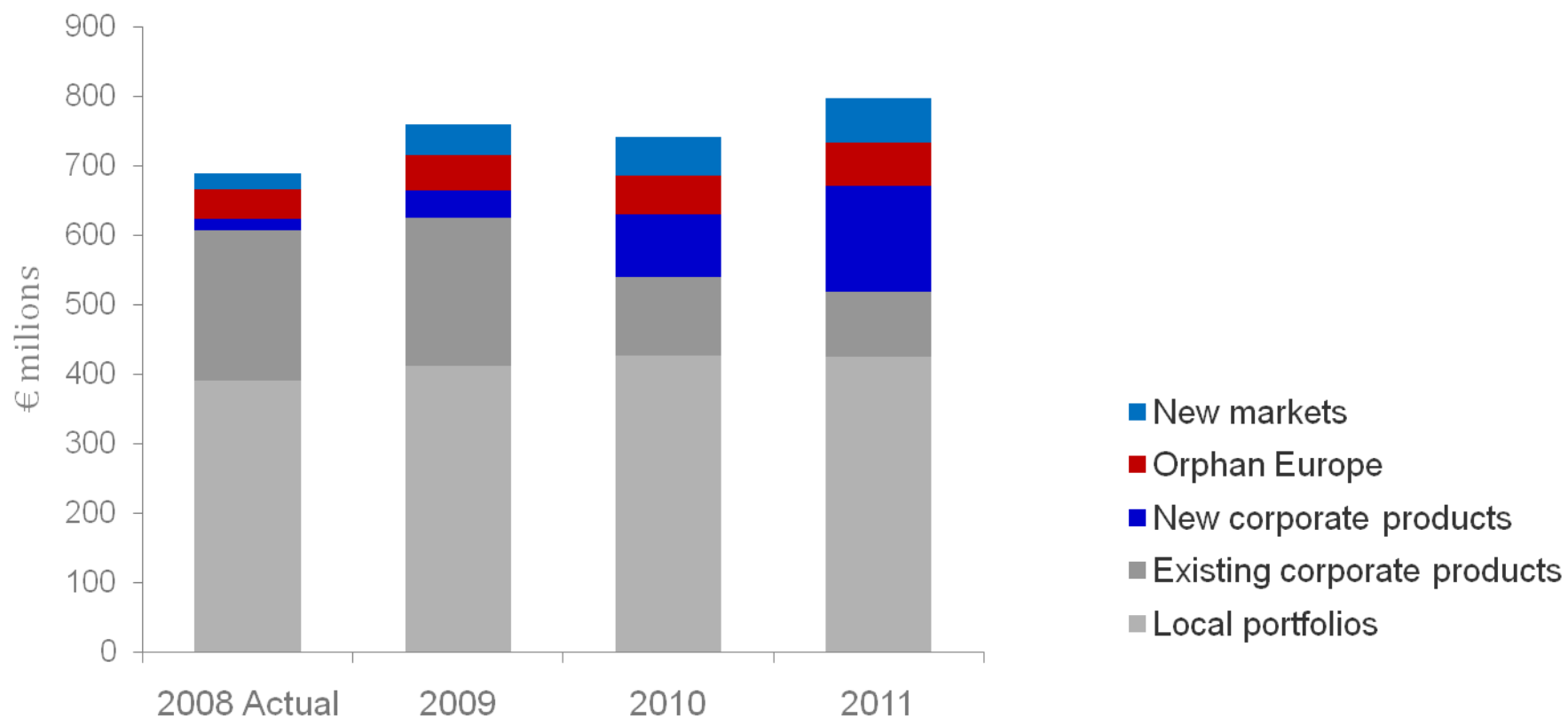
# NET FINANCIAL POSITION AND SHAREHOLDER'S EQUITY

(million Euro)	30 Sep 2009	31 Dec 2008	Change
Cash and short-term financial investments	75.8	95.0	(19.2)
Bank overdrafts and short-term loans	(56.8)	(90.8)	34.0
Loans – due within one year	(2.5)	(2.2)	(0.3)
Loans – due after one year	(82.8)	(82.9)	0.1
<b>NET FINANCIAL POSITION</b>	<b>(66.4)</b>	<b>(81.0)</b>	<b>14.6</b>
<b>SHAREHOLDERS' EQUITY</b>	<b>484.3</b>	<b>445.7</b>	<b>38.5</b>

## SALES DEVELOPMENT

- Zanidip® sales expected to be around € 200 million in 2009. 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%.
- Zanipress® roll-out during 2009. Pitavastatin and silodosin to be launched during 2010. New corporate products will add around € 160 million to sales by 2011.
- Local existing primary care portfolios expected to grow in line with the market
- Orphan Europe current product portfolio CAGR of 10% expected over the 2009-2011 period.
- New markets are expected to represent approx. 10% of sales in 2011. Sales in Russia and other C.I.S. countries expected to be of around € 35 million in 2011. New Turkish subsidiary to add around € 20 million of sales as from 2009 and to reach € 35 million by 2011. New subsidiary in Czech Republic and Slovachia (Herbacos-Bofarma acquired in January 2009) to add around € 12 million sales in 2009.

## SALES DEVELOPMENT



Based on existing business, no new acquisitions included

## 2009 - 2011 PLAN

(million Euro)	2008 Actual	2009 Targets	2010 Plan	2011 Plan
Revenue	689.6	~750	700-720	780-800
Operating income (EBIT)	144.7	>160	135-140	145-150
Net Income	100.4	>110	95-98	102-105

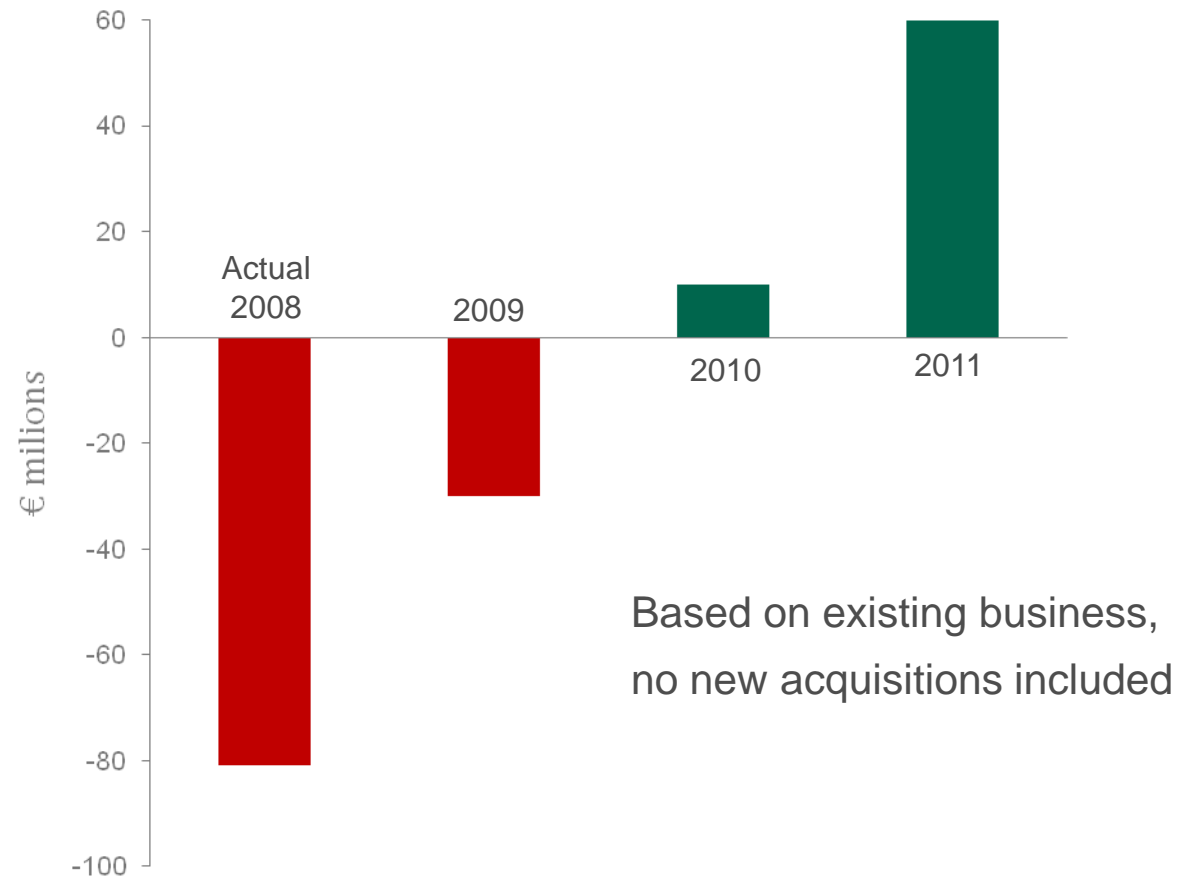
Based on existing business, no new acquisitions included

## Expected cash flow generation

(million Euro)	2009 Plan	2010 Plan	2011 Plan
Cash flow	~140	~125	~130
CAPEX (tangible assets)	~10	~10	~10
Investment in intangible assets	~25	~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

## Expected net financial position



- 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) with a total staff of over 2,950, 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 over 1,450 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 2008 was € 689.6 million, operating income was € 144.7 million and net income was € 100.4 million.**

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