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Consolidated Financial Results for the Nine Months Ended December 31, 2022 [Japanese GAAP]

January 31, 2023

Company name: KISSEI PHARMACEUTICAL CO., LTD.

Stock exchange listing: Tokyo Stock Exchange

Stock code: 4547

URL: <https://www.kissei.co.jp/>

Representative: Mutsuo Kanzawa, Chairman and CEO

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Scheduled date of filing quarterly securities report: February 13, 2023

Scheduled date of commencing dividend payments: -

Availability of supplementary explanatory materials on quarterly financial results: Available

Schedule of quarterly financial results briefing session: Not scheduled

(Amounts of less than one million yen are rounded down.)

1. Consolidated Financial Results for the Nine Months Ended December 31, 2022 (April 1, 2022 – December 31, 2022)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Nine months ended December 31, 2022	51,635	3.1	492	-	2,113	56.5	6,667	(2.2)
December 31, 2021	50,085	(4.0)	(294)	-	1,350	(70.4)	6,819	5.9

(Note) Comprehensive income: Nine months ended December 31, 2022: ¥(2,342) million [-%]

Nine months ended December 31, 2021: ¥(15,268) million [-%]

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
December 31, 2022	144.58	-
December 31, 2021	147.87	-

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Million yen	Million yen	%	Yen
December 31, 2022	230,398	196,701	85.0	4,246.44
March 31, 2022	238,087	202,180	84.6	4,366.96

(Reference) Equity: As of December 31, 2022: ¥195,827 million

As of March 31, 2022: ¥201,385 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2022	–	28.00	–	28.00	56.00
Fiscal year ending March 31, 2023	–	40.00	–		
Fiscal year ending March 31, 2023 (Forecast)				40.00	80.00

(Note) Revision to the forecast for dividends announced most recently: None

3. Consolidated Financial Results Forecast for the Fiscal Year Ending March 31, 2023 (April 1, 2022 - March 31, 2023)

(% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	68,500	4.8	500	-	2,100	273.7	10,800	(16.4)	234.19

(Note) Revision to the financial results forecast announced most recently: None

*** Notes:**

- (1) Changes in significant subsidiaries during the period under review (changes in specified subsidiaries resulting in change in scope of consolidation): None
- (2) Accounting methods adopted particularly for the preparation of quarterly consolidated financial statements: None
- (3) Changes in accounting policies, changes in accounting estimates and retrospective restatement
- 1) Changes in accounting policies due to the revision of accounting standards: Yes
 - 2) Changes in accounting policies other than 1) above: None
 - 3) Changes in accounting estimates: None
 - 4) Retrospective restatement: None
- (4) Total number of issued shares (common shares)
- 1) Total number of issued shares at the end of the period (including treasury shares):

December 31, 2022:	51,811,185 shares
March 31, 2022:	51,811,185 shares
 - 2) Total number of treasury shares at the end of the period:

December 31, 2022:	5,695,501 shares
March 31, 2022:	5,695,353 shares
 - 3) Average number of shares during the period:

Nine months ended December 31, 2022:	46,115,815 shares
Nine months ended December 31, 2021:	46,115,902 shares

* These quarterly consolidated financial results are outside the scope of quarterly review by certified public accountants or an audit firm.

* Explanation of the proper use of financial results forecast and other notes

(Cautionary note on forward-looking statements)

The financial forecasts and other forward-looking statements herein are based on information available to the Company as of the date of publication of this document and certain assumptions as of the date of publication of this document on uncertainties that may have an impact on future financial results and the Company does not in any way guarantee their achievement. Actual results may differ greatly from these forecasts due to a variety of factors. Please refer to “1. Qualitative Information on Quarterly Financial Results (3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information” on page 3 of the Attachments for preconditions underlying the financial forecasts and other matters.

(How to obtain supplementary explanatory materials on quarterly financial results and materials for financial results briefing session)

The supplementary explanatory materials on quarterly financial results are posted on the Company’s website together with the consolidated financial results.

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1. Qualitative Information on Quarterly Financial Results

(1) Explanation of Operating Results

In the nine months ended December 31, 2022, the pharmaceutical industry continued to experience harsh business conditions. As one of the measures to curb medical costs, including the reform of the National Health Insurance (NHI) drug pricing system, a drug price revision was implemented in April 2022, following the mid-year revision of drug prices in April 2021. Although the additional requirements for promoting new drug discovery and eliminating off-label drug use have been expanded, the replacement rate of drugs by generic versions meant more drastic price cuts for drugs that have been listed in the NHI Drug Price Standard for a long period of time. Although strong ICT demand continued in the information services industry, and there were signs of a recovery in capital investment in the construction and merchandising industries, personal consumption declined due to the weak yen, and the competitive environment remained fierce.

In these circumstances, the Company's financial results for the nine months ended December 31, 2022 were as stated below.

(Million yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	Change (%)
Net sales	50,085	51,635	3.1
Operating profit (loss)	(294)	492	-
Ordinary profit	1,350	2,113	56.5
Profit attributable to owners of parent	6,819	6,667	(2.2)

• Net sales

Net sales of the Pharmaceutical Business were ¥43,641 million, an increase of 4.1% 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 as well as the traditional physical interviews. As a result, sales of Beova[®] Tablets, an overactive bladder treatment, and Darbepoetin Alfa BS Injection [JCR] for the treatment of renal anemia increased, which, together with higher technical fees, export sales, and co-promotion fees, contributed to the year-on-year increase in net 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 ¥5,717 million, an increase of 1.8% year on year, net sales of the Construction Business were ¥1,773 million, a decrease of 14.9% year on year, and net sales of the Merchandising Business were ¥502 million, an increase of 12.7% year on year.

• Profit

Despite an increase in selling, general and administrative expenses, the Company recorded a higher operating profit and ordinary profit due to an increase in net sales and an improvement in the cost of sales ratio. 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 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 an NDA in Japan in April 2022 and received marketing authorization approval in Japan in December 2022, and we have been promoting activities to provide drug information, spearheaded by the Rare Disease Project that is specialized in marketing of drugs for rare diseases, in preparation for launch under the brand name "TAVALISSE[®] Tablets 100 mg/150 mg" following listing in the

NHI Drug Price Standard.

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 between ObsEva SA(Switzerland) and the Company has been terminated as of the end of November, 2022. Based on the agreement, certain rights contained in the sublicense agreement between ObsEva and Theramex (U.K.) for worldwide except North America and Asia have been automatically transferred to the Company. Currently, the Company and Theramex have proceeded with discussion about the terms and conditions of a new license agreement in preparation for Theramex's launch of the product in Europe in fiscal 2023. With ObsEva having withdrawn its NDA for linzagolix to the U.S. Food and Drug Administration (FDA) for the indication of uterine fibroids in August 2022, the Company is scrutinizing the data and others used for application in the U.S., and will decide its policy for the development of this agent in accordance with the results of the scrutiny.

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.

(2) Explanation of Financial Position

• Assets

Total assets amounted to ¥230,398 million as of December 31, 2022, down ¥7,689 million from the previous fiscal year-end. Current assets were up ¥2,442 million, to ¥101,785 million, due to increases in notes and accounts receivable - trade, and contract assets, inventories, and other items despite a decrease in cash and deposits. Non-current assets were down ¥10,132 million, to ¥128,613 million, mainly due to a decrease in investment securities.

• Liabilities

Total liabilities amounted to ¥33,696 million as of December 31, 2022, down ¥2,211 million from the previous fiscal year-end. Current liabilities were up ¥586 million, to ¥19,330 million, due to increases in notes and accounts payable - trade and amounts payable in other, despite decreases in income taxes payable and other items. Non-current liabilities were down ¥2,797 million, to ¥14,365 million, mainly due to a decrease in deferred tax liabilities.

• Net assets

Total net assets amounted to ¥196,701 million as of December 31, 2022, down ¥5,478 million from the previous fiscal year-end, mainly due to a decrease in valuation difference on available-for-sale securities.

As a result, the shareholders' equity ratio was 85.0%, up from 84.6% at the previous fiscal year-end.

(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information

The consolidated financial results forecast for the fiscal year ending March 31, 2023 is unchanged from the consolidated financial results forecast announced on November 8, 2022.

2. Quarterly Consolidated Financial Statements and Principal Notes

(1) Quarterly Consolidated Balance Sheets

(Million yen)

	As of March 31, 2022	As of December 31, 2022
Assets		
Current assets		
Cash and deposits	30,013	23,713
Notes and accounts receivable - trade, and contract assets	22,808	27,126
Securities	23,139	23,456
Merchandise and finished goods	10,491	11,031
Work in process	63	482
Raw materials and supplies	8,433	9,525
Other	4,392	6,449
Total current assets	99,342	101,785
Non-current assets		
Property, plant and equipment		
Buildings and structures	39,132	39,209
Accumulated depreciation	(30,525)	(31,013)
Buildings and structures, net	8,607	8,196
Land	12,611	12,611
Construction in progress	—	7
Other	16,469	16,159
Accumulated depreciation	(13,613)	(13,356)
Other, net	2,856	2,802
Total property, plant and equipment	24,074	23,618
Intangible assets	1,569	1,553
Investments and other assets		
Investment securities	96,631	83,534
Retirement benefit asset	2,460	2,781
Deferred tax assets	524	384
Other	13,508	16,774
Allowance for doubtful accounts	(23)	(33)
Total investments and other assets	113,101	103,440
Total non-current assets	138,745	128,613
Total assets	238,087	230,398

(Million yen)

	As of March 31, 2022	As of December 31, 2022
Liabilities		
Current liabilities		
Notes and accounts payable - trade	4,104	5,566
Short-term borrowings	1,640	1,540
Income taxes payable	3,497	25
Provision for bonuses	1,707	806
Other provisions	151	188
Contract liabilities	2,696	1,966
Other	4,946	9,236
Total current liabilities	18,744	19,330
Non-current liabilities		
Deferred tax liabilities	16,259	13,366
Provision for retirement benefits for directors (and other officers)	181	188
Asset retirement obligations	138	138
Other	583	671
Total non-current liabilities	17,163	14,365
Total liabilities	35,907	33,696
Net assets		
Shareholders' equity		
Share capital	24,356	24,356
Capital surplus	24,226	24,226
Retained earnings	118,183	121,714
Treasury shares	(12,912)	(12,912)
Total shareholders' equity	153,854	157,385
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	45,095	36,240
Remeasurements of defined benefit plans	2,435	2,201
Total accumulated other comprehensive income	47,531	38,442
Non-controlling interests	794	874
Total net assets	202,180	196,701
Total liabilities and net assets	238,087	230,398

(2) Quarterly Consolidated Statements of Income and Comprehensive Income
Quarterly Consolidated Statements of Income
Nine Months Ended December 31

(Million yen)

	For the nine months ended December 31, 2021	For the nine months ended December 31, 2022
Net sales	50,085	51,635
Cost of sales	25,976	26,249
Gross profit	24,108	25,385
Selling, general and administrative expenses	24,402	24,892
Operating profit (loss)	(294)	492
Non-operating income		
Interest income	35	16
Dividend income	1,346	1,243
Gain on valuation of securities	66	170
Other	297	242
Total non-operating income	1,746	1,673
Non-operating expenses		
Interest expenses	17	15
Provision of allowance for doubtful accounts	—	15
Other	83	21
Total non-operating expenses	101	52
Ordinary profit	1,350	2,113
Extraordinary income		
Gain on sale of non-current assets	0	—
Gain on sale of investment securities	8,005	6,879
Total extraordinary income	8,005	6,879
Extraordinary losses		
Loss on sale of non-current assets	0	—
Loss on disposal of non-current assets	23	2
Loss on sale of investment securities	—	0
Loss on valuation of investment securities	619	—
Total extraordinary losses	643	2
Profit before income taxes	8,713	8,990
Income taxes - current	1,929	940
Income taxes - deferred	(119)	1,305
Total income taxes	1,810	2,246
Profit	6,903	6,744
Profit attributable to non-controlling interests	84	77
Profit attributable to owners of parent	6,819	6,667

Quarterly Consolidated Statements of Comprehensive Income

Nine Months Ended December 31

(Million yen)

	For the nine months ended December 31, 2021	For the nine months ended December 31, 2022
Profit	6,903	6,744
Other comprehensive income		
Valuation difference on available-for-sale securities	(22,221)	(8,849)
Remeasurements of defined benefit plans, net of tax	49	(237)
Total other comprehensive income	(22,171)	(9,086)
Comprehensive income	(15,268)	(2,342)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(15,356)	(2,422)
Comprehensive income attributable to non-controlling interests	88	80

(3) Notes to Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

Not applicable.

(Notes in case of significant changes in shareholders' equity)

Not applicable.

(Changes in accounting policies)

(Application of the Implementation Guidance on Accounting Standard for Fair Value Measurement)

Effective from the beginning of the first quarter ended June 30, 2022, the Company applies the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, June 17, 2021) and will prospectively apply the new accounting policy stipulated by the Implementation Guidance on Accounting Standard for Fair Value Measurement in accordance with the transitional treatment stipulated in Paragraph 27-2 of the Implementation Guidance on Accounting Standard for Fair Value Measurement. There is no impact on quarterly consolidated financial statements.

(Segment information, etc.)

I. For the nine months ended December 31, 2021 (from April 1, 2021 to December 31, 2021)

1. Information on net sales and profit (loss), and information on the disaggregation of revenue by reportable segment

(Million yen)

	Reportable segment				Total
	Pharmaceutical	Information Services	Construction	Merchandising	
Net sales					
Pharmaceutical Business					
Pharmaceuticals sales	35,510	—	—	—	35,510
Therapeutic and care foods sales	2,765	—	—	—	2,765
Technical fees	400	—	—	—	400
Other	3,263	—	—	—	3,263
Information Services Business	—	6,840	—	—	6,840
Construction Business	—	—	3,075	—	3,075
Merchandising Business	—	—	—	612	612
Revenue arising from contracts with customers	41,939	6,840	3,075	612	52,469
Sales to third parties	41,939	5,616	2,082	445	50,085
Inter-segment sales or transfers	—	1,223	993	166	2,383
Total	41,939	6,840	3,075	612	52,469
Segment profit (loss)	(1,224)	669	132	28	(394)

2. Total amount of profit (loss) of reportable segments, difference from the amount stated in the quarterly consolidated statements of income, and main components of such difference

(Million yen)

Profit	Amount
Total for reportable segments	(394)
Elimination of inter-segment transactions	62
Adjustment of non-current assets	40
Other adjustments	(2)
Operating profit (loss) in the quarterly consolidated statements of income	(294)

II. For the nine months ended December 31, 2022 (from April 1, 2022 to December 31, 2022)

1. Information on net sales and profit (loss), and information on the disaggregation of revenue by reportable segment

(Million yen)

	Reportable segment				Total
	Pharmaceutical	Information Services	Construction	Merchandising	
Net sales					
Pharmaceutical Business					
Pharmaceuticals sales	36,235	—	—	—	36,235
Therapeutic and care foods sales	2,716	—	—	—	2,716
Technical fees	970	—	—	—	970
Other	3,719	—	—	—	3,719
Information Services Business	—	7,247	—	—	7,247
Construction Business	—	—	2,457	—	2,457
Merchandising Business	—	—	—	664	664
Revenue arising from contracts with customers	43,641	7,247	2,457	664	54,011
Sales to third parties	43,641	5,717	1,773	502	51,635
Inter-segment sales or transfers	—	1,530	684	161	2,376
Total	43,641	7,247	2,457	664	54,011
Segment profit (loss)	(325)	654	39	30	398

2. Total amount of profit (loss) of reportable segments, difference from the amount stated in the quarterly consolidated statements of income, and main components of such difference

(Million yen)

Profit	Amount
Total for reportable segments	398
Elimination of inter-segment transactions	76
Adjustment of non-current assets	23
Other adjustments	(5)
Operating profit in the quarterly consolidated statements of income	492

(Revenue recognition)

Information on the disaggregation of revenue arising from contracts with customers is as presented in “Notes (Segment information, etc.)”

3. Other

(1) Sales Results

Sales results by segment for the nine months ended December 31, 2022 are as follows.

Segment classification	Nine months ended December 31, 2021		Nine months ended December 31, 2022		Change	
	Amount (Million yen)	Composition (%)	Amount (Million yen)	Composition (%)	Amount (Million yen)	Change (%)
Pharmaceutical Business	41,939	83.7	43,641	84.5	1,702	4.1
Urology	11,757	23.5	13,517	26.2	1,760	15.0
Renal diseases and dialysis	10,878	21.7	10,797	20.9	(80)	(0.7)
Orphan drugs	60	0.1	641	1.2	581	957.4
Metabolism and endocrinology	5,991	12.0	4,953	9.6	(1,037)	(17.3)
Obstetrics and gynecology	828	1.7	659	1.3	(169)	(20.5)
Ophthalmology	433	0.9	355	0.7	(78)	(18.0)
Other drugs	5,561	11.1	5,310	10.3	(250)	(4.5)
Therapeutic and care foods	2,765	5.5	2,716	5.3	(49)	(1.8)
Technical fees	400	0.8	970	1.9	570	142.6
Other	3,263	6.5	3,719	7.2	456	14.0
Information Services Business	5,616	11.2	5,717	11.1	100	1.8
Construction Business	2,082	4.2	1,773	3.4	(309)	(14.9)
Merchandising Business	445	0.9	502	1.0	56	12.7
Total	50,085	100.0	51,635	100.0	1,549	3.1
[Exports]	[2,723]	[5.4]	[3,741]	[7.2]	[1,017]	[37.4]

(Note) Intersegment transactions are eliminated.