**February 7,2022** 

Supplementary Documents of
Consolidated Financial Results for
the Third Quarter of
the Year Ending in March 31, 2022 (FY2021)



Stock code: 4886 (TSE)

**ASKA Pharmaceutical Holdings Co., Ltd.** 

### **Statements of Income (Consolidated)**

\*The figures announced as ASKA Pharmaceutical Co., Ltd.

(Millions of yen)

	*FY2020 Apr - Dec Actual	FY2021 Apr - Dec Actual	Actual +/-	Growth +/-
Net sales	43,350	44,179	829	1.9%
Operating profit	3,776	4,677	901	23.9%
Ordinary profit	3,227	4,790	1,563	48.4%
Profit attributable to owners of parent	2,451	4,082	1,631	66.5%

#### Major factors for the increase in sales

- ✓ Significant growth among the OB/GYN products of RELUMINA and FREWELL, as well as continuous robust sales for THYRADIN and RIFXIMA within internal medicine.
- ✓ Steady growth of animal drug products as well as feed additives within the total animal health business.

#### Factors for the increase in net income

✓ An extraordinary gain was recorded for the sale and transfer of land and buildings owned by the Company.

### **Net Sales by Business (Consolidated)**

\*The figures announced as ASKA Pharmaceutical Co., Ltd.

(Millions of yen)

	*FY2020 Apr - Dec Actual	FY2021 Apr - Dec Actual	Breakdown	Actual +/-	Growth +/-
Pharmaceutical drugs	39,711	39,685	89.8%	-26	-0.1%
Animal health drugs	3,561	4,377	9.9%	816	22.9%
Others	77	116	0.3%	39	50.6%
Total	43,349	44,178	100.0%	829	1.9%

#### **Negative Growth Factors for the Pharmaceutical Drugs**

✓ Compared to the previous fiscal year, no upfront payments are expected to be recorded for the current fiscal year.

#### **Sales of Main Products**

(Millions of yen)

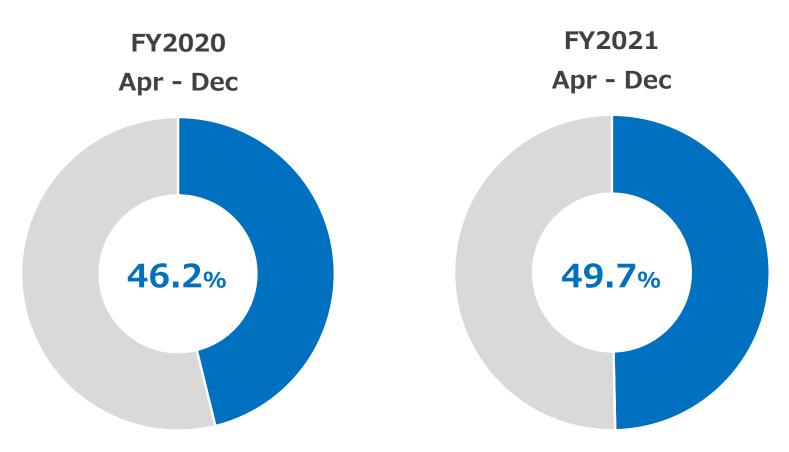
Area	Products (generic name)	FY2020 Apr - Dec	FY2021 Apr - Dec		FY2021	
		Actual	Actual	YOY (%)	Forecast	YOY (%)
M II	CANDESARTAN *1, *2 (candesartan)	9,603	9,795	102.0%	12,056	97.8%
	THYRADIN (levothyroxine)	5,572	5,842	104.8%	7,326	101.6%
Internal Medicine	RIFXIMA (rifaximin)	3,379	3,795	112.3%	4,815	111.1%
al Te	MERCAZOLE (thiamazole)	1,084	1,144	105.5%	1,434	102.4%
	AMLODIPINE *1 (amlodipine)	998	848	85.0%	1,051	81.2%
	RELUMINA (relugolix)	4,365	5,713	130.9%	7,643	133.9%
Gyı	FREWELL *1 (norethindrone/ethinylestradiol)	2,229	2,643	118.6%	3,222	109.1%
Obsterics Gynecology	ANGE (levonorgestrel/ethinylestradiol)	706	665	94.2%	797	87.7%
	MAGSENT *3 (magnesium sulfate)	724	703	97.1%	832	91.7%
	LUTEUM (progesterone)	405	475	117.3%	583	103.9%
Urology	LEUPRORELIN *1, *4 (leuprorelin)	3,629	3,932	108.3%	4,844	107.6%

<sup>\* 1</sup> Generic drugs \* 2 Including combination drugs \* 3 Total value of magnesium sulfate preparation

<sup>\* 4 1.88</sup>mg formulation is for gynecological indications only, but numerical figure is combined with the 3.75mg formulation

## **Sales Proportion of Brand-name Drugs**

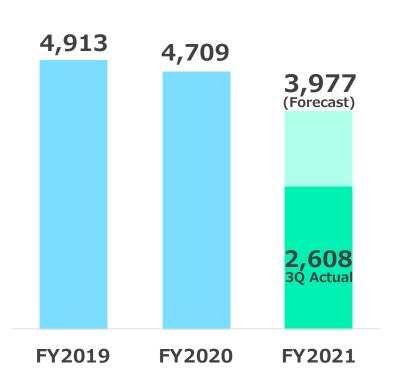
- Brand-name drugs
- **■** Generic drugs



#### **R&D Status**

#### Trend of R&D expenses

(Millions of yen)



#### As of February 7<sup>th</sup>, 2022

Development code (generic name) Indication	Status
TAK-385 (relugolix) Endometriosis	Approved
LF111 (drospirenone) Contraception	PhⅢ*¹
(option agreement) PMS/PMDD	Ph Ⅱ (IIT*²)
(option agreement) Cervical Dysplasia	Ph I / II (Korea)
L-105 (rifaximin) Hepatic encephalopathy (pediatrics)	PhⅡ/Ⅲ
AKP-009(ludaterone acetate) Benign Prostatic Hyperplasia	Ph II *3

<sup>\*1</sup> Initiated a PhⅢ study in December 2021.

<sup>\*2</sup> Investigator-initiated clinical trial

<sup>\*3</sup> Additional PhI trial at a higher dose started in September 2021.

## LF111 (drospirenone), a single-agent luteinizing hormone oral contraceptives (POP)

## Initiated a phase III clinical trial in Japanese women who seek contraception.

#### **Points**

As conventional oral contraceptives (COC) are a combination of estrogen and progestin, those who wish to take COC, but are at increased risk of side effects caused by estrogen as described below, may require cautions or maybe contraindicated from taking COC.

#### Those who are/have:

"Smokers, migraine headaches, breast feeding, obesity, hypertension, diabetes mellitus, history of thrombosis, etc."

Since POP does not contain any estrogen, the WHO has recommended that POP be recommended higher than COC for people that have such conditions as stated above.

The product has been approved and launched in European countries such as Spain, Norway and the United States.

# Providing a new OC treatment option for women seeking contraception.