KISSEI

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

Supplementary Explanatory Materials on Financial Results for the Nine Months ended December 31, 2022

January 31, 2023

KISSEI PHARMACEUTICAL CO., LTD.

Table of Contents

Notes:

· The forward-looking statements herein are based on the information available and the Company's analysis of various trends as of January 2023. 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 ¥43,641 million, an increase of 4.1% year on year. In the midst of COVID-19 pandemic, we promoted a hybrid type of pharmaceutical information activities that effectively utilized various digital contents as well as the traditional physical interviews. As a result, sales of Beova® Tablets, an overactive bladder treatment, and Darbepoetin Alfa BS Injection [JCR] for the treatment of renal anemia increased, which, together with higher technical fees, export sales, and co-promotion fees, contributed to the year-on-year increase in net sales. CAROGRA® Tablets, a treatment for ulcerative colitis, which EA Pharma Co., Ltd. and the Company have jointly developed, was launched in May 2022 and TAVNEOS® Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis was launched in June 2022.

Net sales of the Information Services Business were ¥5,717 million, an increase of 1.8% year on year, net sales of the Construction Business were ¥1,773 million, a decrease of 14.9% year on year, and net sales of the Merchandising Business were ¥502 million, an increase of 12.7% year on year.

• Profit

Despite an increase in selling, general and administrative expenses, the Company recorded a higher operating profit and ordinary profit due to an increase in net sales and an improvement in the cost of sales ratio. Profit attributable to owners of parent decreased despite a gain on sale of investment securities.

• R&D

Regarding difelikefalin (generic name, development code: MR13A9), a treatment for pruritis in dialysis patients, which the Company is jointly developing with Maruishi Pharmaceutical Co., Ltd., an NDA was submitted by Maruishi Pharmaceutical in September 2022. Regarding fostamatinib (generic name, development code: R788), a treatment for chronic idiopathic thrombocytopenic purpura, which was in-licensed from U.S.-based Rigel Pharmaceuticals, Inc., the Company submitted an NDA in Japan in April 2022 and received marketing authorization approval in Japan in December 2022, and we have been promoting activities to provide drug information, spearheaded by the Rare Disease Project that is specialized in marketing of drugs for rare diseases, in preparation for launch under the brand name "TAVALISSE® Tablets 100 mg/150 mg" following listing in the NHI Drug Price Standard.

Regarding linzagolix (generic name, development code: KLH-2109), a treatment for uterine fibroids and endometriosis, which is a drug discovered by the Company, Phase III clinical trials are continuing for the indication of uterine fibroids in Japan.

Overseas, the license agreement between ObsEva SA(Switzerand) and the Company has been terminated as of the end of November,2022. Based on the agreement, certain rights contained in the sublicense agreement between ObsEva and Theramex (U.K.) for worldwide except North America and Asia have been automatically transferred to the Company. Currently, the Company and Theramex have proceeded with discussion about the terms and conditions of a new license agreement in preparation for Theramex's launch of the product in Europe in fiscal 2023. With ObsEva having withdrawn its NDA for linzagolix to the U.S. Food and Drug Administration (FDA) for the indication of uterine fibroids in August 2022, the Company is scrutinizing the data and others used for application in the U.S., and will decide its policy for the development of this agent in accordance with the results of the scrutiny.

With respect to the out-licensing of linzagolix in Asia, the Company granted exclusive development and commercialization rights in China to China-based Bio Genuine in September 2021 and similar exclusive rights in Taiwan to Synmosa Biopharma Corporation of Taiwan in November 2022.

I. Consolidated Statements of Income

(Million yen)

Item \ Fiscal year	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023			
	Nine Months Ended December 31, 2021	Full year	Nine Months Ended December 31, 2022	YoY	Full year (forecast)	YoY
Net sales	50,085	65,381	51,635	3.1 %	68,500	4.8 %
Pharmaceutical Business	41,939	54,147	43,641	4.1 %	57,500	6.2 %
Pharmaceuticals	35,510	45,792	36,235	2.0 %	47,600	3.9 %
Therapeutic and Care Foods	2,765	3,568	2,716	(1.8) %	3,600	0.9 %
Technical Fees*1	400	518	970	142.6 %	1,700	228.1 %
Other*2	3,263	4,268	3,719	14.0 %	4,600	7.8 %
Information Services Business	5,616	7,742	5,717	1.8 %	7,900	2.0 %
Construction Business	2,082	2,948	1,773	(14.9) %	2,400	(18.6) %
Merchandising Business	445	543	502	12.7 %	700	28.8 %
[Export sales included in net sales]	[2,723]	[3,713]	[3,741]	[37.4 %]	[5,300]	[42.7 %]
Cost of sales	25,976	34,143	26,249	1.1 %	34,400	0.8 %
[Cost of sales ratio]	[51.9]	[52.2]	[50.8]		[50.2]	
Gross profit	24,108	31,238	25,385	5.3 %	34,100	9.2 %
Selling, general and administrative expenses	24,402	32,640	24,892	2.0 %	33,600	2.9 %
R&D expenses	7,806	10,363	7,643	(2.1) %	10,500	1.3 %
[Ratio to net sales]	[15.6]	[15.9]	[14.8]		[15.3]	
Operating profit (loss)	(294)	(1,402)	492	–	500	–
Non-operating income	1,746	2,092	1,673	(4.2) %	1,700	(18.7) %
Interest and dividend income	1,381	1,586	1,260	(8.8) %		
Other	364	506	413	13.4 %		
Non-operating expenses	101	127	52	(48.7) %	100	(21.3) %
Interest expenses	17	23	15	(13.2) %		
Other	83	104	36	(56.2) %		
Ordinary profit	1,350	562	2,113	56.5 %	2,100	273.7 %
Extraordinary income	8,005	16,601	6,879	(14.1) %	12,010	(27.7) %
Extraordinary losses	643	656	2	(99.6) %	10	(98.5) %
Profit before income taxes	8,713	16,507	8,990	3.2 %	14,100	(14.6) %
Income taxes - current	1,929	4,017	940	(51.3) %	2,600	(35.3) %
Income taxes - deferred	(119)	(542)	1,305	–	600	–
Profit attributable to non-controlling interests	84	110	77	(8.1) %	100	(9.1) %
Profit attributable to owners of parent	6,819	12,921	6,667	(2.2) %	10,800	(16.4) %
Comprehensive income	[(15,268)]	[(13,764)]	[(2,342)]	[–]		

*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, 2022		Fiscal year ending March 31, 2023			
	Nine Months Ended December 31, 2021	Full year	Nine Months Ended December 31, 2022	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment **Beova®**	6,151	8,141	8,591	39.7%	12,000	47.4%
DESMOPRESSIN Formulations **MINIRIN MELT®, etc.**[*1]	3,132	3,965	2,929	(6.5)%	3,900	(1.6)%
Dysuria Treatment **URIEF®**	2,287	2,878	1,818	(20.5)%	2,300	(20.1)%
Hyperphosphatemia Treatment **P-TOL®**	4,555	5,784	4,480	(1.6)%	6,000	3.7%
Treatment for Renal Anemia **Darbepoetin Alfa BS Injection [JCR]**	2,823	3,730	3,470	22.9%	4,300	15.3%
Treatment for Renal Anemia **Epoetin Alfa BS Injection [JCR]**	3,011	3,834	2,459	(18.3)%	3,100	(19.1)%
Treatment for Diabetes **GLUBES®**	3,037	3,838	2,371	(21.9)%	3,100	(19.2)%
Treatment for Diabetes **GLUFAST®**	887	1,151	848	(4.4)%	1,000	(13.1)%
Treatment for Diabetes **MARIZEV®**	1,003	1,234	847	(15.5)%	1,100	(10.9)%
Treatment for MPA[*2] and GPA[*3] **TAVNEOS®**	–	–	597	–	800	–
Treatment for Ulcerative Colitis **CAROGRA®**	–	–	373	–	600	–
Treatment of Dry Mouth Symptoms **SALAGEN®**	1,151	1,412	857	(25.5)%	1,100	(22.1)%

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

III. R&D Pipeline (In-house)

(As of January 2023)

Product Name / Generic Name / Development Code	Expected Indications	Category	Development Stage	Development Classification
TAVALISSE® Tablets / Fostamatinib	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	Approved	In-licensed / Rigel Pharmaceuticals (U.S.)
Rovatirelin / KPS-0373	Spinocerebellar ataxia	TRH receptor agonist	NDA	In-licensed / Shionogi (Japan)
Difelikefalin / MR13A9	Uremic pruritus in dialysis patients	Kappa opioid receptor agonist	NDA	In-licensed / Co-development with Maruishi Pharmaceutical (Japan)
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

*Changes from previous release (November 2022): TAVALISSE® Tablets NDA → Approved

IV. R&D Pipeline (Out-licensing)

(As of January 2023)

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
			U.S.		
			China	Bio Genuine (China)	Phase I
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 preparation
			China, etc.	Inmagene Biopharmaceuticals (China)	Preparation for clinical trial
KDT-3594	Parkinson's disease	Dopamine receptor agonist	China, etc.	AffaMed Therapeutics (China)	Phase II

*Changes from previous release (November 2022): Linzagolix (uterine fibroids, China) Preparation for clinical trial → Phase III
Linzagolix (endometriosis, China) Preparation for clinical trial → Phase I