

Presentation

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Ger van Jeveren, CEO
Marieke Palstra, IR
Netherlands, 4 September 2014





Pharmaceutical
compounding

1,855 FTE
€ 204 million*)



Developer and
producer of
innovative
healthcare devices

71 FTE
€ 5 million*)



*) Based on HY 2014





FAGRON

R&D SCIENTIFIC
PHARMACEUTICAL
COMPOUNDING COMPANY



Fagron

- Founded in 1990 by Ger van Jeveren
- Started in 1 country with 1 employee and 1 product
- Currently global market leader and active in 30 countries worldwide
- 1,855 employees, including more than 200 pharmacists
- Turnover of € 204 million in first semester 2014



Ger van Jeveren
Founder & CEO

When you go to the Pharmacy?

Specialty

- Glaucoma (ocular disorder)
- API: latanoprost (patent holder Pfizer)
- Medication: Xalatan® eyedrops



Generic

- Latanoprost out of patent
- Different suppliers



Pharmaceutical compounding

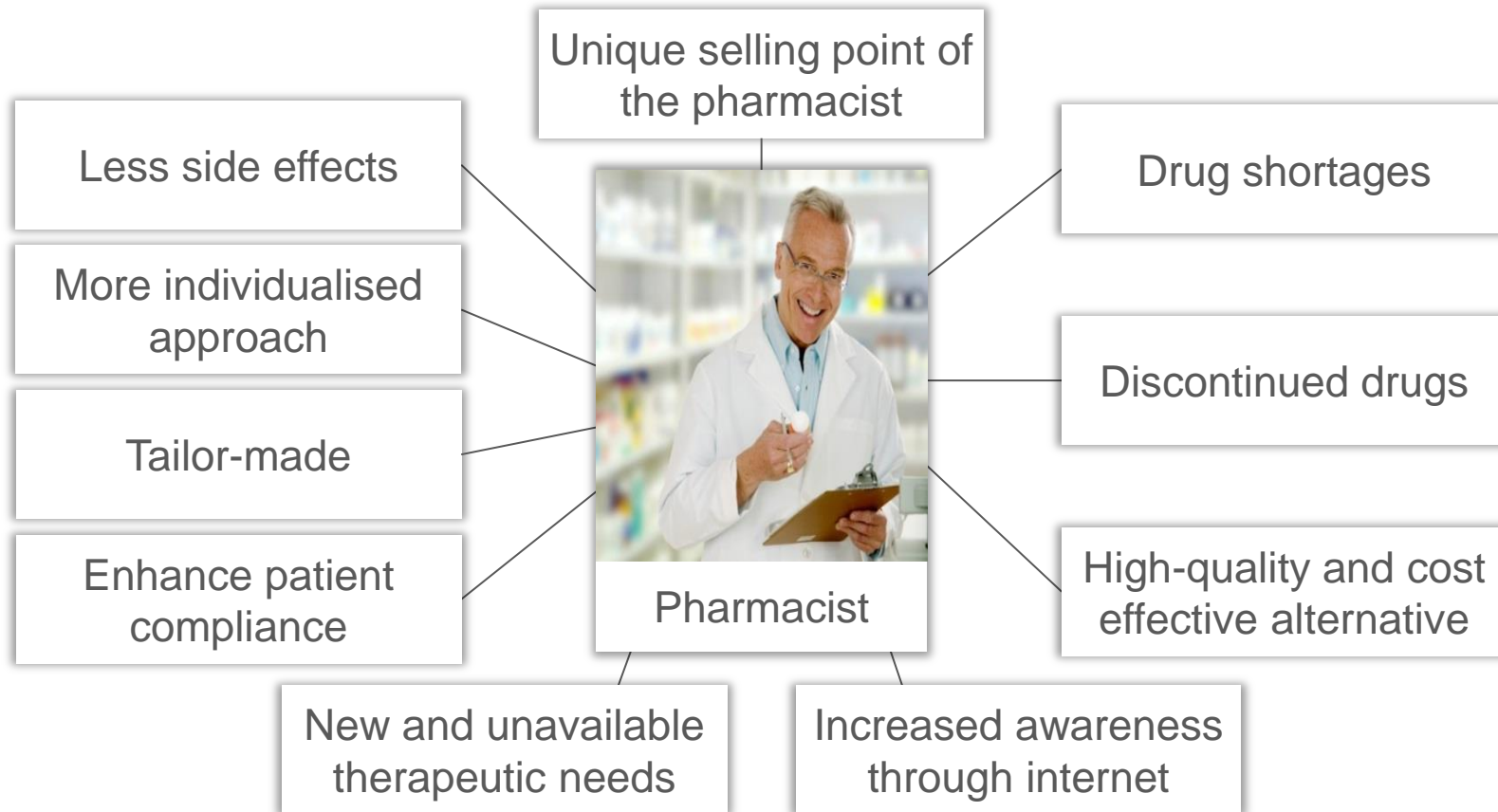
- Scientific studies have shown that latanoprost also stimulates hair growth
- Latanoprost compounding kit developed by Fagron for application on the scalp or eyelashes
- No topical preparations commercially available



What is pharmaceutical compounding?

- Formulations developed by Fagron and/or compounding pharmacists based on APIs which are out of patent
- Tailor-made medication
- Alternative dosage forms
- Alternative dosage strength
- Combination therapy
- Compounded in community and hospital pharmacies or by Fagron, based on a pharmaceutical formulation

Key drivers of pharmaceutical compounding



“Yes, compounding pharmacists enhance medication compliance and save lives... every single day!”

Fagron fact sheet

- **Market position:** #1 in Europe, North America and South America
- 2,000 **FTEs**, including >200 (hospital) pharmacists, >300 pharmacy technicians, >125 QP/QA
- 18 **compounding facilities**, 6 facilities under development, 5 conditioning sites, 3 purchase and audit offices
- **Compliant:** GMP, FDA, Anvisa, ISO9001, EU Falsified Medicines Directive
- >2,600 **raw materials** of pharmaceutical quality Ph. Eur/USP/BP

Fagron fact sheet

- 350 on-site **audits** in China and India by Quality team located in China
- 1,200 **supplier qualifications** by end of 2014
- **Customers:** >200,000 pharmacies in 30 countries
- 10% of turnover in any year comes from **innovations** that were introduced the past two years

Fagron markets – Brazil



- 120,000 pharmacists
- 32,000 pharmacies
- 7,200 compounding pharmacies
- US\$ 4 billion market (est.)



Compounding:

- Way of life, part of Brazilian culture
- Pharmaceutical specialisation at University level
- Regulatory: standardised and implemented
- Innovative (transdermal application)
- Growing market

Fagron markets – United States



- 274,000 pharmacists
- 67,000 pharmacies
- 4,500 compounding pharmacies
- US\$ 8 billion market (est.)



Compounding:

- Embedded in society and culture
- Pharmaceutical specialisation at University level
- Regulatory: standardised and implemented, but in transition
- Innovative (vehicles)
- Growing market

Fagron markets – Europe



- 400,000 pharmacists
- 155,000 pharmacies
- 10,000 compounding pharmacies
- US\$ 2 billion market (est.)



Compounding:

- Not embedded
- Less important at University and pharmacy education
- Regulatory: not-standardised and not implemented
- Traditional
- Growing market

Strategy



Optimise
and Innovate
Compounding

Mission



Compounding

- We are a **R&D Scientific Pharmaceutical Compounding Company** that wants to optimise and innovate compounding in order to widen the therapeutic scope of the prescriber, to enable tailor-made pharmaceutical care
- By doing so, we are supporting the unique selling point of the pharmacist and improve the quality of life of the patient

Values

1

Customer is
number 1



Speed of execution



Innovative



Entrepreneurial

Result driven



Behave as a global
market leader

Win-Win-Win Strategy



Pharmacist

- Time-efficient
- Quality
- Easy-to-use
- Best therapeutic outcome



Prescriber

- Therapeutic applications
- Quality
- Best therapeutic outcome



Patient

- Patient-comfort
- Quality
- Best therapeutic outcome

Fagron Organisation

Executive Committee Fagron Group

Ger van Jeveren (52)	Chairman	Constantijn van Rietschoten (43)	Marketing Innovation & Global Business Development
Jan Peeters (46)	Finance	Michaël Hillaert (35)	Area Manager Germany, Poland, Nordic, France and Belgium
Karin de Jong (35)	Controlling	Rafael Padilla (34)	Area Manager South America, Italy and Iberica
Erik Hoppenbrouwer (48)	Operations	Jake Jackson (32)	President North America
René Clavaux (45)	Information Management		

Fagron Australia	Fagron Colombia	Fagron Brazil	Fagron Argentina	Fagron USA	Fagron Belgium	Fagron France	Fagron UK	Fagron Iberica	Fagron Italy	Fagron Nether- lands	Fagron Czech Republic	Fagron Germany	Fagron Nordic	Fagron Poland	Fagron China
															

Major achievements in 2014

- Organic turnover growth at constant rates of 14.0% (highest level ever)
- Total turnover growth at constant rates of 36.4%
- Savings of € 1.5 million on the procurement of raw materials
- Acquisition and integration of five compounding facilities in Europe and the US
- Acquisition and integration of Fagron Australia
- Acquisition compounding facilities in Greece and in South-Africa
- Acquisitions aligned in North and South America, Europe, Australia and South-Africa
- Fagron has become a full R&D Scientific Pharmaceutical Compounding Company



Major achievements in 2014

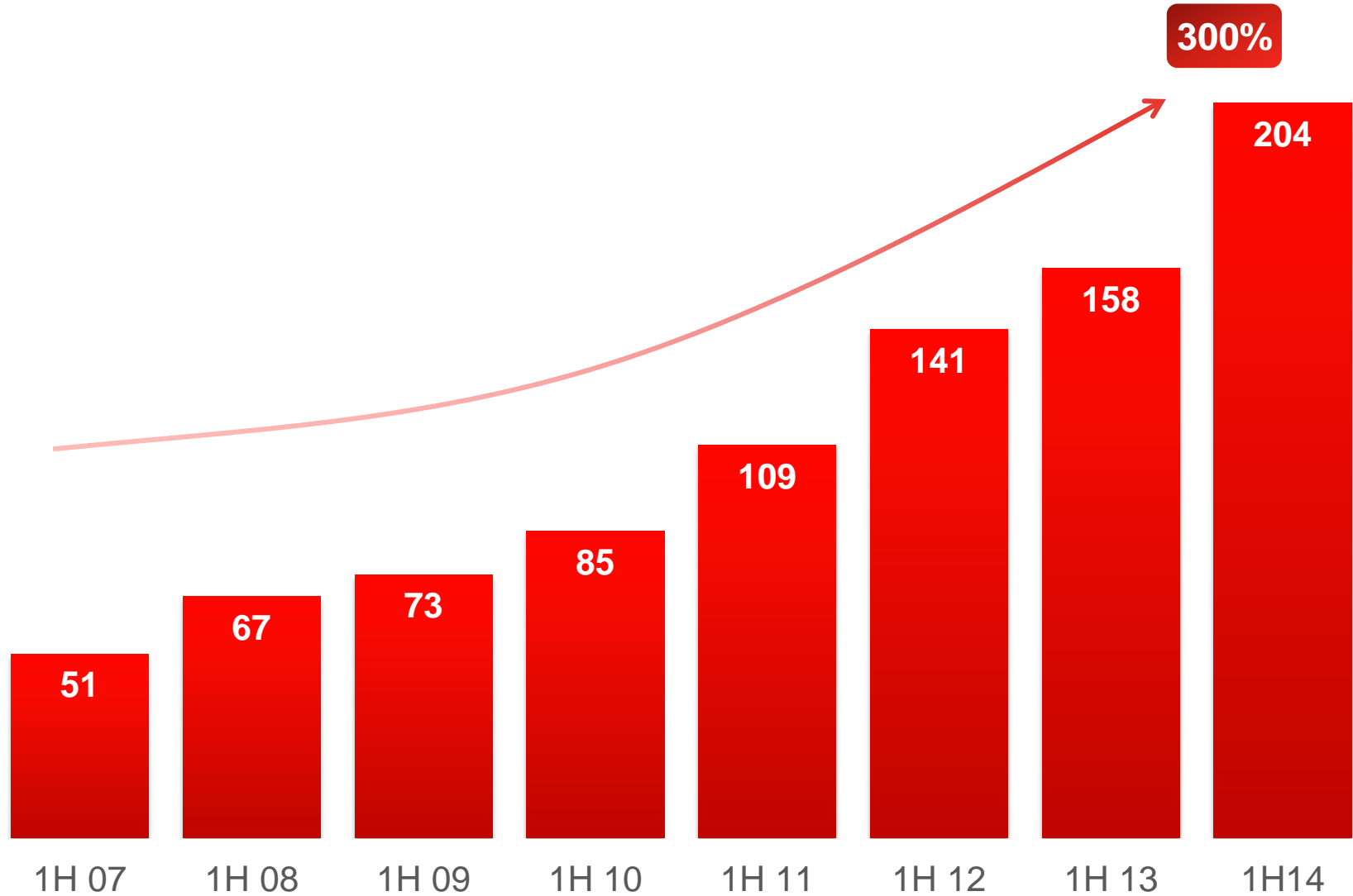
- Full harmonisation of Fagron and FCS brand expressions
- Introduction of Fagron Global Concept Label Directives
- Same look & feel for all Fagron websites/shops
- Global introduction of Fagron Advanced Derma, CapsiCards® System and SyrSpend® SF
- Global launch of Fagron Advanced Derma phase 2
- Introduction of SyrSpend® SF PH4 (dry)
- Introduction of 5 new SyrSpend® kits
- Introduction of 60 hole CapsiCards® Machine, Vibrator and Partial Batch Filler Divider



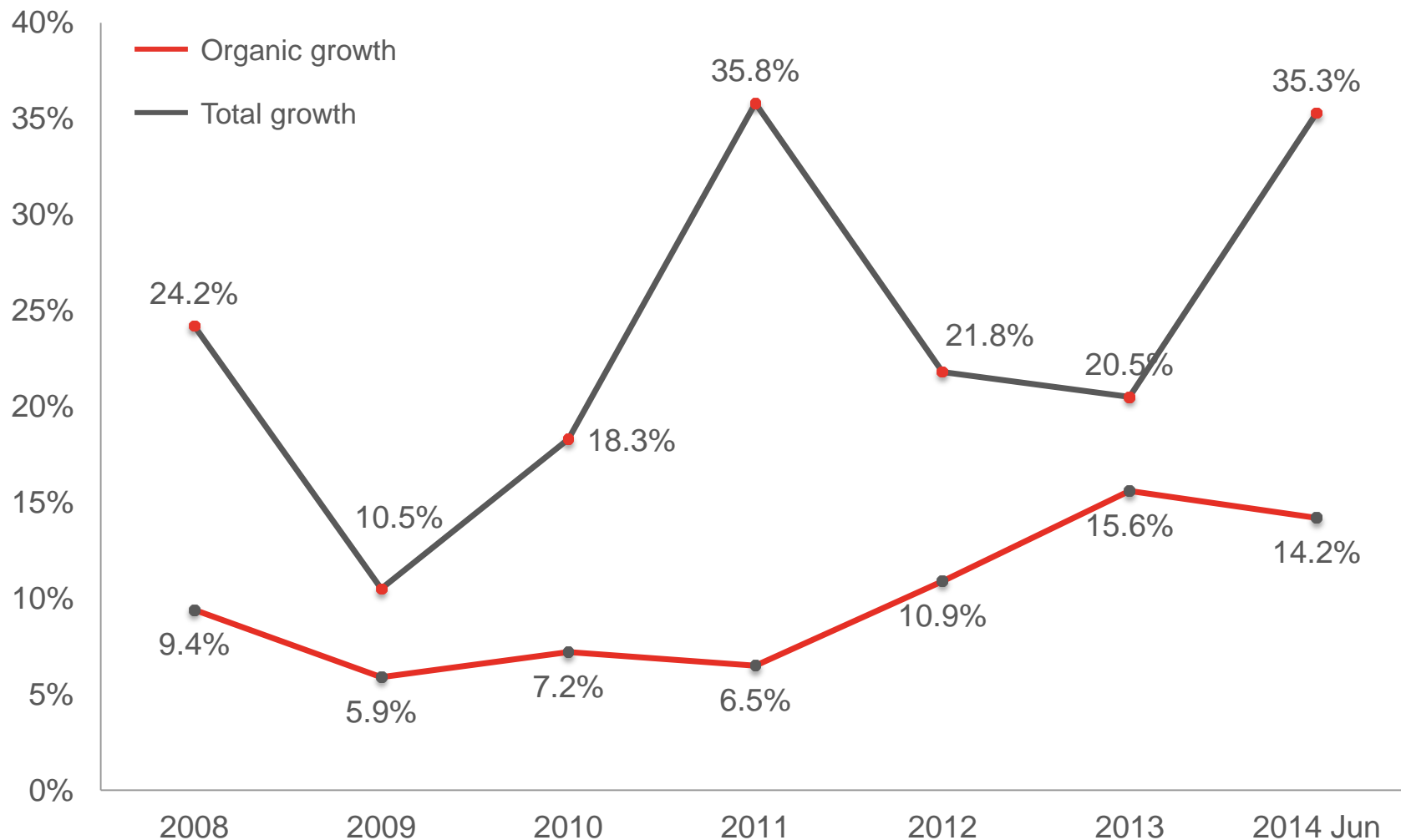
Fagron Brand Directives

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Sales Fagron

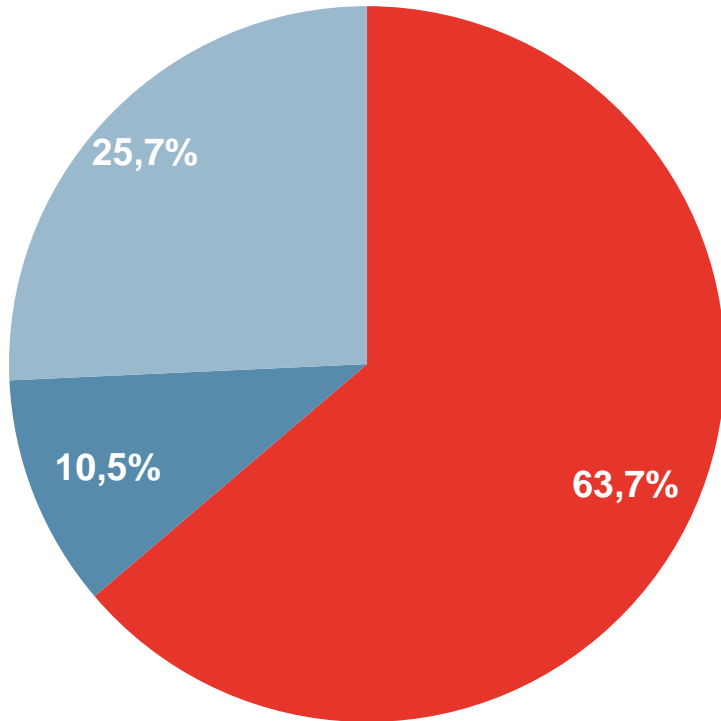


Organic and total turnover growth at constant exchange rates

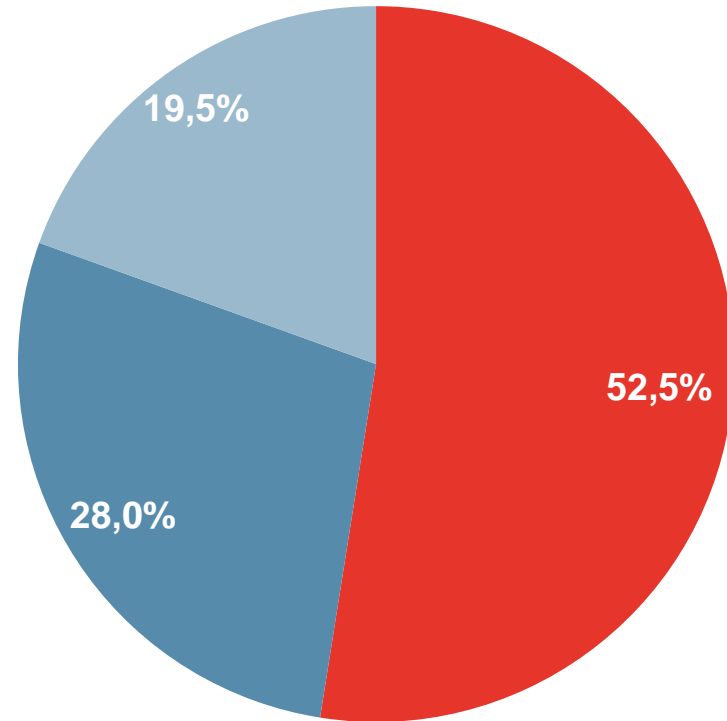


Geographical split

Sales S1 2013

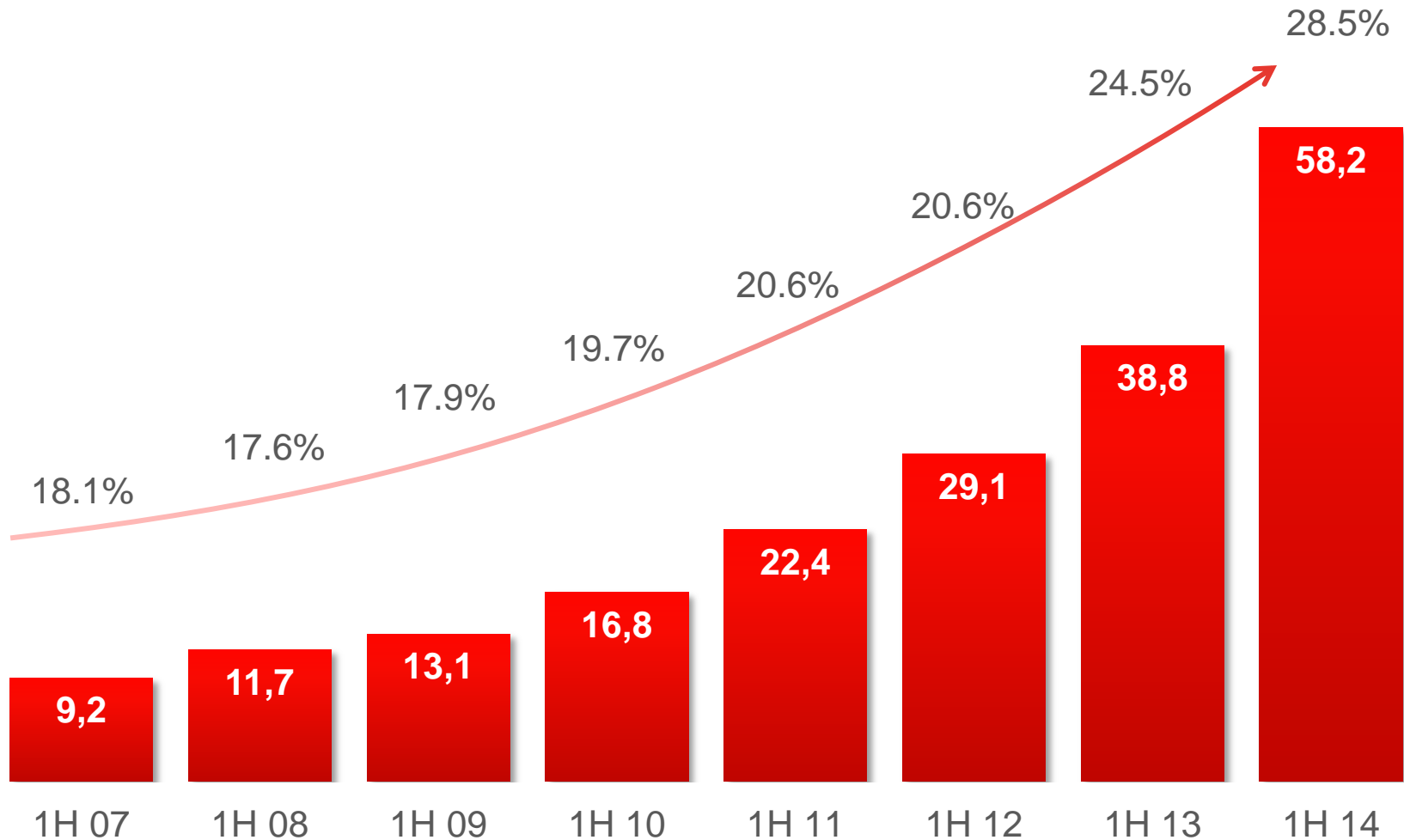


Sales S1 2014

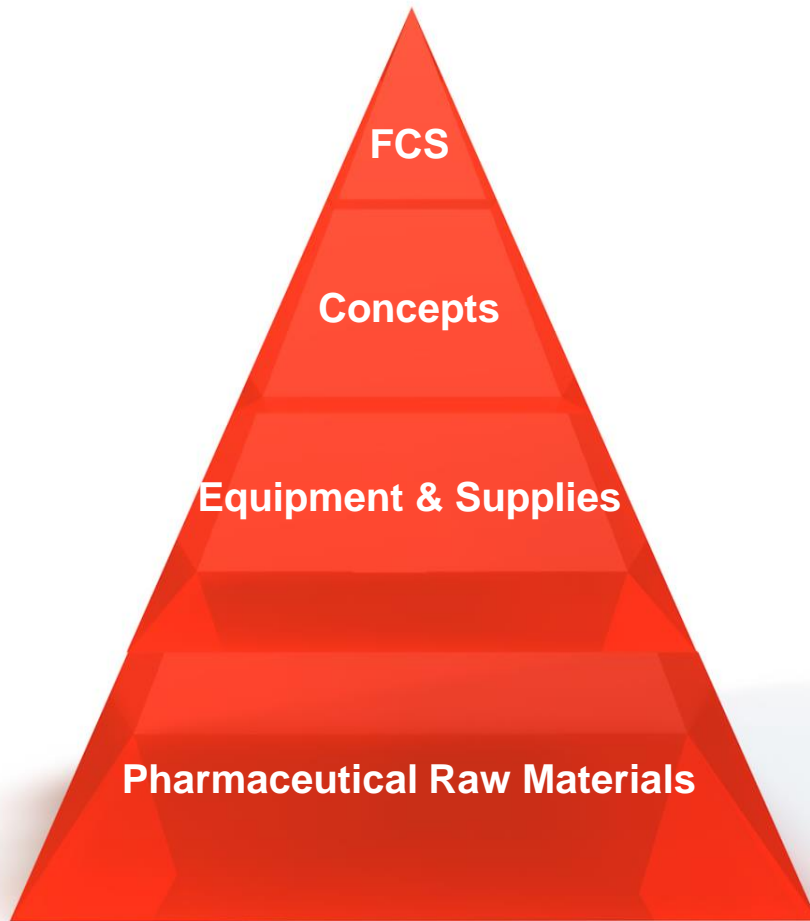


■ Europe ■ North America ■ South America

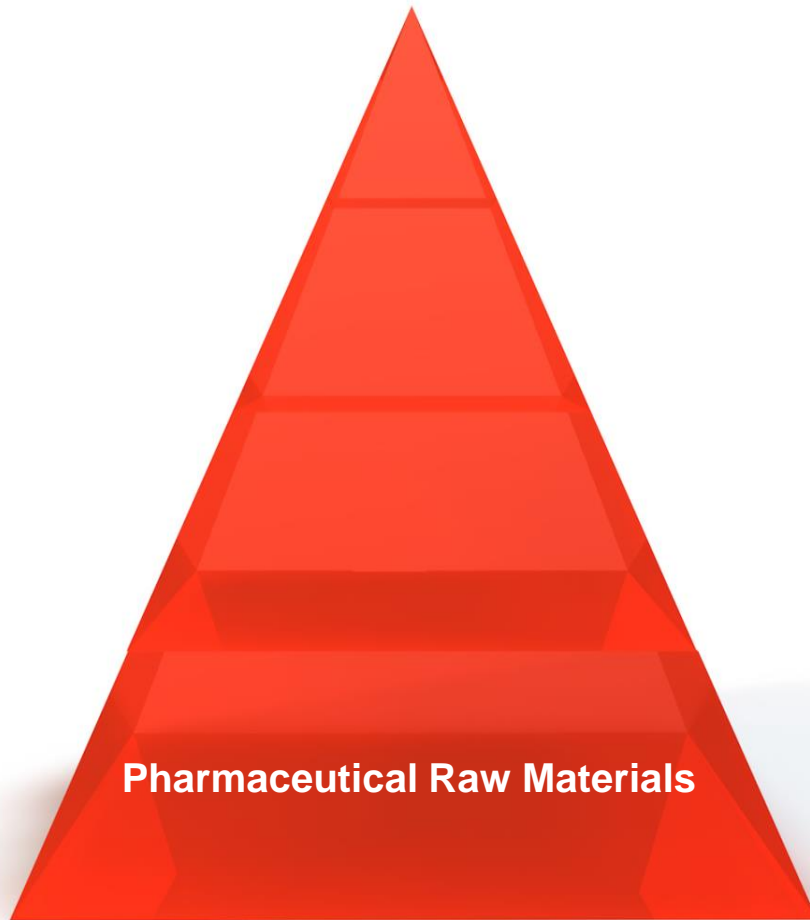
REBITDA Fagron



Business model



Business model



Pharmaceutical Raw Materials

- Amino acids
- Antibiotics
- Cortico steroids
- Excipients
- Extracts
- Food additives
- Hormones
- Minerals
- Nutraceuticals
- Oils and fats
- Opiates
- Vitamins
- Alcohol and flammable products
- Herbs

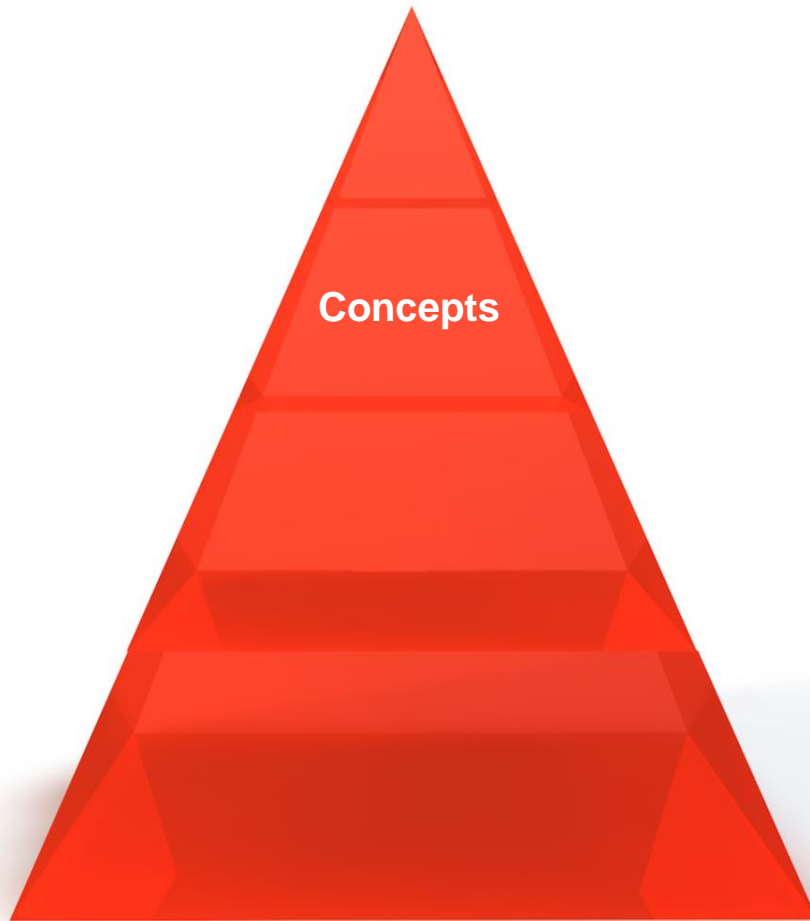
Business model



Equipment & Supplies

- Ointment mills
- Printed matters
- Packaging
- Capsule fillers

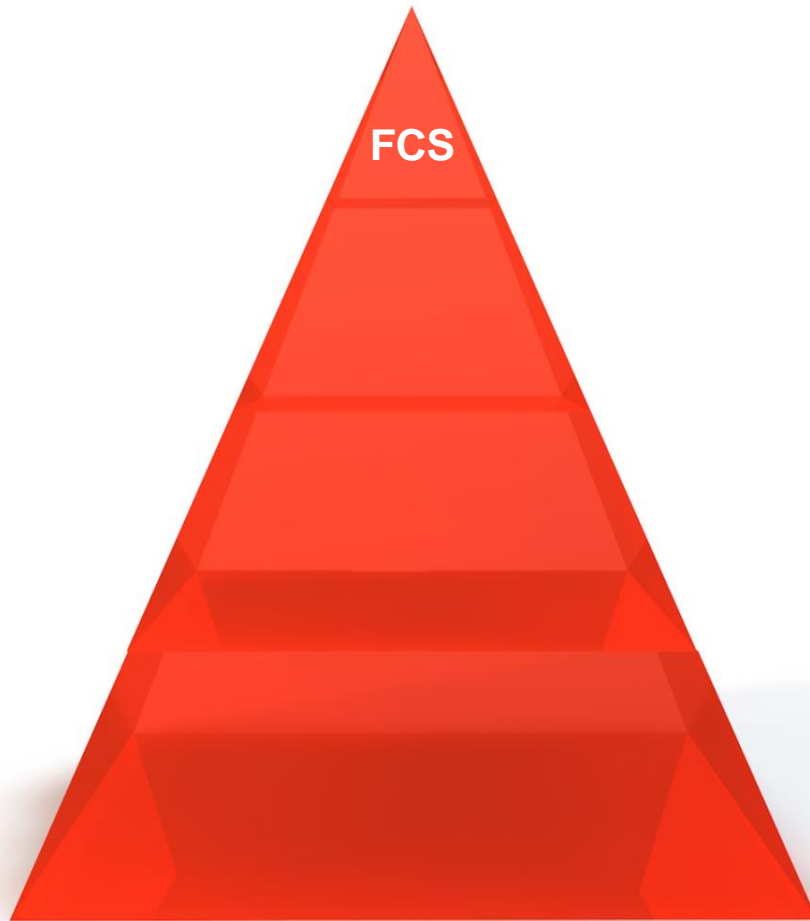
Business model



Concepts

- Fagron Advanced Derma
- SyrSpend® SF
- CapsiCards® System
- Fagron Trademarks
- Fagron PharmaWhite
- KID concept
- Semi-finished products
- Formulations for compounding
- Selective digestive decontamination (SDD)
- Bio-identical hormone replacement therapy

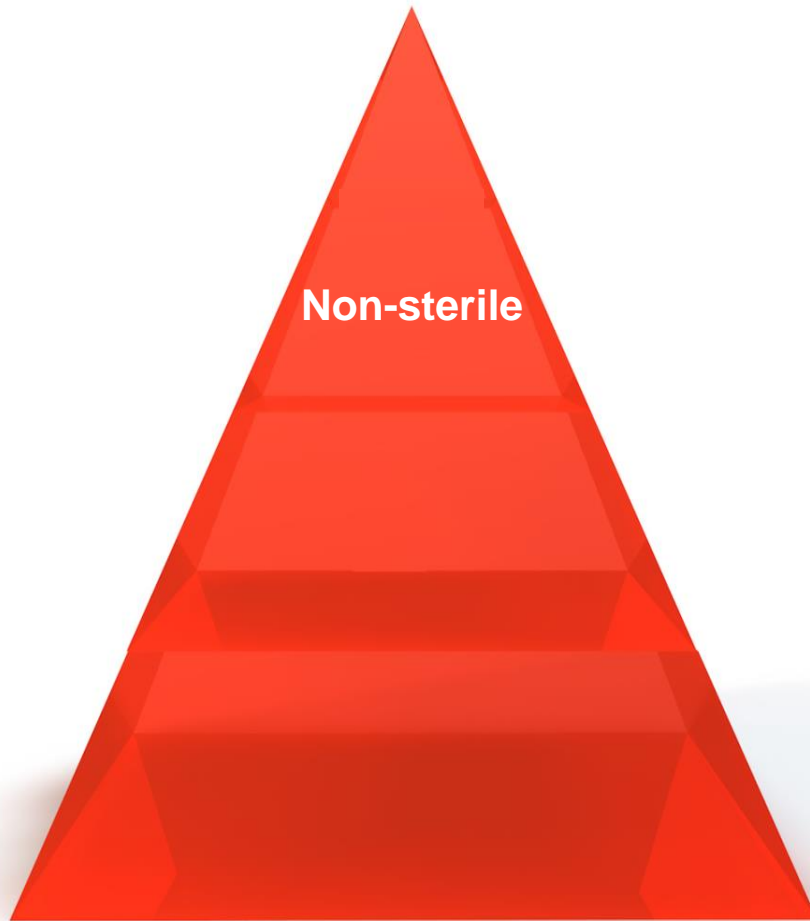
Business model



Fagron Compounding Services

- Sterile
- Aseptic
- Non-sterile

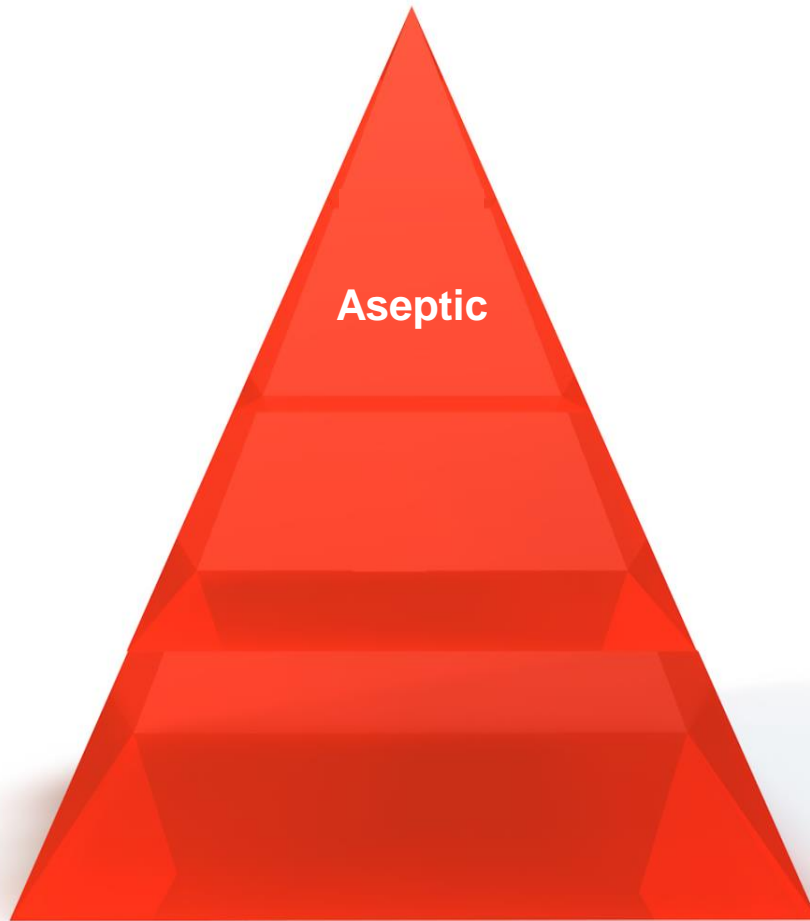
Business model



Non-sterile

- Tablets
- Ointments
- Suspensions
- Rectal
- Solutions

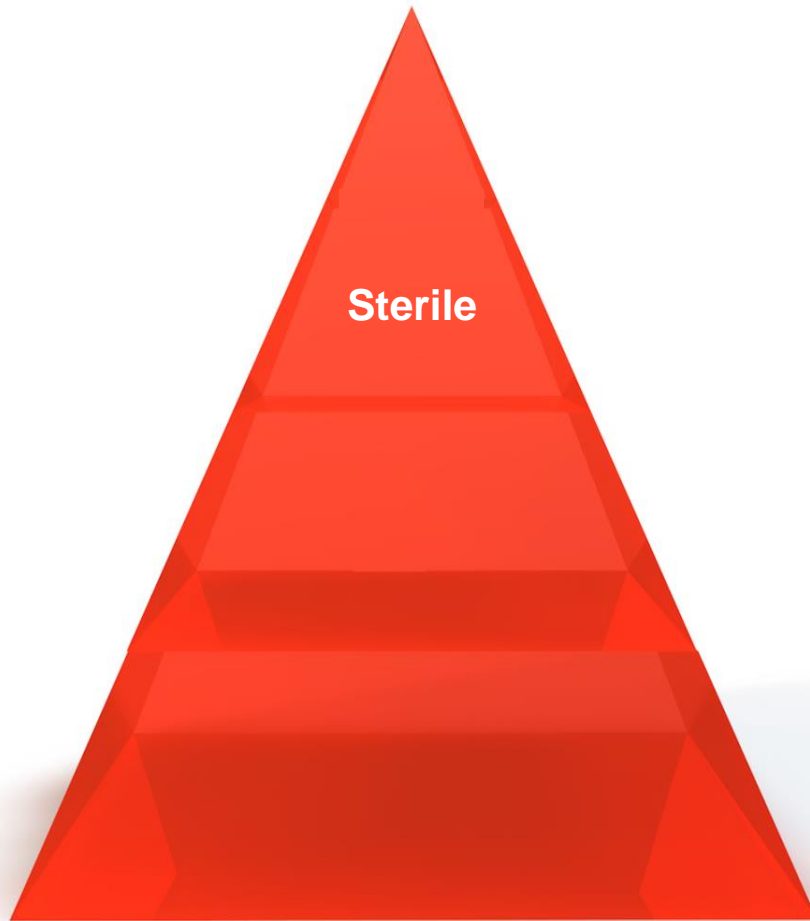
Business model



Aseptic

- Parenteral nutrition
- Ophtalmology
- Syringes
- Intraveneus infusions
- CADD cassettes
- Cytostatics
- Bladder instillation

Business model



Sterile

- IV bags
- Ampoules
- Vials

Fagron Compounding Services

North America

Wichita, Kansas

(non-sterile & aseptic)

St. Louis, Missouri

(non-sterile)

Arlington Heights, Illinois

(non-sterile)

Tamarac, Florida

(non-sterile)

Colombia

Bogotá

(non-sterile)

Cali

(non-sterile)

Medellin

(non-sterile)

Netherlands

Oud Beijerland*

(non-sterile & aseptic)

Helmond

(non-sterile & sterile)

Hoogeveen

(non-sterile & aseptic)

Oldenzaal

(non-sterile & aseptic)

Goes*

(non-sterile, sterile & aseptic)

Belgium

Bornem

(non-sterile & aseptic)

France

Paris

(non-sterile)

Marseille

(non-sterile)

South Africa

Johannesburg

(non-sterile)



* Fagron partners

Developments FCS in 2014 - 1

Acquisitions

- JCB, Kansas, USA (non-sterile and aseptic)
- Pharmacy Services, Missouri, USA (non-sterile)
- Pharmacy Services, Illinois, USA (non-sterile)
- Pharmacy Services, Florida, USA (non-sterile)
- Panoramix, Oldenzaal, the Netherlands (non-sterile and aseptic)
- Compounding facility, Johannesburg, South-Africa (non-sterile)



Developments FCS in 2014 - 2

Under development

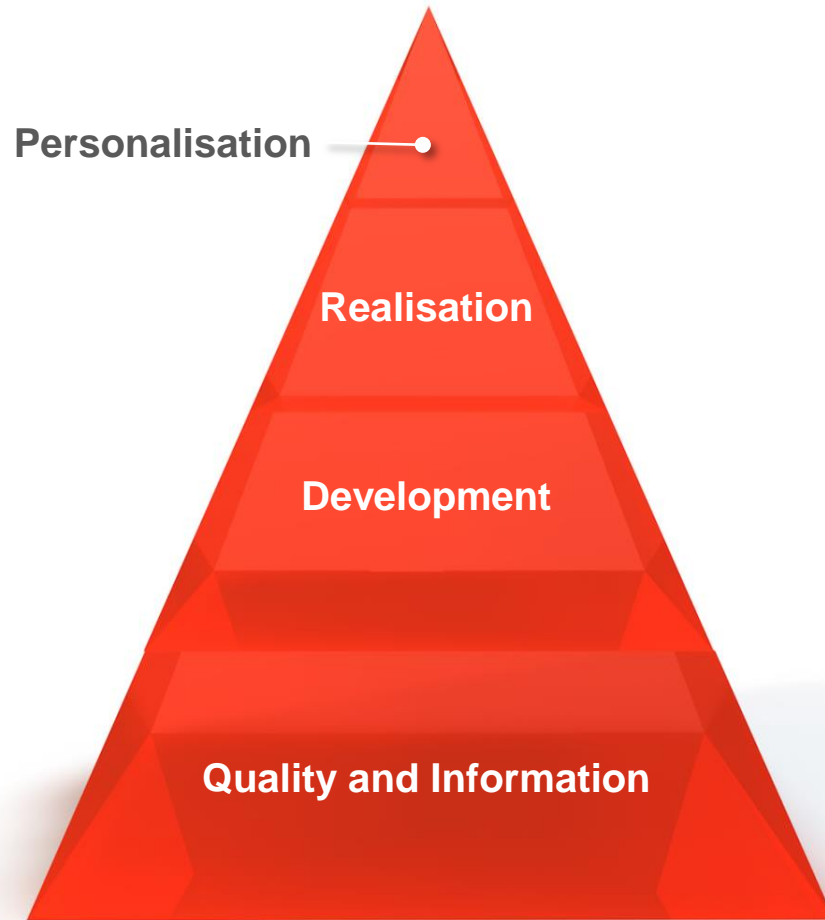
- Sterile facility, Pharmacy Services, USA
- Expansion of JCB in Kansas, USA
- Antibiotic facility in the Netherlands
- Sterile facility in the Netherlands
- Non-sterile facility in Trikala, Greece
- Non-sterile and aseptic facility in Lyon, France

Potential acquisitions in

- Europe
- USA
- South Africa
- Australia



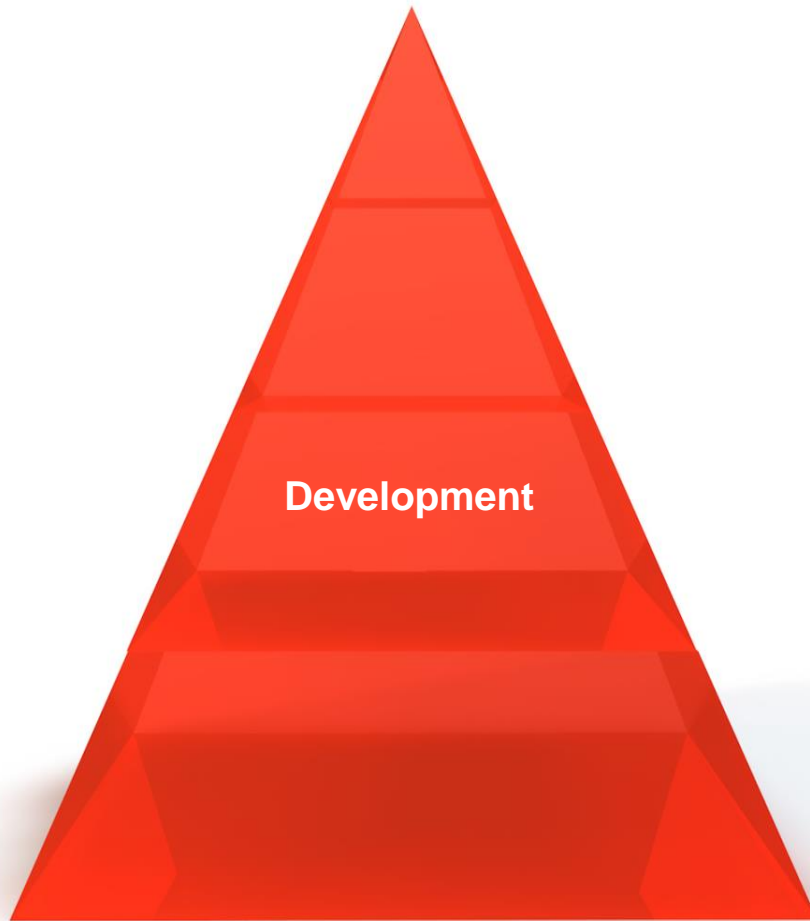
R&D





Quality and Information

- Producer qualification
- Product qualification
- Audits of producers
- CoAs
- MSDS
- DMFs
- Product database
- Patent situations



Development

- Shelf life
- Formulations and compounding protocols
- Product development
- Galenic dosage forms, strength and alterations
- Raw material alterations for use in pharmaceutical compounding
- Professional services / compounding helpdesk
- Fagron Advanced Derma

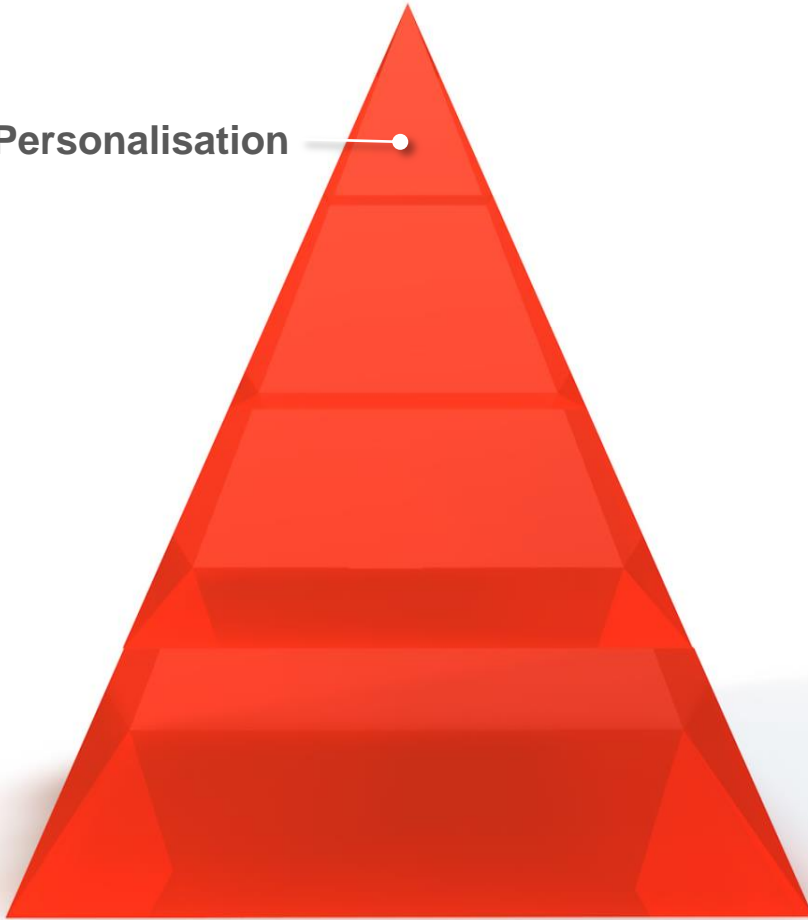


Realisation

Realisation

- Studies
 - Stability studies
 - Penetration studies
 - Evidence studies
- Trademarks

Personalisation



Personalisation

- Registrations
 - Isosorbidedinitraat - vaselinecrème 1%, crème
 - Lidocaine vaselinecrème 3%, crème 30 mg/g

Total spending R&D: € 26 million per year

Fagron Advanced Derma: the total solution



LEADING ADVANCED DERMATOLOGICAL CARE

Added value of Global Derma

A total concept with unique Fagron derma vehicles...

- strengthen the global Fagron brand
- generate prescriptions for Fagron products
- increase Fagron market share
- strengthen Fagron's competitive position










































THE GLOBAL STANDARD FOR INDIVIDUALISED



DERMATOLOGICAL COMPOUNDING CARE

Unique added value

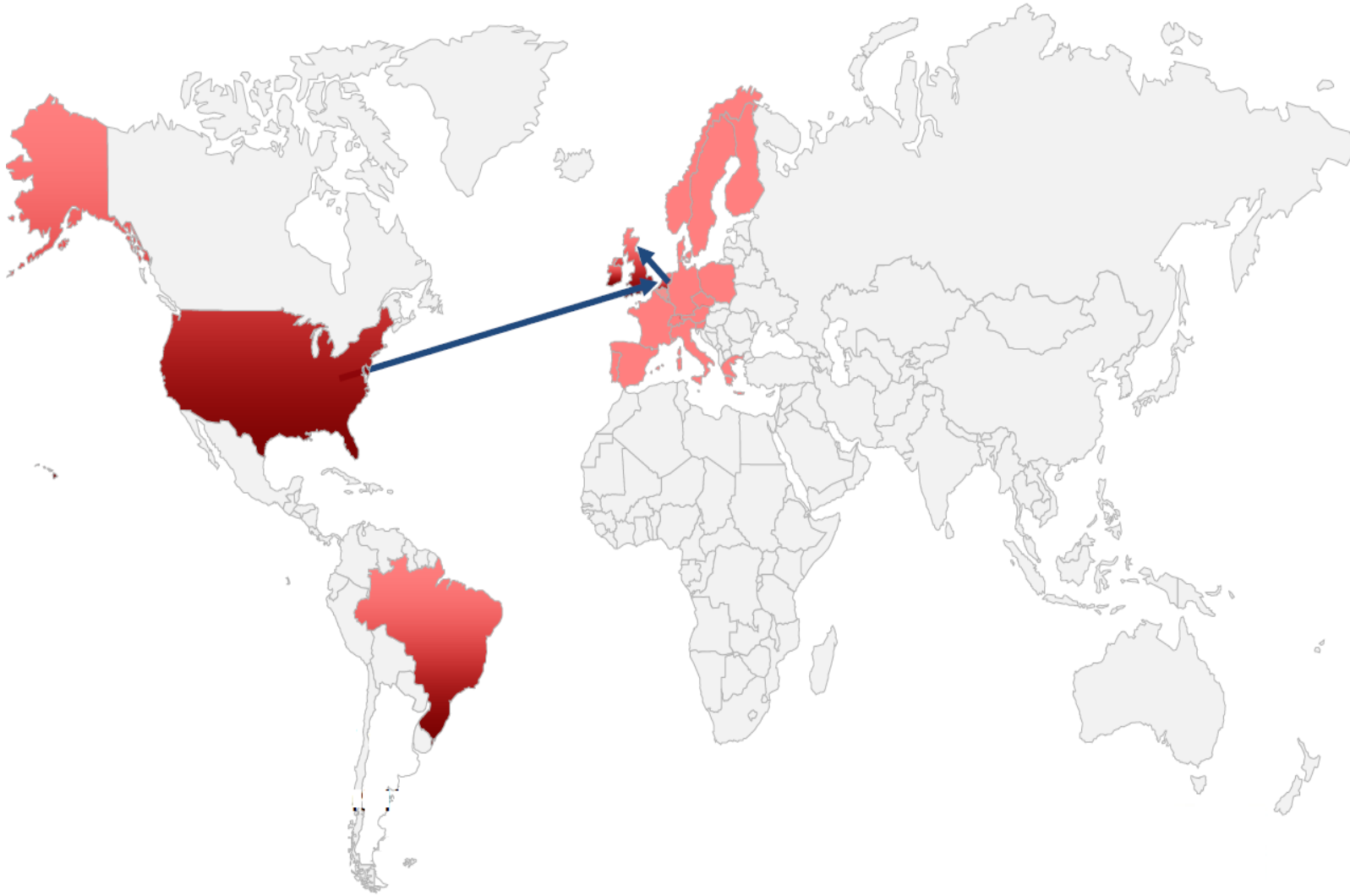
	Vehicle benefits	Especially suitable for
Occluvan™ Hydrophilic ointment base 	<ul style="list-style-type: none"> Protective ointment base with easy spreadability Occlusive, emollient, protective and humectant effects Enhances permeation of incorporated ingredients into deeper skin layers Skin-friendly formulation without preservatives Unique water-absorbing property for flexible compounding Compatible with a broad range of APIs and DCIs 	 Dehydrated skin  Very dehydrated skin  Affected skin
Emolivan™ Natural W/O cold cream base 	<ul style="list-style-type: none"> Innovative water-in-natural oil cold cream base Borate-free formulation with natural oil-based emulsifier Rich in omega-6 and vitamin E Non-greasy skin feel and readily vanishing Excellent protection and hydration effects Unique water-absorbing property for flexible compounding Compatible with a broad range of APIs and DCIs 	 Dehydrated skin  Very dehydrated skin  Affected skin
Versatile™ Rich Enriched O/W cream base 	<ul style="list-style-type: none"> Enriched hydrophilic vanishing cream base Sophisticated, protective formula rich in natural lipids Soft and caring skin feel with minimal greasiness Excellent protection and hydration effects Rapidly vanishes into the skin Non-comedogenic Ideal compounding vehicle for a broad range of high concentrations of APIs and DCIs 	 Dehydrated skin  Very dehydrated skin  Affected skin
Versatile™ Vanishing O/W cream base 	<ul style="list-style-type: none"> Hydrophilic vanishing cream base Sophisticated, elegant formula Pleasant and soft, non-greasy skin feel Excellent hydration effect Immediately vanishes into the skin Non-comedogenic Ideal compounding vehicle for a broad range of high concentrations of APIs and DCIs 	 Balanced skin  Dehydrated skin
Nourivan™ Antiox Antioxidant O/W cream base 	<ul style="list-style-type: none"> Hydrophilic vanishing cream base with antioxidants Nourishing and gentle formula Pleasant, soft skin feel Excellent hydration effect Rapidly vanishes into the skin Non-comedogenic Contains natural antioxidants, protecting APIs susceptible to oxidation 	 Balanced skin  Dehydrated skin  Very dehydrated skin
Fitalite™ Natural gel cream base 	<ul style="list-style-type: none"> Hydrophilic gel cream base Formula with natural emulsifying phytosomes Elegant, light, non-greasy skin feel Gentle moisturising properties Non-comedogenic Compatible with a broad range of APIs and DCIs 	 Oily skin  Balanced skin  Affected skin

	Vehicle benefits	Especially suitable for
Nourilite™ Vanishing O/W emulsion base 	<ul style="list-style-type: none"> Hydrophilic emulsion base with high spreadability Light, non-greasy skin feel Readily vanishing Non-comedogenic Recommended for body and facial areas Ideal compounding vehicle for a broad range of APIs and DCIs due to its compatibility within a wide pH range 	 Oily skin  Balanced skin  Dehydrated skin
Seraqua™ Ultra-light O/W serum base 	<ul style="list-style-type: none"> Innovative hydrophilic serum base Elegant, ultra-light skin feel Excellent spreadability and readily vanishing Hydration and skin protection without an occlusive effect Non-comedogenic Especially recommended for facial area Ideal compounding vehicle for a broad range of high concentrations of APIs and DCIs 	 Oily skin  Balanced skin  Dehydrated skin
Nourisil™ Anhydrous silicone base 	<ul style="list-style-type: none"> Innovative, anhydrous silicone base containing a blend of silicones and vitamin E Ultra-light gel structure Non-greasy, silky skin feel Skin protectant and preservative-free Especially suitable for affected skin, such as scar tissue Hydration supports tissue-healing process and prevention of unaesthetic scars Compatible with a broad range of APIs and DCIs, solvents and oils 	 Affected skin
Solydra™ Natural oil base 	<ul style="list-style-type: none"> Natural oil base with exceptional hydration Rich in omega-6 and vitamin E Soft skin feel and preservative-free Readily dispersed in water Ready-to-use for (very) dehydrated and affected skin Compatible with lipophilic APIs and DCIs 	 Dehydrated skin  Very dehydrated skin  Affected skin
Espumil™ Lipophilic foam base 	<ul style="list-style-type: none"> Innovative base solution for easy compounding of foams Generates a foam when dispensed in Fagron's foam activating pumps Creamy foam formulation with minimal greasiness Without gaseous propellants Light skin feel, drip-free Compatible with lipophilic APIs and DCIs, such as minoxidil 	 Specific skin area

SyrSpend® SF



SyrSpend[®] SF



SyrSpend[®] SF

- Invented by FAUS in 2003
- Technology patented since 2004
- **FANL** was looking for a stable Omeprazole formula
- **FAUK** had an interested customer for a kit
- **FAUS** had the product, tested for stability with Ome
- **FSNL** was the partner for assembling and distribution
- **GMI** coordinates the project to a successful joint venture
- A match was made

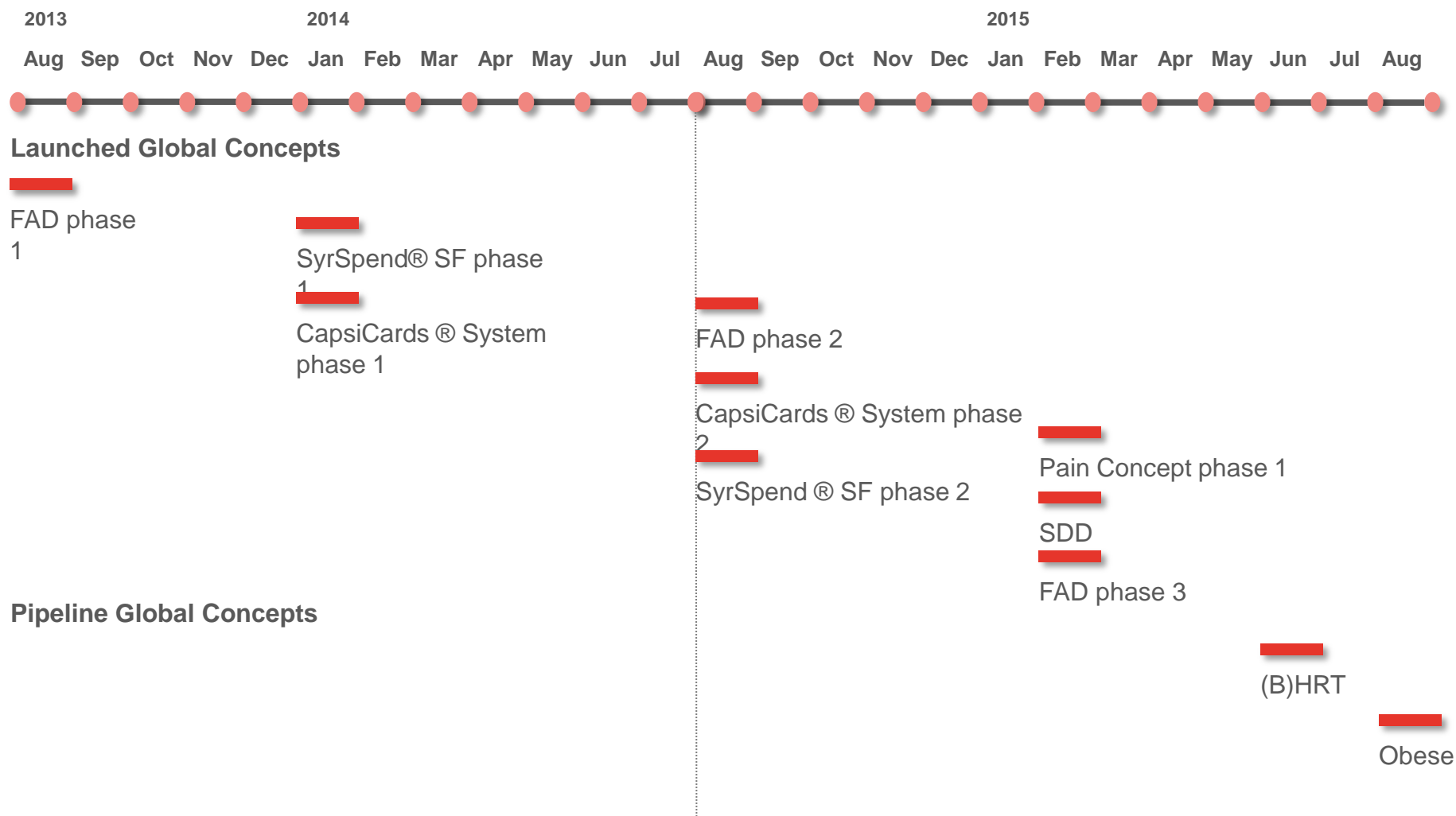
 Peer Reviewed	
Stability of Omeprazole in SyrSpend SF Alka (Reconstituted)	
Paul A. Whaley, BS Mark A. Voudrie II, MS, PMP Bridget Sorenson, CAPM	ABSTRACT Omeprazole is used in the treatment of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, laryngopharyngeal reflux, and Zollinger-Ellison syndrome. Omeprazole is marketed by AstraZeneca under a number of names, most notably Prilosec and Losec, as well as being available from a number of generic manufacturers. Omeprazole is available in both tablet and capsule form, with varying strengths of each. The need for other administration options for those patients who cannot take tablets or capsules has led compounding pharmacies to seek other alternatives. One possible alternative is the use of a suspending agent to create an oral solution or suspension. In the past, this has been accomplished using a sodium bicarbonate solution as the vehicle. However, sodium bicarbonate/omeprazole combination imparts a bitter and unpleasant taste. SyrSpend SF Alka (reconstituted) is a vehicle for making a suspension which has a pleasant taste, thus increasing palatability and compliance. The objective of this study was to determine the stability of omeprazole in SyrSpend SF Alka (for reconstitution). The studied sample was compounded into a 2-mg/mL suspension and stored in a low-actinic plastic prescription bottle at temperatures between 2°C and 8°C. Six samples were assayed at each time point out to 92 days by a stability-indicating high-performance liquid chromatography method. The method was validated for its specificity through forced degradation studies. The shelf life of this product is at least 92 days, based on data collected when refrigerated and protected from light.
INTRODUCTION Omeprazole is a proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer disease (PUD), gastroesophageal reflux disease (GORD/GERD), laryngopharyngeal reflux (LPR), and Zollinger-Ellison syndrome. ¹ It is used to treat a wide range of the patient population, including both infant and geriatric patients. These two groups in particular may experience difficulty in swallowing whole capsules or tablets. In the past, sodium bicarbonate has been used with omeprazole to create an oral solution. Sodium bicarbonate does little to mask the bitter taste of omeprazole. An alkaline suspending agent containing a sweetener masks the bitter taste and increases the palatability of omeprazole. This is of particular importance when considering the treatment of infants, as the masking of the taste increases end-user compliance. Some compounding vehicles contain alcohol and sorbitol. SyrSpend SF Alka (for reconstitution) (Pharm (formerly Gallipot), St. Paul, Minnesota) is a sorbitol- and alcohol-free alkaline suspending agent which could serve as an appropriate vehicle for compounding an omeprazole oral suspension. The objective of this study was to examine the stability of omeprazole when prepared in an oral suspension using SyrSpend SF Alka (for reconstitution). The suspension was stored in a low-actinic plastic prescription bottle at a concentration of 2 mg/mL under United States Pharmacopeia (USP) refrigerated (2°C to 8°C) storage conditions. Stability was assessed by percent recovery studies performed at varying time points throughout 92 days.	MATERIALS AND METHODS Chemical Reagents Omeprazole raw powder was obtained from Gallipot (Lot 0000145012, St. Paul, Minnesota). High-performance liquid chromatographic (HPLC) grade acetonitrile (Lot C2628; Burdick and Jackson, Kalamazoo, Michigan), 85% phosphoric acid ACS-grade (Lot 201103115; OCI, New Delhi, India), monosodium phosphate monohydrate (Lot 107148; Fisher Scientific, Pittsburgh, Pennsylvania), disodium phosphate heptahydrate (Lot B0131727; Acros Organics, Geel, Belgium), and octasulfonic acid (Lot 08K0815; Sigma Aldrich, St. Louis, Missouri) were used in the study. HPLC-grade water was supplied by filtering deionized water from a Millipore Elva through a Millipore Simplicity (Billerica, Massachusetts).
Equipment and Chromatographic Conditions Two different types of HPLCs were used. The first, used for validation and the stability study, was a Perkin Elmer 200-Series (Waltham, Massachusetts) equipped with a quaternary gradient solvent delivery system, a dual wavelength UV-VIS detector, and a 100- μ L programmable autosampler with a Polaris trap, 200- μ L sample loop, and 250- μ L syringe. The second LC system, used for forced degradation studies, was a Varian Prostar (Palo Alto, California) equipped with a tertiary gradient solvent delivery system, a photodiode array detector.	
The authors are affiliated with Dynalabs, LLC, St. Louis, Missouri.	
164 International Journal of Pharmaceutical Compounding Vol. 18 No. 3 March/April 2012	www.IJPC.com

**SYRSPEND® SF HAS
THE LARGEST COMPATIBILITY
TABLE FOR ORAL LIQUIDS
GLOBALLY**

- Available: 86 SyrSpend® SF formulations
- More to follow



R&D Pipeline



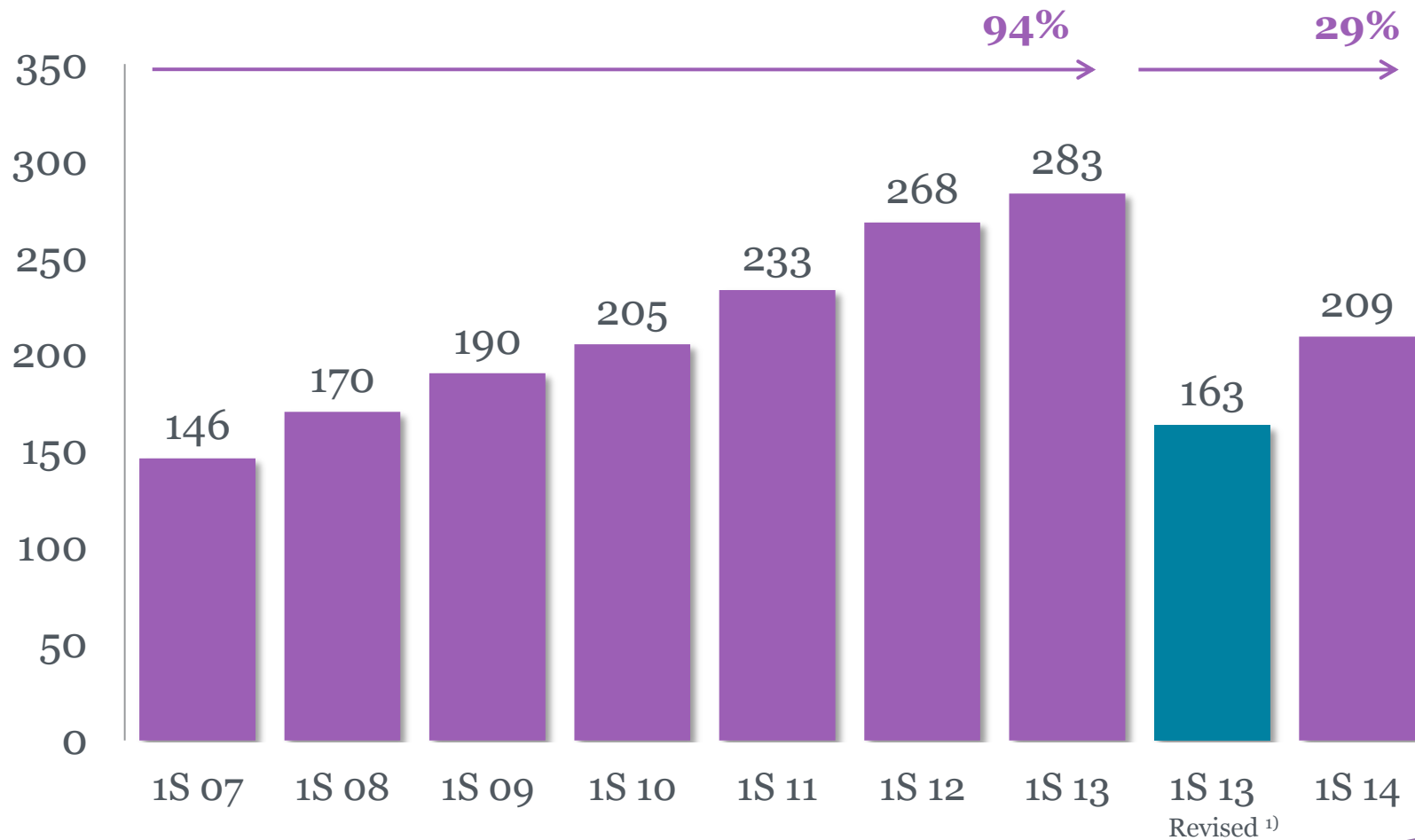


Fagron the global number 1 in pharmaceutical compounding

Financial highlights First Semester 2014

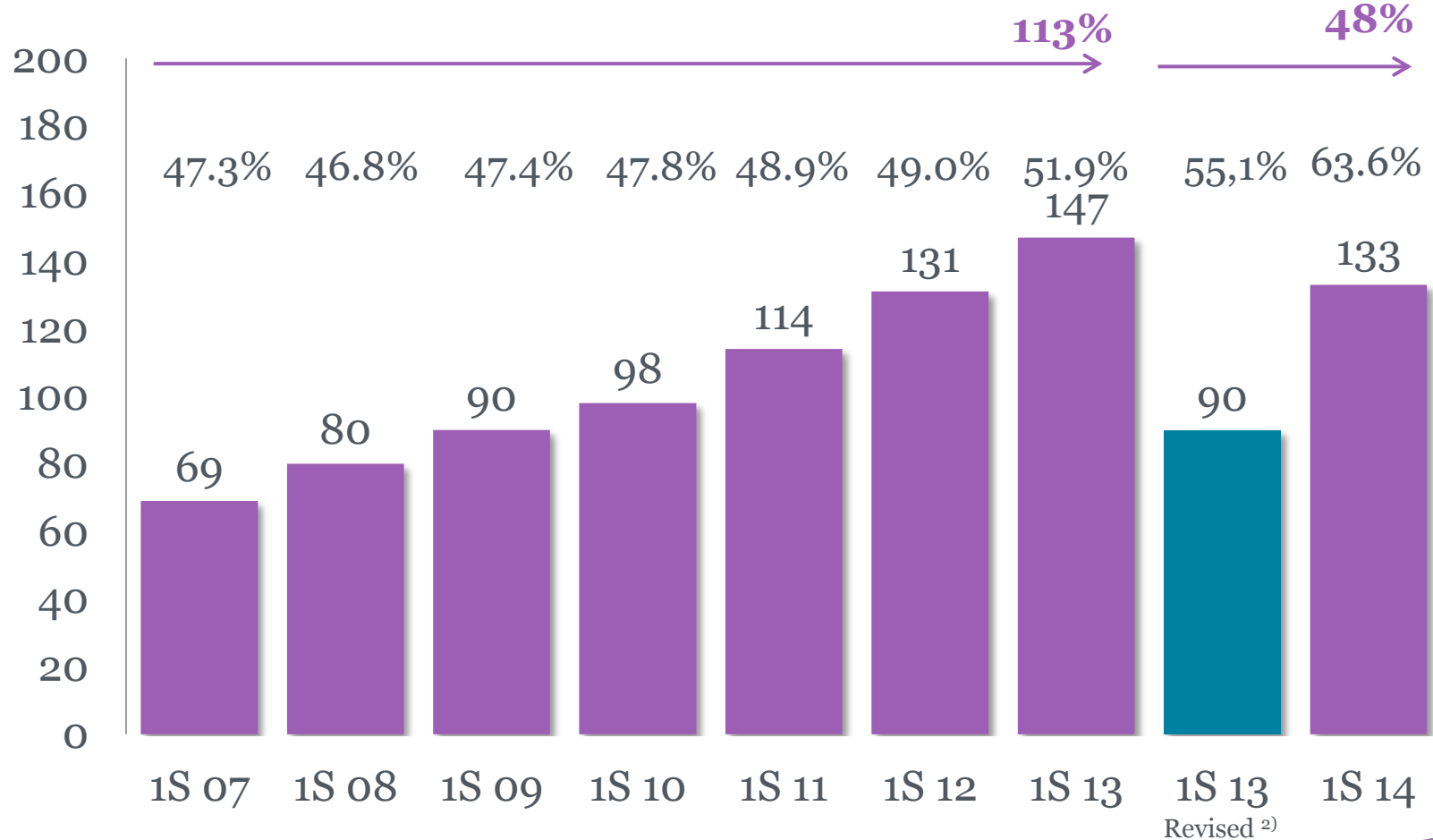


Sales



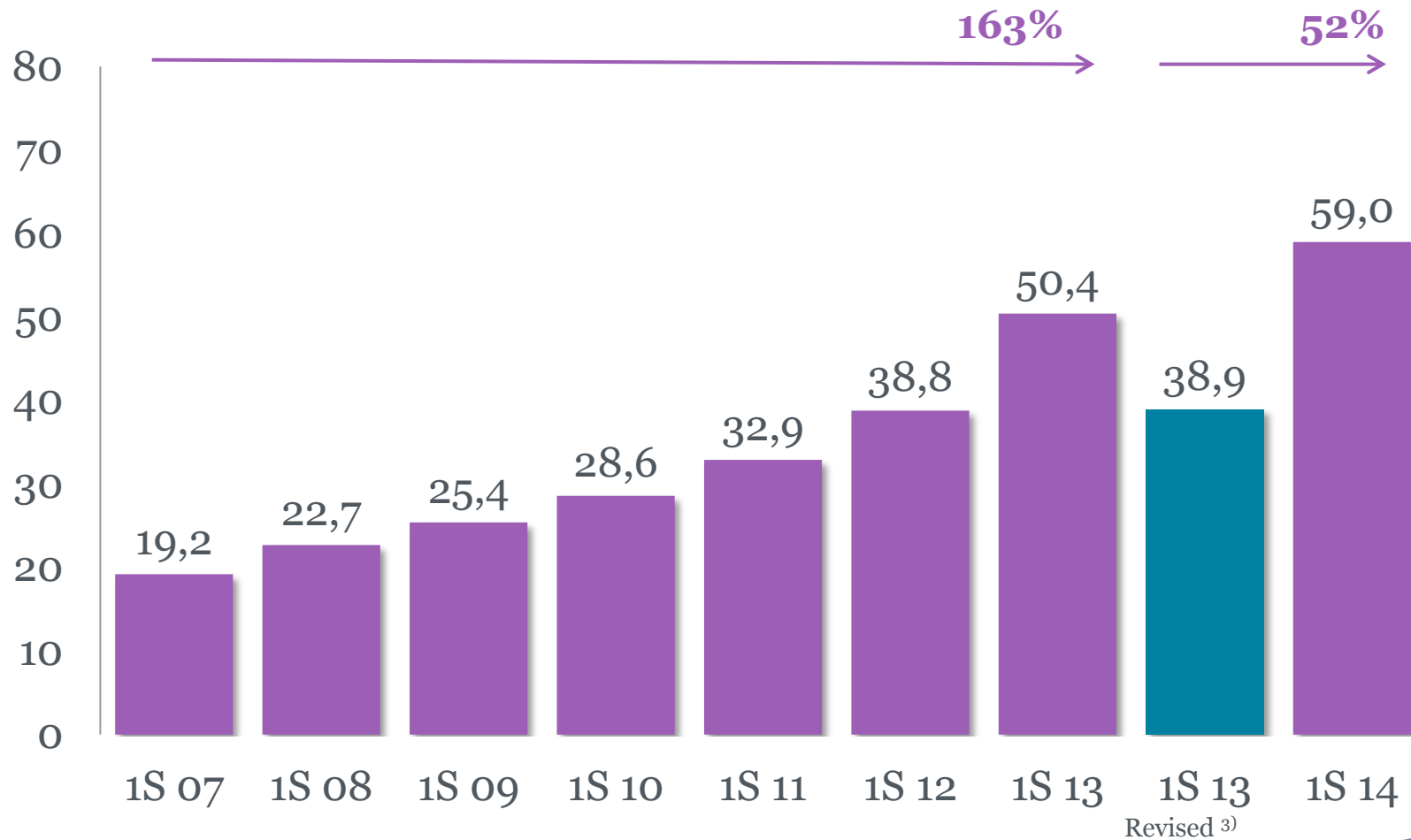
1) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

Gross Margin



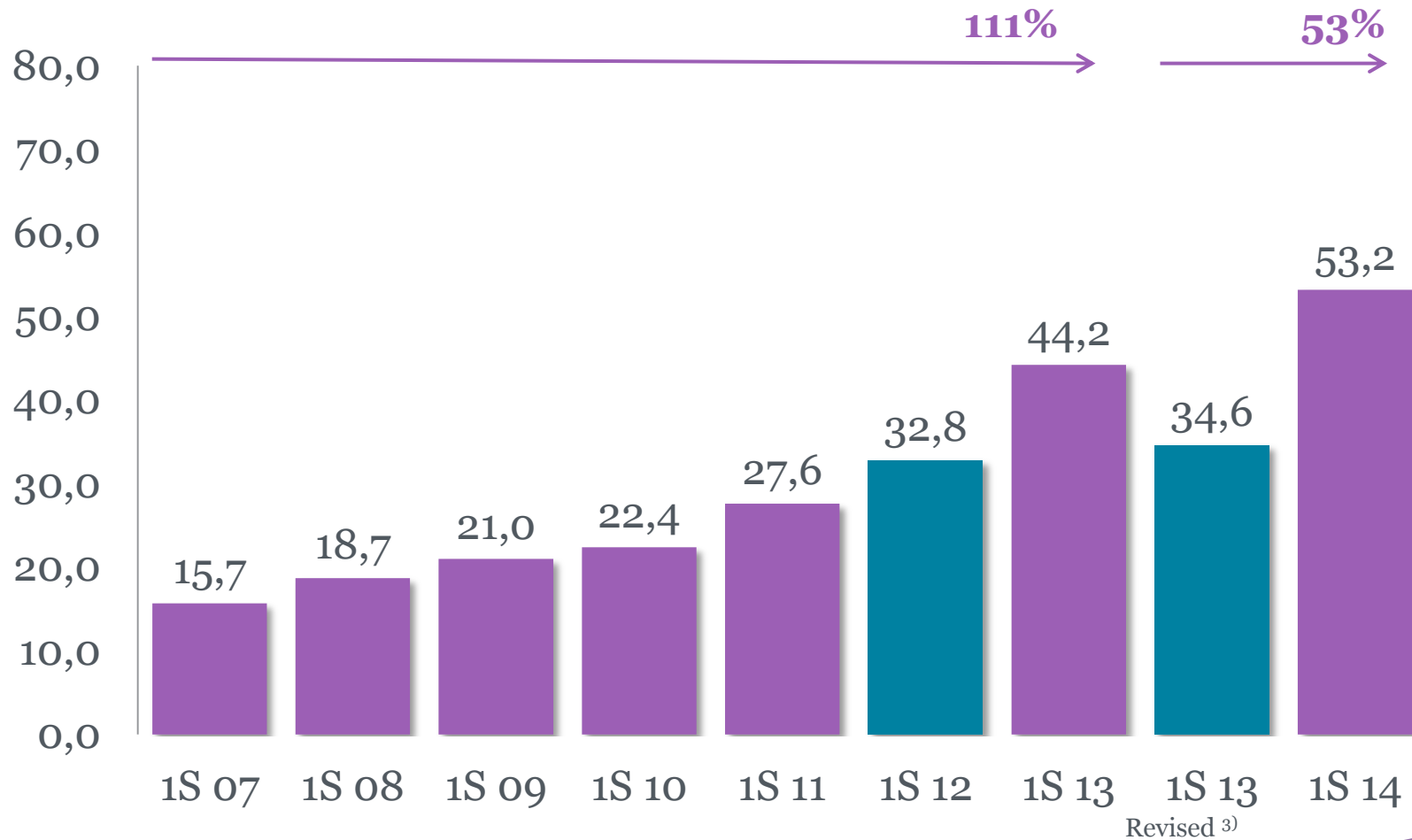
2) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

REBITDA



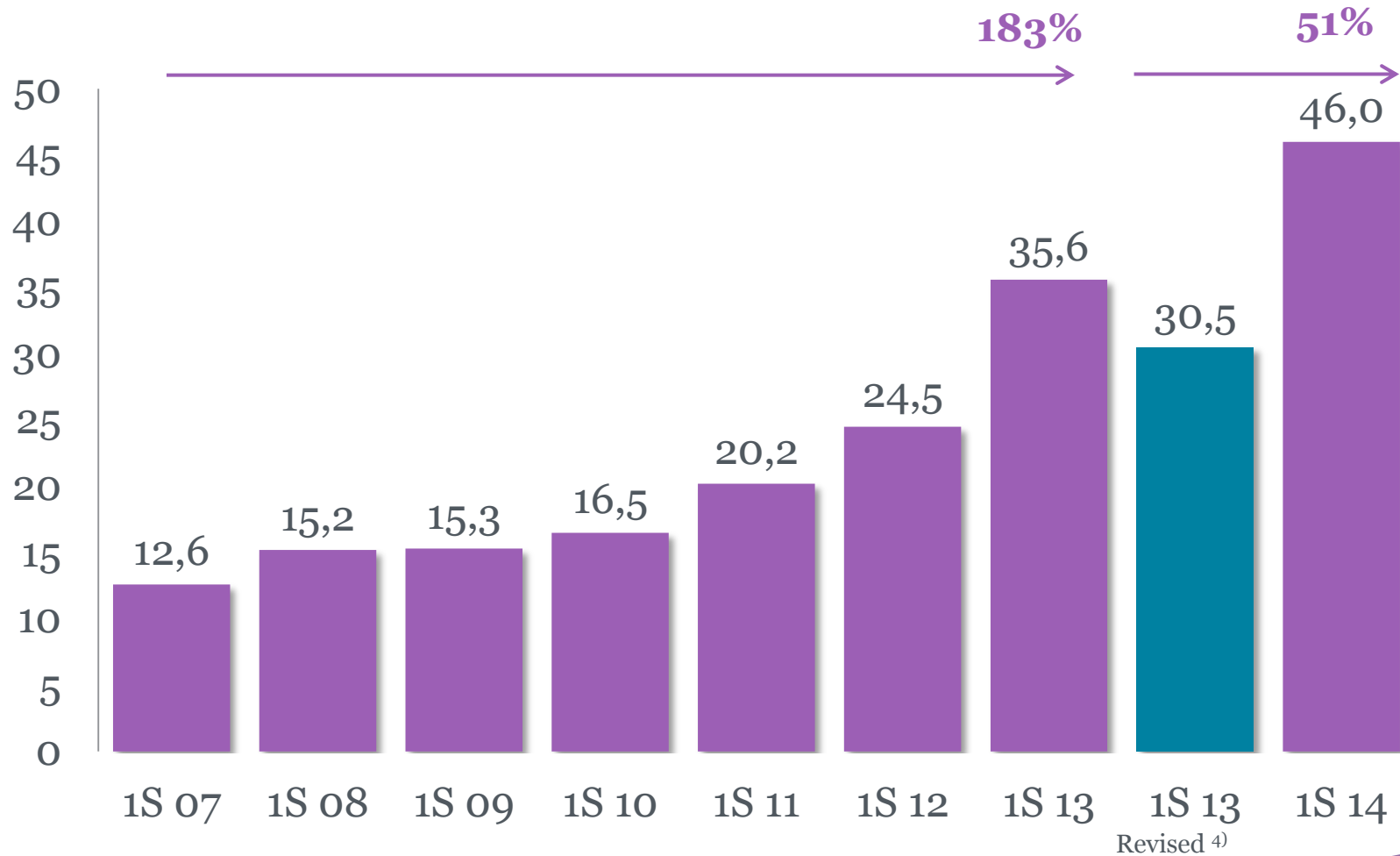
3) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

EBITDA



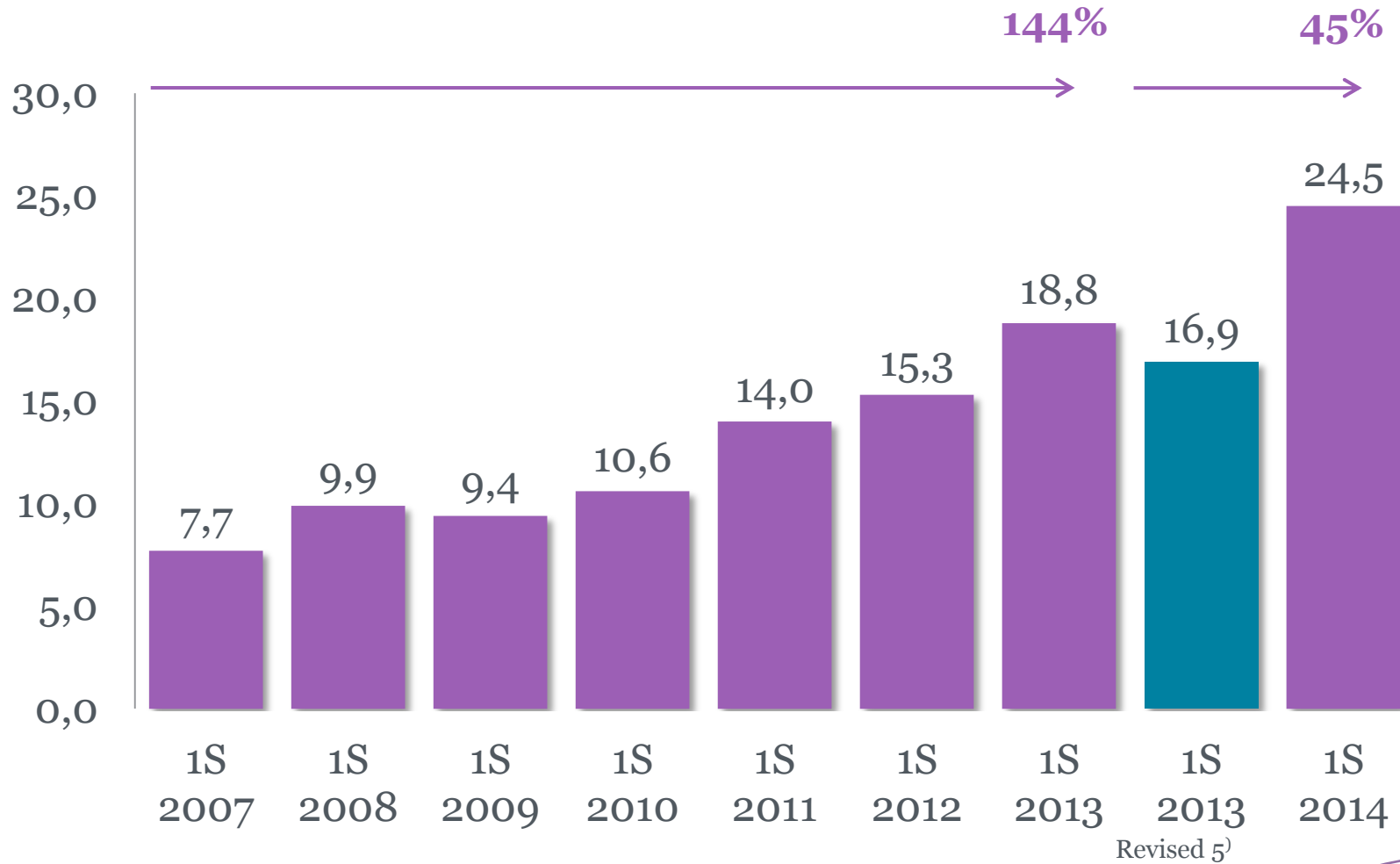
3) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

EBIT



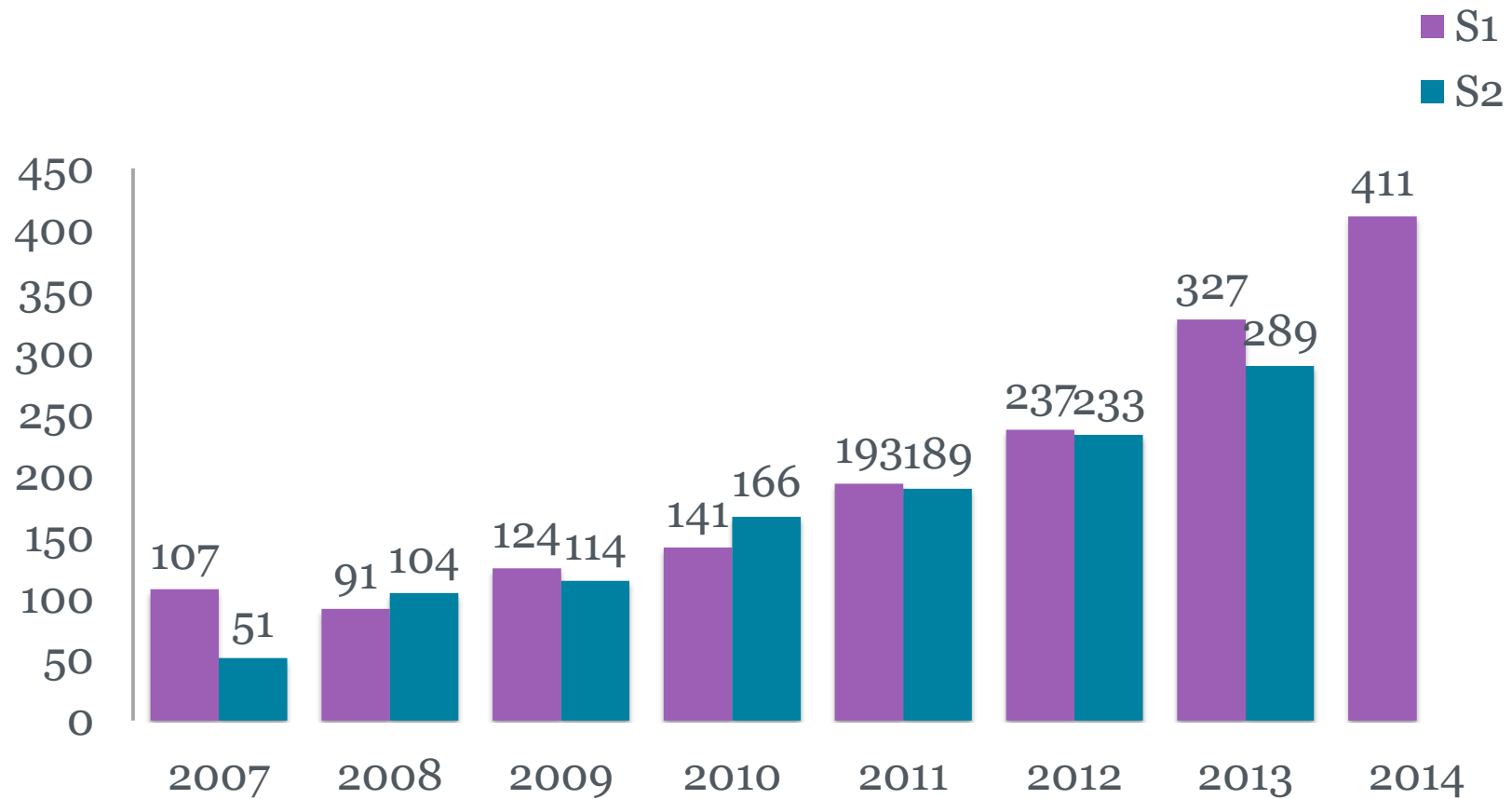
4) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

Net profit

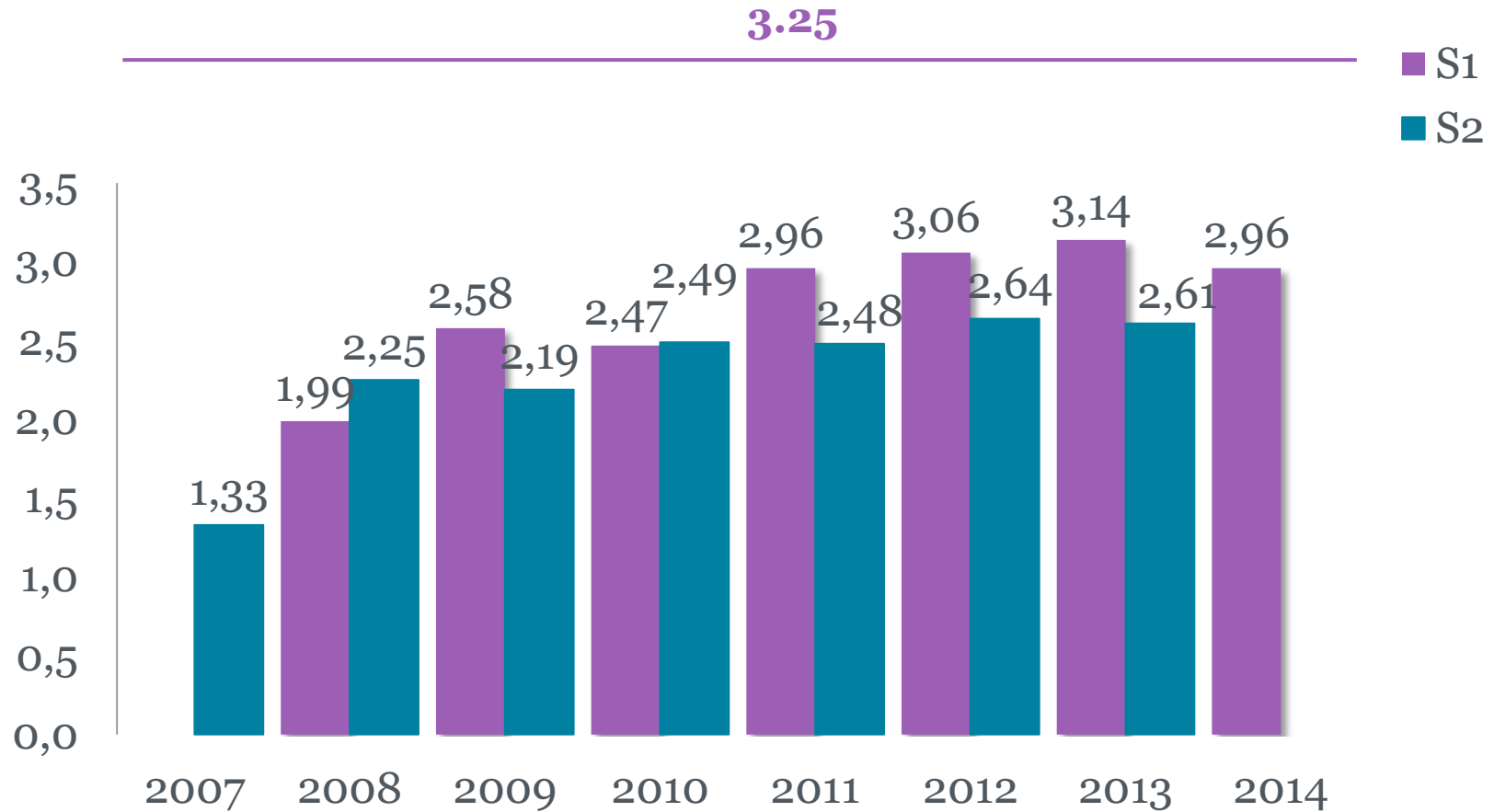


5) The income statement of 2013 is resetated for the application of IFRS 5 and IAS 19 Revised.

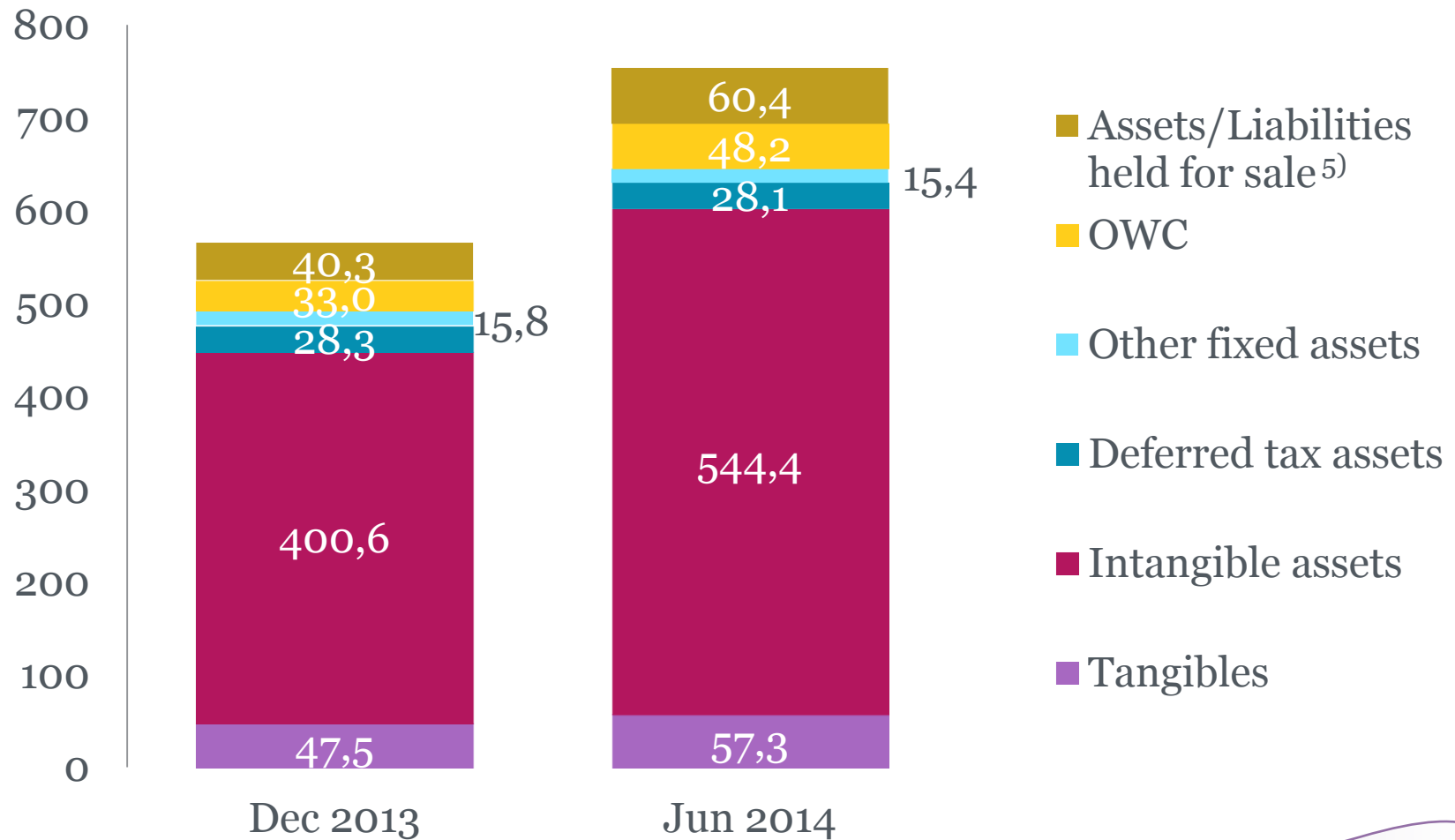
Net Financial Debt – S1 en S2



Financial Covenant

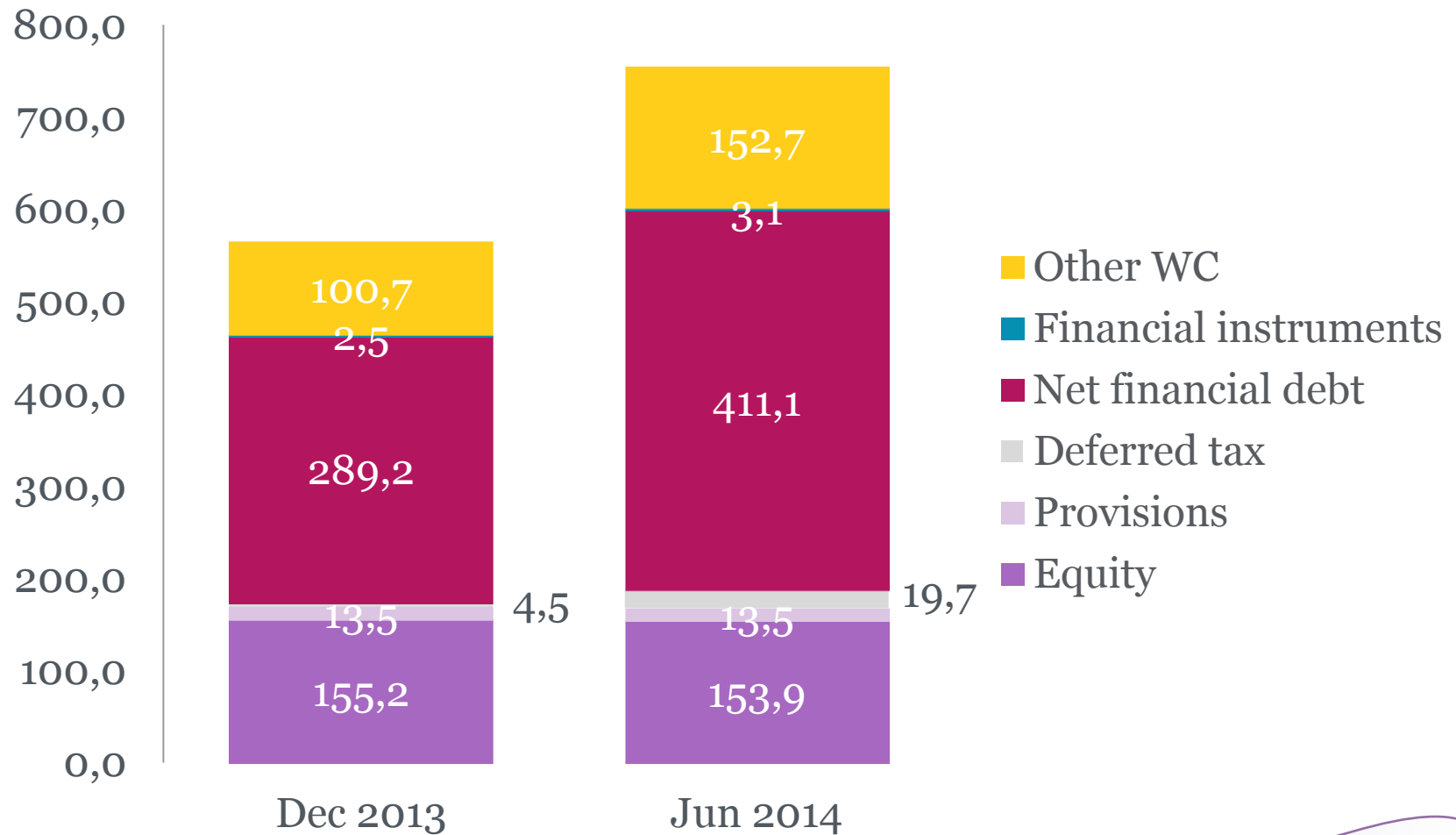


Balance sheet: Assets



5) Excluding net debt for discontinued operations.

Balance sheet: Liabilities



Outlook 2014



Outlook 2014

Arseus expects a turnover from continuing operations of at least € 435 million with an REBITDA margin from continuing operations of 26% in 2014

Thank You

