



at a glance

---

**LUGANO SMALL & MID CAP  
INVESTOR DAY**



**IV Edizione**  
Hotel Splendide Royal  
20 settembre 2013



*Lugano, 20 September 2013*

> 50 years of Pharmaceutical & Life Science Services

# Pierrel S.p.A.

Pierrel S.p.A. is listed on the Italian Stock Exchange (MTA) since May 2006. Pierrel is a full service global provider for life science, biopharma and pharmaceutical industries.

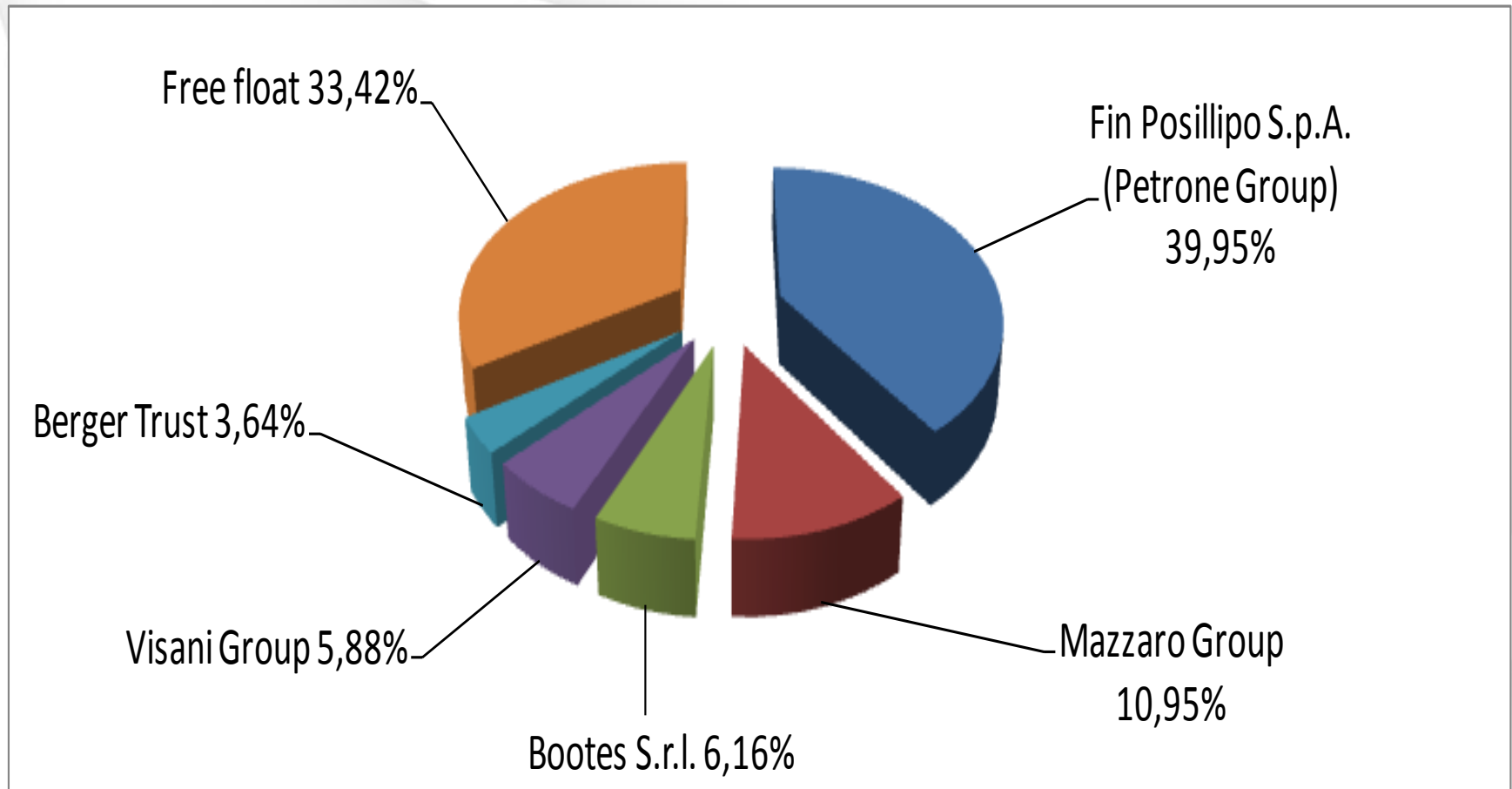


> 50 years of Pharmaceutical & Life Science Services



# Pierrel Shareholders

*...as of 9 September 2013*



# Pierrel Group Today

Pierrel Group is playing a double role supporting its own brand and expanding outsourcing services to life science, biopharma and pharmaceutical companies.

Pierrel' supply chain increases “values” through and along its four divisions:

- ❑ Discovery
- ❑ CRO
- ❑ CMO
- ❑ Pharma



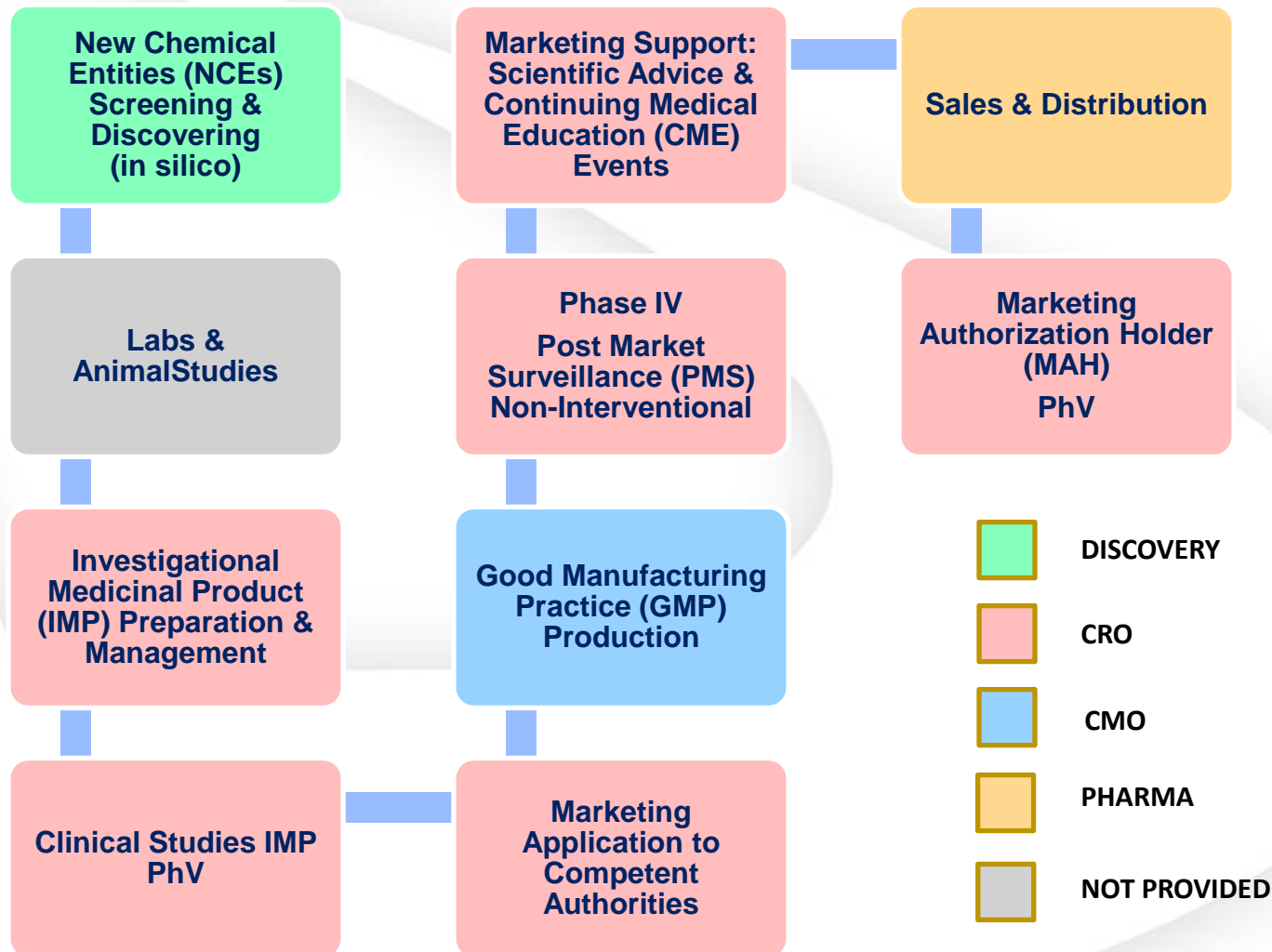
> 50 years of Pharmaceutical & Life Science Services

# Pierrel Group Today (cont'd)

<i>SCOPE</i>	<i>ACTIVITIES</i>	<i>DIVISION</i>
<i>Discovery</i>	Discovery and development of MPCs ("Medicinal Product Candidates") and repurposing/repositioning drugs into new therapeutical indications, through bio-mathematical algorithm	Discovery Division
<i>Research</i>	Full service contract research organization providing regulatory consulting, pharmacovigilance and marketing services, and operational services for clinical trial (Phase I – IV) to test new molecules and drugs	CRO Division
<i>Manufacturing</i>	An FDA approved plant site located in Capua (CE) producing drugs for third parties, specialized in injectable local-regional anesthetics, being worldwide leader in <i>Dental Anesthetics</i> filled in aseptic cartridges	CMO Division
<i>Pharmaceuticals</i>	Owner of Pierrel' International Marketing Authorizations - Orabloc®. Marketing and sales of Orabloc®, Pierrel' dental anesthetic	Pharma Division

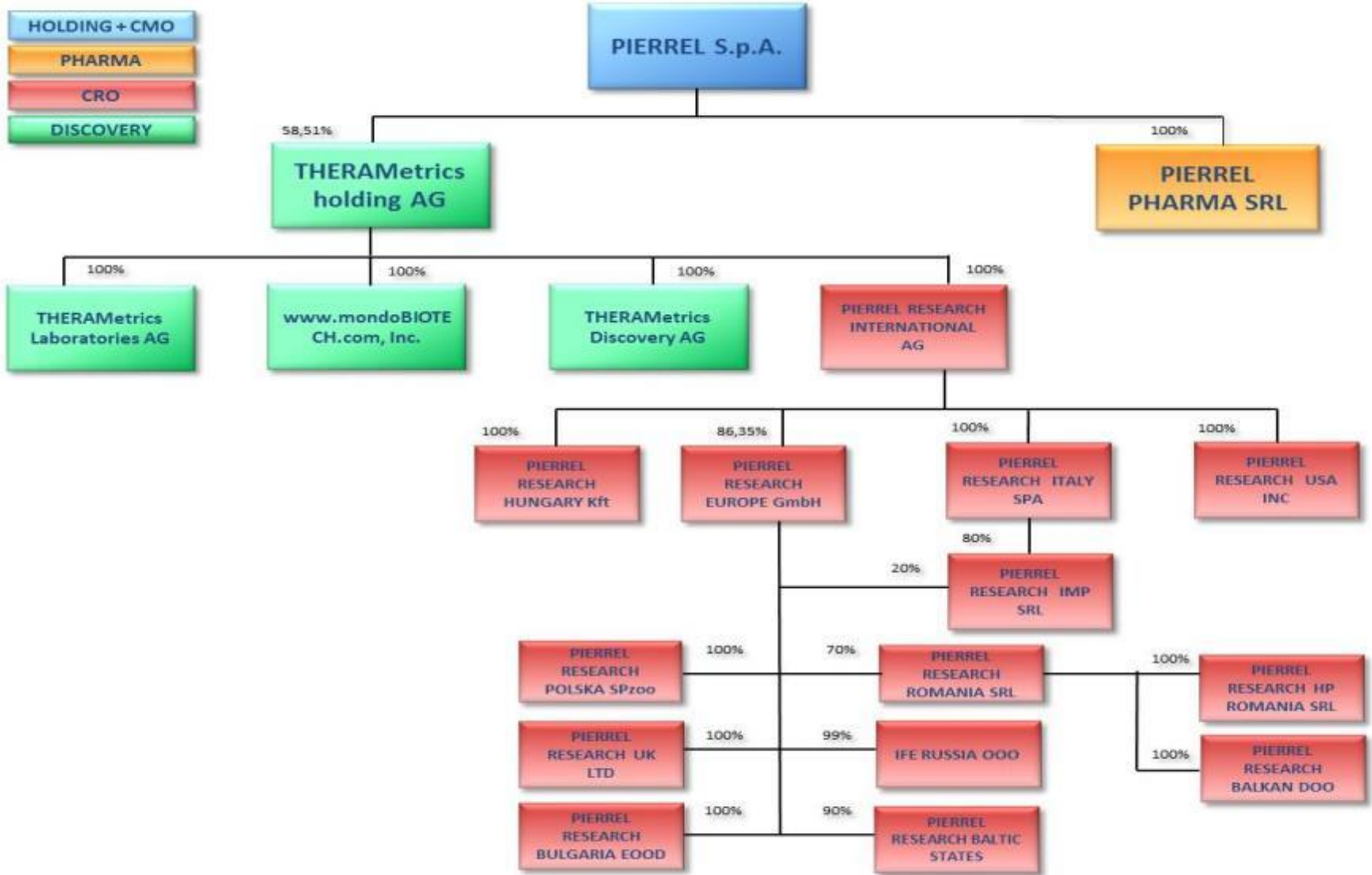
# Pierrel Services Panel

*“from test tube to the patient”*



> 50 years of Pharmaceutical & Life Science Services

# Pierrel Organisation

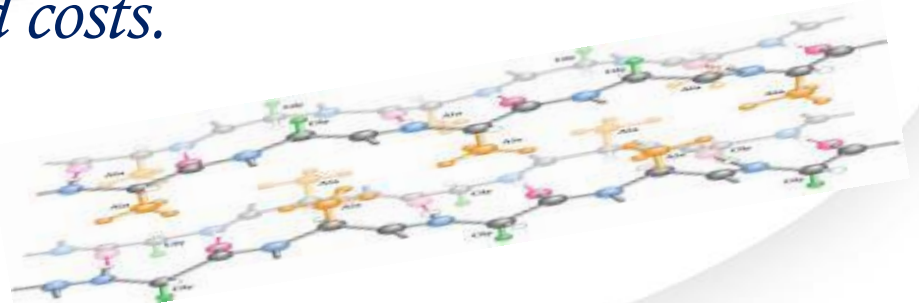


> 50 years of Pharmaceutical & Life Science Services



# Discovery & CRO divisions

*The controlled THERAMetrics holding AG, listed on SIX Swiss Exchange, combines the Discovery and CRO divisions into a full-service TCRDO (“Tech-driven Contract Research & Development Organization”), providing an exclusive technological set of services and solutions to biotech, biopharma and pharmaceutical companies throughout the innovative drug discovery & development value chain with the aim of screening potential drugs “in silico” biosystems, allowing therapies in virtual patients and predicting real-world health outcomes and costs.*



> 50 years of Pharmaceutical & Life Science Services



# Discovery & CRO: competitive strengths

Pierrel, through the combination of advanced bio-modeling and science, can successfully compete in the current market environment by offering consultancy services for clinical and regulatory development programs as well as operational services to effectively conduct global Phase I - IV programs, late phase, and Non-Interventional Studies (“NIS”). The key competitive strengths are the following:

- ❑ **Drug discovery bio-mathematical platform**, which enables to repurpose existing compounds to other indications and allows to project the mechanism of action of any drugs or investigation specific bio-medical interactions as part of a patho-physiological analysis. This bio-mathematical platform is based upon a proprietary mathematical model which is focused on matching the information among biological processes and deriving emerging paths through the patho-physiological signs and symptoms of diseases.
- ❑ **HyperSuite MTP<sup>®</sup>**, a web-based e-clinical trial platform, developed with CINECA, one of the major European supercomputing and IT centers. HyperSuite<sup>®</sup> is a competitive and secure system, which is fully validated for clinical research services, and which delivers higher quality data achieving a significant time saving for data collection in clinical trials and enables to increase the quality and performance of clinical trials, while containing the costs and reducing time.
- ❑ **Our experienced team**, which consists of more than 250 professionals, whose background spans from life sciences and clinical research, pharmacy, biology, medicine and chemistry, to economy, statistics, informatics, engineering and data management.

# Discovery & CRO: main objectives

The primary goal is to build a sustainable business around our core competencies in the field of clinical trials and contract research which is complementary with in-sourced research activity for drug discovery, repurposing and validation. The main objectives are the following:

- To become a key strategic partner of biotech, biopharma and pharmaceutical companies;
- To develop a differentiated commercial proposal addressed to medium-sized pharmaceutical and biotechnology companies with THERAMetrics as a service provider and research partner offering competitive technological solutions in different phases of the drug discovery & development lifecycle;
- To create “excellence centers”, focused on different support activities (drug repurposing, regulatory, quality assurance, medical writing, data management);
- To move compounds faster and more productively through the clinical development process in order to achieve a quicker market approval;
- To reduce the use of third party services and to insource all the stages of the projects within our business.

> 50 years of Pharmaceutical & Life Science Services

# CMO & Pharma divisions

*The perfect mix between the CMO' excellence in drugs manufacturing and Pharma' know how and skills on registration, marketing and sales.*



> 50 years of Pharmaceutical & Life Science Services

# CMO & Pharma: main milestones

- ❑ More than 50 years experience in pharmaceutical and life science services
- ❑ Local anesthetics manufactured at Pierrel since the early 60's in vials and ampoules and dental cartridges since the early 70's
- ❑ Joint collaboration with big pharma players
- ❑ Production site approved by **EMA** ("European Medicines Agency"), for aseptic production of dental anesthetics since 1989, and **FDA** ("Food and Drug Administration") since October 2009 for production of "*Sterile Filled Small Volumes Parenteral Drugs*"
- ❑ Manufacturing, development, registration and marketing of Pierrel branded Articaine with Epinephrine (Orabloc®) in USA, Canada, Italy, Russia, Germany, France, UK, Poland, Austria

# Quality System

**Pierrel Quality System is designed to fulfill the following requirements:**

- EMA Current Good Manufacturing Practice
- FDA Current Good Manufacturing Practice

...as well as all **customers quality** systems, due to numerous audits

## Main regulatory Track Record:

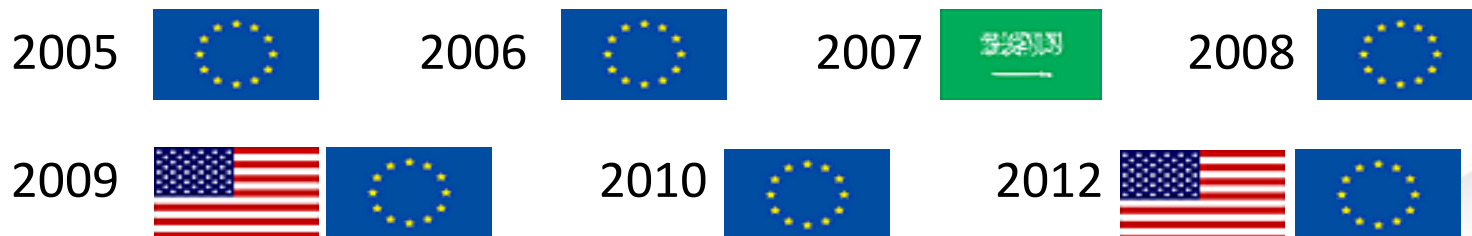
- **AIFA (Italian Medicines Agency – EMA network)**

*January 2008 (inspection and approval of New Cartridges) - January 2010 and January 2012 (inspections for general revision)*

- **US FDA**

*July 2009 (FDA PAI) - February 2010 (FDA/NDA approval) - February 2012 (FDA post marketing approval)*

## Good Manufacturing Practices ("GMP") Compliance-Agencies



> 50 years of Pharmaceutical & Life Science Services

# CMO & Pharma: main objectives

The main **CMO** objectives are:

- To retain actual customers by promoting new services and enlarge the customers portfolio by offering personalized drugs manufacturing. This specific concept is strictly linked to the opportunities outcoming from THERAMetrics' services (i.e. orphan drugs for rare diseases);
- To achieve the total Capua's plant production capacity (spare capacity = 35%) in the different filling machines (NCD<sup>1</sup> Line Aseptic Area, Class A – ECD<sup>2</sup> line Aseptic Area, Class A/B under laminar flow) for ampoules, vials and cartridges in a wide range of sizes.

<sup>1</sup> New Cartridges Department

<sup>2</sup> Existing Cartridges Department

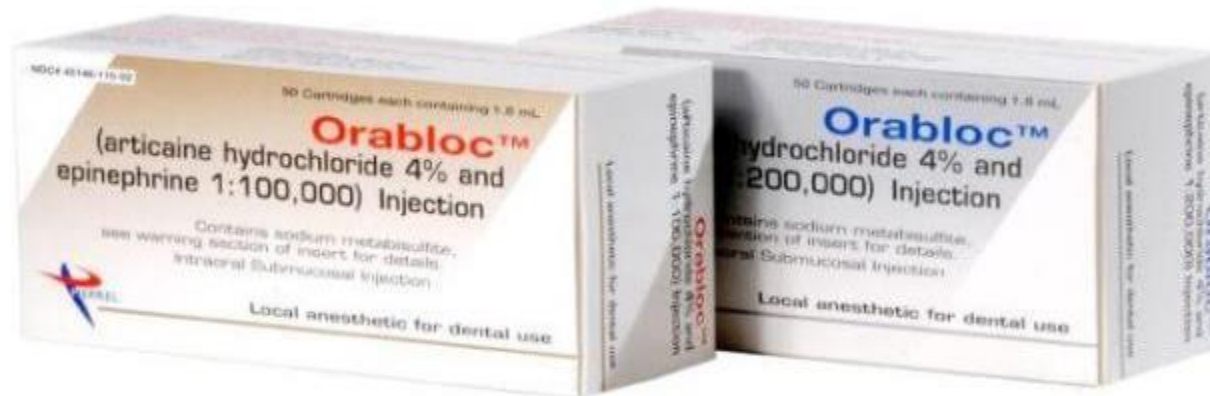
# CMO & Pharma: main objectives

The main **Pharma** objectives are:

- To boost the sales of NDA Orabloc® in the U.S. and Canadian market by leveraging on several distribution agreements recently signed to cover more than 90% of the North America markets;
- To increase sales of the Articaine branded Pierrel on Russian market and in Europe capitalizing on the recent authorization granted by German Medicines Agency (“BfArM”), covering France, UK, Germany, Austria and Poland;
- To consolidate the sales volumes in Italy of Pierrel branded anesthetics (articaine, lidocaine and mepivacaine) as well as to launch on the market a new category of Pierrel branded products, so to increase the profitability of its own brand;
- To speed up the registration of Pierrel branded anesthetics in new markets, such as Middle East and North Africa (i.e. Iraq, Iran, ex CIS countries, etc.), to develop the marketing and sales of our products.

# Orabloc®

*.....the result of a balanced mix between sterile and aseptic Manufacturing competencies and product know how!*



- ✓ NDA approval status granted in **USA** in February 2010
- ✓ Approved in **Russia** in 2010
- ✓ Approved in **Canada** in 2011
- ✓ Approved in **Europe** in 2013, under a DCP procedure ("BfArM")

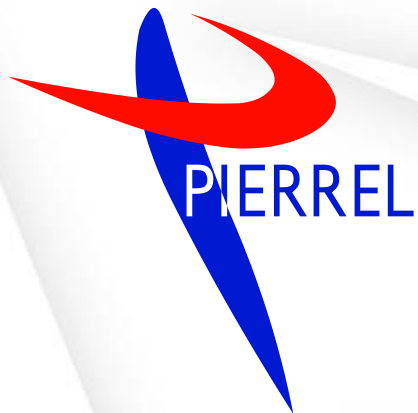


# Pierrel Group – Equity increases in Q3 2013

- ❖ Pierrel S.p.A. (PRL) has offered a capital increase up to EUR 24 million, executed in Q3 2013 and, as of today, the offer was successfully for more than 64%. The offer is still in place under a Private Placement execution period to be finalized within December 2013.
- ❖ THERAMetrics holding AG (TMX), a 58,5% controlling stake, successfully completed the *reverse takeover* process, obtaining the first trading day on SIX Swiss Exchange on 16 September 2013.
- ❖ Pierrel Research International AG (PRINT), fully owned by THERAMetrics and holding of the CRO Division, has successfully cashed its Euro 5.25 million capital increase, entirely subscribed by Fin Posillipo S.p.A., Pierrel's major shareholder.

> 50 years of Pharmaceutical & Life Science Services





**See you again on...  
Stock Exchange!**

