

Stock exchange listing: Tokyo Stock Exchange  
Stock code: 4547

**Supplementary  
Explanatory Materials on  
Financial Results for  
the Six Months ended  
September 30, 2022**

November 8, 2022

 **KISSEI PHARMACEUTICAL CO., LTD.**

## Table of Contents

<b>[Excerpts from “Explanation of Operating Results” of the Quarterly Financial Results]</b>	.....	P 1
<b>I. Consolidated Statements of Income</b>	.....	P 2
<b>II. Consolidated Balance Sheets</b>	.....	P 5
<b>III. Consolidated Statements of Cash Flows</b>	.....	P 7
<b>IV. Trends in Dividends</b>	.....	P 8
<b>V. Trends in Main Product Sales</b>	.....	P 9
<b>VI. R&amp;D Pipeline (In-house)</b>	.....	P 10
<b>VII. R&amp;D Pipeline (Out-licensing)</b>	.....	P 10

Notes:

- The forward-looking statements herein are based on the information available and the Company’s analysis of various trends as of November 2022. 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 ¥27,946 million, an increase of 3.6% 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 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 ¥3,335 million, a decrease of 11.2% year on year, net sales of the Construction Business were ¥1,250 million, a decrease of 7.5% year on year, and net sales of the Merchandising Business were ¥332 million, an increase of 6.1% year on year.

### • Profit

Despite an increase in net sales and an improvement in the cost of sales ratio, the Company recorded an operating loss and a lower ordinary profit due to an increase in selling, general and administrative expenses centering on R&D expenses. Profit attributable to owners of parent decreased despite a gain on sale of investment securities.

### • R&D

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 a New Drug Application (NDA) in Japan in April 2022. 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 have been initiated for the indication of uterine fibroids in Japan.

Overseas, as ObsEva SA (Switzerland), which has exclusive development and commercialization rights worldwide, except certain Asian countries including Japan, to linzagolix, has decided to commence corporate reorganization proceedings, the Company has been working to have all interests related to linzagolix returned from ObsEva. ObsEva has contracted a sublicense agreement with Theramex (U.K.) to commercialize linzagolix in all countries except for North America and Asia. After canceling its license agreement with ObsEva, the Company will have the sublicense agreement between ObsEva and Theramex assigned to the Company in accordance with the agreement. The Company is holding discussions with Theramex on the launch of linzagolix in Europe. In August of this year, ObsEva withdrew its NDA for linzagolix to the U.S. Food and Drug Administration (FDA) for the indication of uterine fibroids. The Company is scrutinizing the application data and others, and will decide its policy for the development of this agent in the U.S. 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.

# I. Consolidated Statements of Income

(Million yen)

Item	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Net sales	32,388	65,381	32,864	1.5 %	68,500	4.8 %
Pharmaceutical Business	26,968	54,147	27,946	3.6 %	57,500	6.2 %
Pharmaceuticals	22,947	45,792	23,550	2.6 %	47,600	3.9 %
Therapeutic and Care Foods	1,813	3,568	1,766	(2.6) %	3,600	0.9 %
Technical Fees* <sup>1</sup>	171	518	220	28.4 %	1,700	228.1 %
Other* <sup>2</sup>	2,036	4,268	2,410	18.4 %	4,600	7.8 %
Information Services Business	3,755	7,742	3,335	(11.2) %	7,900	2.0 %
Construction Business	1,351	2,948	1,250	(7.5) %	2,400	(18.6) %
Merchandising Business	313	543	332	6.1 %	700	28.8 %
[Export sales included in net sales]	[1,877]	[3,713]	[2,407]	[28.2 %]	[5,300]	[42.7 %]
Cost of sales	16,924	34,143	16,680	(1.4) %	34,400	0.8 %
[Cost of sales ratio]	[52.3]	[52.2]	[50.8]		[50.2]	
Gross profit	15,463	31,238	16,184	4.7 %	34,100	9.2 %
Selling, general and administrative expenses	15,193	32,640	16,810	10.6 %	33,600	2.9 %
R&D expenses	4,168	10,363	5,200	24.8 %	10,500	1.3 %
[Ratio to net sales]	[12.9]	[15.9]	[15.8]		[15.3]	
Operating profit (loss)	270	(1,402)	(625)	–	500	–
Non-operating income	1,033	2,092	977	(5.4) %	1,700	(18.7) %
Interest and dividend income	820	1,586	742	(9.5) %		
Other	212	506	235	10.4 %		
Non-operating expenses	21	127	43	98.0 %	100	(21.3) %
Interest expenses	11	23	10	(11.6) %		
Other	9	104	32	229.0 %		
Ordinary profit	1,281	562	308	(75.9) %	2,100	273.7 %
Extraordinary income	6,634	16,601	4,111	(38.0) %	12,010	(27.7) %
Extraordinary losses	642	656	2	(99.6) %	10	(98.5) %
Profit before income taxes	7,273	16,507	4,418	(39.3) %	14,100	(14.6) %
Income taxes - current	1,837	4,017	629	(65.8) %	2,600	(35.3) %
Income taxes - deferred	(279)	(542)	420	–	600	–
Profit attributable to non-controlling interests	49	110	42	(14.5) %	100	(9.1) %
Profit attributable to owners of parent	5,666	12,921	3,326	(41.3) %	10,800	(16.4) %

Comprehensive income [(10,037)] [(13,764)] [26] [–]

\*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: 3.6% increase in net sales</p> <p>Sales of pharmaceuticals increased. Overall sales of pharmaceuticals increased due to increases in sales of Beova<sup>®</sup>, Darbepoetin Alfa BS and other products, the launch of CAROGRA<sup>®</sup> and TAVNEOS<sup>®</sup>, an increase in export sales, and other factors. Sales of therapeutic and care foods slightly decreased and revenue from technical fees slightly increased, while other sales, primarily revenue from co-promotion fees, increased.</p> <p>Other businesses: 9.3% decrease in net sales</p> <p>Net sales of the Information Services Business decreased 11.2%, net sales of the Construction Business decreased 7.5%, and net sales of the Merchandising Business increased 6.1%.</p> <p>Forecast:</p> <p>Pharmaceutical Business: 6.2% increase in net sales</p> <p>Sales of pharmaceuticals are expected to increase because of the Company's ongoing efforts to promote its products such as Beova<sup>®</sup> and P-TOL<sup>®</sup> as well as new products, CAROGRA<sup>®</sup> and TAVNEOS<sup>®</sup>, and an increase in export sales.</p> <p>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: 2.1% decrease in net sales</p> <p>Net sales of the Information Services Business and the Merchandising Business are expected to increase. Net sales of the Construction Business are expected to decrease.</p>
Cost of sales	<p>Results: 1.5-percentage-point improvement in cost of sales ratio</p> <p>The cost of sales ratio of the Pharmaceutical Business improved owing mainly to the change in the composition of product sales. In addition, the cost of sales of other businesses also improved owing mainly to the change of the business structure.</p> <p>Forecast: 2.0-percentage-point improvement in cost of sales ratio</p> <p>The cost of sales 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: 10.6% increase YoY</p> <p>Selling expenses, general and administrative expenses, and R&amp;D expenses all increased. The increase in selling expenses was due to increases in expenses for operating activities and in depreciation and amortization. R&amp;D expenses increased mainly due to an increase in clinical trial expenses, including expenses for overseas clinical trials taken over from ObsEva.</p> <p>Forecast: 2.9% increase YoY</p> <p>Selling expenses, general and administrative expenses, and R&amp;D expenses are all expected to increase. The increases in selling expenses and R&amp;D expenses are due to the same factors as those for the first half of the fiscal year ending March 31, 2023.</p>
Non-operating income and expenses	<p>Results: Main items included decreases in interest income, 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 for the second half of the fiscal year ending March 31, 2023, as was the case for the first half of the fiscal year.</p>

[Other Items (Consolidated)]

(Million yen)

Item	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023			
	1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Depreciation and amortization	1,755	3,730	1,994	13.6 %	4,100	9.9 %
Capital investment	841	1,488	627	(25.4) %	1,100	(26.1) %
Main items	Production equipment, etc.	Production equipment, etc.	Production equipment, etc.		Production equipment, etc.	
	391	428	56		200	
	Other	Other	Other		Other	
	450	1,059	571		900	
Number of employees at end of period	1,870	1,828	1,841	(29)	–	–

## II. Consolidated Balance Sheets

(Million yen)

Item		Fiscal year	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023	Change (from the previous fiscal year-end)
			As of September 30, 2021	As of March 31, 2022	As of September 30, 2022	
Assets	Current assets		95,595	99,342	99,515	173
	Cash and deposits		25,364	30,013	28,388	(1,624)
	Notes and accounts receivable - trade, and contract assets		21,573	22,808	22,399	(408)
	Investments in specified trusts and securities		27,345	26,862	26,411	(450)
	Inventories		18,705	18,988	19,998	1,009
	Other current assets		2,607	669	2,317	1,648
	Non-current assets		155,461	138,745	134,074	(4,671)
	Property, plant and equipment		24,328	24,074	23,862	(212)
	Intangible assets		1,592	1,569	1,604	34
	Investments and other assets		129,540	113,101	108,607	(4,493)
	Investment securities		114,675	96,631	91,908	(4,722)
	Retirement benefit assets		–	2,460	2,675	214
	Long-term prepaid expenses		13,341	12,480	12,568	88
	Deferred tax assets		529	524	477	(46)
	Other		1,029	1,027	1,011	(16)
Allowance for doubtful accounts		(34)	(23)	(33)	(10)	
Total assets			251,056	238,087	233,589	(4,498)

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

(Million yen)

Item		Fiscal year	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023	Change (from the previous fiscal year-end)
			As of September 30, 2021	As of March 31, 2022	As of September 30, 2022	
Liabilities	Total liabilities		43,857	35,907	32,674	(3,233)
	Current liabilities		20,565	18,744	16,499	(2,245)
	Notes and accounts payable - trade		4,994	4,104	5,052	948
	Short-term borrowings		1,735	1,640	1,590	(50)
	Income taxes payable		2,056	3,497	859	(2,638)
	Contract liabilities		2,879	2,696	2,554	(141)
	Other		8,899	6,806	6,442	(363)
	Non-current liabilities		23,292	17,163	16,175	(988)
	Deferred tax liabilities		21,281	16,259	15,163	(1,096)
	Retirement benefit liability		1,104	–	–	–
Other		906	903	1,011	108	
Net assets	Total net assets		207,198	202,180	200,915	(1,264)
	Shareholders' equity		147,890	153,854	155,889	2,035
	Share capital		24,356	24,356	24,356	–
	Capital surplus		24,226	24,226	24,226	–
	Retained earnings		112,219	118,183	120,218	2,035
	Treasury shares		(12,911)	(12,912)	(12,912)	–
	Total accumulated other comprehensive income		58,620	47,531	44,189	(3,342)
	Non-controlling interests		688	794	836	42
Total liabilities and net assets			251,056	238,087	233,589	(4,498)

Notes and accounts payable - trade	<ul style="list-style-type: none"> <li>Increased in the Pharmaceutical Business and the Information Services Business</li> </ul>
Income taxes payable	<ul style="list-style-type: none"> <li>Decreased due to a decrease in income of the Pharmaceutical Business</li> </ul>
Other current liabilities	<ul style="list-style-type: none"> <li>A decrease in accrued consumption taxes in the Pharmaceutical Business</li> </ul>
Deferred tax liabilities	<ul style="list-style-type: none"> <li>Decreased due to a decrease in unrealized gains on investment securities</li> </ul>
Other non-current liabilities	<ul style="list-style-type: none"> <li>An increase in lease liabilities in the Pharmaceutical Business</li> </ul>
Retained earnings	<ul style="list-style-type: none"> <li>Dividends paid: -¥1,291 million; Profit attributable to owners of parent: +¥3,326 million</li> </ul>
Total accumulated other comprehensive income	<ul style="list-style-type: none"> <li>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</li> </ul>



### III. Consolidated Statements of Cash Flows

(Million yen)

Item	Fiscal year	Fiscal year ended March 31, 2022	Fiscal year ending March 31, 2023	Change
		1st half	1st half	
Cash flows from operating activities		931	(3,158)	(4,089)
Cash flows from investing activities		5,280	2,936	(2,343)
Cash flows from financing activities		(1,300)	(1,407)	(107)
Effect of exchange rate change on cash and cash equivalents		0	8	8
Net increase (decrease) in cash and cash equivalents		4,912	(1,620)	(6,532)
Cash and cash equivalents at beginning of period		43,447	53,004	9,557
Cash and cash equivalents at end of period		48,359	51,383	3,024

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

1. Cash flows from operating activities: Decreased

Net cash used in operating activities amounted to ¥3,158 million for the six months ended September 30, 2022 due to cash outflow factors such as increases in other current assets, inventories, and income taxes paid, despite cash inflow factors such as an increase in trade payables.

2. Cash flows from investing activities: Decreased (higher cash outflows)

Net cash provided by investing activities amounted to ¥2,936 million for the six months ended September 30, 2022 due to cash inflows such as proceeds from sale of investment securities, despite cash outflows such as recording long-term prepaid expenses.

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

Net cash used in financing activities was ¥1,407 million for the six months ended September 30, 2022. The main factor was dividends paid.

## IV. Trends in Dividends

(Yen)

Item \ Fiscal year	Fiscal year ended March 31, 2020	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022	Fiscal year ending March 31, 2023 (Forecast)
Interim dividend	26	27	28	40
Annual dividend	52	54	56	80

(Reference)

(Million yen)

Purchase of treasury shares	–	1,303	–	–
(Number of shares purchased)	–	(600 thousand shares)	–	–
Cancellation of treasury shares	–	–	–	–
(Number of shares cancelled)	–	–	–	–

## V. Trends in Main Product Sales

(Million yen)

Product name	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022		Fiscal year ending March 31, 2023			
		1st half	Full year	1st half	YoY	Full year (forecast)	YoY
Overactive Bladder Treatment <b>Beova</b> <sup>®</sup>	7,024	3,973	8,141	5,183	30.5%	12,000	47.4%
DESMOPRESSIN Formulations <b>MINIRIN MELT</b> <sup>®</sup> , etc.* <sup>1</sup>	3,464	2,022	3,965	1,925	(4.8)%	3,900	(1.6)%
Dysuria Treatment <b>URIEF</b> <sup>®</sup>	3,671	1,476	2,878	1,200	(18.7)%	2,300	(20.1)%
Hyperphosphatemia Treatment <b>P-TOL</b> <sup>®</sup>	5,885	2,946	5,784	2,951	0.2%	6,000	3.7%
Treatment for Renal Anemia <b>Darbepoetin Alfa BS Injection [JCR]</b>	4,883	1,787	3,730	2,229	24.7%	4,300	15.3%
Treatment for Renal Anemia <b>Epoetin Alfa BS Injection [JCR]</b>	4,416	1,979	3,834	1,653	(16.4)%	3,100	(19.1)%
Treatment for Diabetes <b>GLUBES</b> <sup>®</sup>	4,308	1,964	3,838	1,573	(19.9)%	3,100	(19.2)%
Treatment for Diabetes <b>GLUFAST</b> <sup>®</sup>	1,161	530	1,151	562	6.0%	1,000	(13.1)%
Treatment for Diabetes <b>MARIZEV</b> <sup>®</sup>	1,547	641	1,234	559	(12.8)%	1,100	(10.9)%
Treatment for MPA* <sup>2</sup> and GPA* <sup>3</sup> <b>TAVNEOS</b> <sup>®</sup>	–	–	–	213	–	800	–
Treatment for Ulcerative Colitis <b>CAROGRA</b> <sup>®</sup>	–	–	–	207	–	600	–
Treatment of Dry Mouth Symptoms <b>SALAGEN</b> <sup>®</sup>	1,526	734	1,412	564	(23.2)%	1,100	(22.1)%

\*1: MINIRIN MELT<sup>®</sup>, DESMOPRESSIN Intranasal, DESMOPRESSIN Nasal Spray, and DESMOPRESSIN I.V. Injection

\*2: Microscopic polyangiitis

\*3: Granulomatosis with polyangiitis

## VI. R&D Pipeline (In-house)

(As of November 2022)

Generic Name / Development Code	Expected Indications	Category	Development Stage	Development Classification
Rovatrielin / KPS-0373	Spinocerebellar ataxia	TRH receptor agonist	NDA	In-licensed / Shionogi (Japan)
Fostamatinib / R788	Chronic idiopathic thrombocytopenic purpura	Tyrosine kinase inhibitor	NDA	In-licensed / Rigel Pharmaceuticals (US)
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 (US)
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 (August 2022): Difelikefalin Phase III → NDA

## VII. R&D Pipeline (Out-licensing)

(As of November 2022)

Generic Name / Development Code	Expected Indications	Category	Countries & Regions	Development Company	Development Stage
Linzagolix	Uterine fibroids	GnRH receptor antagonist	EU	Theramex (UK)	Approved
			China	Bio Genuine (China)	Preparation for clinical trial
			Taiwan	Synmosa Biopharma (Taiwan)	NDA preparation
	Endometriosis		EU	Theramex (UK)	Phase III
			US		
			China	Bio Genuine (China)	Preparation for clinical trial
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
			Hong Kong	Immagene Biopharmaceuticals (China)	NDA
			China, etc.		Preparation for clinical trial
KDT-3594	Parkinson's disease	Dopamine receptor agonist	China, etc.	AffaMed Therapeutics (China)	Phase II

\*Changes from previous release (August 2022): Linzagolix (uterine fibroids, endometriosis, EU) ObsEva SA (Switzerland) → Theramex (UK)  
 Linzagolix (uterine fibroids, US) ObsEva SA (Switzerland) NDA → Withdrawal of NDA (deleted)  
 Linzagolix (uterine fibroids, Taiwan) Synmosa (Taiwan) → NDA preparation (newly listed)  
 Linzagolix (endometriosis, US) ObsEva SA (Switzerland) → (deleted)  
 Bedoradrine (acute exacerbation of asthma) MediciNova (US) Phase II → Expiration of contract (deleted)