

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

**Supplementary
Explanatory Materials on
Financial Results for
the Six Months Ended
September 30, 2023**

November 6, 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 November 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 ¥30,765 million, an increase of 10.1% year on year. As for pharmaceuticals in Japan, in addition to the increase of sales of CAROGRA[®] 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 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.

Net sales of the Information Services Business were ¥4,133 million, an increase of 23.9% year on year, net sales of the Construction Business were ¥1,663 million, an increase of 33.0% year on year, and net sales of the Merchandising Business were ¥416 million, an increase of 25.1% 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

Regarding Difelikefalin (generic name, development code: MR13A9), a treatment for pruritis in dialysis patients, for which an NDA had been submitted in September 2022 by Maruishi Pharmaceutical Co., Ltd., the Company’s joint development partner, marketing authorization approval was obtained in September 2023, and the Company is preparing for the launch of the product under the brand name “KORSUVA[®] IV Injection Syringe 17.5µg, 25.0µg, and 35.0µg” following listing in the NHI Drug Price Standard. 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, the Company has revised the schedule for the launch of the product, and preparations are now underway by Theramex (U.K.), the licensee, for launch in Europe during FY2024 as a treatment for uterine fibroids.

I. Consolidated Statements of Income

(Million yen)

Item	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Net sales	32,864	67,493	36,978	12.5 %	77,500	14.8 %
Pharmaceutical Business	27,946	56,243	30,765	10.1 %	65,000	15.6 %
Pharmaceuticals	23,550	47,077	26,420	12.2 %	54,500	15.8 %
Therapeutic and Care Foods	1,766	3,461	1,763	(0.1) %	3,600	4.0 %
Technical Fees ^{*1}	220	1,053	171	(22.2) %	1,900	80.4 %
Other ^{*2}	2,410	4,650	2,410	0.0 %	5,000	7.5 %
Information Services Business	3,335	8,285	4,133	23.9 %	8,400	1.4 %
Construction Business	1,250	2,343	1,663	33.0 %	3,300	40.8 %
Merchandising Business	332	621	416	25.1 %	800	28.8 %
[Export sales included in net sales]	[2,407]	[4,584]	[2,268]	[(5.8) %]	[5,600]	[22.2 %]
Cost of sales	16,680	35,118	18,677	12.0 %	39,300	11.9 %
[Cost of sales ratio]	[50.8]	[52.0]	[50.5]		[50.7]	
Gross profit	16,184	32,374	18,300	13.1 %	38,200	18.0 %
Selling, general and administrative expenses	16,810	33,503	16,284	(3.1) %	33,200	(0.9) %
R&D expenses	5,200	10,391	4,499	(13.5) %	9,400	(9.5) %
[Ratio to net sales]	[15.8]	[15.4]	[12.2]		[12.1]	
Operating profit (loss)	(625)	(1,129)	2,015	–	5,000	–
Non-operating income	977	1,837	1,531	56.7 %	2,000	8.9 %
Interest and dividend income	742	1,402	728	(1.9) %		
Other	235	434	803	241.8 %		
Non-operating expenses	43	109	81	89.7 %	300	175.2 %
Interest expenses	10	20	9	(10.8) %		
Other	32	89	72	122.0 %		
Ordinary profit	308	598	3,465	–	6,700	–
Extraordinary income	4,111	13,086	4,054	(1.4) %	7,000	(46.5) %
Extraordinary losses	2	4	17	680.2 %	200	–
Profit before income taxes	4,418	13,680	7,502	69.8 %	13,500	(1.3) %
Income taxes - current	629	2,113	1,334	112.0 %	2,500	18.3 %
Income taxes - deferred	420	932	411	(2.2) %	900	(3.4) %
Profit attributable to non-controlling interests	42	105	78	86.0 %	100	(4.8) %
Profit attributable to owners of parent	3,326	10,528	5,678	70.7 %	10,000	(5.0) %

[Comprehensive income]

[26]

[(4,229)]

[9,608]

[–]

*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.

Net sales	<p>Results:</p> <p>Pharmaceutical Business: 10.1% increase in net sales Sales of pharmaceuticals increased. Overall sales of pharmaceuticals increased due to increases in sales of Beova®, TAVNEOS® and CAROGRA®, the launch of TAVALISSE®, and other factors. Sales of therapeutic and care foods slightly decreased and revenue from technical fees decreased, while other sales remained the same despite an increase in co-promotion fees.</p> <p>Other businesses: 26.3% increase in net sales Net sales of the Information Services Business increased 23.9%, net sales of the Construction Business increased 33.0%, and net sales of the Merchandising Business increased 25.1%.</p> <p>Forecast:</p> <p>Pharmaceutical Business: 15.6% increase in net sales Sales of pharmaceuticals are expected to increase because of the Company's ongoing efforts to promote its products such as Beova®, TAVNEOS® and CAROGRA® as well as new products, TAVALISSE® and KORSUVA®. Sales of therapeutic and care foods are expected to increase slightly. Both revenue from technical fees and other sales are expected to increase.</p> <p>Other businesses: 11.1% increase in net sales Net sales of all of the Information Services Business, the Merchandising Business and the Construction Business are expected to increase.</p>
Cost of sales	<p>Results: 0.3-percentage-point improvement in cost of sales ratio The cost of sales ratio of the Pharmaceutical Business slightly improved owing mainly to the change in the composition of product sales and an increase in co-promotion fees. In addition, the cost of sales of other businesses also improved owing mainly to the change of the business structure.</p> <p>Forecast: 1.3-percentage-point improvement in cost of sales ratio The cost of sales ratio of the Pharmaceutical Business is expected to improve owing mainly to the change in the composition of product sales, as well as revenue from technical fees. The cost of sales of other businesses is also expected to improve owing mainly to the change of the business structure.</p>
Selling, general and administrative expenses	<p>Results: 3.1% decrease YoY Selling expenses and general and administrative expenses slightly increased, and R&D expenses decreased. The decrease in R&D expenses is attributable to a decrease in clinical trial expenses due to the expenses for milestone payments on in-licensed products recorded in the corresponding period of the previous fiscal year and progress on clinical trials in late-stage development projects.</p> <p>Forecast: 0.9% decrease YoY Selling expenses are expected to increase, while general and administrative expenses and R&D expenses are expected to decrease. The decrease in R&D expenses is due to the same factors as those for the first half of the fiscal year ending March 31, 2024.</p>
Non-operating income and expenses	<p>Results: Main items included increases in gain on sale of securities and gain on valuation of securities.</p> <p>Forecast: No extraordinary items are expected.</p>
Extraordinary income and losses	<p>Results: The main item was a decrease in gain on sale of investment securities.</p> <p>Forecast: A gain on sale of investment securities is expected to be recorded for the second half of the fiscal year ending March 31, 2024, as was the case for the first half of the fiscal year. An impairment loss due to the redevelopment of the Nihonbashi area of Tokyo is expected to be recorded.</p>

[Other Items (Consolidated)]

(Million yen)

Item	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Depreciation	1,994	4,109	2,049	2.8 %	4,300	4.6 %
Capital investment	627	2,187	480	(23.5) %	2,000	(8.6) %
Main items	Production equipment, etc. 56 Other 571	Production equipment, etc. 110 Other 2,077	Production equipment, etc. 70 Other 410		Production equipment, etc. 800 Other 1,200	
Number of employees at end of period	1,841	1,795	1,808	(33)	—	—

II. Consolidated Balance Sheets

(Million yen)

Item	Fiscal year	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024	Change (from the previous fiscal year-end)
		As of September 30, 2022	As of March 31, 2023	As of September 30, 2023	
Assets	Current assets	99,515	100,641	105,869	5,228
	Cash and deposits	28,388	25,893	24,234	(1,658)
	Notes and accounts receivable - trade, and contract assets	22,399	22,780	27,064	4,284
	Investments in specified trusts and securities	26,411	27,541	27,616	75
	Inventories	19,998	22,798	24,582	1,784
	Other current assets	2,317	1,627	2,370	743
	Non-current assets	134,074	120,558	126,009	5,450
	Property, plant and equipment	23,862	24,579	24,276	(302)
	Intangible assets	1,604	1,507	1,582	74
	Investments and other assets	108,607	94,472	100,151	5,678
	Investment securities	91,908	74,769	81,301	6,531
	Long-term prepaid expenses	12,568	15,209	14,107	(1,101)
	Retirement benefit assets	2,675	3,089	3,304	214
	Deferred tax assets	477	433	442	8
	Other	1,011	988	1,013	25
	Allowance for doubtful accounts	(33)	(18)	(18)	—
Total assets		233,589	221,200	231,879	10,679

Cash and deposits	<ul style="list-style-type: none"> Decreased mainly due to some of the accounts receivable - trade that remained unsettled because September 30, 2023 was a bank holiday, despite an increase due to profit
Notes and accounts receivable - trade, and contract assets	<ul style="list-style-type: none"> Increases in the Pharmaceuticals Business and the other businesses and an increase due to some of the accounts receivable - trade that remained unsettled because September 30, 2023 was a bank holiday
Inventories	<ul style="list-style-type: none"> An increase in products and raw materials in the Pharmaceutical Business and a decrease in work in process in the Information Services Business
Other current assets	<ul style="list-style-type: none"> An increase in prepaid expenses in the Pharmaceutical Business
Property, plant and equipment	<ul style="list-style-type: none"> Decreased mainly due to depreciation
Investment securities	<ul style="list-style-type: none"> An increase in unrealized gains due to fair value evaluation
Long-term prepaid expenses	<ul style="list-style-type: none"> Decreased mainly due to depreciation

(Million yen)

Item		Fiscal year	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024	Change (from the previous fiscal year-end)
			As of September 30, 2022	As of March 31, 2023	As of September 30, 2023	
Liabilities	Total liabilities		32,674	26,385	30,251	3,865
	Current liabilities		16,499	14,957	16,763	1,806
	Notes and accounts payable - trade		5,052	4,617	4,705	87
	Short-term borrowings		1,590	1,490	1,390	(100)
	Income taxes payable		859	408	1,511	1,102
	Contract liabilities		2,554	1,846	1,734	(112)
	Other		6,442	6,594	7,423	828
	Non-current liabilities		16,175	11,428	13,487	2,059
	Deferred tax liabilities		15,163	10,426	12,527	2,100
	Other		1,011	1,001	959	(41)
Net assets	Total net assets		200,915	194,814	201,628	6,814
	Shareholders' equity		155,889	161,246	164,130	2,884
	Share capital		24,356	24,356	24,356	—
	Capital surplus		24,226	24,226	24,226	(0)
	Retained earnings		120,218	125,576	123,705	(1,870)
	Treasury shares		(12,912)	(12,912)	(8,158)	4,754
	Total accumulated other comprehensive income		44,189	32,653	36,503	3,849
	Non-controlling interests		836	914	995	80
Total liabilities and net assets			233,589	221,200	231,879	10,679

Notes and accounts payable - trade	<ul style="list-style-type: none"> Decreased in the Pharmaceutical Business and increased in the Information Services Business and the Construction Business
Income taxes payable	<ul style="list-style-type: none"> Increased due to an increase in income of the Pharmaceutical Business
Other current liabilities	<ul style="list-style-type: none"> An increase in accrued consumption taxes in the Pharmaceutical Business
Deferred tax liabilities	<ul style="list-style-type: none"> Increased due to an increase in unrealized gains on investment securities
Retained earnings	<ul style="list-style-type: none"> Dividends paid: -¥1,844 million; Retirement of treasury shares: -¥5,704 million; Profit attributable to owners of parent: +¥5,678 million
Total accumulated other comprehensive income	<ul style="list-style-type: none"> An increase in valuation difference on available-for-sale securities due to an increase in unrealized gains on investment securities; a decrease in remeasurements of defined benefit plans

III. Consolidated Statements of Cash Flows

(Million yen)

Item	Fiscal year ended March 31, 2023 1st half	Fiscal year ending March 31, 2024 1st half	Change
Cash flows from operating activities	(3,158)	(2,333)	825
Cash flows from investing activities	2,936	3,653	717
Cash flows from financing activities	(1,407)	(2,959)	(1,551)
Effect of exchange rate change on cash and cash equivalents	8	5	(2)
Net increase (decrease) in cash and cash equivalents	(1,620)	(1,632)	(11)
Cash and cash equivalents at beginning of period	53,004	48,884	(4,120)
Cash and cash equivalents at end of period	51,383	47,251	(4,131)

Main factors for increases and decreases (from the same period of the previous fiscal year)

1. Cash flows from operating activities

Net cash used in operating activities amounted to ¥2,333 million for the six months ended September 30, 2023. This was attributable to cash outflow factors such as increases in trade receivables and inventories despite cash inflow factors such as an increase in other current liabilities.

2. Cash flows from investing activities

Net cash provided by investing activities amounted to ¥3,653 million for the six months ended September 30, 2023, up ¥717 million from the previous corresponding period, mainly due to an increase in proceeds from sale of investment securities and a decrease in purchase of long-term prepaid expenses.

3. Cash flow from financing activities

Net cash used in financing activities was ¥2,959 million for the six months ended September 30, 2023, up ¥1,551 million from the previous corresponding period, mainly due to purchase of treasury shares and dividends paid.

IV. Trends in Dividends

(Yen)

Item \ Fiscal year	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Fiscal year ending March 31, 2024 (Forecast)
Interim dividend	27	28	40	41
Annual dividend	54	56	80	82

(Reference)

(Million yen)

Purchase of treasury shares (Number of shares purchased)	1,303 (600 thousand shares)	–	–	6,000 (2,000 thousand shares)
Cancellation of treasury shares (Number of shares cancelled)	–	–	–	5,704 (2,500 thousand shares)

V. Trends in Main Product Sales

(Million yen)

Product name	Fiscal year	Fiscal year ended March 31, 2023		Fiscal year ending March 31, 2024			
	Fiscal year ended March 31, 2022	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment Beova®	8,141	5,183	11,795	7,087	36.7%	15,800	34.0%
DESMOPRESSIN Formulations MINIRIN MELT®, etc.*1	3,965	1,925	3,703	1,885	(2.1)%	3,450	(6.8)%
Dysuria Treatment URIEF®	2,878	1,200	2,345	1,087	(9.4)%	2,100	(10.4)%
Hyperphosphatemia Treatment P-TOL®	5,784	2,951	5,665	2,770	(6.1)%	5,800	2.4%
Treatment for pruritis in dialysis patients KORSUVA®	—	—	—	—	—	500	—
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR]	3,730	2,229	4,386	2,090	(6.3)%	4,100	(6.5)%
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR]	3,834	1,653	3,055	1,248	(24.5)%	2,300	(24.7)%
Treatment for Diabetes GLUBES®, GLUFAST®	4,990	2,135	4,061	1,983	(7.1)%	3,800	(6.4)%
Treatment for Diabetes MARIZEV®	1,234	559	1,059	549	(1.8)%	1,200	13.3%
Treatment of Dry Mouth Symptoms SALAGEN®	1,412	564	1,073	509	(9.8)%	1,000	(6.8)%
Treatment for MPA*2 and GPA*3 TAVNEOS®	—	213	1,029	2,141	904.9%	5,000	385.9%
Treatment for Ulcerative Colitis CAROGRA®	—	207	500	585	182.2%	1,400	180.0%
Treatment for chronic ITP*4 TAVALISSE®	—	—	21	308	—	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

VI. R&D Pipeline (In-house)

(As of November 2023)

Product Name / Generic Name / Development Code	Expected Indications	Category	Development Stage	Development Classification
KORSUVA® / Difelikefalin / MR13A9	Uremic pruritus in dialysis patients*	Kappa opioid receptor agonist	Approved	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

*Approved efficacy or effect: Improvement in uremic pruritus in dialysis patients (limited to cases where existing treatments have produced insufficient effects)

*1 Rovatiorelin (spinocerebellar degeneration): Withdrew the application and considering the possibility of conducting additional clinical trials

*2 Change from previous release (July 2023): KORSUVA®: NDA → Approved

VII. R&D Pipeline (Out-licensing)

(As of November 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	
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.	Inmage 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 (July 2023): None