

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

**Supplementary
Explanatory Materials on
Financial Results for
the Six Months Ended
September 30, 2024**

November 5, 2024

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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 November 2024. 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 Semi-annual Financial Results]

- Net sales

Net sales of the Pharmaceutical Business were ¥36,633 million, an increase of 19.1% year on year. In addition to the sales of Beova® Tablets, an overactive bladder treatment, sales increased for four products (CAROGRAM® Tablets, a treatment for ulcerative colitis; TAVNEOS® Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis; TAVALLISSE® Tablets, a treatment for chronic idiopathic thrombocytopenic purpura; and KORSUVA® IV Injection Syringe, a treatment for pruritis in dialysis patients), 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.

Net sales of the Information Services Business were ¥4,032 million, a decrease of 2.4% year on year, net sales of the Construction and Facility Maintenance Business were ¥1,307 million, a decrease of 21.4% year on year, and net sales of the Merchandising Business were ¥492 million, an increase of 18.3% year on year.

- Profit

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

- R&D

Linzagolix (generic name, development code: KLH-2109), a treatment for uterine fibroids and endometriosis, which was created by the Company, achieved primary endpoints in two Phase III clinical trials for the indication of uterine fibroids in Japan, and NDA preparations have commenced. Also, 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, it was launched to the market in September 2024 by Theramex (U.K.), the licensee, under the product name Yselt® in Europe for the indication of uterine fibroids. Theramex has submitted an NDA of this drug to the European Medicines Agency (EMA) for the indication of endometriosis (additional indication), and approval is currently under review. Also, the Company granted exclusive rights to develop and market Linzagolix in South Korea to JW Pharmaceutical (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.

The licensing agreement with AffaMed Therapeutics (China), which had been granting rights to develop and market a treatment for Parkinson’s disease KDT-3594 (development code), which was discovered by the Company, in China and other countries, was terminated in May 2024.

I. Consolidated Statements of Income

(Million yen)

Item \ Fiscal year	Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Net sales	36,978	75,579	42,466	14.8 %	86,500	14.4 %
Pharmaceutical Business	30,765	63,348	36,633	19.1 %	74,000	16.8 %
Pharmaceuticals	26,420	54,237	31,161	17.9 %	63,500	17.1 %
Therapeutic and Care Foods	1,763	3,545	1,800	2.1 %	3,600	1.6 %
Technical Fees ^{*1}	171	714	1,430	736.1 %	2,100	194.1 %
Other ^{*2}	2,410	4,850	2,241	(7.0)%	4,800	(1.0) %
Information Services Business	4,133	8,399	4,032	(2.4)%	8,500	1.2 %
Construction and Facility Maintenance Business	1,663	3,022	1,307	(21.4)%	3,150	4.2 %
Merchandising Business	416	809	492	18.3 %	850	5.1 %
[Export sales included in net sales]	[2,268]	[4,510]	[3,581]	[57.9 %]	[6,300]	[39.7 %]
Cost of sales	18,677	38,238	21,068	12.8 %	43,200	13.0 %
[Cost of sales ratio]	[50.5]	[50.6]	[49.6]		[49.9]	
Gross profit	18,300	37,341	21,397	16.9 %	43,300	16.0 %
Selling, general and administrative expenses	16,284	33,324	19,616	20.5 %	38,300	14.9 %
R&D expenses	4,499	9,474	7,091	57.6 %	13,000	37.2 %
[Ratio to net sales]	[12.2]	[12.5]	[16.7]		[15.0]	
Operating profit	2,015	4,017	1,781	(11.6)%	5,000	24.5 %
Non-operating income	1,531	2,329	786	(48.6)%	1,500	(35.6) %
Interest and dividend income	728	1,319	735	1.0 %		
Other	803	1,009	51	(93.6)%		
Non-operating expenses	81	203	330	303.1 %	500	146.3 %
Interest expenses	9	18	9	6.4 %		
Other	72	185	320	341.5 %		
Ordinary profit	3,465	6,142	2,237	(35.4)%	6,000	(2.3) %
Extraordinary income	4,054	8,349	5,190	28.0 %	10,500	25.8 %
Extraordinary losses	17	43	269	—	300	597.7 %
Profit before income taxes	7,502	14,449	7,159	(4.6)%	16,200	12.1 %
Income taxes - current	1,334	3,263	1,954	46.5 %	4,300	31.8 %
Income taxes - deferred	411	(104)	(47)	—	150	—
Profit attributable to non-controlling interests	78	128	2	(96.5)%	50	(60.9) %
Profit attributable to owners of parent	5,678	11,160	5,249	(7.6)%	11,700	4.8 %

[Comprehensive income]

[9,608]

[36,044]

[1,447]

[(84.9)%]

*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: 19.1% increase in net sales Sales of pharmaceuticals increased. Overall sales of pharmaceuticals increased due to increases in sales of four new products (CAROGRA®, TAVNEOS®, TAVALLISSE®, and KORSUVA®) as well as Beova®. Sales of therapeutic and care foods slightly increased and revenue from technical fees increased, while other sales decreased despite an increase in co-promotion fees.</p> <p>Other businesses: 6.1% decrease in net sales Net sales of the Information Services Business decreased 2.4%, net sales of the Construction and Facility Maintenance Business decreased 21.4%, and net sales of the Merchandising Business increased 18.3%.</p> <p>Forecast:</p> <p>Pharmaceutical Business: 16.8% 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® and the new four products. Sales of therapeutic and care foods are expected to increase slightly. Revenue from technical fees is expected to increase and other sales are expected to slightly decrease.</p> <p>Other businesses: 2.2% increase in net sales Net sales of all of the Information Services Business, the Construction and Facility Maintenance Business and the Merchandising Business are expected to increase.</p>
Cost of sales	<p>Results: 0.9-percentage-point improvement in cost of sales ratio The cost of sales ratio of the Pharmaceutical Business improved owing mainly to the change in the composition of product sales and an increase in revenue from technical fees. Meanwhile, the cost of sales of the other businesses also rose slightly owing mainly to the change in the business structure.</p> <p>Forecast: 0.7-percentage-point improvement in cost of sales ratio The same trends as those for the first half of the fiscal year ending March 31, 2025 are expected for the Pharmaceutical Business and other businesses.</p>
Selling, general and administrative expenses	<p>Results: 20.5% increase YoY Selling expenses and general and administrative expenses slightly increased, and R&D expenses increased. An increase in R&D expenses is mainly caused by the recording of lump-sum payment for contracts of new in-licensing, and an increase in research expenses for beginning of clinical trials of drug discovery themes.</p> <p>Forecast: 14.9% increase YoY Selling expenses and general and administrative expenses are expected to slightly increase, and R&D expenses are expected to increase. The increase in R&D expenses is due to the same factors as those for the first half of the fiscal year ending March 31, 2025.</p>
Non-operating income and expenses	<p>Results: Main items included the recording of loss on valuation of securities and an increase in foreign exchange losses.</p> <p>Forecast: No extraordinary items are expected.</p>
Extraordinary income and losses	<p>Results: The main item was an increase 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, 2025, as was the case for the first half of the fiscal year.</p>

[Other Items (Consolidated)]

(Million yen)

Item \ Fiscal year	Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Depreciation	2,049	4,254	2,282	11.4 %	4,900	15.2 %
Capital investment	480	1,879	2,304	379.4 %	4,400	134.2 %
Main items	Production equipment, etc. 70	Production equipment, etc. 733	Production equipment, etc. 932		Production equipment, etc. 2,000	
	Other 410	Other 1,145	Other 1,372		Other 2,400	
Number of employees at end of period	1,808	1,779	1,811	3	—	—

II. Consolidated Balance Sheets

(Million yen)

Item \ Fiscal year		Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025 As of September 30, 2024	Change (from the previous fiscal year-end)
		As of September 30, 2023	As of March 31, 2024		
Assets	Current assets	105,869	104,551	107,009	2,457
	Cash and deposits	24,234	22,894	26,444	3,550
	Notes and accounts receivable - trade, and contract assets	27,064	28,680	27,433	(1,246)
	Investments in specified trusts and securities	27,616	24,901	25,202	300
	Inventories	24,582	26,297	26,313	15
	Other current assets	2,370	1,778	1,615	(162)
	Non-current assets	126,009	156,377	153,329	(3,048)
	Property, plant and equipment	24,276	24,861	26,149	1,288
	Intangible assets	1,582	1,992	1,863	(129)
	Investments and other assets	100,151	129,523	125,316	(4,207)
	Investment securities	81,301	106,361	100,663	(5,697)
	Long-term prepaid expenses	14,107	14,219	15,424	1,204
	Retirement benefit asset	3,304	7,311	7,629	318
	Deferred tax assets	442	608	459	(149)
	Other	1,013	1,040	1,156	116
	Allowance for doubtful accounts	(18)	(18)	(18)	—
Total assets		231,879	260,929	260,339	(590)

Cash and deposits	<ul style="list-style-type: none"> Increased mainly due to profit
Notes and accounts receivable - trade, and contract assets	<ul style="list-style-type: none"> A decrease in the Pharmaceutical Business and increases in other businesses
Other current assets	<ul style="list-style-type: none"> A decrease in prepaid expenses in the Pharmaceutical Business
Property, plant and equipment	<ul style="list-style-type: none"> Increases in construction in progress in the Pharmaceutical Business and buildings and structures in the Information Services Business despite a decrease in depreciation
Investment securities	<ul style="list-style-type: none"> A decrease due to sales and a decrease in unrealized gains due to fair value evaluation
Long-term prepaid expenses	<ul style="list-style-type: none"> Increased owing to the acquisition of new assets in the Pharmaceutical Business despite a decrease caused by depreciation

(Million yen)

Item		Fiscal year	Fiscal year ended March 31, 2024		Fiscal year ending March 31, 2025 As of September 30, 2024	Change (from the previous fiscal year-end)
			As of September 30, 2023	As of March 31, 2024		
Liabilities	Total liabilities		30,251	39,793	39,568	(224)
	Current liabilities		16,763	17,663	19,448	1,785
	Notes and accounts payable - trade		4,705	4,893	5,243	349
	Short-term borrowings		1,390	1,340	1,260	(80)
	Income taxes payable		1,511	2,380	2,145	(235)
	Contract liabilities		1,734	1,486	1,011	(475)
	Other		7,423	7,562	9,788	2,226
	Non-current liabilities		13,487	22,129	20,119	(2,009)
	Deferred tax liabilities		12,527	21,188	19,257	(1,931)
	Other		959	941	862	(78)
Net assets	Total net assets		201,628	221,136	220,770	(365)
	Shareholders' equity		164,130	162,683	166,120	3,436
	Share capital		24,356	24,356	24,356	—
	Capital surplus		24,226	24,226	24,226	—
	Retained earnings		123,705	127,310	130,747	3,437
	Treasury shares		(8,158)	(13,209)	(13,209)	(0)
	Total accumulated other comprehensive income		36,503	57,344	53,537	(3,807)
	Non-controlling interests		995	1,107	1,113	5
Total liabilities and net assets			231,879	260,929	260,339	(590)

Notes and accounts payable - trade	<ul style="list-style-type: none"> Increased in the Pharmaceutical Business and decreased in other businesses
Other current liabilities	<ul style="list-style-type: none"> An increase in accounts payable in the Pharmaceutical Business
Deferred tax liabilities	<ul style="list-style-type: none"> Decreased due to sale of investment securities and a decrease in unrealized gains due to fair value evaluation
Retained earnings	<ul style="list-style-type: none"> Dividends paid: ¥1,812 million; Profit attributable to owners of parent: +¥5,249 million
Total accumulated other comprehensive income	<ul style="list-style-type: none"> A decrease in valuation difference on available-for-sale securities due to a decrease 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	Fiscal year ended March 31, 2024 1st half	Fiscal year ending March 31, 2025 1st half	Change
Cash flows from operating activities	(2,333)	2,775	5,108
Cash flows from investing activities	3,653	2,779	(874)
Cash flows from financing activities	(2,959)	(1,960)	998
Effect of exchange rate change on cash and cash equivalents	5	(40)	(46)
Net increase (decrease) in cash and cash equivalents	(1,632)	3,553	5,186
Cash and cash equivalents at beginning of period	48,884	45,887	(2,997)
Cash and cash equivalents at end of period	47,251	49,440	2,188

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

1. Cash flows from operating activities

Net cash provided by operating activities amounted to ¥2,775 million for the six months ended September 30, 2024, up ¥5,108 million from the previous corresponding period, mainly due to cash inflow factors such as a decrease in trade receivables and contract assets and a decrease in inventories exceeding cash outflow factors such as an increase in income taxes paid.

2. Cash flows from investing activities

Net cash provided by investing activities amounted to ¥2,779 million for the six months ended September 30, 2024, down ¥874 million from the previous corresponding period, mainly due to an increase in expenditures for the purchase of property, plant and equipment despite proceeds from sale of investment securities continuing from the previous year.

3. Cash flows from financing activities

Net cash used in financing activities was ¥1,960 million for the six months ended September 30, 2024, down ¥998 million from the previous corresponding period, mainly due to a decrease in expenditure for the purchase of treasury shares.

IV. Trends in Dividends

(Yen)

Fiscal year Item	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Fiscal year ended March 31, 2024	Fiscal year ending March 31, 2025 (Forecast)
Interim dividend	28	40	41	45
Annual dividend	56	80	82	90

(Reference)

(Million yen)

Purchase of treasury shares	—	—	6,000	5,292
(Number of shares purchased)	—	—	(1,910 thousand shares)	(1,400 thousand shares)
Cancellation of treasury shares	—	—	5,704	5,292
(Number of shares cancelled)	—	—	(2,500 thousand shares)	(1,400 thousand shares)

V. 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			
		1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment Beova®	11,795	7,087	15,335	8,793	24.1%	18,200	18.7%
Treatment for MPA* ¹ and GPA* ² TAVNEOS®	1,029	2,141	5,161	4,224	97.3%	8,800	70.5%
Hyperphosphatemia Treatment P-TOL®	5,665	2,770	5,241	2,361	(14.8)%	4,800	(8.4)%
Treatment for Pruritis in Dialysis KORSUVA®	—	—	757	2,251	—	4,700	520.9%
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR]	4,386	2,090	4,077	1,941	(7.1)%	3,600	(11.7)%
DESMOPRESSIN Formulations MINIRIN MELT®, etc.*³	3,703	1,885	3,662	1,822	(3.4)%	3,400	(7.1)%
Treatment for Diabetes GLUBES®, GLUFAST®	4,061	1,983	3,806	1,703	(14.2)%	3,300	(13.3)%
Treatment for Chronic ITP* ⁴ TAVALISSE®	21	308	818	984	218.6%	2,500	205.6%
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR]	3,055	1,248	2,336	962	(22.9)%	1,800	(22.9)%
Treatment for Ulcerative Colitis CAROGRA®	500	585	1,091	627	7.2%	1,600	46.7%
Dysuria Treatment URIEF®	2,345	1,087	2,076	647	(40.5)%	1,300	(37.4)%
Treatment for Diabetes MARIZEV®	1,059	549	1,073	496	(9.6)%	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

VI. R&D Pipeline (In-house)

(As of November 2024)

Generic Name / Development Code	Expected Indications	Category	Development Stage	Development Classification
CG0070	Non-muscle-invasive bladder cancer	Oncolytic Viral Therapy	Phase III	In-licensed / CG Oncology (U.S.)
Linzagolix / K LH-2109	Uterine fibroids	GnRH receptor antagonist	NDA preparation	Kissei
	Endometriosis		Phase II	Kissei
KDT-3594	Parkinson's disease	Dopamine receptor agonist	Phase II	Kissei
KSP-0243	Ulcerative colitis		Phase II	Kissei

- * Rovatirelin (spinocerebellar degeneration):
Under consideration on the possibility of conducting additional clinical trials
- * Changes from previous release (July 2024):
Linzagolix (uterine fibroids) Phase III → NDA preparation

VII. R&D Pipeline (Out-licensing)

(As of November 2024)

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.)	NDA
Fostamatinib	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	Korea	JW Pharmaceutical (Korea)	NDA
Silodosin	Dysuria associated with benign prostatic hyperplasia	Alpha 1A adrenergic receptor antagonist	Vietnam, etc.	Eisai (Japan)	NDA

- * Changes from previous release (July 2024):

Linzagolix (uterine fibroids, EU):	Approved →	Launched (Germany, Spain, etc.)
Linzagolix (uterine fibroids, Australia):	→	NDA (addition)
Linzagolix (uterine fibroids, China):	Phase III →	Termination of the licensing agreement with Bio Genuine (deletion)
Linzagolix (endometriosis, EU):	Phase III →	NDA
Linzagolix (endometriosis, China):	Phase III →	Termination of the licensing agreement with Bio Genuine (deletion)