KISSEI

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

Supplementary Explanatory Materials on Financial Results for the Three Months ended June 30, 2022

August 1, 2022

KISSEI PHARMACEUTICAL CO., LTD.

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Notes:

· The forward-looking statements herein are based on the information available and the Company's analysis of various trends as of August 2022. 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 ¥13,915 million, a decrease of 0.1% 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 in addition to the traditional physical interviews. While sales of Beova® Tablets, an overactive bladder treatment, and Darbepoetin Alfa BS Injection [JCR] for the treatment of renal anemia increased, net sales decreased mainly because of the impact of the NHI drug price revision implemented in April 2022 and a decrease in export 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 ¥1,582 million, a decrease of 15.3% year on year, net sales of the Construction Business were ¥612 million, a decrease of 11.5% year on year, and net sales of the Merchandising Business were ¥175 million, an increase of 16.8% year on year.

- Profit

  Despite an improvement in the cost of sales ratio, operating profit decreased due to a decrease in net sales and an increase in selling, general and administrative expenses centering on R&D expenses. On the other hand, ordinary profit increased, and profit attributable to owners of parent decreased despite a gain on sale of investment securities.

- R&D

  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 a New Drug Application (NDA) in Japan in April 2022. 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 have been initiated for the indication of uterine fibroids in Japan.

  Overseas, ObsEva SA (Switzerland), which has exclusive development and commercialization rights worldwide, except certain Asian countries including Japan, to linzagolix, has announced that they have decided to commence composition proceedings. ObsEva has obtained marketing authorization from the European Commission for linzagolix in June this year. ObsEva has also contracted a sublicense agreement with Theramex (U.K.) to commercialize linzagolix in all countries except for North America and Asia. Under the terms of the license agreement of the Company and ObsEva, the Company terminates this agreement and obtains the assignment of sublicense agreement of Theramex and ObsEva. The Company will now lead the way to target the launch in Europe in the first quarter of 2023, and continue to move forward the global expansion of linzagolix.

I. Consolidated Statements of Income

(Million yen)

Fiscal year / Item	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023			
	1st quarter	Full year	1st quarter	YoY	Full year (forecast)	1st half (forecast)
Net sales	16,635	65,381	16,285	(2.1)%	68,000	31,000
Pharmaceutical Business	13,924	54,147	13,915	(0.1)%	57,000	25,500
Pharmaceuticals	12,010	45,792	11,800	(1.7)%	44,700	21,000
Therapeutic and Care Foods	874	3,568	862	(1.4)%	3,600	1,800
Technical Fees*1	74	518	106	43.4%	4,200	300
Other*2	965	4,268	1,146	18.8%	4,500	2,400
Information Services Business	1,869	7,742	1,582	(15.3)%	7,200	3,700
Construction Business	691	2,948	612	(11.5)%	3,300	1,500
Merchandising Business	150	543	175	16.8%	500	300
[Export sales included in net sales]	[1,086]	[3,713]	[825]	[(24.0)%]	[7,500]	[1,700]
Cost of sales	8,769	34,143	8,135	(7.2)%	33,700	16,100
[Cost of sales ratio]	[52.7]	[52.2]	[50.0]		[49.6]	[51.9]
Gross profit	7,866	31,238	8,150	3.6%	34,300	14,900
Selling, general and administrative expenses	7,573	32,640	8,019	5.9%	31,500	16,200
R&D expenses	2,189	10,363	2,425	10.8%	9,000	5,000
[Ratio to net sales]	[13.2]	[15.9]	[14.9]		[13.2]	[16.1]
Operating profit (loss)	293	(1,402)	130	(55.4)%	2,800	(1,300)
Non-operating income	645	2,092	699	8.5%	1,700	850
Interest and dividend income	585	1,586	591	1.1%		
Other	59	506	108	81.0%		
Non-operating expenses	174	127	23	(86.4)%	100	50
Interest expenses	5	23	5	(7.9)%		
Other	168	104	18	(89.1)%		
Ordinary profit (loss)	764	562	806	5.6%	4,400	(500)
Extraordinary income	3,531	16,601	1,334	(62.2)%	9,000	4,500
Extraordinary losses	22	656	0	(99.9)%	–	–
Profit before income taxes	4,273	16,507	2,141	(49.9)%	13,400	4,000
Income taxes - current	1,180	4,017	366	(69.0)%	2,800	800
Income taxes - deferred	(579)	(542)	119	–	500	150
Profit attributable to non-controlling interests	28	110	20	(26.6)%	100	50
Profit attributable to owners of parent	3,644	12,921	1,635	(55.1)%	10,000	3,000
Comprehensive income	(1,373)		1,890	–		

*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			
	1st quarter	Full year	1st quarter	YoY	Full year (forecast)	1st half (forecast)
Overactive Bladder Treatment **Beova®**	2,047	8,141	2,798	36.7%	11,000	4,600
DESMOPRESSIN Formulations **MINIRIN MELT®, etc.**[*1]	1,068	3,965	1,028	(3.8)%	3,900	1,900
Dysuria Treatment **URIEF®**	777	2,878	631	(18.8)%	2,200	1,100
Hyperphosphatemia Treatment **P-TOL®**	1,502	5,784	1,513	0.7%	6,300	3,100
Treatment for Renal Anemia **Darbepoetin Alfa BS Injection [JCR]**	912	3,730	1,088	19.3%	3,600	1,700
Treatment for Renal Anemia **Epoetin Alfa BS Injection [JCR]**	1,070	3,834	859	(19.7)%	2,200	1,200
Treatment for Diabetes **GLUBES®**	1,030	3,838	830	(19.4)%	3,400	1,700
Treatment for Diabetes **GLUFAST®**	270	1,151	295	9.3%	1,000	500
Treatment for Diabetes **MARIZEV®**	358	1,234	294	(17.9)%	1,200	600
Treatment for MPA[*2] and GPA[*3] **TAVNEOS®**	–	–	30	–	700	200
Treatment for Ulcerative Colitis **CAROGRA®**	–	–	86	–	350	150
Treatment of Dry Mouth Symptoms **SALAGEN®**	386	1,412	297	(23.0)%	1,100	550

*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 August 2022)

Generic Name / Development Code	Expected Indications	Category	Development Stage	Development Classification
Rovatirelin / KPS-0373	Spinocerebellar ataxia	TRH receptor agonist	NDA	In-licensed / Shionogi (Japan)
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	NDA	In-licensed / Rigel Pharmaceuticals (U.S.)
Difelikefalin / MR13A9	Uremic pruritus in dialysis patients	Kappa opioid receptor agonist	Phase III	In-licensed / Co-development with Maruishi Pharmaceutical (Japan) Primary endpoint achieved
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 (May 2022):
TAVNEOS®: Preparation for launch →Launched on June 7, 2022 (deleted)
CAROGRA®: Preparation for launch →Launched on May 30, 2022 (deleted)
Linzagolix (Uterine fibroids) →Phase III (newly listed)
KSP-0243: Phase I (Inflammatory bowel disease) →Phase II (Ulcerative colitis)

IV. R&D Pipeline (Out-licensing)

(As of August 2022)

Generic Name / Development Code	Expected Indications	Category	Countries & Regions	Development Company	Development Stage
Linzagolix	Uterine fibroids	GnRH receptor antagonist	EU	ObsEva SA (Switzerland)	Approved
			US		NDA
	Endometriosis		EU, US		Phase III
	Uterine fibroids, Endometriosis		China	Bio Genuine (China)	Preparation for clinical trial
Silodosin	Dysuria associated with benign prostatic hyperplasia	Alpha 1A adrenergic receptor antagonist	Vietnam, etc.	Eisai (Japan)	NDA
KDT-3594	Parkinson's disease	Dopamine receptor agonist	China, etc.	AffaMed Therapeutics (China)	Phase II
Bedoradrine	Acute exacerbation of asthma	Beta 2 adrenergic receptor agonist	US	MediciNova (U.S.)	Phase II
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	Korea	JW Pharmaceutical (Korea)	NDA preparation
			Hong Kong	Inmagene Biopharmaceuticals (China)	NDA
			China, etc.		Preparation for clinical trial

*Changes from previous release (May 2022):
Linzagolix (Uterine fibroids, EU): NDA →Approved
Fostamatinib (Hong Kong) →NDA (newly listed)