

ACS Dobfar Group

Company Presentation

Consolidated Financial Statements 31/12/2017



MISSION

To enable and offer our stakeholders
with cutting edge anti-infective products
by providing the required research,
development and manufacturing services
in a timely and cost-effective way,
leveraging technology and innovative solutions

Fully Integrated Supply of APIs and FDFs

- ❖ Privately held Italian company
- ❖ Leader in cephalosporins and carbapenems, strong position in sterile penicillins
- ❖ Partner of choice for innovative companies with service offerings spanning the entire value chain
- ❖ Yearly Consolidated turnover of approximately 575 M EUR with consistent track record of profitable business
- ❖ About 2100 employees worldwide
- ❖ 8 API plants involved in the production of sterile and oral APIs
- ❖ 6 FDF facilities manufacturing oral and parenteral finished dosage forms

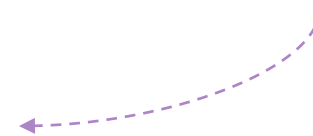
COMPANY OVERVIEW

Advanced Intermediates & Active Pharmaceutical Ingredients



- *Generic sales to third parties*
- *Custom pharmaceutical services for innovators*

Cephalosporins
Penicillins
Carbapenems
Other non-betalactams anti-infectives



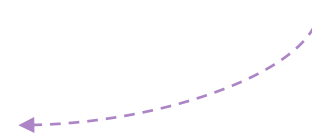
COMPANY OVERVIEW

Finished Dosage Forms



*Dry powder vials
Single and multidose bags
Infusion bags
Capsules
Tablets non-coated, coated and modified
release
Oral suspensions*

- Generic sales to third parties*
- Custom pharmaceutical services for innovators*
- Contract manufacturing*



MILESTONES

Active Pharmaceutical Ingredients

2014	Fermentation processes	DPhar1_Anagni, Italy (former ACSD6)	Spin-off of Anagni plant and foundation of DPhar S.p.A.
2003	Sterile Cephalosporins	Cosmopolis, Brazil	Acquisition of former Eli Lilly facility and foundation of ABL
2001	Sterile Cephalosporins	ACSD8_Sesto Ulteriano Italy	Acquisition of facility
1996	Fermentation processes	ACSD6_Anagni, Italy	Acquisition of former N.Nordisk / BMS facility
1995	Non betalactam APIs & Carbapenem APIs	ACSD5_Albano S. Alessandro Italy	Acquisition of facility
1990	Intermediates	ACSD3_Tribiano, Italy	Acquisition of facility
1984	Sterile Cephalosporins & Carbapenems	ACSD2_Tribiano, Italy	Construction of facility
1980	Sterile penicillins	ACSD1_Tribiano, Italy	Foundation of plant
1973	Non-sterile Cephalosporins	ACSD4_Vimercate, Italy	Foundation of plant

MILESTONES

Finished Dosage Forms

2014	Acquisition of MEQ	Valinhos, Brazil	Pharmaceutical Compounding
2013	Acquisition of second ABL facility (former Medley)	Sumare, Brazil	Injectable Cephalosporins
2011	Acquisition of Beker	Embu, Brazil	Hospital Injectables
2003	Acquisition of former Eli Lilly facility and foundation of ABL	Cosmopolis, Brazil	Oral and Injectable Cephalosporins, other injectables
2000	Acquisition of Facta Farmaceutici plants	Pomezia and Teramo, Italy	Injectables and Oral Cephalosporins

COMPANY STRUCTURE

Active Pharmaceutical Ingredients

ACS Dobfar SpA
Italy

DPhar
Italy

ABL
Brazil

Finished Dosage Forms

Beker Produtos
Farmaco Hospitalares
Brazil

Facta Farmaceutici
Italy

MEQ Corporation Ltda
Brazil

GLOBAL MANUFACTURING



8 APIs facilities:

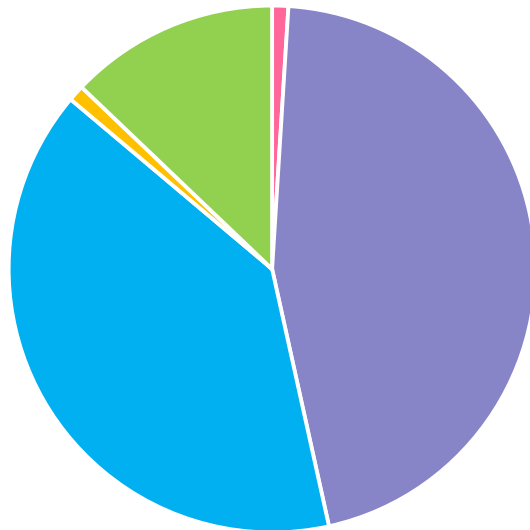
- ❖ ACS DOBFAR, Tribiano (Milan), Italy – 3 facilities
- ❖ ACS DOBFAR, Vimercate (Milan), Italy
- ❖ ACS DOBFAR, Sesto Ulteriano (Milan), Italy
- ❖ ACS DOBFAR, Albano S. Alessandro (Bergamo), Italy
- ❖ Dphar, Anagni (Rome), Italy
- ❖ ABL, Cosmopolis, Brazil

5 FDFs facilities:

- ❖ FACTA FARMACEUTICI, Teramo, Italy
- ❖ FACTA FARMACEUTICI, Pomezia, Italy
- ❖ ABL, Cosmopolis, Brazil
- ❖ ABL, Sumare, Brazil
- ❖ BEKER PRODUTOS FARMACO HOSPITALARES, Embu, Brazil
- ❖ MEQ CORPORATION Ltda, Valinhos, Brazil

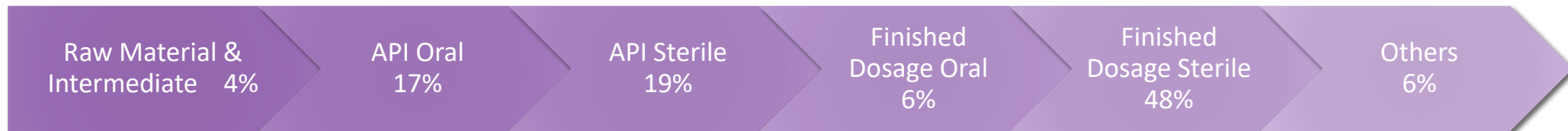
SALES

GLOBAL SALES 2017



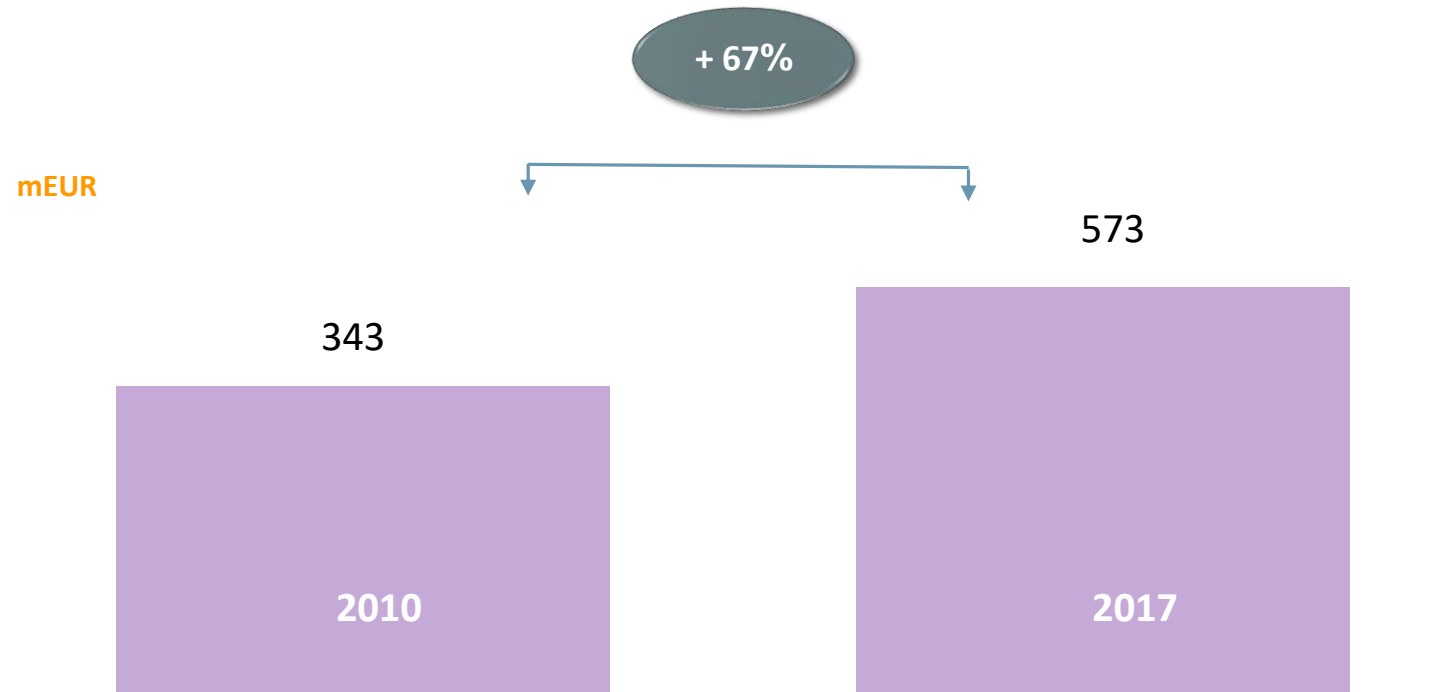
■ AFRICA ■ EUROPA ■ AMERICA ■ OCEANIA ■ ASIA

- ACS Dobfar is present in worldwide market supplying APIs and FDFs to over 90 countries
- Focus on North America, Europe and emerging markets, also through acquisitions, results in growth rate outpacing average dynamics in the generic industry



SALES

NET CONSOLIDATED SALES DYNAMIC



MANUFACTURING PLATFORM APIs and INTERMEDIATES

	ACS DOBFAR					DPhar	ABL	
LOCATION	ACSD1 Tribiano (Milan, Italy)	ACSD2 Tribiano (Milan, Italy)	ACSD3 Tribiano (Milan, Italy)	ACSD4 Vimercate (Milan, Italy)	ACSD5 Albano S.Alessandro (Bergamo, Italy)	ACSD8 Sesto Ulteriano (Milan, Italy)	ACSD6 Anagni (Rome, Italy)	Cosmopolis (San Paolo, Brazil)
MAIN PRODUCTS	APIs sterile penicillins	Intermediates and APIs sterile cephalosporins & carbapenems	Intermediates	Intermediates and APIs non-sterile cephalosporins	Non-beta-lactam APIs & Carbapenem APIs	APIs sterile cephalosporins	Lipopeptide APIs Enzymes Organoleptic additives	APIs sterile cephalosporins
TECHNOLOGY	Sterile manufacturing	Chemical synthesis Sterile manufacturing	Chemical synthesis	Chemical synthesis Enzymatic synthesis	Chemical synthesis	Sterile manufacturing	Enzymatic synthesis fermentation	Chemical synthesis Sterile manufacturing
APPROVALS LATEST INSPECTIONS	AIFA Jan 2017 FDA Nov 2015	AIFA Jun 2017 FDA Nov 2015 ANVISA Sep 2014 KFDA Nov 2017 Russia MoH May 2017	n.a.	AIFA Jun 2016 FDA Sep 2014 ANVISA Sep 2014 Russia MoH May 2017	AIFA Oct 2015 FDA Jun 2016 KFDA Nov 2017	AIFA Nov 2016 CFDA Jun 2015	AIFA Mar 2017 FDA Nov 2015	ANVISA Apr 2016 FDA Apr 2016 KFDA (Korea) Apr 2014 TGA (Australia) Jan 2012 PMDA (Japan) Apr 2013 ZAB (Germany) Nov 2013

MANUFACTURING PLATFORM FDFs

	FACTA FARMACEUTICI		ABL		BEKER	MEQ
LOCATION	Teramo (Teramo, Italy)	Pomezia (Rome, Italy)	Cosmopolis (San Paolo, Brazil)	Sumare (San Paolo, Brazil)	Embu (San Paolo, Brazil)	Valinhos (San Paolo, Brazil)
PRODUCTS	Injectable cephalosporins carbapenems	Oral cephalosporins	Injectable and oral Cephalosporins Other injectables secondary packaging Injectables glycopeptides	Injectable cephalosporins Secondary packaging	Injectable hospital products, mostly not anti-infectives	Pharmaceutical Compounding
DOSAGE FORMS	Dry powder fill vials 10-100ml Dry powder and solvent fill bags Tablets	Capsules (hard shell) Tablets Suspensions Other solids dosage forms: powder and granulates	Capsules Tablets Suspensions Vials	Vials	Infusion bags 50-500ml	Infusion bags 150-3000ml
APPROVALS / LATEST INSPECTIONS	AIFA Jan 2016 ANVISA Jul 2013 FDA Jul 2017 Only Carbapenems: GCC March 2014 Only Cephalosporins: Turkish MOH April 2013 Taiwan TFDA July 2013 Kazakistan MOH 2014 Russina MoH May 2017	AIFA Nov 2016 MINSAN Feb 2016 Ministry of Industry and Trade of Russian Federation Oct 2017	ANVISA Apr 2018 FDA Apr 2016 INVIMA (Columbia) Oct 2016 AIFA Dec 2016 MoH Perù May 2018	ANVISA Oct 2017	ANVISA May 2016	ANVISA May 2016

WORLDWIDE LEADER STERILE CEPHALOSPORINS

NON-STERILE

CEFALEXIN
CEFRADINE
CEFACLOR
CEFADROXIL
CEFPROZIL
CEFDINIR

APIs

ACSD 4 / Italy



FDFs

FACTA Pomezia / Italy

ABL / Brazil

STERILE

CEFEPIME
CEFOTETAN
CEFOTAXIME
CEFUROXIME
CEFTAZIDIME
CEFTRIAXONE
CEFAZOLIN
CEFOPERAZONE
CEFAMANDOLE
CEFOXITIN
CEFALOTHIN
CEFAPIRIN
CEFQUINOME
CEFTAROLINE
CEFTOLOZANE

ACSD 2/ Italy

ACSD 8 / Italy

ABL / Brazil



FACTA Teramo / Italy

ABL / Brazil

STRONG GLOBAL PRESENCE IN STERILE PENICILLINS

APIs

ACSD 1 / Italy



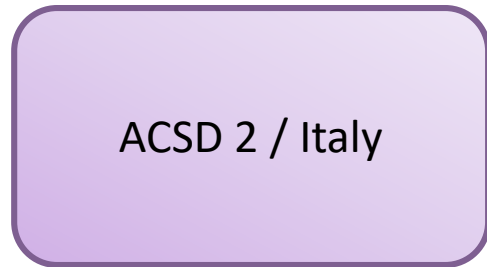
FDFs

Contract manufacturer inspected
by FDA in 2016 and by AIFA in 2016

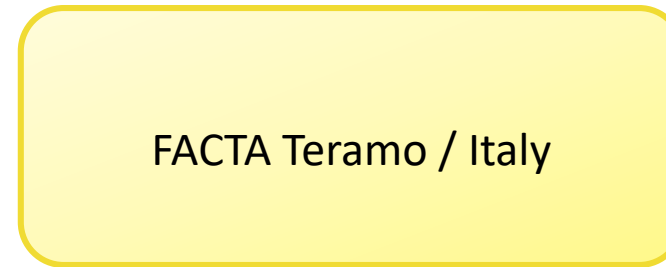
- ❖ PIPERACILLIN
- ❖ AMPICILLIN SODIUM
- ❖ AMPICILLIN TRIHYDRATE
- ❖ PENICILLIN G
- ❖ AMPICILLIN+SULBACTAM
- ❖ NAFCILLIN
- ❖ CLOXACILLIN SODIUM
- ❖ CLOXACILLIN BENZATHINE

LEADER IN CARBAPENEMS IN REGULATED MARKETS

APIs



FDFs



- ❖ IMIPENEM+CILASTATIN
- ❖ MEROPENEM
- ❖ DORIPENEM*
- ❖ ERTAPENEM*

*Under development, dependent on a patent expiration

OTHER NON BETA-LACTAM ANTIBIOTICS

APIs



- ❖ AMIKACIN
- ❖ AMPHOTERICIN B
- ❖ CILASTATIN
- ❖ CLINDAMYCIN
- ❖ DAPTOMYCIN
- ❖ GENTAMYCIN
- ❖ VANCOMYCIN

FDFs



- ❖ AZITHROMYCIN
- ❖ CLARITROMYCIN
- ❖ TEICoplanin
- ❖ TOBRAMYCIN
- ❖ VANCOMYCIN

OTHER PRODUCTS TO COMPLETE HOSPITAL PORTFOLIO

Infusional Bags

ANTIBIOTICS:

CIPROFLOXACIN inf (**)

LEVOFLOXACIN inf (*)

LINEZOLID inf (**)

OTHER ANTI INFECTIVES:

METRONIDAZOLE inf (*)

FLUCONAZOLE inf (*)

OTHER PRODUCTS:

WATER FOR INJECTION

PERITONEAL DIALYSIS SOLUTION

DEXTROSE 5%; 10%; inf

DEXTROSE 5% + 0,9% SODIUM

CHLORIDE

MANNITOL 20% inf

RINGER LACTATE inf

SODIUM CHLORIDE 0,9 % inf

PARACETAMOL inf (*)

*= under development

**= ANVISA approval pending



PATENTED PACKAGING SYSTEM FOR STERILE & NON-STERILE APIs

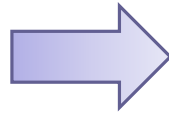
Sterbag® is a patented packaging system for Sterile APIs. Product is filled into polyethylene bags (LDPE and HDPE), sealed under vacuum and protected by a third bag containing aluminum. The aluminum bag is sealed under vacuum too, protecting the product from light and water. **Sterbag®** grants high stability of the product, saving space and disposal. The integrity of the package can be easily detected checking for the “brick-like” shape.



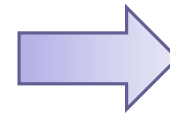
PATENTED INJECTABLE DELIVERY SYSTEM

Monodose systems

- Dry powder fill vials
- Infusion bags
- Ampoules



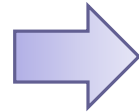
FillChoice® is used as mixing and drug infusion device, therefore it is not only a container, but a withdrawal and mixing system



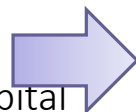
System benefits: Its main feature is the absence of needles connecting the components. The system is a close circuit. It does not require the multiple punching of caps, thus eliminates the risk of particle contamination and prevents the nurse from any sensibilisation.

PATENTED INJECTABLE DELIVERY SYSTEM

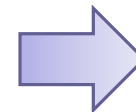
Multidose systems



SmartPak® is a Drug Delivery & Packaging System designed to simplify the reconstitution of antibiotics in the Hospital Pharmacy Compounding Center



Available for Cephalosporins:
Cefazolin
Cefalothin
Cefuroxime
Ceftriaxone
Ceftazidime
Vancomycin



System benefits:

- Dramatically reduces potential for medication errors
- Traceability.
- No glass means no breakage.
- Complete safety for the operators.
- Few operative steps.
- Reduction of contamination risks.
- A totally closed system.
- Maximum sterility.
- Less material wastage.
- Costs reduction.

BUSINESS ASPIRATION 1/2

Net sales growth: 8-10% annually reaching 630M EUR by 2018

Portfolio:

- ❖ Keep the leading position in cephalosporins
- ❖ Further develop carbapenems
- ❖ Further develop ready-to-use bags

BUSINESS ASPIRATION 2/2

News:

- ❖ New Lyophilization Plant under AIFA authorization in ACSD2 Site for production of Sterile Bulk Cephalosporins
- ❖ New Crystallization Plant under AIFA authorization in ACSD1 Site for production of Sterile Bulk Penicillins
- ❖ New Lyophilization Plant under construction in ACSD1 Site for production of Sterile Bulk Penicillins
- ❖ New Line Extrema under construction in FACTA Teramo site for production of Penem Injectables Finished Dosage Forms
- ❖ New Line under construction in FACTA Teramo site for production of Penem Oral Finished Dosage Forms
- ❖ New Plant under construction in ACSD9 Site for production of Penem Oral Finished Dosage Forms

Thank you

