KISSEI

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

# Supplementary Explanatory Materials on Financial Results for the Three Months Ended June 30, 2025

July 29, 2025

KISSEI PHARMACEUTICAL CO., LTD.

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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 July 2025. 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 Quarterly Financial Results]**

• Net sales

Net sales of the Pharmaceutical Business were ¥18,681 million, an increase of 1.0% year on year. The sales increase of Beova®, an overactive bladder treatment, TAVNEOS® for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, KORSUVA®, a treatment for pruritus in dialysis patients, and TAVALISSE®, a treatment for chronic idiopathic thrombocytopenic purpura, etc., contributed to the year-on-year increase in net sales.

In addition, Linzagolix (generic name), which was discovered by the Company and licensed out to Theramex (U.K.), was launched to the market in Germany in September 2024 under the product name Yselty® for the indication of uterine fibroids. Furthermore, in November 2024, an additional indication of endometriosis for this drug was approved, and preparations for launch in other European countries and other regions continued during the period under review, with export sales increasing steadily.

Net sales of the Information Services Business were ¥2,280 million, an increase of 16.8% year on year, net sales of the Construction and Facility Maintenance Business were ¥992 million, an increase of 104.4% year on year, and net sales of the Merchandising Business were ¥236 million, an increase of 2.2% year on year.

• Profit

Regarding profit, although the Company secured higher net sales, operating profit decreased due to an increase in the cost of sales ratio and an increase in selling, general and administrative expenses, while ordinary profit and profit attributable to owners of parent increased. The Company also recorded gain on sale of investment securities as extraordinary income.

• R&D

The Company continues to advance the stage-up of our research and development themes, including participation in an international collaborative Phase III clinical trial being conducted by CG Oncology, Inc. (U.S.), the originator of the development program, for Cretostimogene grenadenorepvec (generic name, development code: CG0070), a treatment for non-muscle invasive bladder cancer in high-risk patients; domestic Phase III clinical trials for Linzagolix (generic name, development code: KLH-2109) to obtain additional indication for endometriosis; additional domestic Phase III clinical trials for Rovatirelin (generic name, development code: KPS-0373), a treatment for spinocerebellar degeneration; and preparations for initiating domestic clinical trials for Olutasidenib (generic name), a treatment for acute myeloid leukemia.

Fostamatinib (generic name, domestic brand name: TAVALISSE®), which the Company in-licensed from Rigel Pharmaceuticals, Inc. (U.S.), was newly launched in July 2025 by JW Pharmaceutical Corporation (South Korea), the sublicensee of the drug in South Korea.

# I. Consolidated Statements of Income

(Million yen)

| Item \ Fiscal year | Fiscal year ended March 31, 2025 | | Fiscal year ending March 31, 2026 | | | |
|---|---|---|---|---|---|---|
| | 1st quarter | Full year | 1st quarter | YoY | Full year [*1] (forecast) | 1st half [*1] (forecast) |
| Net sales | 21,164 | 88,330 | 22,191 | 4.9 % | 91,500 | 44,300 |
| Pharmaceutical Business | 18,494 | 75,299 | 18,681 | 1.0 % | 75,500 | 37,200 |
| Domestic Pharmaceuticals | 15,969 | 63,975 | 16,371 | 2.5 % | 65,800 | 32,200 |
| Pharmaceutical products | 14,855 | 59,108 | 15,315 | 3.1 % | 60,700 | 29,800 |
| Other[*2] | 1,114 | 4,866 | 1,056 | (5.2) % | 5,100 | 2,400 |
| Overseas Licensing | 1,626 | 7,770 | 1,431 | (12.0) % | 6,100 | 3,200 |
| Technical Fees[*3] | 588 | 2,209 | 15 | (97.3) % | 800 | 700 |
| Export | 1,037 | 5,561 | 1,415 | 36.4 % | 5,300 | 2,500 |
| Therapeutic and Care Foods | 898 | 3,553 | 878 | (2.3) % | 3,600 | 1,800 |
| Information Services Business | 1,952 | 8,735 | 2,280 | 16.8 % | 11,400 | 4,700 |
| Construction and Facility Maintenance Business | 485 | 3,435 | 992 | 104.4 % | 3,700 | 1,900 |
| Merchandising Business | 231 | 860 | 236 | 2.2 % | 900 | 500 |
| Cost of sales | 10,283 | 44,265 | 11,111 | 8.1 % | 47,100 | 22,400 |
| [Cost of sales ratio] | [48.6] | [50.1] | [50.1] | | [51.5] | [50.6] |
| Gross profit | 10,881 | 44,065 | 11,079 | 1.8 % | 44,400 | 21,900 |
| Selling, general and administrative expenses | 8,723 | 38,291 | 8,971 | 2.9 % | 48,400 | 29,600 |
| R&D expenses | 2,586 | 12,889 | 2,509 | (3.0) % | 23,000 | 16,600 |
| [Ratio to net sales] | [12.2] | [14.6] | [11.3] | | [25.1] | [37.5] |
| Operating profit | 2,158 | 5,773 | 2,108 | (2.3) % | (4,000) | (7,700) |
| Non-operating income | 732 | 1,542 | 839 | 14.6 % | 1,500 | 850 |
| Interest and dividend income | 651 | 1,450 | 692 | 6.3 % | | |
| Other | 81 | 92 | 147 | 81.6 % | | |
| Non-operating expenses | 14 | 341 | 32 | 117.7 % | 100 | 50 |
| Interest expenses | 4 | 21 | 6 | 38.4 % | | |
| Other | 9 | 319 | 25 | 157.2 % | | |
| Ordinary profit | 2,876 | 6,974 | 2,915 | 1.4 % | (2,600) | (6,900) |
| Extraordinary income | 2,812 | 12,033 | 2,857 | 1.6 % | 19,300 | 15,000 |
| Extraordinary losses | 166 | 3,398 | 25 | (84.9) % | – | – |
| Profit before income taxes | 5,521 | 15,610 | 5,747 | 4.1 % | 16,700 | 8,100 |
| Income taxes - current | 1,284 | 2,918 | 1,460 | 13.7 % | 6,300 | 4,500 |
| Income taxes - deferred | 131 | 716 | (233) | – | (2,000) | (2,650) |
| Profit attributable to non-controlling interests | (1) | 14 | 1 | – | 100 | 50 |
| Profit attributable to owners of parent | 4,106 | 11,961 | 4,519 | 10.1 % | 12,300 | 6,200 |
| [Comprehensive income] | [1,594] | [(1,914)] | [5,677] | [256.0%] | | |

*1: Forecast values presented in the financial statements for the three months ended June 30, 2025.
*2: Includes revenue from supply to domestic sales partners and revenue from co-promotion fees.
*3: Includes revenue contracting fees related to out-licensing, milestone payments, and running royalties.

# II. Trends in Main Product Sales

(Million yen)

| Fiscal year / Product name | Fiscal year ended March 31, 2025 | | Fiscal year ending March 31, 2026 | | | |
|---|---|---|---|---|---|---|
| | 1st quarter | Full year | 1st quarter | YoY | Full year [*1] (forecast) | 1st half [*1] (forecast) |
| Overactive Bladder Treatment **Beova®** | 4,580 | 18,662 | 5,238 | 14.4 % | 20,400 | 10,000 |
| Treatment for MPA[*2] and GPA[*3] **TAVNEOS®** | 2,168 | 8,989 | 2,851 | 31.5 % | 11,400 | 5,400 |
| Treatment for Pruritus in Dialysis **KORSUVA®** | 997 | 5,284 | 1,793 | 79.9 % | 7,100 | 3,400 |
| Hyperphosphatemia Treatment **P-TOL®** | 1,226 | 4,442 | 1,042 | (15.1)% | 4,600 | 2,400 |
| Treatment for Chronic ITP[*4] **TAVALISSE®** | 491 | 2,190 | 848 | 72.7 % | 3,700 | 1,700 |
| Treatment for Renal Anemia **Darbepoetin Alfa BS Injection [JCR]** | 951 | 3,792 | 891 | (6.3)% | 3,200 | 1,600 |
| Treatment for Diabetes **GLUBES®, GLUFAST®** | 894 | 3,209 | 715 | (20.1)% | 2,800 | 1,400 |
| Treatment for Renal Anemia **Epoetin Alfa BS Injection [JCR]** | 504 | 1,771 | 377 | (25.2)% | 1,600 | 800 |
| Treatment for Ulcerative Colitis **CAROGRA®** | 310 | 1,153 | 286 | (7.7)% | 1,400 | 700 |
| Treatment for Diabetes **MARIZEV®** | 277 | 939 | 213 | (23.1)% | 1,000 | 500 |

*1: Forecast values presented in the financial statements for the fiscal year ended March 31, 2025.
*2: Microscopic polyangiitis
*3: Granulomatosis with polyangiitis
*4: Idiopathic thrombocytopenic purpura

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

(As of July 2025)

| Generic name / Development code | Expected indications | Category | Development stage | Development classification |
|---|---|---|---|---|
| Linzagolix / KLH-2109 | Uterine fibroids | GnRH receptor antagonist | NDA | Kissei |
| | Endometriosis | | Phase III | Kissei |
| Cretostimogene grenadenorepvec / CG0070 | Non-muscle-invasive bladder cancer in high-risk patients | Oncolytic Viral Therapy | Phase III | In-licensed / CG Oncology (U.S.) |
| Rovatirelin / KPS-0373 | Spinocerebellar degeneration | TRH receptor agonist | Phase III | In-licensed / Shionogi (Japan) |
| Matsupexole / KDT-3594 | Parkinson's disease | Dopamine receptor agonist | Phase II | Kissei |
| Olutasidenib | Relapsed/refractory acute myeloid leukemia | IDH1 inhibition | Clinical trial preparation | In-licensed / Rigel (U.S.) |

* Changes from previous release (May 2025):
Olutasidenib (relapsed/refractory acute myeloid leukemia) → Clinical trial preparation (addition)

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

(As of July 2025)

| Generic name | Expected indications | Category | Countries & Regions | Development company | Development stage |
|---|---|---|---|---|---|
| Linzagolix | Uterine fibroids | GnRH receptor antagonist | 4 countries[*1] | Theramex (U.K.) | NDA |
| | | | Taiwan | Synmosa Biopharma (Taiwan) | NDA |
| | Endometriosis | | 3 countries[*2] | Theramex (U.K.) | NDA |
| Silodosin | Dysuria associated with benign prostatic hyperplasia | Alpha 1A adrenergic receptor antagonist | Vietnam, etc. | Eisai (Japan) | NDA |

*1: Switzerland, Brazil, Republic of South Africa and Mexico
*2: Brazil, Republic of South Africa and Mexico

* Changes from previous release (May 2025):
Linzagolix (endometriosis, EU): Approved → Launched (deletion)
Linzagolix (endometriosis, 3 countries): → NDA (addition)
Fostamatinib (Korea): Launch preparation → Launched (deletion)