



**KAKEN PHARMACEUTICAL CO., LTD.**

# **IR Meeting**

## **Fiscal 2016**

(Year Ended March 31, 2017)

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# Comments:

- **The assumptions made in this document are based on available data current at May 2017 and on the rationale of Kaken Pharmaceuticals.**
- **Preceding the launch of any new drug, much time and money is spent on development. Drug development is based on numerous trials which test for effectiveness and safety. The development of some drugs is abandoned during this process.**
- **The “Development Status” is based on the development plans available in May 2017. Accordingly, the status may change in accordance with progress in the development plans.**
- **These financial highlights may not be in accordance with normal U.S. and international accounting standards.**

# Main Points for Fiscal 2016 (ended March 31, 2017)

- Increase in sales of Clenafin ( +8.8%, year on year )
- Decrease revenue by 7.5% due to impact of the NHI drug price revision, decrease in Jublia-related revenue, etc.
- Increase in net income ( +4.1%, year on year )
- Fifteenth consecutive year of increased dividends and share buybacks
  - Annual dividends 150.00 yen per share (up 4.00 yen on a post-share consolidation basis)
  - Undertook share buybacks totaling 0.53million shares, (3.5 billion yen), bringing total outstanding shares to 40,871 thousand shares

## ~Topics~

- Acquired regulatory approval for the manufacturing and sale of "REGROTH", a medicinal product for periodontal regeneration
- Licensed "CLENAFIN," a topical formulation for Onychomycosis, to Dong-A St Co., Ltd., South Korea
- Started co-promoting "DESALEX," an anti-allergic therapeutic agent, with Kyorin Pharmaceutical

# Consolidated Performance in FY2016 (ended March 31, 2017)

(Millions of yen, rounded down)

	FY2015	FY2016	Change	Change (%)	FY2016 (Est.)*	Achieved (%)
Net sales	109,730	101,479	▲ 8,250	92.5	106,100	95.6
Cost of sales	47,580	44,539	▲ 3,041	93.6	46,400	96.0
Selling, general and administrative expenses	26,490	26,745	254	101.0	30,800	86.8
R&D expenses	5,883	6,450	566	109.6	10,200	63.2
Operating income	35,146	30,707	▲ 4,439	87.4	28,900	106.3
Ordinary income	35,365	30,981	▲ 4,384	87.6	29,100	106.5
Income before income taxes	35,292	31,092	▲ 4,199	88.1	29,000	107.2
Net income	21,143	22,017	873	104.1	20,800	105.9

\* FY2016 (Est.) : 12<sup>th</sup> May 2017

# Breakdown of Consolidated Net Sales

(Millions of yen, rounded down)

	FY2015	FY2016	Change	Change (%)
Pharmaceuticals and medical devices (sales to medical institutions)	90,849	85,404	▲ 5,444	94.0
Agrochemicals	5,620	5,629	8	100.2
Real estate rental	2,338	2,386	47	102.0
Other	10,921	8,059	▲ 2,862	73.8
Sales of Jublia*	5,722	2,469	▲ 3,253	43.1
Total	109,730	101,479	▲ 8,250	92.5

(\* including sales of API and finished product, royalty revenue, milestone revenue and initial payment)

# Sales Breakdown of Pharmaceuticals and Medical Devices

(Millions of yen, rounded down)

	FY2015	FY2016	Change (%)
Artz	30,760	28,978	94.2
Clenafin	19,868	21,624	108.8
Seprafilm	11,262	11,036	98.0
Lipidil	4,526	4,430	97.9
Fiblast Spray	3,617	3,700	102.3
Generic products (total)	13,292	11,903	89.6

# Consolidated Balance Sheets / Consolidated Cash Flows

## Consolidated Balance Sheets

(Millions of yen, rounded down)

	FY2015	FY2016	Change
Current assets	88,991	90,494	1,502
Non-current assets	43,999	44,565	565
<b>Total assets</b>	<b>132,991</b>	<b>135,060</b>	<b>2,068</b>
Current liabilities	33,861	24,020	-9,840
Non-current liabilities	9,255	8,384	870
<b>Total liabilities</b>	<b>43,116</b>	<b>32,405</b>	<b>-10,711</b>
<b>Total net assets</b>	<b>89,875</b>	<b>102,655</b>	<b>12,779</b>

### Major Changes

#### ◆ Assets:

Cash and cash equivalents: 43,767million yen  
(+2,023 million yen )

#### ◆ Liabilities:

Interest-bearing debt: 3,875 million yen

#### ◆ Net assets:

Retained earnings: 84,331 million yen  
(+15,722 million yen)

Treasury stock: -19,813 million yen  
(-3,512 million yen )

## Consolidated Cash Flows

	FY2015	FY2016	Change
Net cash provided by (used in) operating activities	27,067	15,327	-11,739
Net cash provided by (used in) investing activities	-4,105	-3,503	602
Net cash provided by (used in) financing activities	-5,984	-9,800	-3,816
<b>Cash and cash equivalents at end of period</b>	<b>41,744</b>	<b>43,767</b>	<b>2,023</b>

### Major Changes

#### ◆ Net cash provided by (used in) operating activities:

Income before income taxes: 31,092 million yen

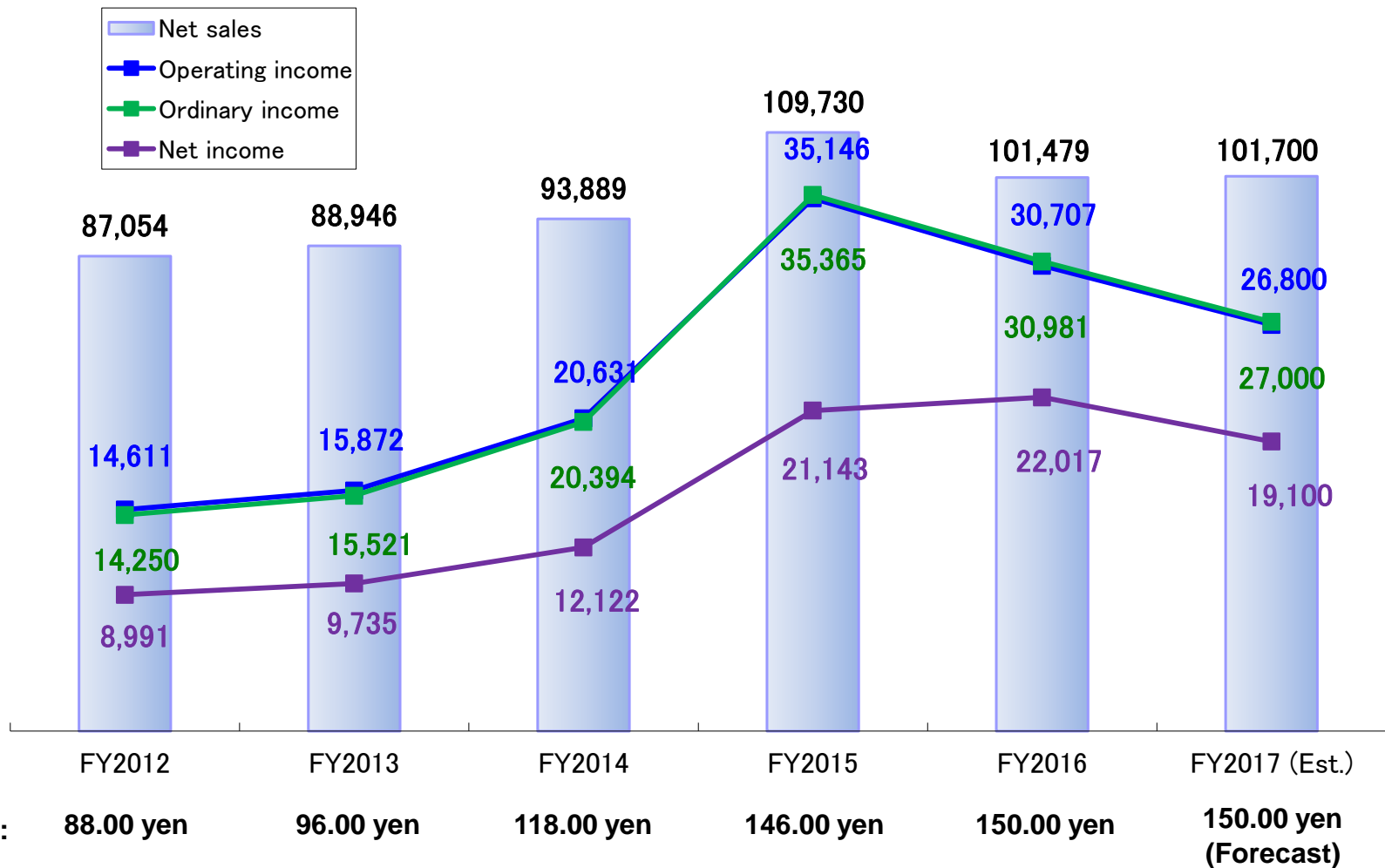
#### ◆ Net cash provided by (used in) investing activities:

Purchase of property, plant and equipment:  
2,166 million yen

#### ◆ Net cash provided by (used in) financing activities:

Cash dividends paid: 6,288 million yen

# Consolidated Performance



\* Common shares were consolidated in the ratio of 1 share for every 2 shares as of October 1, 2015. Annual dividends per share is shown on a post-share consolidation basis.



# Development Status

Code	Indication	Stage	Remarks
KAG-308	Ulcerative colitis	PII	Developed jointly with Asahi Glass Co., Ltd.; Oral-use prostaglandin analog
BBI-4000	Primary focal hyperhidrosis	PII	Licensed from Brickell Biotech, Inc.; Topical anticholinergic
KMW-1	Removal of eschar with thermal burns	Preparing for clinical trial	Licensed from MediWound Ltd.; Topically-applied enzymatic product Overseas product name : NexoBrid

Licensing agreements:

Terminated contracts with Sunstar Inc. (dental field) and Olympus Corporation (wound healing applications), to which it licensed out bFGF in the US and Europe.

## Consolidated Performance Forecast for FY2017 (ending March 2018)

	FY2016	FY2017 (Est.)	Change	Change (%)
Net sales	101,479	101,700	221	100.2
Operating income	30,707	26,800	▲ 3,907	87.3
Ordinary income	30,981	27,000	▲ 3,981	87.1
Income before income taxes	31,092	27,000	▲ 4,092	86.8
Net income	22,017	19,100	▲ 2,917	86.8
R&D expenses	6,450	10,900	4,450	169.0

# Sales Forecast for Pharmaceuticals and Medical Devices

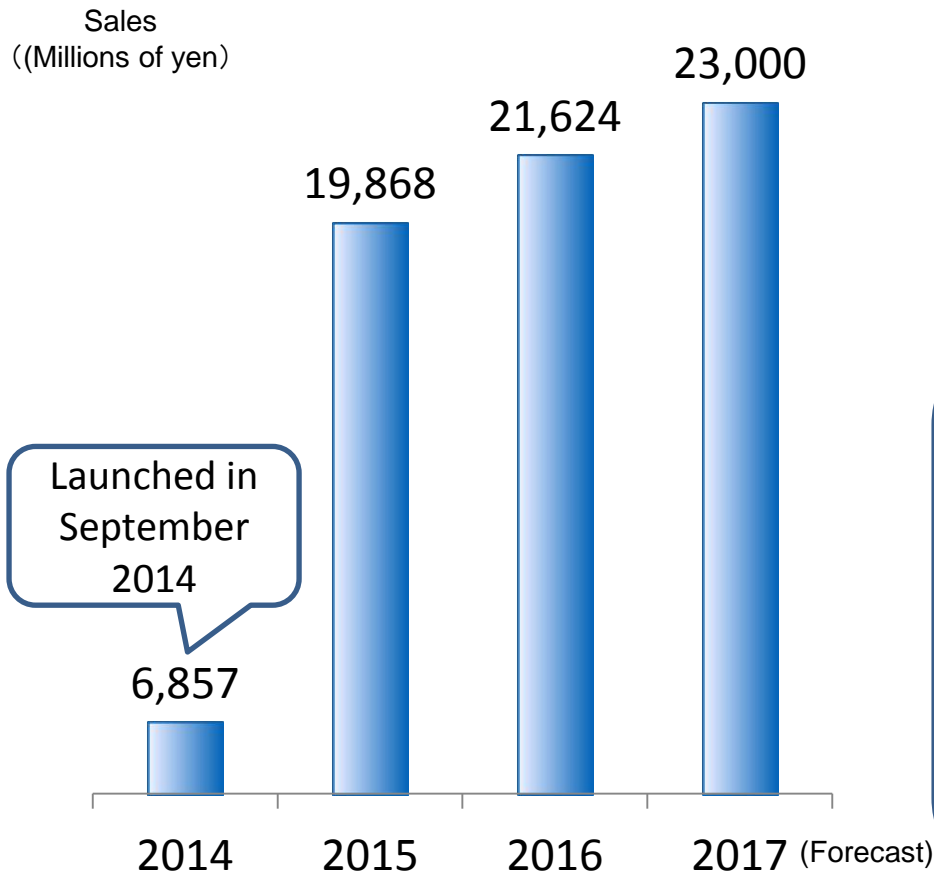
(Millions of yen, rounded down)

	FY2016	FY2017 (Est.)	Change (%)
Artz	28,978	29,700	102.5
Clenafin	21,624	23,000	106.4
Seprafilm	11,036	11,200	101.5
Lipidil	4,430	4,600	103.8
Fiblast Spray	3,700	3,800	102.7
Generic products (total)	11,903	12,000	100.8

# Domestic pharmaceuticals and medical devices

## Topical onychomycosis treatment

### Clenafin



Results for FY2016: 108.8%, year on year  
Growth owing to an increase in prescriptions to new patients

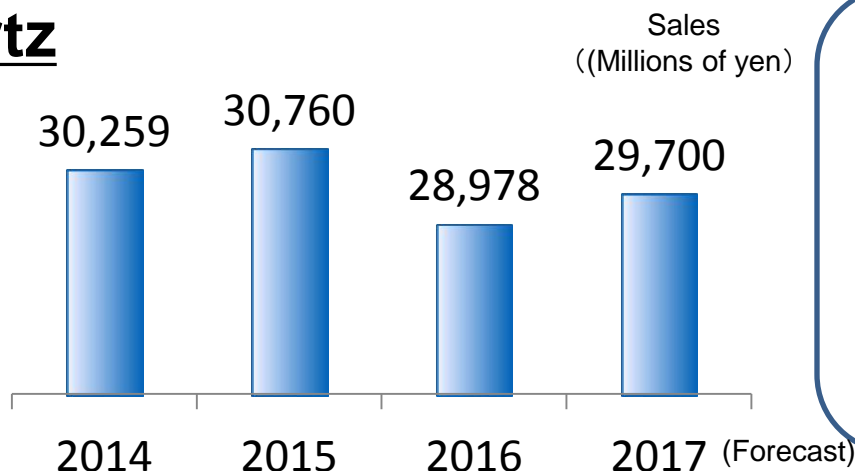
Forecasts for FY2017: 106.4%, year on year  
Aim to expand the market by capturing prescription demand from potential patients

- Disease awareness activities for patients (Newspaper ads, public lectures, etc.)
- Strengthen providing information to dermatologists
- Disease awareness activities targeting doctors in other departments (Recommend diagnostic collaborations with dermatologists)

# Domestic pharmaceuticals and medical devices

## Anti-osteoarthritis product

### Artz

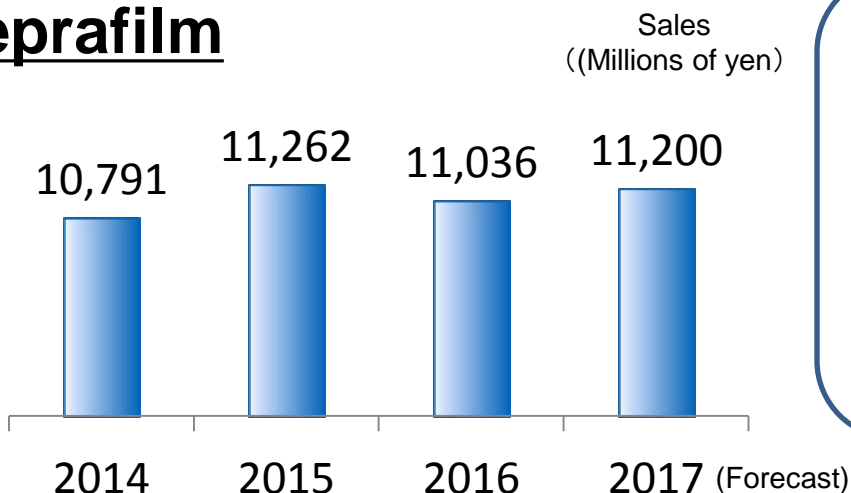


Results for FY2016: 94.2%, year on year  
Despite impact from NHI drug price revisions, alleviate a portion of impact with growth in sales volume

Forecasts for FY2017: 102.5%, year on year  
Continue to focus on expanding market share by pushing forward with market penetration of new formulation released in April 2016

## Anti-adhesive absorbent barrier

### Seprafilm



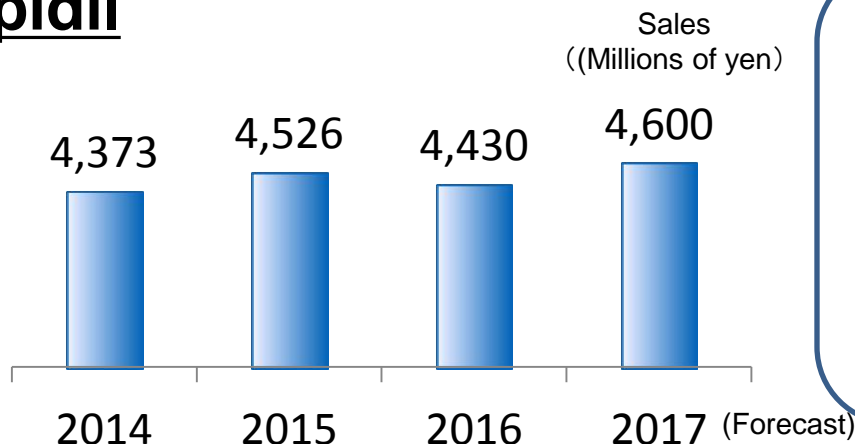
Results for FY2016: 98.0% year on year  
Impact from shift to laparoscopic surgery

Forecasts for FY2017: 101.5% year on year  
Aim to boost understanding of methods of use and efficacy for laparoscopic surgery and cesarean section

# Domestic pharmaceuticals and medical devices

## Anti-hyperlipidemia product

### Lipidil

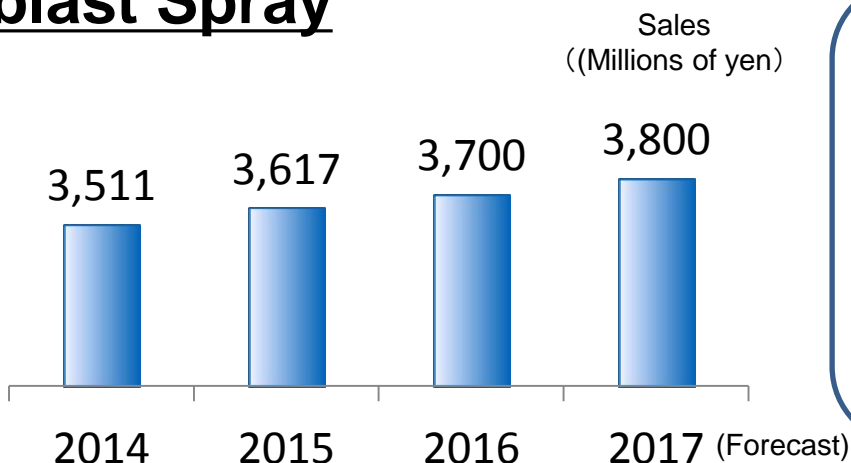


Results for FY2016 : 97.9%, year on year  
Despite impact from NHI drug price revisions, alleviate a portion of impact with growth in sales volume

Forecasts for FY2017: 103.8% year on year  
Improve understand of efficacy by employing related guidelines, including the Guidelines for the Treatment of Diabetes 2016

## Wound-healing product

### Fiblast Spray



Results for FY2016: 102.3%, year on year  
Expanded the significance for use, such as using the Guidelines for the Treatment of Burn Injuries, which were revised in March 2015

Forecasts for FY2017: 102.7% year on year  
Strengthen activities to provide information using wound guidelines, including the Guidelines for the Treatment of Burn Injuries

# Medium-term business plan 2018

**Establish growth platform that eyes the future**

**[Priority measure-1]  
Enhancement of pipeline**

**[Priority measure-2]  
Maximize Value for Clenafin & new products  
Strengthen of ales bases and boost efficiency  
for existing products**

**[Priority measure-3]  
Foster personnel with strong  
creativity**

~ Target figures ~  
Consolidated net sales for Fiscal 2018: 110 billion yen

# Key Topic-1: Enhancement of Pipeline

## 1. Strengthen drug discovery capabilities

- Plan to focus on themes that leverage our experience, technologies, and platforms mainly in the following domains

Inflammation &  
allergy

Mycosis

Pain

Perioperative

- Continue to consider new research themes
- Expand range of joint researches

## 2. Effectively use business opportunities from outside

- Licensing-in targets, opportunities mainly in domains where Kaken has a strong presence (orthopedic surgery, dermatology)

**KMW-1 (NexoBrid), a medicinal product for the removal of eschar with thermal burns, was licensed in April 2016**



# Key Topic-2: Maximize value for Clenafin & new products

## Strengthen and boost efficiency and sales bases for existing products

### ◆ Domestic ◆

## 1. Clenafin

**Recommend as early treatment by boosting recognition as a treatment for onychomycosis**

- (1) Disease awareness for patients and recommendation of consultation at dermatologists carried out by DTC
- (2) Disease awareness through public lectures (implemented in FY2016)



## 2. New products

- ~ Medicinal product for periodontal regeneration REGROTH ~
- Filed application on Oct. 1, 2015; Approved on Sep. 28, 2016
  - Sales launched in Dec. 2016; Begin providing information from university hospitals, etc.
  - Start information providing from Apr. 2017 to all dentists with experience in periodontal surgery



**Full-fledged start of domestic information providing of world's first periodontal regeneration medicine**

## 3. Existing products

Further enhance presence by strengthening sales bases and boosting efficiency in areas of expertise

# Key Topic-2: Maximize value for Clenafin & new products

## Strengthen and boost efficiency and sales bases for existing products

### ◆ Overseas ◆

## 1. Clenafin (Jublia)

### (1) North America market

- Valeant: Review and strengthen structure in dermatology domain (increase sales staff, etc.)
- Strengthen cooperation with Kaken (set up opportunities for high-level comprehensive discussions)

### (2) Kaken territory

- Korea: Licensed out (May 2016) to Dong-A ST and application under review by NDA. Market launch scheduled for 2017.
- China and Taiwan: Considering filing application to regulatory authorities and finding licensing partners

### (3) Valeant territory outside the US and Canada

- Currently in discussions with Valeant to begin sales in regions in Europe and Asia, etc.

## 2. Regroth, Fiblast Spray

⇒ Start searching for new partner to pursue overseas expansion