

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

**Supplementary
Explanatory Materials on
Financial Results for
the Three Months ended
June 30, 2023**

July 31, 2023

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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 July 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 ¥16,065 million, an increase of 15.4% year on year. As for pharmaceuticals in Japan, in addition to the increase of sales of CAROGRAM[®] Tablets, a treatment for ulcerative colitis, and TAVNEOS[®] Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, both of which were launched in the previous fiscal year, the sales of Beova[®] Tablets, an overactive bladder treatment, and TAVALISSE[®] Tablets, a treatment for chronic idiopathic thrombocytopenic purpura, which were launched in April 2023, as well as co-promotion fees and other items increased. These increases, together with higher export sales and revenue from supply to domestic sales partners and other items, contributed to the year-on-year increase in net sales.

Net sales of the Information Services Business were ¥2,285 million, an increase of 44.4% year on year, net sales of the Construction Business were ¥763 million, an increase of 24.7% year on year, and net sales of the Merchandising Business were ¥199 million, an increase of 13.7% year on year.

- Profit

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

- R&D

As for R&D, we continue to promote R&D for products under each theme to move on to the next development stage. 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 and other matters.

I. Consolidated Statements of Income

(Million yen)

Item	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
	1st quarter	Full year	1st quarter	YoY	Full year (forecast)	1st half (forecast)
Net sales	16,285	67,493	19,313	18.6 %	74,500	35,500
Pharmaceutical Business	13,915	56,243	16,065	15.4 %	62,500	29,500
Pharmaceuticals	11,800	47,077	13,748	16.5 %	51,500	25,000
Therapeutic and Care Foods	862	3,461	890	3.3 %	3,600	1,800
Technical Fees* ¹	106	1,053	99	(6.7) %	3,000	500
Other* ²	1,146	4,650	1,327	15.8 %	4,400	2,200
Information Services Business	1,582	8,285	2,285	44.4 %	7,900	3,700
Construction Business	612	2,343	763	24.7 %	3,300	1,900
Merchandising Business	175	621	199	13.7 %	800	400
[Export sales included in net sales]	[825]	[4,584]	[1,419]	[71.9 %]	[7,500]	[2,300]
Cost of sales	8,135	35,118	9,730	19.6 %	37,600	18,500
[Cost of sales ratio]	[50.0]	[52.0]	[50.4]		[50.5]	[52.1]
Gross profit	8,150	32,374	9,583	17.6 %	36,900	17,000
Selling, general and administrative expenses	8,019	33,503	7,949	(0.9) %	32,700	16,100
R&D expenses	2,425	10,391	2,201	(9.2) %	9,200	4,500
[Ratio to net sales]	[14.9]	[15.4]	[11.4]		[12.3]	[12.7]
Operating profit (loss)	130	(1,129)	1,633	—	4,200	900
Non-operating income	699	1,837	1,141	63.1 %	1,100	650
Interest and dividend income	591	1,402	661	11.9 %		
Other	108	434	479	343.6 %		
Non-operating expenses	23	109	62	162.4 %	100	50
Interest expenses	5	20	4	(12.2) %		
Other	18	89	57	214.4 %		
Ordinary profit	806	598	2,712	236.2 %	5,200	1,500
Extraordinary income	1,334	13,086	1,638	22.7 %	9,000	5,000
Extraordinary losses	0	4	1	—	—	—
Profit before income taxes	2,141	13,680	4,349	103.1 %	14,200	6,500
Income taxes - current	366	2,113	1,177	221.7 %	2,600	1,250
Income taxes - deferred	119	932	(151)	—	900	400
Profit attributable to non-controlling interests	20	105	57	176.2 %	100	50
Profit attributable to owners of parent	1,635	10,528	3,265	99.6 %	10,600	4,800
Comprehensive income		[1,890]	[4,653]	[146.2 %]		

*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 ended March 31, 2023		Fiscal year ending March 31, 2024			
	1st quarter	Full year	1st quarter	YoY	Full year (forecast)	1st half (forecast)
Overactive Bladder Treatment Beova®	2,798	11,795	3,735	33.5 %	16,200	7,500
DESMOPRESSIN Formulations MINIRIN MELT®, etc.*1	1,028	3,703	983	(4.4) %	3,450	1,700
Dysuria Treatment URIEF®	631	2,345	537	(14.8) %	1,900	1,000
Hyperphosphatemia Treatment P-TOL®	1,513	5,665	1,444	(4.5) %	5,800	2,900
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR]	1,088	4,386	1,057	(2.8) %	3,800	1,900
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR]	859	3,055	654	(23.8) %	2,300	1,200
Treatment for Diabetes GLUBES® and GLUFAST®	1,125	4,061	1,054	(6.4) %	3,800	2,000
Treatment for Diabetes MARIZEV®	294	1,059	293	(0.2) %	1,200	600
Treatment for Dry Mouth Symptoms SALAGEN®	297	1,073	272	(8.6) %	1,000	500
Treatment for MPA ^{*2} and GPA ^{*3} TAVNEOS®	30	1,029	948	—	3,200	1,300
Treatment for Ulcerative Colitis CAROGRA®	86	500	275	219.3 %	1,400	600
Treatment of Chronic ITP ^{*4} TAVALISSE®	—	21	117	—	400	100

*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 July 2023)

Generic name / Development code	Expected indications	Category	Development stage	Development classification
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 (May 2023):

Rovatisrelin (Spinocerebellar ataxia): NDA → Application has been withdrawn and the possibility of conducting additional clinical trials is under consideration (deleted from the table)

IV. R&D Pipeline (Out-licensing)

(As of July 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
	EU		Theramex (U.K.)	Phase III	
	China		Bio Genuine (China)	Phase III	
	Endometriosis				
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 (May 2023):

Linzagolix (Endometriosis, China): Phase I → Phase III