



***A Specialty  
Pharmaceutical Group***

BofA MERRILL LYNCH Global Healthcare Conference 2015, September 16, 2015

# *A strategy of growth and geographical expansion*

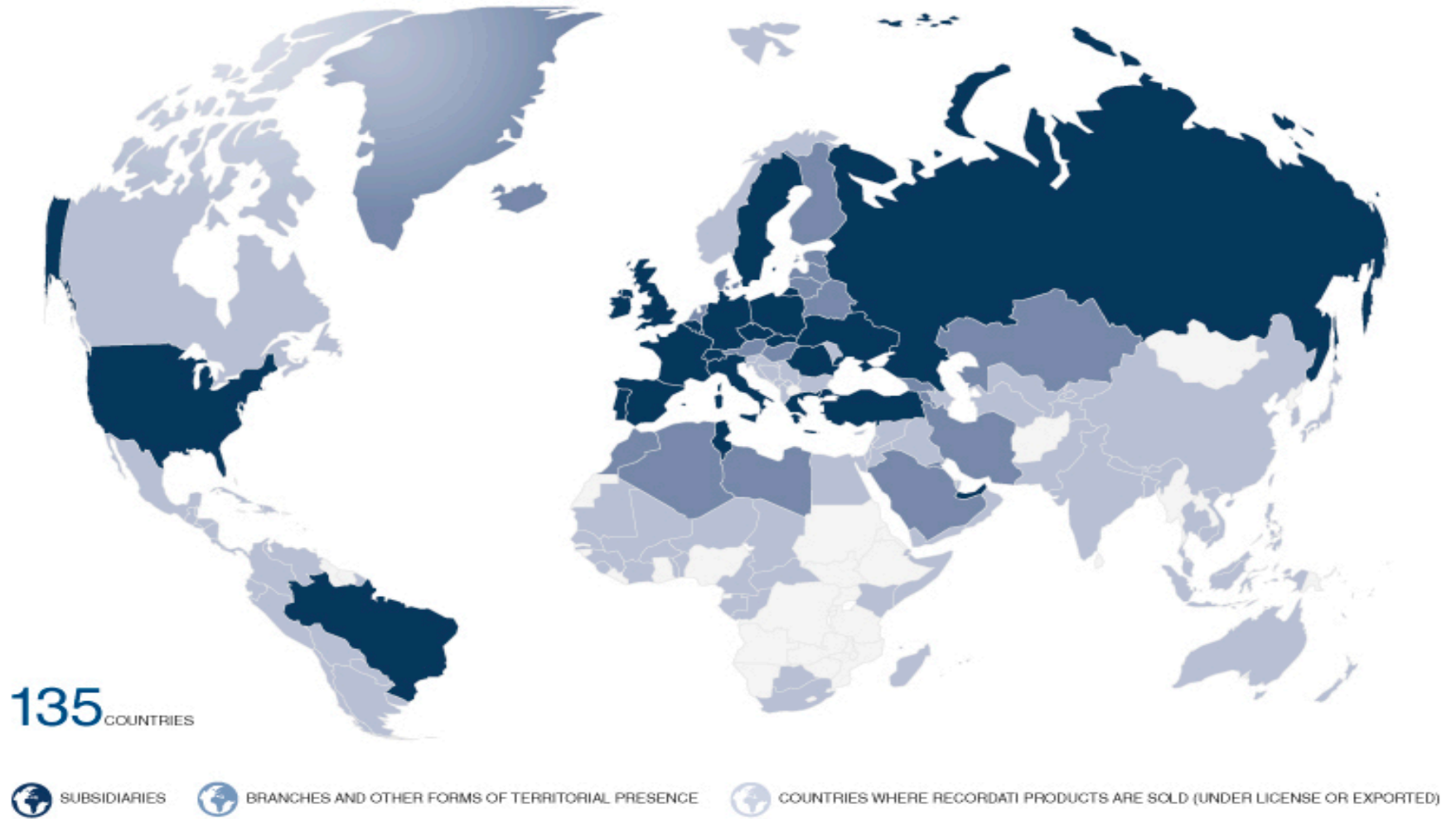
## Profile

- An international specialty pharmaceutical group (€ 987.4 m sales in 2014 and 4,000 employees).
- 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
- R&D in specialty care and in treatments for rare diseases

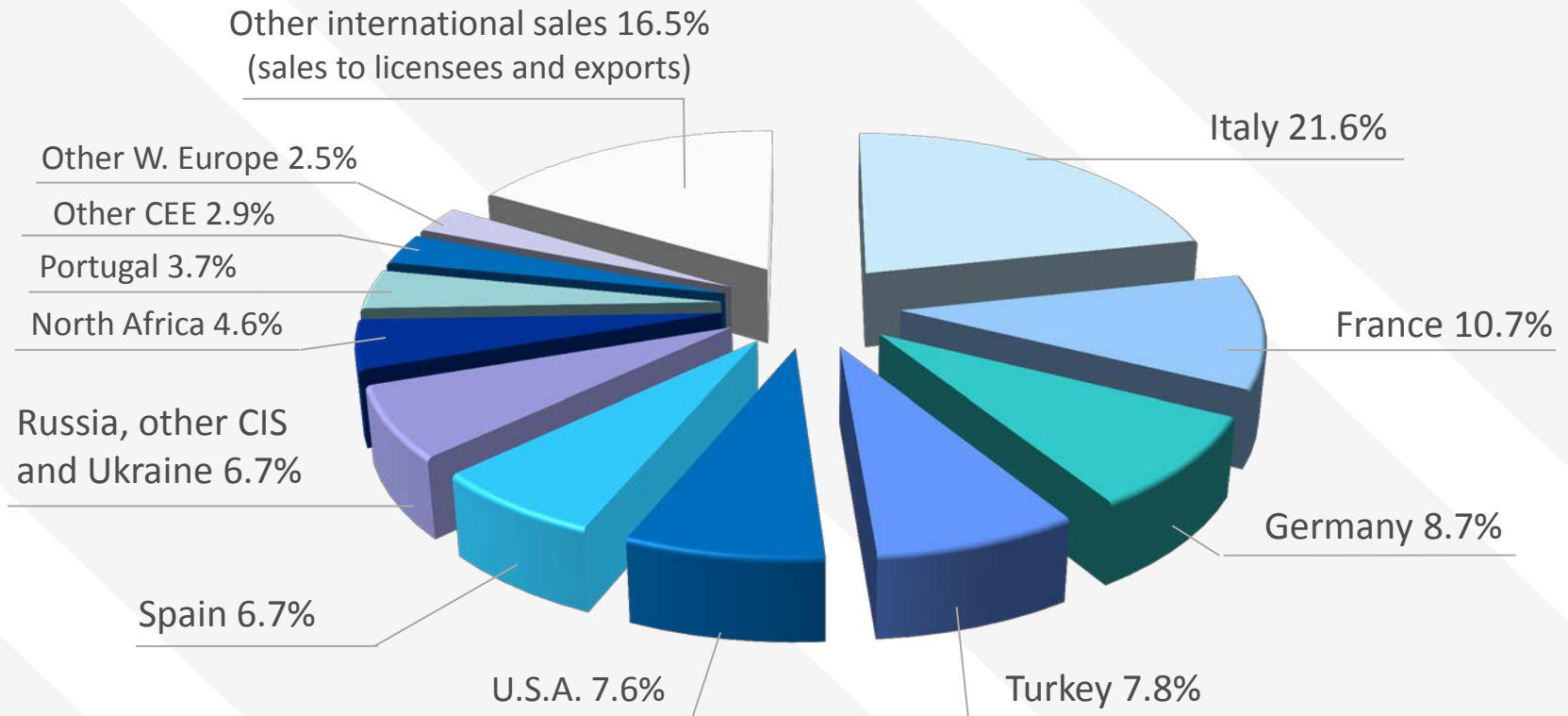
## Strategy

- 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 with high potential
- Treatments for rare diseases: develop a global presence

# *Extensive geographical footprint*

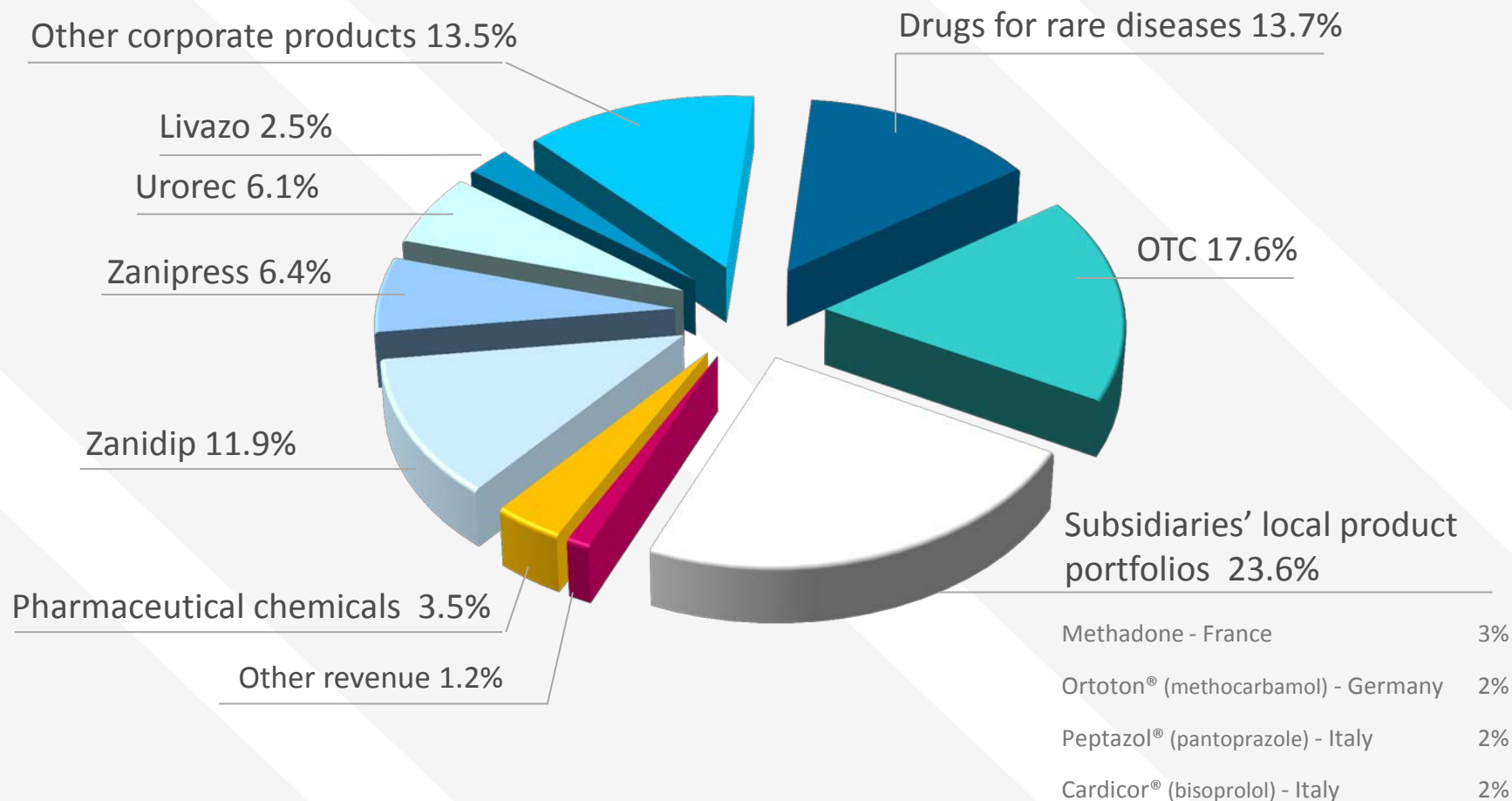


# Geographical breakdown of pharmaceutical revenue



Data: First half 2015  
Pharmaceutical revenue € 520.3 m

# A diversified product portfolio



Data: First Half 2015  
 Total revenue € 539.1 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 -12.7%) following its patent expiry at the beginning of 2010.
- Zanipress<sup>®</sup> (lercanidipine+enalapril) now launched in 25 markets and growing steadily
- Zanipress<sup>®</sup> to be rolled-out progressively in new markets
- Zanipress<sup>®</sup> prices will come under pressure due to generic competition
- Sales of the Zanidip<sup>®</sup> / Zanipress<sup>®</sup> franchise expected to remain at around € 170 million in 2015 and to decrease to around € 140 million thereafter

## 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 30 markets: Armenia, Azerbaijan, 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, Tunisia, 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 of around € 2.1 billion.



# 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, ongoing.
- R&D in rare diseases:
  - Carbaglu<sup>®</sup>, indication in organic acidemias in the U.S.A., phase III
  - Cystadrops<sup>®</sup>, ocular cystinosis, filed 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 2014 total € 123.2 million. CAGR of 18.8% over the past six years

## *Drugs for rare diseases*

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

**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.

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

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

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

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

**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 product pipeline

NAME	ORIGINATOR	INDICATION	DEVELOPMENT STATUS
<b>VITAROS®</b>	Apricus	Erectile dysfunction	Approved by a number of health authorities in Europe
<b>CARBAGLU®</b>	Recordati	Organic acidemias	Approved in EU Phase III in U.S.A.
<b>CYSTADROPS®</b>	Recordati	Ocular cystinosis	Filed in EU
<b>FORTACIN™</b>	Plethora Solutions	Premature ejaculation	Variation of EU approval
<b>methadone</b>		Treatment of cancer-related pain in cases of resistance or intolerance to opioids	Filed in France
<b>CITRAFLEET®</b>	Recordati/Casen	Cleansing of the colon in preparation for colonoscopy.	Split dose administration MA variation filed
<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	Pre-filing in EU Phase II b
<b>REC 0438</b>	Recordati/UFPeptides	Overactive bladder (OAB) in patients with spinal lesions	Phase I in EU

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

- **VITAROS®** (alprostadil) is a topically applied cream formulation of alprostadil for the treatment of erectile dysfunction. A patient-friendly form of alprostadil as an alternative to PDE-5 inhibitors for difficult to treat patients.
- **CARBAGLU®** (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).
- **CYSTADROPS®** (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.
- **FORTACIN™** (lidocaine+prilocaine) is an easy-to-use fast acting topical spray formulation of lidocaine and prilocaine for the treatment of premature ejaculation.
- **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.

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

- **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. Graspas® 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 2015 highlights*

- Revenue € 539.1 million, up 6.2%
- EBITDA € 163.9 million or 30.4% of sales, up 15.5%
- Operating income (EBIT) € 145.2 million or 26.9% of sales, up 19.2%
- Net income € 103.2 million or 19.2% of sales, up 24.3%
- Net debt € 139.9 million, a reduction of € 46.2 million as compared to year-end 2014.

## Main product sales

**Corporate products including drugs for rare diseases account for 59.3% of revenue**

(million Euro)	1H 2015	1H2014	Change %
Zanidip <sup>®</sup> (lercanidipine)	<b>63.9</b>	58.4	9.4
Zanipress <sup>®</sup> (lercanidipine+enalapril)	<b>34.3</b>	31.2	9.9
Urorec <sup>®</sup> (silodosin)	<b>33.0</b>	28.4	16.1
Livazo <sup>®</sup> (pitavastatin)	<b>13.4</b>	12.4	7.9
Other corporate products*	<b>101.0</b>	96.2	4.9
Drugs for rare diseases	<b>73.9</b>	60.3	22.6

\* Include the OTC corporate products for an amount of € 28.0 million in 2015 and € 23.8 million in 2014.

# Composition of revenue by geography

## Solid volume growth

(million Euro)	1H 2015	1H 2014	Change %
Italy	<b>112.7</b>	119.7	(5.9)
France	<b>55.5</b>	55.3	0.4
Germany	<b>45.3</b>	40.5	11.8
Turkey	<b>40.6</b>	33.6	20.6
U.S.A.	<b>39.8</b>	27.7	43.8
Spain	<b>34.8</b>	33.8	3.1
Russia, other CIS countries and Ukraine	<b>34.6</b>	39.3	(11.9)
North Africa	<b>23.9</b>	19.9	20.0
Portugal	<b>19.1</b>	18.0	5.8
Other CEE countries	<b>15.2</b>	12.4	22.8
Other W. Europe countries	<b>13.0</b>	11.6	12.2
Other international sales	<b>85.8</b>	78.2	9.7
<b>TOTAL PHARMACEUTICALS</b>	<b>520.3</b>	490.0	6.2
<b>PHARMACEUTICAL CHEMICALS</b>	<b>18,8</b>	17.6	6.8

(In local currency, millions)	1H 2015	1H 2014	Change %
Russia (RUB)	<b>1,918.2</b>	1,539.9	24.6
Turkish subsidiary (TRY)	<b>110.1</b>	94.5	16.5
U.S.A. (USD)	<b>44.4</b>	37.9	17.2



# First half 2015 results

## Further margin growth

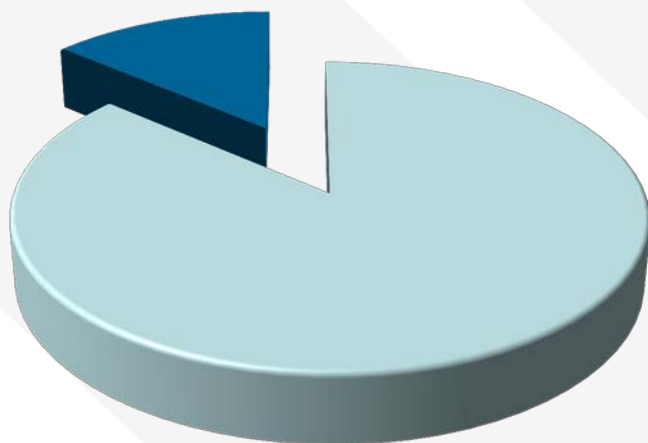
(million Euro)	1H 2015	1H 2014	Change %
<b>Revenue</b>	<b>539.1</b>	<b>507.6</b>	<b>6.2</b>
Gross Profit	366.8	336.6	9.0
as % of revenue	68.0	66.3	
SG&A Expenses	182.1	173.6	4.9
as % of revenue	33.8	34.2	
R&D Expenses	37.9	40.7	(6.8)
as % of revenue	7.0	8.0	
Other Income (Expense), net	(1.6)	(0.5)	232.6
as % of revenue	(0.3)	(0.1)	
<b>Operating Income</b>	<b>145.2</b>	<b>121.8</b>	<b>19.2</b>
as % of revenue	26.9	24.0	
<b>Net Income</b>	<b>103.2</b>	<b>83.0</b>	<b>24.3</b>
as % of revenue	19.2	16.4	
EBITDA	163.9	141.9	15.5
as % of revenue	30.4	27.9	

# First half 2015 results

## Operating segments

### Revenue

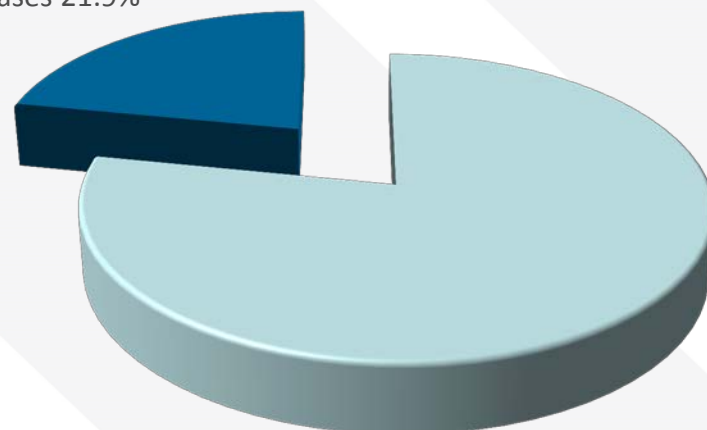
Treatments for rare diseases 13.7%



Primary & specialty care  
86.3%

### EBIT

Treatments for rare diseases 21.9%



Primary & specialty care  
78.1%

#### EBIT margin on sales:

Treatments for rare diseases, 42.9%

Primary & Specialty care, 24.4%

## Financial position and Shareholders' equity

(million Euro)	<b>30 Jun 2015</b>	31 Dec 2014	Change
Cash and short-term financial investments	<b>186.8</b>	137.0	49.8
Bank overdrafts and short-term loans	<b>(10.0)</b>	(8.6)	(1.4)
Loans – due within one year	<b>(29.9)</b>	(28.3)	(1.6)
Loans – due after one year	<b>(286.8)</b>	(286.2)	(0.6)
<b>NET FINANCIAL POSITION</b>	<b>(139.9)</b>	(186.0)	46.2
<b>SHAREHOLDERS' EQUITY</b>	<b>874.9</b>	787.4	87.4

# Financial projections

## 2015 targets and 2017 plan

(million Euro)	2014 Actual	2015 Targets		2017 Plan
Revenue	987.4	± 1,040		± 1,150
Operating income (EBIT)	231.0	± 270	EBIT margin	25% - 26%
Net Income	161.2	± 190	Net income margin	17% - 18%

- Cash generated to be invested in corporate development activities, primarily in product portfolio enhancement.
- Organic growth about one half of 2017 increase in revenues.

## 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.

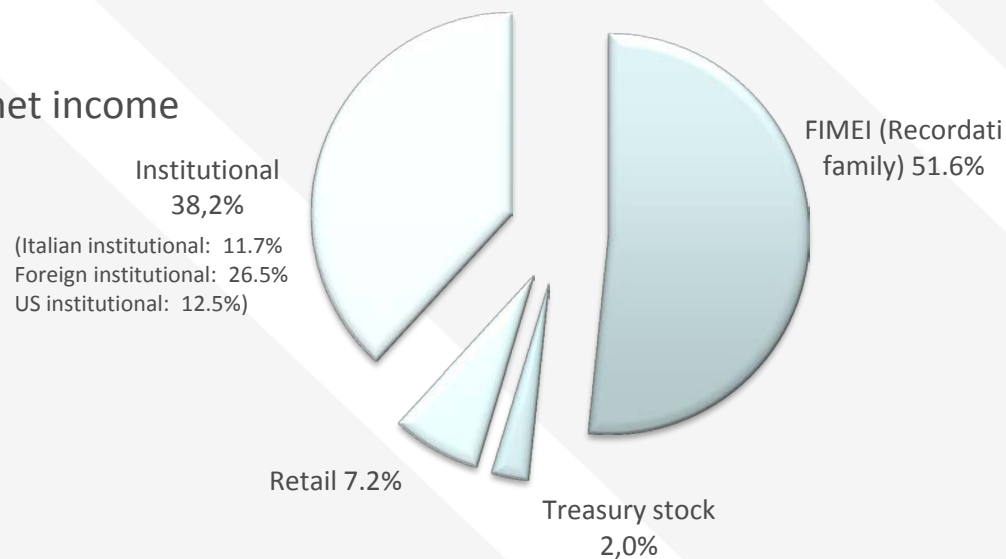
Share capital consists of **209,125,156** ordinary (common) shares with a par value of € 0.125 each.

2014 EPS (diluted): € 0.771

2014 dividend per share: € 0.50

Dividend pay-out ratio:  $\pm 60\%$  of group net income

### 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 2014 is € 987.4 million, operating income is € 231.0 million and net income is € 161.2 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)**