KISSEI

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

Supplementary Explanatory Materials on Financial Results for the Nine Months Ended December 31, 2024

February 3, 2025

KISSEI PHARMACEUTICAL CO., LTD.

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Note:

- The forward-looking statements herein are based on the information available and the Company's analysis of various trends as of February 2025. Actual results may differ greatly from these statements due to business risks and uncertainties.

[Excerpts from "Overview of Operating Results for the Period under Review" of the Quarterly Financial Results]

• Net sales

Net sales of the Pharmaceutical Business were ¥56,572 million, an increase of 16.4% year on year. In addition to the sales of Beova® Tablets, an overactive bladder treatment, sales increased for four products (TAVNEOS® Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis; KORSUVA® IV Injection Syringe, a treatment for pruritus in dialysis patients, TAVALISSE® Tablets, a treatment for chronic idiopathic thrombocytopenic purpura; and CAROGRA® Tablets, a treatment for ulcerative colitis), which were launched during the period of the medium-term management plan, "PEGASUS," and revenue from technical fees, etc. also increased. These factors contributed to the year-on-year increase in net sales.
In addition, Linzagolix (generic name), which was discovered by the Company and licensed out to Theramex (U.K.), was launched to the market in Germany in September 2024 under the product name Yselty® for the indication of uterine fibroids, followed by the launch and preparations for launch in other European countries. Furthermore, in November 2024, an additional indication of endometriosis for this drug was approved. The Company recorded revenue from technical fees based on an agreement with Theramex in relation to these developments.
Net sales of the Information Services Business were ¥5,987 million, a decrease of 2.4% year on year, net sales of the Construction and Facility Maintenance Business were ¥2,394 million, a decrease of 2.0% year on year, and net sales of the Merchandising Business were ¥715 million, an increase of 7.4% year on year.

• Profit

Regarding profit, the Company recorded higher operating profit due to an increase in net sales as well as improvement in the cost of sales ratio, despite an increase in selling, general and administrative expenses centering on R&D expenses. However, the Company's ordinary profit decreased because of a decrease in non-operating income, while profit attributable to owners of parent increased. The Company also recorded gain on sale of investment securities as extraordinary income. Additionally, in relation to the termination of the domestic co-promotion agreement with Ferring Pharmaceuticals Co., Ltd. for Minirin Melt® and Desmopressin formulations on March 31, 2025, the reversal of long-term prepaid expenses (impairment losses on marketing rights) was recorded as extraordinary losses.

• R&D

Linzagolix (generic name, development code: KLH-2109), which was discovered by the Company, achieved primary endpoints in two Phase III clinical trials in Japan for the indication of uterine fibroids, and the Company is preparing for an NDA. Additionally, the Company has also begun preparations for Phase III clinical trials in Japan for the additional indication of endometriosis. Preparations have also begun for additional Phase III clinical trials in Japan for a treatment for spinocerebellar degeneration Rovatirelin (generic name, development code: KPS-0373). In September 2024, the Company entered into an agreement with Rigel Pharmaceuticals, Inc. (U.S.) to acquire exclusive rights to develop and market the acute myeloid leukemia (AML) drug Olutasidenib (generic name) in Japan, South Korea, and Taiwan.
In the overseas development of Linzagolix, the Company granted exclusive rights to develop and market Linzagolix in South Korea to JW Pharmaceutical (South Korea) in June 2024. In September 2024, the Company notified Bio Genuine (China) of the termination of the licensing agreement granting it rights to develop and market the treatment in China and other countries.
In January 2025, the Company entered into a sub-licensing agreement with Tai Tien Pharmaceuticals Co., Ltd. (Taiwan, a consolidated subsidiary of Mitsubishi Tanabe Pharma Corporation) granting it rights to develop and market in Taiwan Fostamatinib (generic name, domestic brand name: TAVALISSE® Tablets), a treatment for chronic idiopathic thrombocytopenic purpura, which the Company in-licensed from Rigel Pharmaceuticals, Inc. In January 2025, JW Pharmaceutical (South Korea), the sublicensee of the drug in South Korea, has obtained marketing authorization for the same indication.
The development of KSP-0243 (development code), a treatment for ulcerative colitis originally discovered by the Company, was discontinued due to failure to meet primary endpoints in an early Phase II clinical trials.

I. Consolidated Statements of Income

(Million yen)

Item \ Fiscal year	Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025			
	Nine months ended December 31,2023	Full year	Nine months ended December 31, 2024	YoY	Full year (forecast)	YoY
Net sales	57,859	75,579	65,669	13.5 %	86,500	14.4 %
Pharmaceutical Business	48,616	63,348	56,572	16.4 %	74,000	16.8 %
Pharmaceuticals	41,414	54,237	48,252	16.5 %	63,500	17.1 %
Therapeutic and Care Foods	2,776	3,545	2,787	0.4 %	3,600	1.6 %
Technical Fees*1	649	714	1,876	188.8 %	2,100	194.1 %
Other*2	3,775	4,850	3,655	(3.2) %	4,800	(1.0) %
Information Services Business	6,132	8,399	5,987	(2.4) %	8,500	1.2 %
Construction and Facility Maintenance Business	2,443	3,022	2,394	(2.0) %	3,150	4.2 %
Merchandising Business	666	809	715	7.4 %	850	5.1 %
[Export sales included in net sales]	[3,470]	[4,510]	[4,805]	[38.5 %]	[6,300]	[39.7 %]
Cost of sales	29,294	38,238	32,551	11.1 %	43,200	13.0 %
[Cost of sales ratio]	[50.6]	[50.6]	[49.6]		[49.9]	
Gross profit	28,565	37,341	33,118	15.9 %	43,300	16.0 %
Selling, general and administrative expenses	24,400	33,324	28,880	18.4 %	38,300	14.9 %
R&D expenses	6,762	9,474	10,095	49.3 %	13,000	37.2 %
[Ratio to net sales]	[11.7]	[12.5]	[15.4]		[15.0]	
Operating profit	4,164	4,017	4,238	1.8 %	5,000	24.5 %
Non-operating income	2,067	2,329	1,392	(32.7) %	1,500	(35.6) %
Interest and dividend income	1,265	1,319	1,328	5.0 %		
Other	802	1,009	63	(92.0) %		
Non-operating expenses	131	203	331	151.4 %	500	146.3 %
Interest expenses	13	18	15	11.7 %		
Other	118	185	316	167.7 %		
Ordinary profit	6,100	6,142	5,298	(13.1) %	6,000	(2.3) %
Extraordinary income	5,032	8,349	9,329	85.4 %	10,500	25.8 %
Extraordinary losses	32	43	3,054	–	300	597.7 %
Profit before income taxes	11,100	14,449	11,574	4.3 %	16,200	12.1 %
Income taxes - current	1,727	3,263	2,634	52.5 %	4,300	31.8 %
Income taxes - deferred	920	(104)	84	(90.8) %	150	–
Profit attributable to non-controlling interests	115	128	14	(87.3) %	50	(60.9) %
Profit attributable to owners of parent	8,337	11,160	8,840	6.0 %	11,700	4.8 %
[Comprehensive income]	[11,697]	[36,044]	[(723)]	[–]		

*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)

Fiscal year / Product name	Fiscal year ended March 31, 2023	Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025			
		Nine months ended December 31, 2023	Full year	Nine months ended December 31, 2024	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment **Beova®**	11,795	11,482	15,335	14,016	22.1 %	18,200	18.7 %
Treatment for MPA[*1] and GPA[*2] **TAVNEOS®**	1,029	3,746	5,161	6,753	80.2 %	8,800	70.5 %
Hyperphosphatemia Treatment **P-TOL®**	5,665	4,196	5,241	3,510	(16.3) %	4,800	(8.4)%
Treatment for Pruritus in Dialysis **KORSUVA®**	–	244	757	3,864	–	4,700	520.9 %
Treatment for Renal Anemia **Darbepoetin Alfa BS Injection [JCR]**	4,386	3,246	4,077	2,999	(7.6) %	3,600	(11.7)%
DESMOPRESSIN Formulations **MINIRIN MELT®, etc.**[*3]	3,703	2,904	3,662	2,770	(4.6) %	3,400	(7.1)%
Treatment for Diabetes **GLUBES®, GLUFAST®**	4,061	3,023	3,806	2,534	(16.2) %	3,300	(13.3)%
Treatment for Chronic ITP[*4] **TAVALISSE®**	21	584	818	1,637	180.1 %	2,500	205.6 %
Treatment for Renal Anemia **Epoetin Alfa BS Injection [JCR]**	3,055	1,874	2,336	1,421	(24.2) %	1,800	(22.9)%
Treatment for Ulcerative Colitis **CAROGRA®**	500	879	1,091	920	4.6 %	1,600	46.7 %
Dysuria Treatment **URIEF®**	2,345	1,628	2,076	877	(46.1) %	1,300	(37.4)%
Treatment for Diabetes **MARIZEV®**	1,059	854	1,073	747	(12.5) %	1,100	2.5 %

*1: Microscopic polyangiitis
*2: Granulomatosis with polyangiitis
*3: MINIRIN MELT®, DESMOPRESSIN Nasal Spray, and DESMOPRESSIN I.V. Injection
*4: Idiopathic thrombocytopenic purpura

III. R&D Pipeline (In-house)

(As of February 2025)

Generic name / Development code	Expected indications	Category	Development stage	Development classification
Linzagolix / KLH-2109	Uterine fibroids	GnRH receptor antagonist	NDA preparation	Kissei
	Endometriosis		Phase III preparation	Kissei
CG0070	Non-muscle-invasive bladder cancer	Oncolytic Viral Therapy	Phase III	In-licensed / CG Oncology (U.S.)
Rovatirelin / KPS-0373	Spinocerebellar degeneration	TRH receptor agonist	Phase III preparation	In-licensed / Shionogi (Japan)
KDT-3594	Parkinson's disease	Dopamine receptor agonist	Phase II	Kissei

* Changes from previous release (November 2024):
Linzagolix (endometriosis): Phase II → Phase III preparation
Rovatirelin (spinocerebellar degeneration): Under consideration on the possibility of conducting additional clinical trials → Phase III preparation
KSP-0243 (ulcerative colitis): Phase II→ Deletion (termination of development)

IV. R&D Pipeline (Out-licensing)

(As of February 2025)

Generic name	Expected indications	Category	Countries & Regions	Development company	Development stage
Linzagolix	Uterine fibroids	GnRH receptor antagonist	Australia	Theramex (U.K.)	NDA
			Taiwan	Synmosa Biopharma (Taiwan)	NDA
	Endometriosis		EU	Theramex (U.K.)	Approved
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	Korea	JW Pharmaceutical (Korea)	Approved
Silodosin	Dysuria associated with benign prostatic hyperplasia	Alpha 1A adrenergic receptor antagonist	Vietnam, etc.	Eisai (Japan)	NDA

* Changes from previous release (November 2024):
Linzagolix (endometriosis, EU): NDA → Approved
Fostamatinib (Korea): NDA → Approved