

# KISSEI

Stock exchange listing: Tokyo Stock Exchange  
Stock code: 4547

**Supplementary  
Explanatory Materials on  
Financial Results for  
the Nine Months Ended  
December 31, 2023**

January 30, 2024

 **KISSEI PHARMACEUTICAL CO., LTD.**

# Table of Contents

<b>[Excerpts from “Explanation of Operating Results” of the Quarterly Financial Results]</b>	..... P 1
<b>I. Consolidated Statements of Income</b>	..... P 2
<b>II. Trends in Main Product Sales</b>	..... P 3
<b>III. R&amp;D Pipeline (In-house)</b>	..... P 4
<b>IV. R&amp;D Pipeline (Out-licensing)</b>	..... P 4

Note:

- The forward-looking statements herein are based on the information available and the Company’s analysis of various trends as of January 2024. Actual results may differ greatly from these statements due to business risks and uncertainties.

## [Excerpts from “Explanation of Operating Results” of the Quarterly Financial Results]

- Net sales

Net sales of the Pharmaceutical Business were ¥48,616 million, an increase of 11.4% year on year. As for pharmaceuticals in Japan, in addition to the increase of sales of TAVNEOS® Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, and CAROGRA® Tablets, a treatment for ulcerative colitis, both of which were launched in FY2022, the sales of Beova® Tablets, an overactive bladder treatment, and TAVALISSE® Tablets, a treatment for chronic idiopathic thrombocytopenic purpura launched in April 2023, as well as co-promotion fees and other items increased. These factors contributed to the year-on-year increase in net sales. In addition, “KORSUVA® IV Injection Syringe,” a treatment for pruritis in dialysis patients, which the Company had been jointly developing with Maruishi Pharmaceutical Co., Ltd., was launched in December 2023.

Net sales of the Information Services Business were ¥6,132 million, an increase of 7.3% year on year, net sales of the Construction Business were ¥2,443 million, an increase of 37.8% year on year, and net sales of the Merchandising Business were ¥666 million, an increase of 32.6% year on year.

- Profit

Regarding profit, the Company recorded a higher operating profit, ordinary profit, and profit attributable to owners of parent due to an increase in net sales as well as an improvement in the cost of sales ratio and a decrease in selling, general and administrative expenses centering on R&D expenses. The Company also recorded a gain on sale of securities and a gain on valuation of securities as non-operating income and a gain on sale of investment securities as extraordinary income.

- R&D

The Company continues to promote R&D for products under each theme to move on to the next development stage. In the meantime, the Company temporarily withdrew the application for marketing approval in Japan for a treatment for spinocerebellar degeneration Rovatirelin (generic name, development code: KPS-0373) in July 2023 and now is in consideration on the possibility of conducting additional clinical trials.

Overseas, regarding Linzagolix (generic name), a treatment for uterine fibroids and endometriosis, preparations are now underway by Theramex (U.K.), the licensee, for launch in Europe during FY2024 as a treatment for uterine fibroids. In addition, the sublicensing agreement with Inmagine Biopharmaceuticals (China), which had been granting rights to develop and market fostamatinib (generic name, development code: R788), a treatment for chronic idiopathic thrombocytopenic purpura, in China, was terminated in December 2023.

# I. Consolidated Statements of Income

(Million yen)

Item	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
	Nine months ended December 31, 2022	Full year	Nine months ended December 31, 2023	YoY	Full year (forecast)	YoY
Net sales	51,635	67,493	57,859	12.1 %	77,500	14.8 %
Pharmaceutical Business	43,641	56,243	48,616	11.4 %	65,000	15.6 %
Pharmaceuticals	36,235	47,077	41,414	14.3 %	54,500	15.8 %
Therapeutic and Care Foods	2,716	3,461	2,776	2.2 %	3,600	4.0 %
Technical Fees*1	970	1,053	649	(33.1) %	1,900	80.4 %
Other*2	3,719	4,650	3,775	1.5 %	5,000	7.5 %
Information Services Business	5,717	8,285	6,132	7.3 %	8,400	1.4 %
Construction Business	1,773	2,343	2,443	37.8 %	3,300	40.8 %
Merchandising Business	502	621	666	32.6 %	800	28.8 %
[Export sales included in net sales]	[3,741]	[4,584]	[3,470]	[(7.3) %]	[5,600]	[22.2 %]
Cost of sales	26,249	35,118	29,294	11.6 %	39,300	11.9 %
[Cost of sales ratio]	[50.8]	[52.0]	[50.6]		[50.7]	
Gross profit	25,385	32,374	28,565	12.5 %	38,200	18.0 %
Selling, general and administrative expenses	24,892	33,503	24,400	(2.0) %	33,200	(0.9) %
R&D expenses	7,643	10,391	6,762	(11.5) %	9,400	(9.5) %
[Ratio to net sales]	[14.8]	[15.4]	[11.7]		[12.1]	
Operating profit (loss)	492	(1,129)	4,164	745.9 %	5,000	—
Non-operating income	1,673	1,837	2,067	23.5 %	2,000	8.9 %
Interest and dividend income	1,260	1,402	1,265	0.4 %		
Other	413	434	802	94.2 %		
Non-operating expenses	52	109	131	153.0 %	300	175.2 %
Interest expenses	15	20	13	(10.4) %		
Other	36	89	118	221.7 %		
Ordinary profit	2,113	598	6,100	188.6 %	6,700	—
Extraordinary income	6,879	13,086	5,032	(26.8) %	7,000	(46.5) %
Extraordinary losses	2	4	32	—	200	—
Profit before income taxes	8,990	13,680	11,100	23.5 %	13,500	(1.3) %
Income taxes - current	940	2,113	1,727	83.7 %	2,500	18.3 %
Income taxes - deferred	1,305	932	920	(29.5) %	900	(3.4) %
Profit attributable to non-controlling interests	77	105	115	48.7 %	100	(4.8) %
Profit attributable to owners of parent	6,667	10,528	8,337	25.0 %	10,000	(5.0) %
[Comprehensive income]	[(2,342)]	[(4,229)]	[11,697]	[—]		

\*1: Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties.

\*2: Includes revenue from supply to domestic sales partners and revenue from co-promotion fees.

## II. Trends in Main Product Sales

(Million yen)

Product name	Fiscal year	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
		Nine months ended December 31, 2022	Full year	Nine months ended December 31, 2023	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment <b>Beova®</b>		8,591	11,795	11,482	33.7%	15,800	34.0%
DESMOPRESSIN Formulations <b>MINIRIN MELT®, etc.*1</b>		2,929	3,703	2,904	(0.9)%	3,450	(6.8)%
Dysuria Treatment <b>URIEF®</b>		1,818	2,345	1,628	(10.4)%	2,100	(10.4)%
Hyperphosphatemia Treatment <b>P-TOL®</b>		4,480	5,665	4,196	(6.3)%	5,800	2.4%
Treatment for Pruritis in Dialysis Patients <b>KORSUVA®</b>		—	—	244	—	500	—
Treatment for Renal Anemia <b>Darbepoetin Alfa BS Injection [JCR]</b>		3,470	4,386	3,246	(6.5)%	4,100	(6.5)%
Treatment for Renal Anemia <b>Epoetin Alfa BS Injection [JCR]</b>		2,459	3,055	1,874	(23.8)%	2,300	(24.7)%
Treatment for Diabetes <b>GLUBES®, GLUFAST®</b>		3,220	4,061	3,023	(6.1)%	3,800	(6.4)%
Treatment for Diabetes <b>MARIZEV®</b>		847	1,059	854	0.8%	1,200	13.3%
Treatment of Dry Mouth Symptoms <b>SALAGEN®</b>		857	1,073	785	(8.5)%	1,000	(6.8)%
Treatment for MPA*2 and GPA*3 <b>TAVNEOS®</b>		597	1,029	3,746	527.3%	5,000	385.9%
Treatment for Ulcerative Colitis <b>CAROGRA®</b>		373	500	879	135.7%	1,400	180.0%
Treatment for Chronic ITP*4 <b>TAVALISSE®</b>		—	21	584	—	700	—

\*1: MINIRIN MELT®, DESMOPRESSIN Intranasal, DESMOPRESSIN Nasal Spray, and DESMOPRESSIN I.V. Injection

\*2: Microscopic polyangiitis

\*3: Granulomatosis with polyangiitis

\*4: Idiopathic thrombocytopenic purpura

### III. R&D Pipeline (In-house)

(As of January 2024)

Generic name / Development code	Expected indications	Category	Development stage	Development classification
CG0070	Non-muscle-invasive bladder cancer	Oncolytic Viral Therapy	Phase III	In-licensed / CG Oncology (U.S.)
Linzagolix / KLH-2109	Uterine fibroids	GnRH receptor antagonist	Phase III	Kissei
	Endometriosis		Phase II	Kissei
KDT-3594	Parkinson's disease	Dopamine receptor agonist	Phase II	Kissei
KSP-0243	Ulcerative colitis		Phase II	Kissei

\* Rovatirelin (spinocerebellar degeneration):

Withdrew the application (July 2023) and considering the possibility of conducting additional clinical trials

\* Change from previous release (November 2023):

KORSUVA<sup>®</sup>: Approved → Launched on December 13, 2023 (deleted)

### IV. R&D Pipeline (Out-licensing)

(As of January 2024)

Generic name / Development code	Expected indications	Category	Countries & Regions	Development company	Development stage
Linzagolix	Uterine fibroids	GnRH receptor antagonist	EU	Theramex (U.K.)	Approved
			China	Bio Genuine (China)	Phase III
			Taiwan	Synmosa Biopharma (Taiwan)	NDA preparation
	Endometriosis		EU	Theramex (U.K.)	Phase III
			China	Bio Genuine (China)	Phase III
Silodosin	Dysuria associated with benign prostatic hyperplasia	Alpha 1A adrenergic receptor antagonist	Vietnam, etc.	Eisai (Japan)	NDA
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	Korea	JW Pharmaceutical (Korea)	NDA
KDT-3594	Parkinson's disease	Dopamine receptor agonist	China, etc.	AffaMed Therapeutics (China)	Phase II

\* Changes from previous release (November 2023):

Fostamatinib (Korea): NDA preparation → NDA

Fostamatinib (China): Preparation for clinical trial → Terminated the sublicensing agreement with Inmagene Biopharmaceuticals (deleted)