



***A Specialty Pharmaceutical Group***

MORGAN STANLEY HEALTHCARE CONFERENCE  
New York – 8-10 SEPTEMBER 2014

# A strategy of growth and geographical expansion

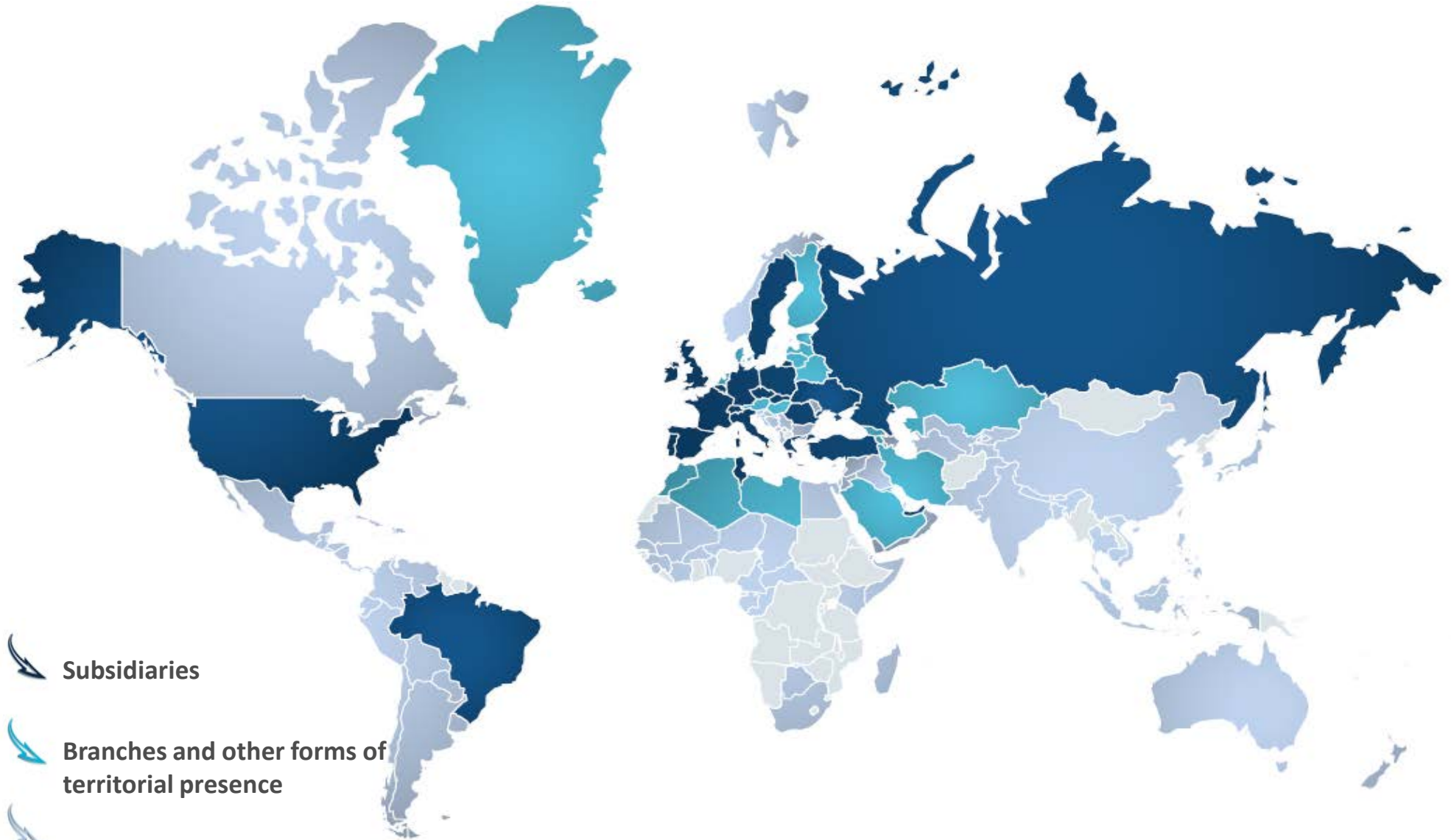
## Profile

- An international specialty pharmaceutical group (€ 941.6 m sales in 2013 and 4,000 employees).
- R&D mainly in urology, in specialty care and in treatments for rare diseases
- Marketing operations in the main European markets, in Russia, Poland and other Central and Eastern European countries, in Turkey, in the U.S.A. and in North Africa
- Drugs for the treatment of rare diseases marketed worldwide
- Proprietary drugs sold worldwide through licensees


## Strategy


- Expand through organic development and through acquisitions
- Develop product portfolio by enhancing product pipeline and new product acquisitions. Prioritize special care.
- Increase presence in new markets characterized by high growth
- Treatments for rare diseases: develop a global presence

# *Our products are sold in 135 countries*

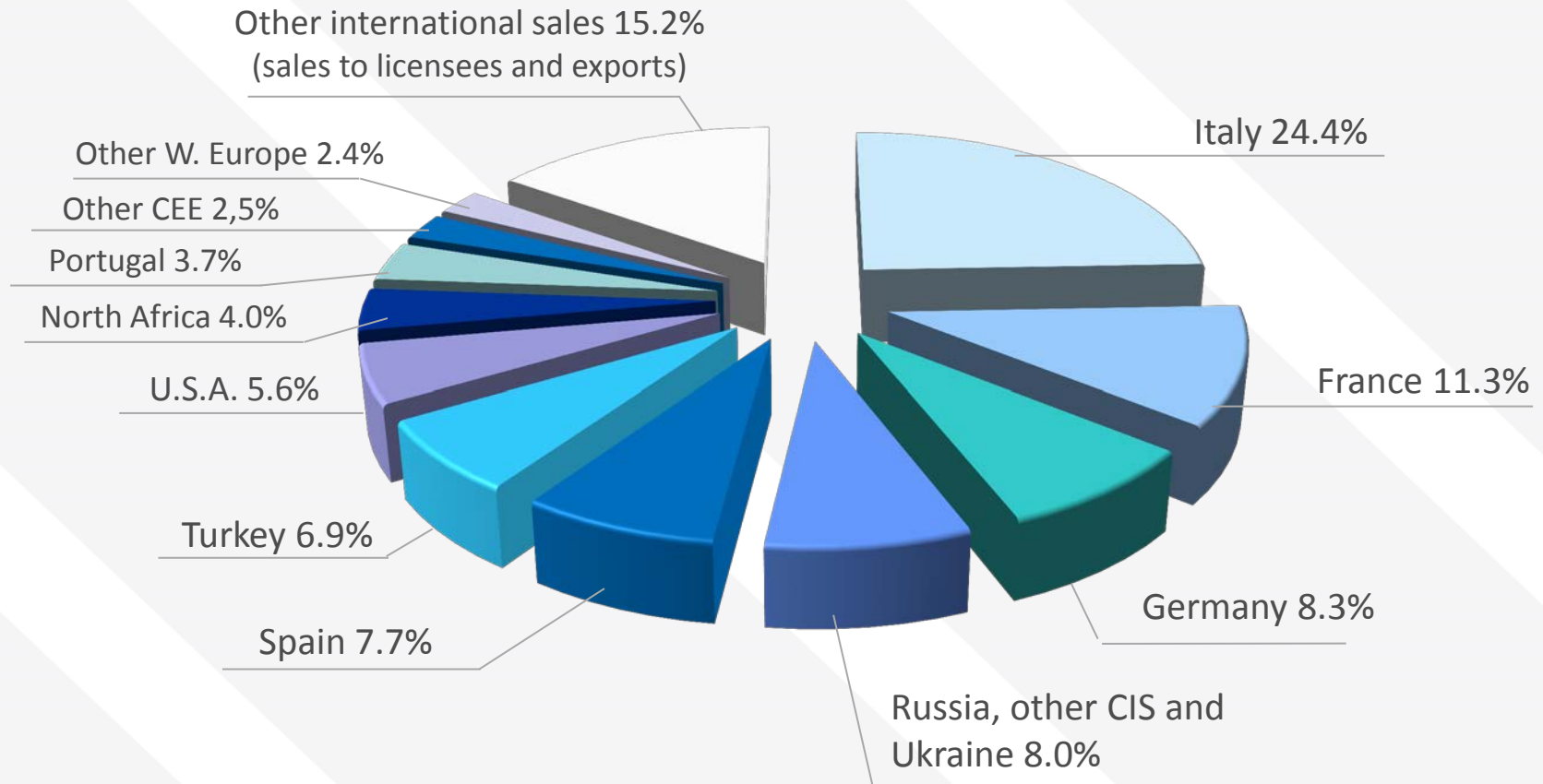


 **Subsidiaries**

 **Branches and other forms of territorial presence**

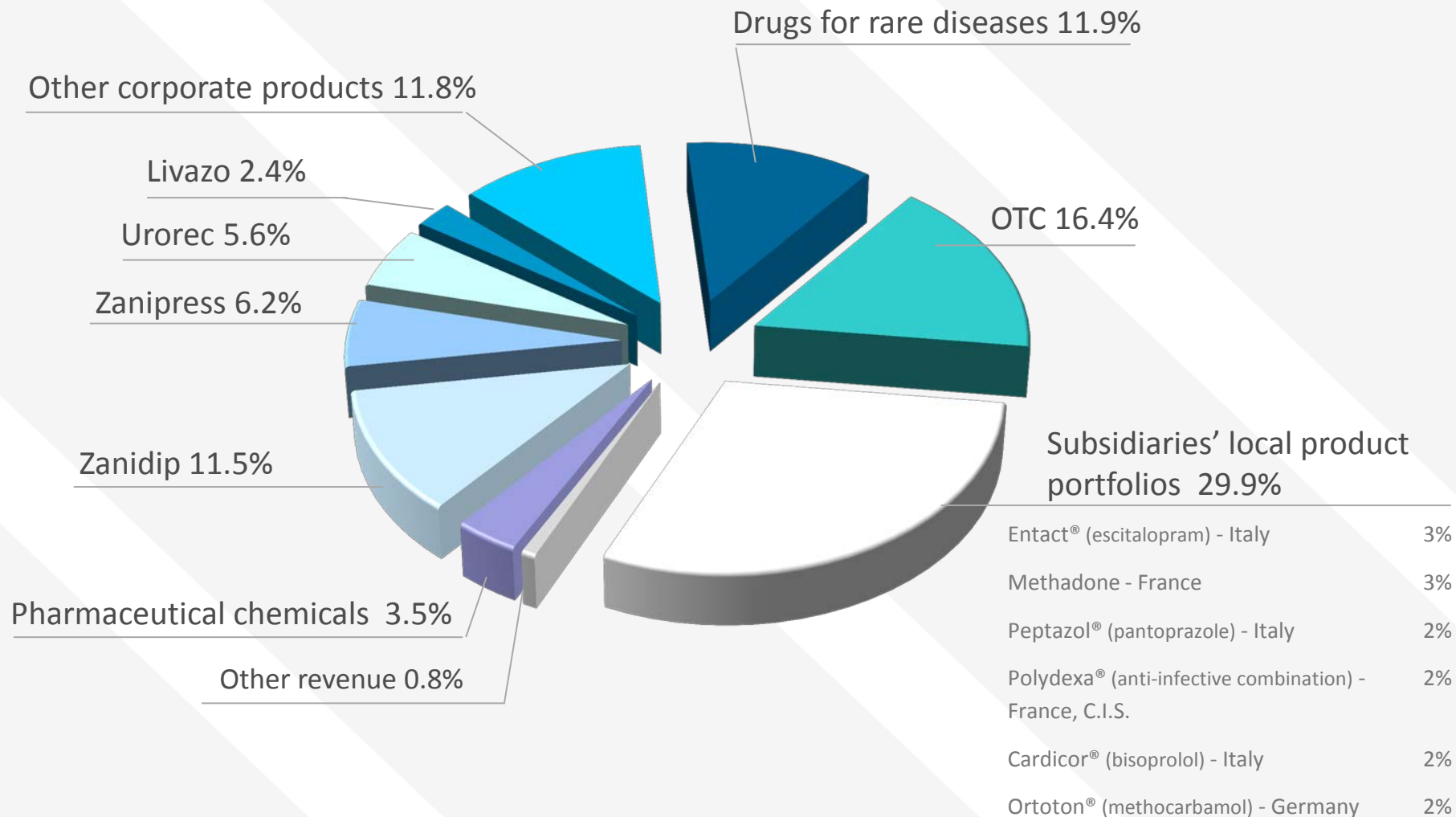
 **Countries where Recordati products are sold**  
(under license or exported)

# Geographical breakdown of pharmaceutical revenue



Data: First half 2014  
Pharmaceutical revenue € 490.0 m

# A diversified product portfolio



Data: First half 2014  
 Total revenue € 507.6 m

## *Core corporate products*

### **Zanipress<sup>®</sup> (lercanidipine+enalapril)** **Zanidip<sup>®</sup> (lercanidipine)**

- Lercanidipine is a proprietary latest generation calcium channel blocker indicated for the treatment of hypertension. Enalapril is an ACE inhibitor indicated for the treatment of hypertension.
- Sales of Zanidip<sup>®</sup> (lercanidipine) have eroded (CAGR -15.7%) following its patent expiry at the beginning of 2010.
- Zanipress<sup>®</sup> (lercanidipine+enalapril) now launched in 25 markets and growing significantly
- Zanipress<sup>®</sup> to be rolled-out progressively in new markets
- Zanipress<sup>®</sup> prices will come under pressure
- Sales of the Zanidip<sup>®</sup> / Zanipress<sup>®</sup> franchise expected to stabilize at between € 160 and € 165 million

## Core corporate products

### Urorec<sup>®</sup> (silodosin)

- Highly selective  $\alpha_{1A}$  receptor antagonist indicated for the treatment of symptoms associated with benign prostatic hyperplasia (BPH).
- Fast onset of action. High efficacy. Very good cardiovascular safety.
- Launched in 28 markets: Armenia, Belarus, Belgium/Luxembourg, Bulgaria, Croatia, Cyprus, Czech Rep., France, Georgia, Germany, Greece, Ireland, Italy, Kuwait, Lebanon, Moldavia, the Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Spain, South Africa, Turkey, Ukraine and the United Arab Emirates. Further launches to take place.
- License and co-marketing agreements in place with important players
- BPH market in 16 main countries approx. € 0.8 billion

## Core corporate products

### Livazo<sup>®</sup> (pitavastatin)

- Highly effective HMG-CoA reductase inhibitor indicated for the treatment of hypercholesterolaemia.
- Thanks to its unique chemical structure Livazo<sup>®</sup> is a potent LDL-lowering drug with a consistent and progressive HDL-raising effect. (*Atherosclerosis Supplements 2010; 11:15-22*)
- Livazo<sup>®</sup>, unlike most statins, is only minimally metabolized through a CYP pathway thereby reducing the risk of drug-drug interactions and providing a clear benefit in patients receiving polypharmacy. (*Atherosclerosis Supplements 2010; 11:15-22*)
- Launched in Spain, Portugal, Switzerland, Ukraine and Greece, further launches to take place.
- Statins market in the 11 key countries covered by the agreement is € 2.1 billion in 2013.



# Drugs for rare diseases

## **A worldwide business**

**Huge market potential: > 6,000 rare diseases identified for which treatments exist for only around 300.**

**Progressive country introduction of rare disease plans and access to diagnostic tests will stimulate the market for orphan drugs.**

- Acquisition of Orphan Europe end 2007. Establishment of Recordati Rare Diseases in the U.S.A. in 2013 following the acquisition of Lundbeck's U.S. portfolio of rare disease treatments.
- Present throughout Europe, Middle East and the U.S.. Sales coverage of new territories, either directly or through partnerships, planned.
- R&D in rare diseases:
  - Carbaglu<sup>®</sup>, indication in organic acidemias in the U.S.A., phase III
  - Cystadrops<sup>®</sup>, ocular cystinosis, pre-registration in the EU
  - Grasp<sup>®</sup>, partnership with Erytech, development of indication in Acute Myeloid Leukemia, phase II b
- Sales of drugs for rare diseases in 2013 total € 127.9 million, an increase of 68.6%

## ***Drugs for rare diseases***

**ADAGEN**<sup>®</sup> (pegademase bovine), indicated in the treatment of SCID-ADA deficiency

**CARBAGLU**<sup>®</sup> (carglumic acid), indicated in the treatment of hyperammonaemia due to NAGS deficiency and to the main organic acidemias

**COSMEGEN**<sup>®</sup> (dactinomycin), used mainly in the treatment of three rare cancers, Wilms' tumor, childhood rhabdomyosarcoma and choriocarcinoma.

**CYSTADANE**<sup>®</sup> (betaine anhydrous), indicated in the treatment of homocystinuria

**CYSTAGON**<sup>®</sup> (cysteamine bitartrate), indicated in the treatment of nephropathic cystinosis

**NORMOSANG**<sup>®</sup> (EU-RoW) /**PANHEMATIN**<sup>®</sup> (US) (human haemin), used to treat acute attacks of hepatic porphyria

**PEDEA**<sup>®</sup> (EU-RoW)/**NEOPROFEN**<sup>®</sup> (US) (ibuprofen I.V.), indicated in the treatment of patent *ductus arteriosus*

**VEDROP**<sup>®</sup> (water soluble vitamin E), indicated in the treatment of vitamin E deficiency in pediatric patients suffering from congenital chronic cholestasis

**WILZIN**<sup>®</sup> (zinc acetate), indicated in the treatment of Wilson's disease

## A well balanced R&D pipeline

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
<b>CARBAGLU®</b>	Recordati	Organic acidemias	Approved in EU Phase III in U.S.A.
<b>ZANIPRESS®*</b>	Recordati	Essential hypertension	Approved in EU
<b>CYSTADROPS®</b>	Recordati	Ocular cystinosis	Filed in EU
<b>REC 0482 (NX-1207)</b>	Nymox	Benign prostatic hyperplasia (BPH)	Phase III in U.S.A. (Nymox) Phase III in EU (Recordati)
<b>methadone</b>		Treatment of cancer-related pain in cases of resistance or intolerance to opioids	Phase III b
<b>CITRAFLEET®</b>	Recordati/Casen	Cleansing of the colon in preparation for colonoscopy. Split dose administration.	Phase III
<b>GRASPA®</b>	Erytech	Acute lymphoblastic leukemia (ALL) in patients with first recurrence of Philadelphia chromosome negative ALL Acute myeloid leukemia (AML) in patients >65 unfit for chemotherapy	Phase III Phase II b
<b>REC 0438</b>	Recordati/UFPeptides	Overactive bladder (OAB) in patients with spinal lesions	Phase I in EU
* New dosage			

## A well balanced R&D pipeline (cont'd)

- **CARBAGLU**<sup>®</sup> (carglumic acid), currently approved for the treatment of hyperammonaemia due to NAGS deficiency, approved in Europe and in phase III clinical development in the USA for additional indications in organic acidemias (orphan drug designation granted).
- **ZANIPRESS**<sup>®</sup> (lercanidipine+enalapril) new formulation containing 20 mg of lercanidipine and 20 mg of enalapril.
- **CYSTADROPS**<sup>®</sup> (cysteamine chlorhydrate) are eye drops developed for “ocular manifestations of cystinosis” which cannot be controlled by orally administered cysteamine, specially formulated in a patient-friendly gel form.
- **REC 0482** (NX-1207) is a novel patented drug developed by Nymox, currently in Phase III trials in the U.S., which involves a new targeted approach to the treatment of benign prostatic hyperplasia (BPH). The drug is administered by a urologist in an office setting directly into the zone of the prostate where the enlargement occurs. No anesthesia or catheterization are required. A single dose of NX-1207 has been found to produce very promising symptomatic improvements and follow-up studies have shown evidence of long lasting benefit with a significant proportion of men who received a single dose reporting maintained improvement in BPH symptoms without other treatments for several years.

## *A well balanced R&D pipeline (cont'd)*

- **Methadone**, currently used in France, where it is distributed by Bouchara Recordati, as replacement therapy for major opioid drugs dependence. In 2012 Recordati started, in France, an open, multicenter, randomized, national Phase III b clinical study on methadone for the treatment of cancer-related pain inadequately relieved by opioids.
- **CITRAFLEET®** is an intestinal evacuant used in preparation for colonoscopy. The objective of the trial is to assess the clinical effectiveness of a split-dose administration schedule compared to that of the current SmPC regimen.
- **GRASPA®** is L-asparaginase encapsulated in homologous human red blood cells. L-asparaginase has been shown to possess a powerful antitumor activity, but this enzyme is highly toxic and a large part of the patient population presents with a hypersensitivity and does not tolerate well the current treatment protocols. This population represents a large currently unmet medical need. Grasp<sup>®</sup> avoids toxicity and hypersensitivity issues associated with L-asparaginase treatments while maintaining its antitumor activity.
- **REC 0438** represents a structurally different class of compounds and is being studied for the treatment of OAB in patients with spinal lesions



## First half 2014 highlights

- Revenue € 507,6 million, up 6.3%
- EBITDA € 141.9 million or 27.9% of sales, up 18.2%
- Operating income (EBIT) € 121.8 million or 24.0% of sales, up 18.8%
- Net income € 83.0 million or 16.4% of sales, up 18.1%
- Exclusive license for Vitaros<sup>®</sup> from Apricus Biosciences
- Acquisition of a further 23% of Opalia Pharma in Tunisia
- Orphan drug designation for the use of Carbaglu<sup>®</sup> to treat organic acidemias in the U.S.A.

## Main product sales

**Corporate products including drugs for rare diseases account for 50.6% of revenue**

(million Euro)	1H 2014	1H 2013	Change %
Zanidip <sup>®</sup> (lercanidipine)	<b>58.4</b>	61.3	(4.6)
Zanipress <sup>®</sup> (lercanidipine+enalapril)	<b>31.2</b>	29.3	6.5
Urorec <sup>®</sup> (silodosin)	<b>28.4</b>	22.7	25.4
Livazo <sup>®</sup> (pitavastatin)	<b>12.4</b>	11.2	11.2
Other corporate products*	<b>65.8</b>	55.3	19.0
Drugs for rare diseases	<b>60.3</b>	60.8	(0.7)

\* Includes OTC product Procto-Glyvenol<sup>®</sup>

# Composition of revenue by geography

## New products and new markets drive growth

(million Euro)	1H 2014	1H 2013	Change %
Italy	119.7	120.7	(0.8)
France	55.3	57.2	(3.4)
Germany	40.5	37.0	9.6
Russia, other CIS countries and Ukraine	39.3	44.3	(11.3)
Spain	37.8	15.6	142.6
Turkey	33.6	34.8	(3.3)
U.S.A.	27.7	23.9	15.6
North Africa	19.8	10.0	97.7
Portugal	18.0	15.7	15.1
Other CEE countries	12.4	17.4	(28.9)
Other W. Europe countries	11.6	12.6	(8.0)
Other international sales	74.3	71.6	3.8
<b>TOTAL PHARMACEUTICALS</b>	<b>490.0</b>	460.8	6.3
PHARMACEUTICAL CHEMICALS	17.6	17.0	3.7

(In local currency, millions)	1H 2014	1H 2013	Change %
Russia (million RUB)	1,570.5	1,550.2	1.3
Turkish subsidiary (million TRY)	94.5	78.6	20.2



## First half 2014 results

### Significant margin growth

(million Euro)	1H 2014	1H 2013	Change %
<b>Revenue</b>	<b>507.6</b>	<b>477.7</b>	<b>6.3</b>
Gross Profit	336.6	312.1	7.9
as % of revenue	66.3	65.3	
SG&A Expenses	173.6	169.7	2.3
as % of revenue	34.2	35.5	
R&D Expenses	40.7	37.9	7.2
as % of revenue	8.0	7.9	
Other Income (Expense), net	(0.5)	(1.9)	(75.3)
as % of revenue	(0.1)	(0.4)	
<b>Operating Income</b>	<b>121.8</b>	<b>102.6</b>	<b>18.8</b>
as % of revenue	24.0	21.5	
<b>Net Income</b>	<b>83.0</b>	<b>70.3</b>	<b>18.1</b>
as % of revenue	16.4	14.7	
EBITDA	141.9	120.0	18.2
as % of revenue	27.9	25.1	

## Financial position and Shareholders' equity

(million Euro)	30 Jun 2014	31 Dec 2013	Change
Cash and short-term financial investments	<b>117.2</b>	52.3	64.9
Bank overdrafts and short-term loans	<b>(26.9)</b>	(34.0)	7.1
Loans – due within one year	<b>(88.2)</b>	(82.5)	(5.7)
Loans – due after one year	<b>(213.1)</b>	(196.8)	(16.3)
NET FINANCIAL POSITION	<b>(211.0)</b>	(261.0)	50.0
SHAREHOLDERS' EQUITY	<b>772.1</b>	701.8	70.3

## Objectives

- Consolidated sales slightly below € 1 billion. Objective includes a significant negative currency effect in addition to Adagen® and Entact® license terminations.
- Margin improvement
  - EBIT to exceed € 220 million
  - Net Income to exceed € 150 million
- No new acquisitions, milestones or up-front payments for new projects included in our 2014 targets.

## The Recordati share

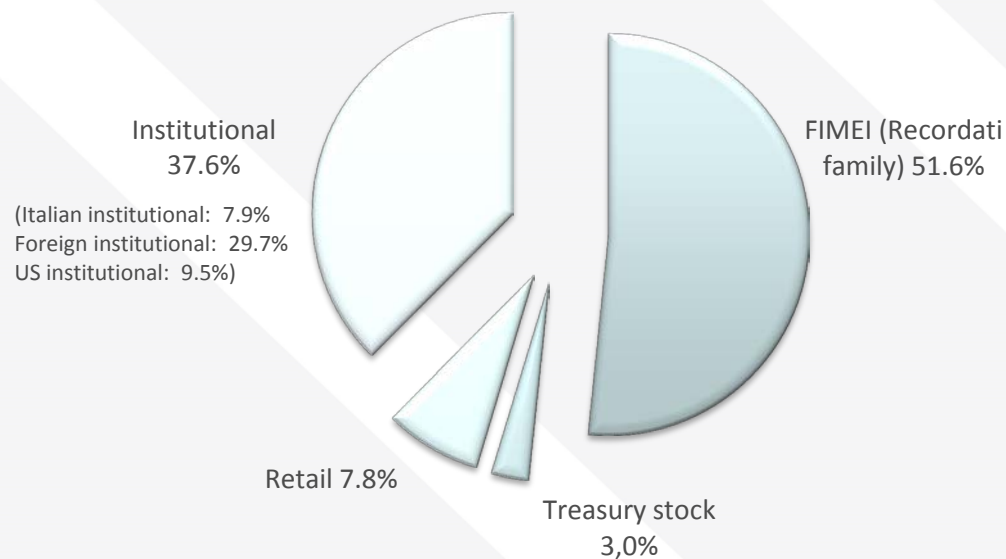
The Recordati share (ticker REC, **Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271**) has been listed on the Italian Stock Exchange since 1984. It belongs to the FTSE IT Mid Cap and FTSE IT Health Care indexes.

Share capital consists of **209,125,156** ordinary (common) shares with a par value of € 0.125 each.

2013 EPS (diluted): € 0.631

2013 dividend per share: € 0.33

### Ownership:



# 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 an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271) with a total staff of around 4,000, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Russia, in other Central and Eastern European countries, in Turkey, in the United States of America and in North Africa. An efficient field force of 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 is a partner of choice for new product licenses for its territories. 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 2013 is € 941,6 million, operating income is € 195,4 million and net income is € 133,7 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)**