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Stock code: 4547

**Supplementary
Explanatory Materials on
Financial Results for
the Fiscal Year Ended
March 31, 2023**

May 8, 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 May 2023. Actual results may differ greatly from these statements due to business risks and uncertainties.

[Excerpts from “Overview of Operating Results for the Fiscal Year under Review” of the Annual Financial Results]

• Net sales

Net sales of the Pharmaceutical Business were ¥56,243 million, an increase of 3.9% year on year. CAROGRA[®] Tablets, a treatment for ulcerative colitis, which EA Pharma Co., Ltd. and the Company have jointly developed, was launched in May 2022, TAVNEOS[®] Capsules for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis was launched in June 2022, and TAVALISSE[®] Tablets, a treatment for chronic idiopathic thrombocytopenic purpura, was launched in April 2023. In the midst of COVID-19 pandemic, we promoted a hybrid type of pharmaceutical information activities that effectively utilized various digital tools as well as the traditional physical interviews. As a result, the introduction into the market of these new products were implemented as planned, and the sales of Beova[®] Tablets, an overactive bladder treatment, and Darbepoetin Alfa BS Injection [JCR] for the treatment of renal anemia, as well as co-promotion fees increased. These increases, together with higher technical fees and export sales, contributed to the year-on-year increase in net sales.

Net sales of the Information Services Business were ¥8,285 million, an increase of 7.0% year on year, net sales of the Construction Business were ¥2,343 million, a decrease of 20.5% year on year, and net sales of the Merchandising Business were ¥621 million, an increase of 14.3% year on year.

• Profit

Regarding profit, despite an increase in net sales and a slight improvement in the cost of sales ratio, an increase in selling, general and administrative expenses centering on selling expenses could not be absorbed, resulting in an operating loss. On the other hand, while ordinary profit increased, 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 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 with ObsEva S.A. (Switzerland), which had been granted exclusive worldwide rights to develop and market Linzagolix, excluding Japan and other parts of Asia, was terminated at the end of November last year. The sublicensing agreement between ObsEva and Theramex (U.K.) for the commercialization of the drug outside North America and Asia, which was automatically succeeded by the Company upon termination of the agreement, has been renewed in April 2023 after a review of its terms and conditions in accordance with the latest situation. Preparations are currently underway by Theramex for the launch of this product in Europe during fiscal year 2023.

Furthermore, development of the product in the U.S. will not be made by the Company, and the Company will rather consider entering into a partnership with other companies for development. The New Drug Application (NDA) for Linzagolix for the indication of uterine fibroids was withdrawn by ObsEva in August 2022.

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 ended March 31, 2022	Fiscal year ended March 31, 2023			Fiscal year ending March 31, 2024 (Forecast)		
		Forecast*1	Results	YoY	Full year	YoY	1st half
Net sales	65,381	68,500	67,493	3.2%	74,500	10.4%	35,500
Pharmaceutical Business	54,147	57,500	56,243	3.9%	62,500	11.1%	29,500
Pharmaceuticals	45,792	47,600	47,077	2.8%	51,500	9.4%	25,000
Therapeutic and Care Foods	3,568	3,600	3,461	(3.0)%	3,600	4.0%	1,800
Technical Fees*2	518	1,700	1,053	103.4%	3,000	184.7%	500
Other*3	4,268	4,600	4,650	8.9%	4,400	(5.4)%	2,200
Information Services Business	7,742	7,900	8,285	7.0%	7,900	(4.6)%	3,700
Construction Business	2,948	2,400	2,343	(20.5)%	3,300	40.8%	1,900
Merchandising Business	543	700	621	14.3%	800	28.8%	400
[Export sales included in net sales]	[3,713]	[5,300]	[4,584]	[23.4%]	[7,500]	[63.6%]	[2,300]
Cost of sales	34,143	34,400	35,118	2.9%	37,600	7.1%	18,500
[Cost of sales ratio]	[52.2]	[50.2]	[52.0]		[50.5]		[52.1]
Gross profit	31,238	34,100	32,374	3.6%	36,900	14.0%	17,000
Selling, general and administrative expenses	32,640	33,600	33,503	2.6%	32,700	(2.4)%	16,100
R&D expenses	10,363	10,500	10,391	0.3%	9,200	(11.5)%	4,500
[Ratio to net sales]	[15.9]	[15.3]	[15.4]		[12.3]		[12.7]
Operating profit (loss)	(1,402)	500	(1,129)	—	4,200	—	900
Non-operating income	2,092	1,700	1,837	(12.2)%	1,100	(40.1)%	650
Interest and dividend income	1,586		1,402	(11.6)%			
Other	506		434	(14.2)%			
Non-operating expenses	127	100	109	(14.5)%	100	(8.5)%	50
Interest expenses	23		20	(14.2)%			
Other	104		89	(14.6)%			
Ordinary profit (loss)	562	2,100	598	6.4%	5,200	768.4%	1,500
Extraordinary income	16,601	12,010	13,086	(21.2)%	9,000	(31.2)%	5,000
Extraordinary losses	656	10	4	(99.3)%	—	—	—
Profit before income taxes	16,507	14,100	13,680	(17.1)%	14,200	3.8%	6,500
Income taxes - current	4,017	2,600	2,113	(47.4)%	2,600	23.0%	1,250
Income taxes - deferred	(542)	600	932	—	900	(3.5)%	400
Profit attributable to non-controlling interests	110	100	105	(4.6)%	100	(5.2)%	50
Profit attributable to owners of parent	12,921	10,800	10,528	(18.5)%	10,600	0.7%	4,800
Comprehensive income	(13,764)	(4,229)	—				

*1: Forecast values presented in the financial statements for the six months ended September 30, 2022.

*2: Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties.

*3: Includes revenue from supply to domestic sales partners and revenue from co-promotion fees.

Net sales	<p>Results:</p> <p>Pharmaceutical Business: 3.9% increase in net sales Sales of pharmaceuticals increased. Net sales increased mainly because of increases in sales of Beova[®], Darbepoetin Alfa BS and other products, the introduction into the market of CAROGRAM[®] and TAVNEOS[®], and an increase in export sales. Sales of therapeutic and care foods slightly decreased and revenue from technical fees increased, while other sales, primarily revenue from co-promotion fees, increased.</p> <p>Other businesses: 0.1% increase in net sales Net sales of the Information Services Business increased 7.0%, net sales of the Construction Business decreased 20.5%, and net sales of the Merchandising Business increased 14.3%.</p> <p>Forecast:</p> <p>Pharmaceutical Business: 11.1% increase in net sales Sales of pharmaceuticals are expected to increase mainly because of the Company's ongoing efforts to promote its products, such as Beova[®], TAVNEOS[®] and CAROGRAM[®] and the introduction into the market of TAVALLISSE[®]. Sales of therapeutic and care foods are expected to increase slightly, technical fees are expected to increase, while other sales are expected to decrease.</p> <p>Other businesses: 6.7% increase in net sales Net sales of the Construction Business and the Merchandising Business are expected to increase. Net sales of the Information Services Business are expected to decrease.</p>
Cost of sales	<p>Results: 0.2-percentage-point improvement in cost of sales ratio The cost of sales ratio of the Pharmaceutical Business improved slightly owing mainly to the increase in revenue from technical fees and co-promotion fees. In addition, the cost of sales of other businesses also improved slightly owing mainly to the change in the business structure.</p> <p>Forecast: 1.5-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. On the other hand, the cost of sales of other businesses is expected to increase owing mainly to the change in the business structure.</p>
Selling, general and administrative expenses	<p>Results: 2.6% increase YoY Selling expenses, general and administrative expenses, and R&D expenses all increased. The increase in selling expenses was due to increases in expenses for operating activities and in depreciation and amortization. R&D expenses were spent overall in almost the same amount as the previous fiscal year due to the decrease in milestone payments on in-licensed products, while expenses for overseas clinical trials taken over from ObsEva were recorded.</p> <p>Forecast: 2.4% decrease YoY Although selling expenses are expected to increase, general and administrative expenses and R&D expenses are expected to decrease. The increase in selling expenses is due to similar reasons as in the previous fiscal year. R&D expenses are expected to decrease mainly due to clinical development expenses and milestone payments on in-licensed products.</p>
Non-operating income and expenses	<p>Results: Main items included decreases in interest, dividend income, and a 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.</p>

[Other Items (Consolidated)]

(Million yen)

Item	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023			Fiscal year ending March 31, 2024 (Forecast)		
		Forecast*	Results	YoY	Full year	YoY	1st half
Depreciation and amortization	3,730	4,100	4,109	10.1%	4,400	7.1%	2,200
Capital investment	1,488	1,100	2,187	47.0%	1,770	(19.1)%	550
Main items	Production equipment, etc. 428 Other 1,059	Production equipment, etc. 200 Other 900	Production equipment, etc. 110 Other 2,077		Production equipment, etc. 420 Other 1,020		Production equipment, etc. 120 Other 300
Number of employees at end of period	1,828	—	1,795	(33)	—	—	—

*: Forecast values presented in the financial statements for the six months ended September 30, 2022.

II. Consolidated Balance Sheets

(Million yen)

Fiscal year		Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Change
Item				
Assets	Current assets	99,342	100,641	1,299
	Cash and deposits	30,013	25,893	(4,119)
	Notes and accounts receivable - trade, and contract assets	22,808	22,780	(27)
	Investments in specified trusts and securities	26,862	27,541	679
	Inventories	18,988	22,798	3,810
	Other current assets	669	1,627	957
	Non-current assets	138,745	120,558	(18,186)
	Property, plant and equipment	24,074	24,579	504
	Intangible assets	1,569	1,507	(62)
	Investments and other assets	113,101	94,472	(18,628)
	Investment securities	96,631	74,769	(21,861)
	Long-term prepaid expenses	12,480	15,209	2,728
	Retirement benefit assets	2,460	3,089	629
	Deferred tax assets	524	433	(90)
	Other	1,027	988	(39)
	Allowance for doubtful accounts	(23)	(18)	5
Total assets		238,087	221,200	(16,887)

Cash and deposits	<ul style="list-style-type: none"> • Main factor: A decrease due to income taxes paid and purchase of long-term prepaid expenses despite an increase due to profit
Notes and accounts receivable - trade, and contract assets	<ul style="list-style-type: none"> • Increased in the Pharmaceutical Business and decreased in the Information Services Business and the Construction Business
Inventories	<ul style="list-style-type: none"> • An increase in products and raw materials in the Pharmaceutical Business and an increase in work in process in the Information Services Business
Other current assets	<ul style="list-style-type: none"> • Increases in accounts receivable and prepaid expenses in the Pharmaceutical Business
Property, plant and equipment	<ul style="list-style-type: none"> • Increased due to leased assets in the Pharmaceutical Business despite a decrease due to depreciation
Investment securities	<ul style="list-style-type: none"> • A decrease in unrealized gains due to fair value evaluation
Long-term prepaid expenses	<ul style="list-style-type: none"> • Increased owing to acquisition of new assets in the Pharmaceutical Business despite a decrease caused by depreciation and amortization

(Million yen)

Fiscal year		Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023	Change
Item				
Liabilities	Total liabilities	35,907	26,385	(9,521)
	Current liabilities	18,744	14,957	(3,786)
	Notes and accounts payable - trade	4,104	4,617	513
	Short-term borrowings	1,640	1,490	(150)
	Income taxes payable	3,497	408	(3,089)
	Contract liabilities	2,696	1,846	(850)
	Other	6,806	6,594	(211)
	Non-current liabilities	17,163	11,428	(5,735)
	Deferred tax liabilities	16,259	10,426	(5,833)
	Other	903	1,001	98
Net assets	Total net assets	202,180	194,814	(7,365)
	Shareholders' equity	153,854	161,246	7,392
	Share capital	24,356	24,356	—
	Capital surplus	24,226	24,226	—
	Retained earnings	118,183	125,576	7,392
	Treasury shares	(12,912)	(12,912)	(0)
	Total accumulated other comprehensive income	47,531	32,653	(14,878)
	Non-controlling interests	794	914	120
Total liabilities and net assets		238,087	221,200	(16,887)

Notes and accounts payable - trade	<ul style="list-style-type: none"> Increased in the Pharmaceutical Business and decreased in the Construction Business
Income taxes payable	<ul style="list-style-type: none"> Decreased due to a decrease in income of the Pharmaceutical Business
Other current liabilities	<ul style="list-style-type: none"> A decrease in accrued consumption taxes in the Pharmaceutical Business
Deferred tax liabilities	<ul style="list-style-type: none"> Decreased due to a decrease in unrealized gains on investment securities
Other non-current liabilities	<ul style="list-style-type: none"> An increase in lease liabilities in the Pharmaceutical Business
Retained earnings	<ul style="list-style-type: none"> Dividends paid: -¥3,135 million; Profit attributable to owners of parent: +¥10,528 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 ended March 31, 2022	Fiscal year ended March 31, 2023	Change
Cash flows from operating activities	1,533	(6,679)	(8,212)
Cash flows from investing activities	10,776	6,001	(4,775)
Cash flows from financing activities	(2,756)	(3,420)	(663)
Effect of exchange rate change on cash and cash equivalents	4	(21)	(25)
Net increase (decrease) in cash and cash equivalents	9,557	(4,120)	(13,677)
Cash and cash equivalents at beginning of period	43,447	53,004	9,557
Cash and cash equivalents at end of period	53,004	48,884	(4,120)

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

1. Cash flows from operating activities: Decreased (higher cash outflows)

Net cash used in operating activities amounted to ¥6,679 million for the fiscal year ended March 31, 2023 due to cash outflow factors, such as an increase in inventories, a decrease in contract liabilities and an increase in income taxes paid, despite cash inflow factors such as an increase in trade payables.

2. Cash flows from investing activities: Decreased

Net cash provided by investing activities amounted to ¥6,001 million yen for the fiscal year ended March 31, 2023, due to proceeds from sale of investment securities, despite cash outflows such as recording of long-term prepaid expenses.

3. Cash flow from financing activities: Decreased (higher cash outflows)

Net cash used in financing activities was ¥3,420 million for the fiscal year ended March 31, 2023. The main factor was 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	1,303	—	—	6,000
(Number of shares purchased)	(600 thousand shares)	—	—	(2,000 thousand shares)
Cancellation of treasury shares	—	—	—	—
(Number of shares cancelled)	—	—	—	(2,500 thousand shares)

V. Trends in Main Product Sales

(Million yen)

Product name	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023			Fiscal year ending March 31, 2024 (Forecast)		
		Forecast*1	Results	YoY	Full year	YoY	1st half
Overactive Bladder Treatment Beova®	8,141	12,000	11,795	44.9%	16,200	37.3%	7,500
DESMOPRESSIN Formulations MINIRIN MELT®, etc.*2	3,965	3,900	3,703	(6.6)%	3,450	(6.8)%	1,700
Dysuria Treatment URIEF®	2,878	2,300	2,345	(18.5)%	1,900	(19.0)%	1,000
Hyperphosphatemia Treatment P-TOL®	5,784	6,000	5,665	(2.1)%	5,800	2.4%	2,900
Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR]	3,730	4,300	4,386	17.6%	3,800	(13.4)%	1,900
Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR]	3,834	3,100	3,055	(20.3)%	2,300	(24.7)%	1,200
Treatment for Diabetes GLUBES®, GLUFAST®	4,990	4,100	4,061	(18.6)%	3,800	(6.4)%	2,000
Treatment for Diabetes MARIZEV®	1,234	1,100	1,059	(14.2)%	1,200	13.3%	600
Treatment of Dry Mouth Symptoms SALAGEN®	1,412	1,100	1,073	(24.0)%	1,000	(6.8)%	500
Treatment for MPA*3 and GPA*4 TAVNEOS®	–	800	1,029	–	3,200	210.8%	1,300
Treatment for Ulcerative Colitis CAROGRA®	–	600	500	–	1,400	179.7%	600
Treatment for Chronic ITP*5 TAVALLISSE®	–	–	21	–	400	–	100

*1: Forecast values presented in the financial statements for the six months ended September 30, 2022.

*2: MINIRIN MELT®, DESMOPRESSIN Intranasal, DESMOPRESSIN Nasal Spray, and DESMOPRESSIN I.V. Injection

*3: Microscopic polyangiitis

*4: Granulomatosis with polyangiitis

*5: Idiopathic thrombocytopenic purpura

VI. R&D Pipeline (In-house)

(As of May 2023)

Generic name / Development code	Expected indications	Category	Development stage	Development classification
Rovatrielin / 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 (January 2023): TAVALISSE® Tablets: Approved → Launched on April 6, 2023 (deleted)

VII. R&D Pipeline (Out-licensing)

(As of May 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
			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 (January 2023): linzagolix (Endometriosis, US): Phase III → (deleted)