

KAKEN Pharmaceutical Co., Ltd.



<http://www.kaken.co.jp>

February 2018

Profile

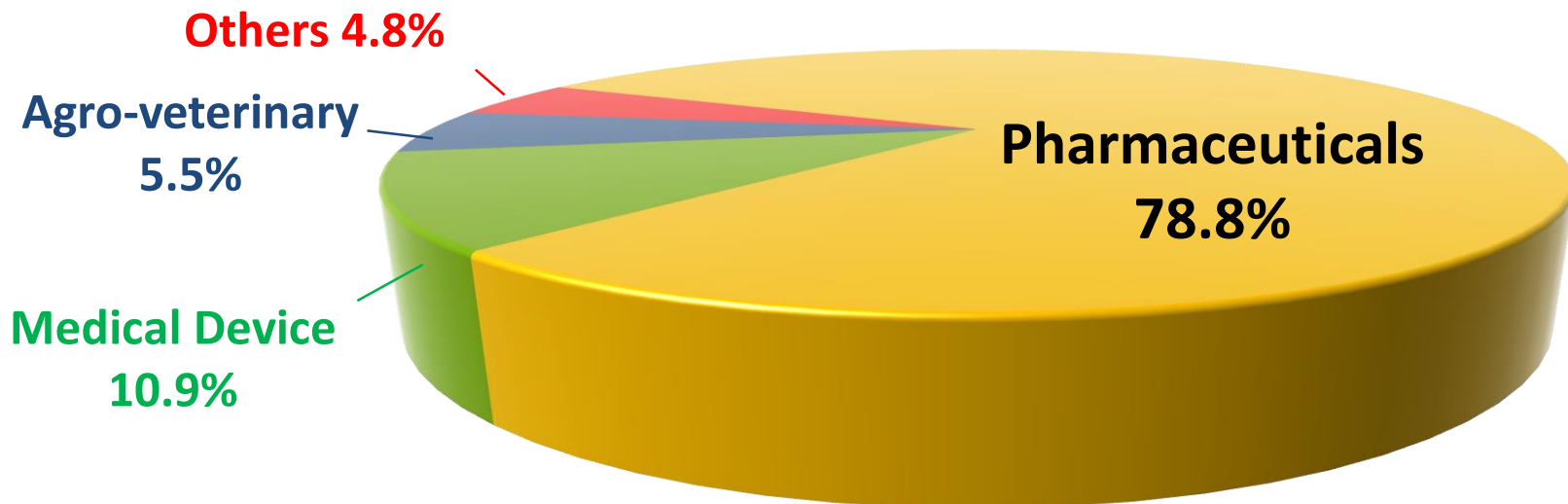
Head Office : Tokyo, Japan

Founded : March 1, 1948

Employees : 1,397 (as of Mar. 2017)

Net Sales : JPY 101.5 Billion (FY2016, ended Mar. 2017)

Business : Pharmaceuticals & Agro-veterinary Products



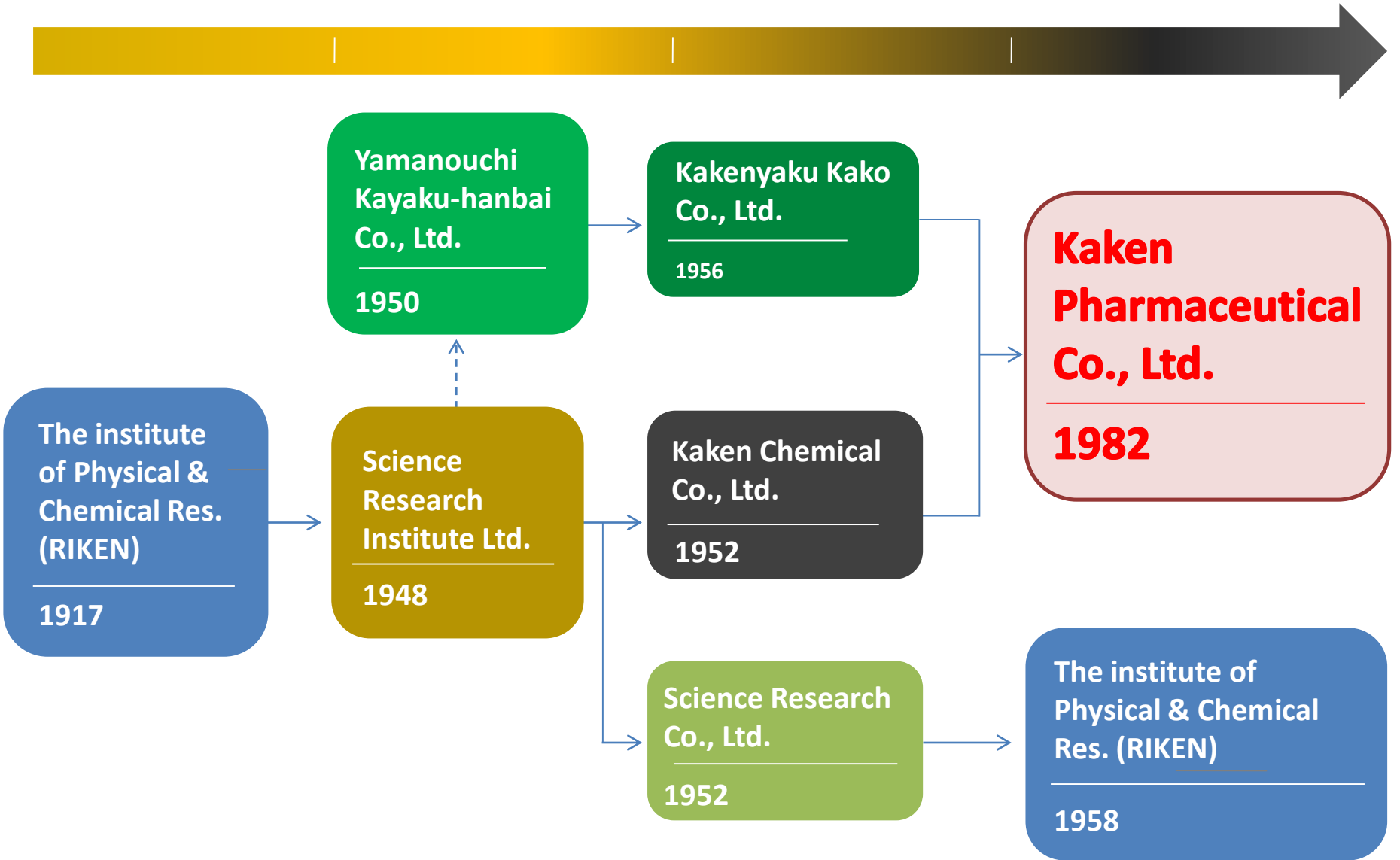
Philosophy



*Bringing Smiles
to Everyone*

- **Creating joy for patients**
 - **Creating joy as a company**
 - **Creating joy for our employees**
-
- **Kaken helps improve the quality of life for patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.**

History



Locations

Kyoto Research Laboratories



Head office (Tokyo)

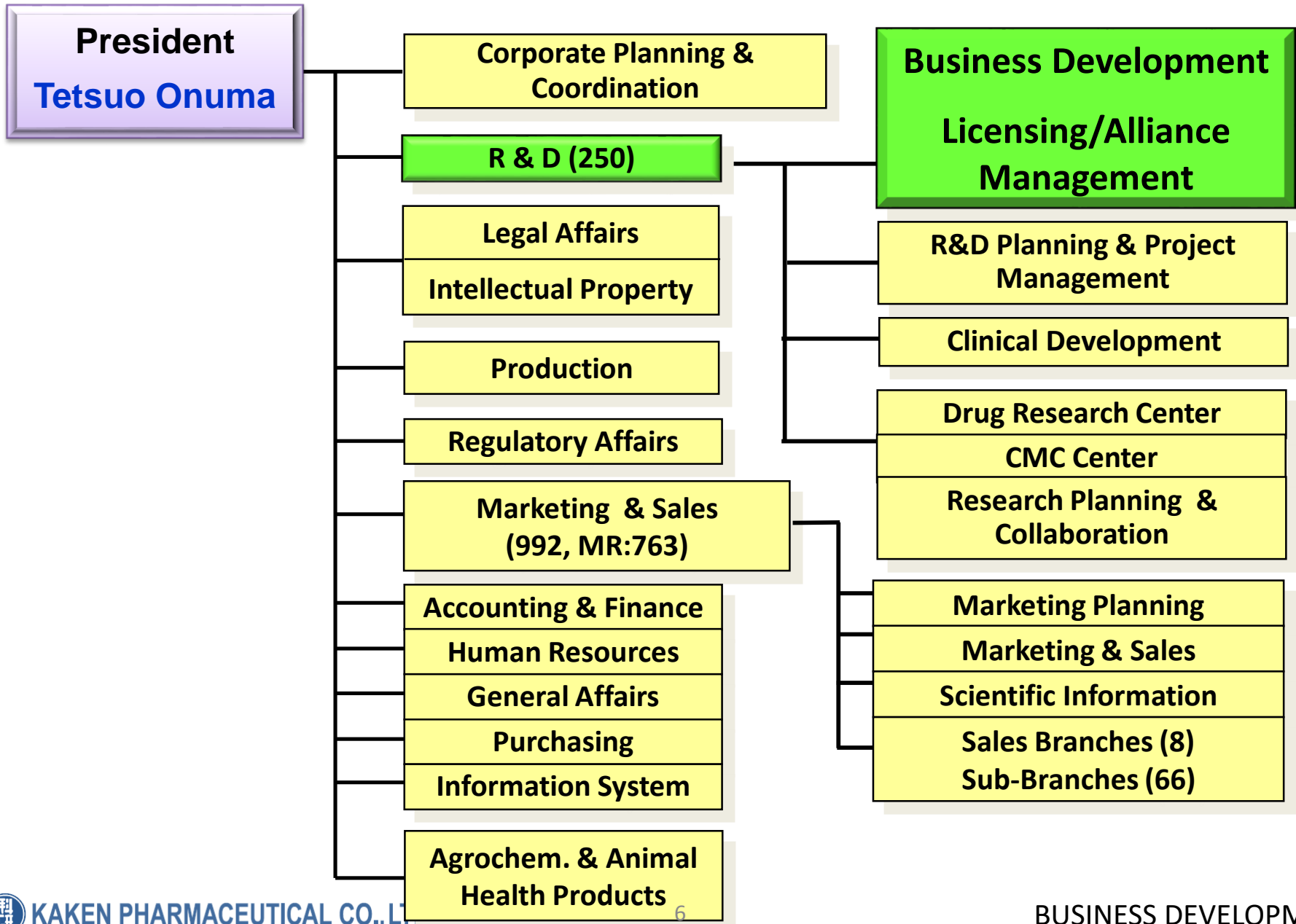


Shizuoka Research Laboratories
Shizuoka Plant



Sales offices: 8 branches (●) and 66 sub-branches

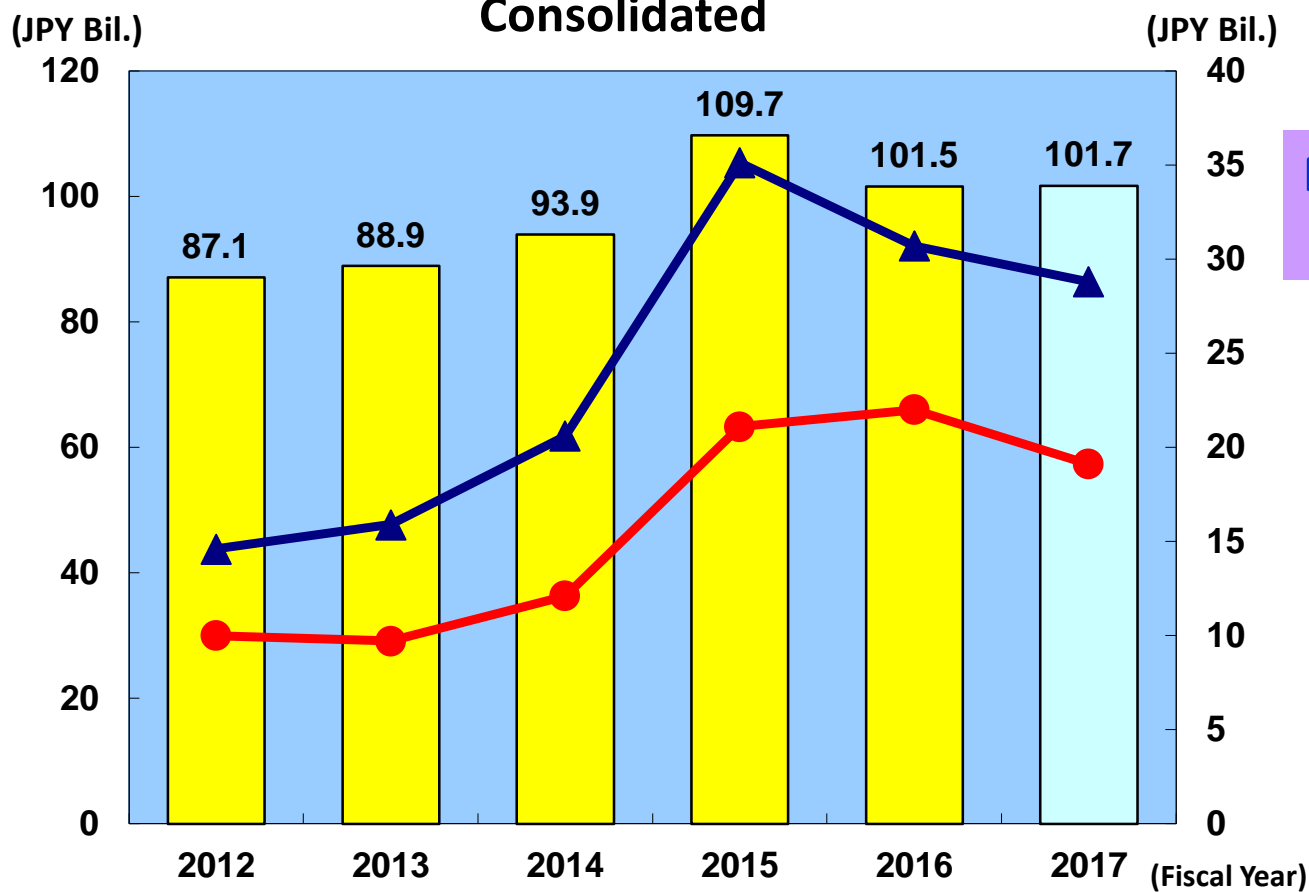
Organization



Financial Information

FY 2016: JPY 101.5 Bil. (US \$1.01 Bil., \$1=¥100, €894 Mil., €1=¥113)

Consolidated



**Medium-term
business plan 2018**

Net Sales ≥ JPY 110 Bil.

Net Sales Operating Income Net Income

Products Sales (FY2016)

	Brand Name <i>Generic Name</i>	Indication / Description	Sales (NHI)	
			JPY Bil.	(US\$Mil.)
1	Artz <i>Purified Sodium Hyaluronate</i>	OA, RA (Intra-articular)	32.3	(299)
2	Clenafin <i>Efinaconazole</i>	Onychomycosis	23.7	(221)
3	Seprafilm <i>Sodium Hyaluronate and CMC</i>	Preventing Abdominal Adhesions	12.3	(114)
4	Lipidil <i>Fenofibrate</i>	Anti-hyperlipidemia	4.9	(45)
5	Fiblast Spray <i>Trafermin (rh-bFGF)</i>	Pressure Sores, Dermal Ulcers	4.1	(38)
6	Adofeed <i>Flurbiprofen</i>	Pain / NSAID Poultice	2.4	(23)
7	Procylin <i>Beraprost Sodium</i>	Chronic Artery Occlusive Disease	2.3	(21)
8	Ebrantil <i>Urapidil</i>	Hypertension, Dysuria	2.2	(20)
9	Clexane <i>Enoxaparin Sodium</i>	Venous Thromboembolism	1.5	(14)
10	Pronase MS <i>Pronase</i>	Endoscopic flushing	1.1	(10)

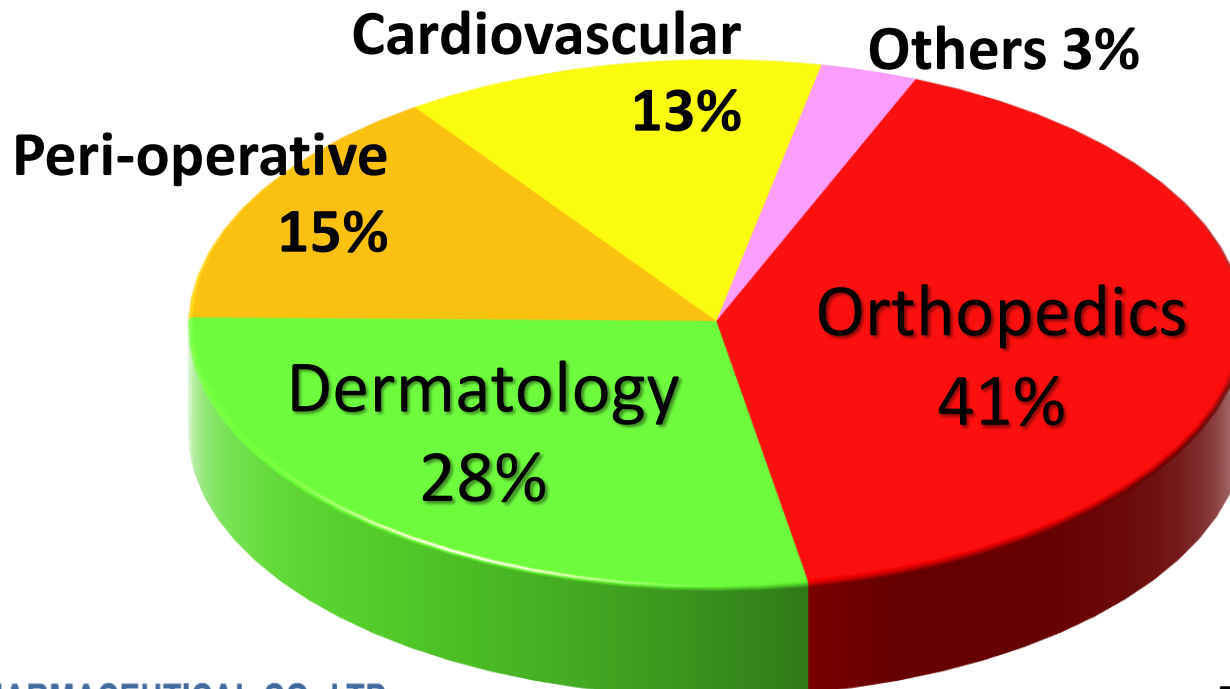


Sales by Therapeutic Category (FY2016)

Products Portfolio

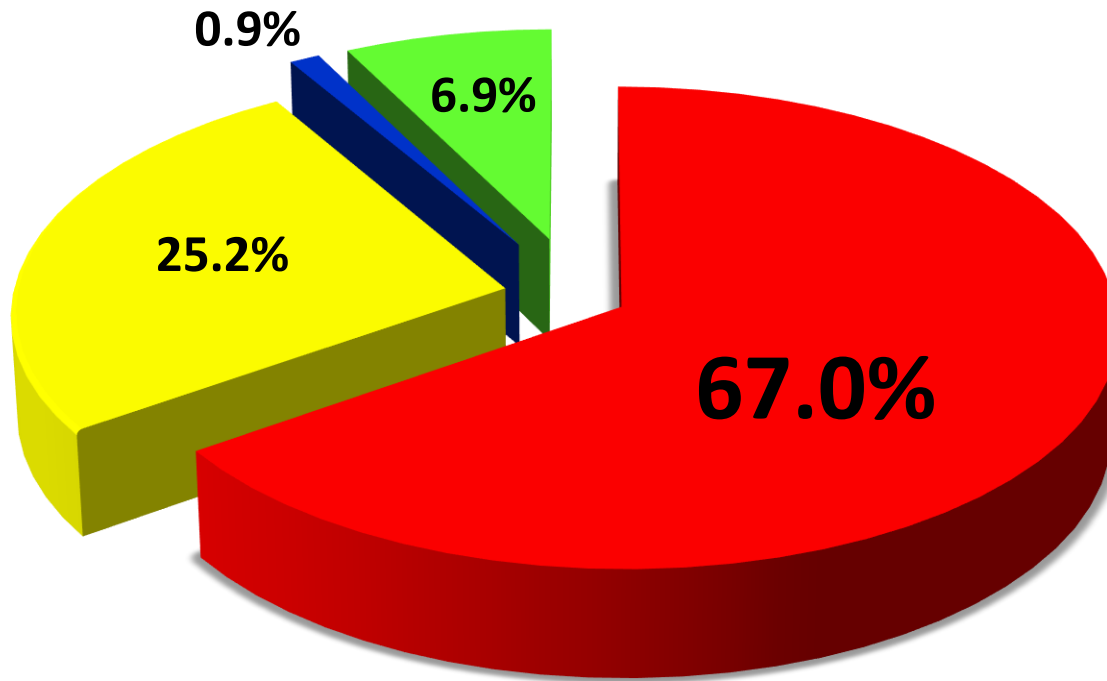
Orthopedics		Dermatology	Peri-operative	Cardiovascular		Others	
Artz Artz Dispo Adofeed Brufen	Loxoprofen Alendronate	Clenafin Fiblast Spray Mentax	Seprafilm Ropion Clexane	Procylin Lipidil Ebrantil Berasus	Amlodipine Prink Pravastain Gluconsan Clopidgrel	Pronase MS Proheparum	Eyecare Rabeprazole Rebamipide Donepezil Pranlukast

Sales of Generics : ¥11.9 Bil.



Artz

No. 1 Sales Share of HA Products for OA



Disposable Syringe Formulation

Strength of Kaken in Dermatology

Key Milestones in Dermatology



Korakuen Stadium !



1953 Asretan



1988 Derimain



1968 Dermacid



2004 Mentax Spray

2001 Fiblast

1992 Mentax Cream



2014 Clenafin



Clenafin/Jublia (KP-103)

- topical onychomycosis treatment -

Clenafin

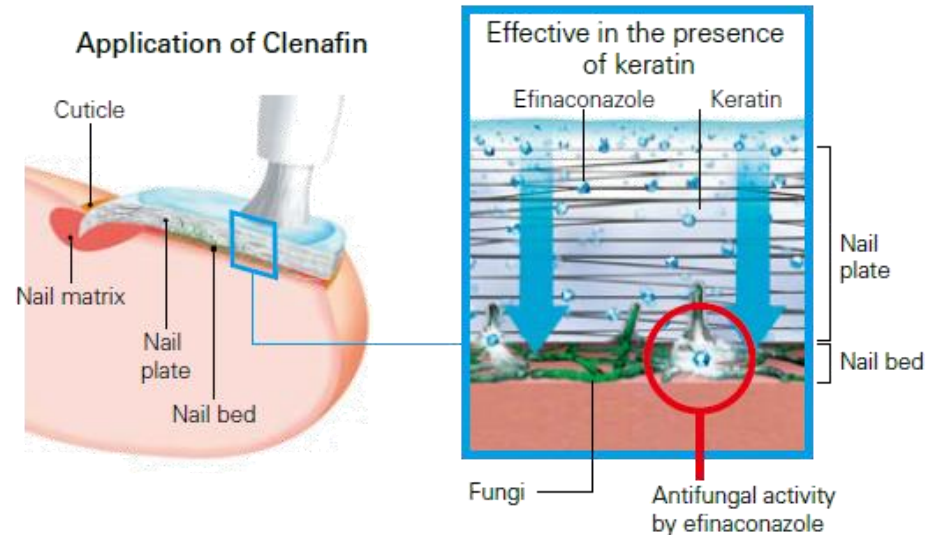
Topical onychomycosis treatment



Launched in 2014

- Kaken-original triazole antifungal.
- Broad anti-fungal spectrum and high nail permeability
- Successful Global PIII clinical trial (US, JP, Canada)
- Approved in Canada (2013), US, and Japan (2014) and Korea (2017).
- Successful initial penetration in the Japanese market

Action Mechanism of Clenafin (Efinaconazole)



Fiblast Spray and Regroth

- Innovative products for tissue regeneration -

Fiblast Spray

Wound-healing product



Launched in 2001

Regroth

Periodontal regeneration product



Launched in 2016

- Trafermin, recombinant human basic FGF (rh-bFGF), as an API.
- rh-bFGF promotes angiogenesis and granulation formation.
- Fiblast Spray is the world's first human recombinant bFGF product for dermal ulcer.
- Regroth is the first regenerative medicine for periodontitis in the world.

Pipeline

STAGE	PRODUCT	API	INDICATION / DESCRIPTION
NDA	SI-6603	Condoliase	Lumbar Disc Herniation (Marketing Right from Seikagaku)
Phase IIb (PIIb/US)	BBI-4000	mAChR antagonist (Topical)	Hyperhidrosis
Phase II	KAG-308	EP4 agonist	Ulcerative Colitis
Pre-IND (Marketed/EU PIII/US)	KMW-1 (NexoBrid®)	Proteolytic Enzyme	Removal of eschar with thermal burn
Pre-IND	KP-607	Antifungal agent	Onychomycosis

Recent Licensing Activities

in-license

bFGF (Worldwide Right)
Novartis (ex-Chiron)

Anti- α 9 Integrin Abs
Gene Techno Science

Clexane (Distribution/Japan)
Sanofi K.K.

SI-6603 (Distribution/Japan)
Seikagaku

BBI-4000 (Japan/Asia Right)
Brickell Biotech, Inc. (US)

NexoBrid (Japan Right)
MediWound, Ltd. (Israel)

Desloratadine (Co-promotion/Japan)
Kyorin

Multi-specific Antibody
(collaboration research),
Numab AG (Switzerland)



out-license

Fiblast Spray (China)
Beijing Tide

Fiblast Spray (Korea)
Daewoong Pharma.

KP-103 (US/EU)
DPSI (Valeant)

KP-103 (ROW excl. JPN, PRC, ROC, KOR)
DPSI (Valeant)

Jublia (Tech Transfer)
DPSI (Valeant)

Trafermin ENT (Japan/Korea/US)
Nobel Pharma

KP-103 (Korea)
Dong-A ST

KP-103 (Taiwan)
Tai Tien

International Partners

EUROPE

Aesica
BASF
Farmak
Rotta / Madaus
Nordmark
Novartis
Sanofi
Takeda / Nycomed
Numab

U.S.A.

Abbott
Bayer
Brickell Biotech
J&J / Scios
Mylan
Pfizer
Valeant / DPS

ASIA/others

Beijing Tide
Daewoong
Dong-A ST
Hikma
JW Shinyak
MediWound
Perrigo
Sam Oh
Tai Tien
Yungjin

Partners in Japan



Partnering Interests

R&D Collaboration / Marketing Alliance

Orthopedics (Inflammation/Pain)

RA / OA / Arthritis Pain / Low-back Pain

Dermatology

Dermatitis / Acne / Psoriasis

Mycology

Topical / Systemic

Peri-operative

Medical Device

Others

Gynecology, Ophthalmology, Niche etc