

Stock exchange listing: Tokyo Stock Exchange
Stock code: 4547

**Supplementary
Explanatory Materials on
Financial Results for
the Fiscal Year ended
March 31, 2022**

May 10, 2022

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Notes:

- Effective from the beginning of the fiscal year ended March 31, 2022, the Company applies the Accounting Standard for Revenue Recognition (ASBJ Statement No. 29, March 31, 2020), etc. Consolidated operating results for the previous fiscal year are not restated by retrospectively applying the Accounting Standard for Revenue Recognition, etc. Therefore, the % changes from the previous corresponding period indicated for the consolidated operating results for the fiscal year ended March 31, 2022 are for reference.
- The forward-looking statements herein are based on the information available and the Company’s analysis of various trends as of May 2022. 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 ¥54,147 million, a decrease of 4.0% year on year. Continuing from the previous fiscal year, we endeavored to provide drug information in such a manner as to prevent COVID-19 infection during the pandemic. Although sales increased for certain products, including Beova[®] Tablets, an overactive bladder treatment; MINIRIN MELT[®] OD tablets 25µg and 50µg, a treatment of nocturia due to nocturnal polyuria in males; and MINIRIN MELT[®] OD Tablets 60µg, 120µg, and 240µg and DESMOPRESSIN formulations, treatments for nocturnal enuresis and central diabetes insipidus, net sales decreased mainly because of the impact of the NHI drug price revisions implemented in April 2021 and a decrease in export sales.

UPASITA[®] IV Injection Syringes for the treatment of secondary hyperparathyroidism for which the Company concluded a co-promotion agreement in Japan with SANWA KAGAKU KENKYUSHO Co., Ltd., were launched by SANWA KAGAKU KENKYUSHO in August 2021. Regarding TAVNEOS[®] Capsules 10mg (generic name: avacopan) for the treatment of microscopic polyangiitis and granulomatosis with polyangiitis, for which the Company received marketing authorization approval in Japan in September 2021, 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 following listing in the NHI Drug Price Standard.

Net sales of the Information Services Business were ¥7,742 million, a decrease of 8.8% year on year, net sales of the Construction Business were ¥2,948 million, a decrease of 16.7% year on year, and net sales of the Merchandising Business were ¥543 million, a decrease of 10.9% year on year.

As a result of the application of the Accounting Standard for Revenue Recognition, etc., compared with the figures under the previous accounting standard, net sales of the Pharmaceutical Business decreased ¥456 million, net sales of the Information Services Business increased ¥96 million, net sales of the Construction Business increased ¥517 million, and net sales of the Merchandising Business decreased ¥363 million.

• Profit

Regarding profit, operating loss was recorded and ordinary profit decreased owing mainly to an increase in selling, general and administrative expenses centering on R&D expenses, in addition to a decrease in net sales. On the other hand, profit attributable to owners of parent increased owing mainly to recording of a gain on sale of investment securities.

As a result of the application of the Accounting Standard for Revenue Recognition, etc., compared with the figures under the previous accounting treatment, operating profit and ordinary profit decreased ¥409 million, respectively.

• R&D

Regarding carotegrast methyl (generic name, development code: AJM300), a treatment for ulcerative colitis, which EA Pharma Co., Ltd. and the Company have jointly developed and for which EA Pharma submitted a New Drug Application (NDA) in Japan in May 2021, EA Pharma received marketing authorization approval in Japan in March 2022. Preparations are underway for the launch of the product under the brand name “CAROGR[®]A Tablets 120 mg” following listing in the NHI Drug Price Standard. Furthermore, regarding rovatirelin (generic name, development code: KPS-0373), a treatment for spinocerebellar ataxia, which was in-licensed from Shionogi & Co., Ltd. and 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 NDAs in Japan in December 2021 and April 2022, respectively.

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., the primary endpoints were achieved in phase III clinical studies in Japan.

Overseas, regarding linzagolix (generic name, development code: KLH-2109), a treatment for uterine fibroids and endometriosis, which is a drug discovered by the Company, ObsEva SA based in Switzerland, the licensee

for linzagolix worldwide excluding Japan and certain other countries in Asia, has been promoting development for the indication of uterine fibroids in Europe and the U.S. ObsEva submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for linzagolix for the treatment of uterine fibroids in November 2020, and a recommendation for approval was issued from the Committee for Medicinal Products for Human Use (CHMP) of the EMA in December 2021. Additional inquiries were received thereafter, and a renewed recommendation for approval was adopted in April 2022. Moreover, ObsEva submitted an NDA to the U.S. Food and Drug Administration (FDA) for linzagolix in September 2021.

With respect to licensing in Asia, the Company granted exclusive development and commercialization rights for linzagolix in China to China-based Bio Genuine in September 2021. For fostamatinib, the Company granted development and commercialization rights in South Korea to JW Pharmaceutical Corporation in June 2021 and those in China to China-based Inmagene Biopharmaceuticals in August 2021, respectively.

I. Consolidated Statements of Income

(Million yen)

| Item | Fiscal year ended March 31, 2021 | Fiscal year ended March 31, 2022 | | | Fiscal year ending March 31, 2023 (Forecast) | | |
|--------------------------------------------------|----------------------------------|----------------------------------|----------|-----------|----------------------------------------------|----------|----------|
| | | Forecast*1 | Results | YoY | Full year | YoY | 1st half |
| Net sales | 69,044 | 65,400 | 65,381 | (5.3)% | 68,000 | 4.0% | 31,000 |
| Pharmaceutical Business | 56,407 | 54,600 | 54,147 | (4.0)% | 57,000 | 5.3% | 25,500 |
| Pharmaceuticals | 48,140 | 46,200 | 45,792 | (4.9)% | 44,700 | (2.4)% | 21,000 |
| Therapeutic and Care Foods | 3,726 | 3,700 | 3,568 | (4.2)% | 3,600 | 0.9% | 1,800 |
| Technical Fees*2 | 891 | 400 | 518 | (41.9)% | 4,200 | 710.7% | 300 |
| Other*3 | 3,649 | 4,300 | 4,268 | 17.0% | 4,500 | 5.4% | 2,400 |
| Information Services Business | 8,489 | 7,200 | 7,742 | (8.8)% | 7,200 | (7.0)% | 3,700 |
| Construction Business | 3,538 | 3,000 | 2,948 | (16.7)% | 3,300 | 11.9% | 1,500 |
| Merchandising Business | 609 | 600 | 543 | (10.9)% | 500 | (8.0)% | 300 |
| [Export sales included in net sales] | [4,600] | [3,700] | [3,713] | [(19.3)%] | [7,500] | [102.0%] | [1,700] |
| Cost of sales | 36,322 | 34,500 | 34,143 | (6.0)% | 33,700 | (1.3)% | 16,100 |
| [Cost of sales ratio] | [52.6] | [52.8] | [52.2] | | [49.6] | | [51.9] |
| Gross profit | 32,722 | 30,900 | 31,238 | (4.5)% | 34,300 | 9.8% | 14,900 |
| Selling, general and administrative expenses | 31,217 | 32,500 | 32,640 | 4.6% | 31,500 | (3.5)% | 16,200 |
| R&D expenses | 9,626 | 10,000 | 10,363 | 7.7% | 9,000 | (13.2)% | 5,000 |
| [Ratio to net sales] | [13.9] | [15.3] | [15.9] | | [13.2] | | [16.1] |
| Operating profit (loss) | 1,505 | (1,600) | (1,402) | – | 2,800 | – | (1,300) |
| Non-operating income | 2,154 | 2,000 | 2,092 | (2.9)% | 1,700 | (18.8)% | 850 |
| Interest and dividend income | 1,273 | | 1,586 | 24.6% | | | |
| Other | 881 | | 506 | (42.6)% | | | |
| Non-operating expenses | 183 | 100 | 127 | (30.5)% | 100 | (21.7)% | 50 |
| Interest expenses | 23 | | 23 | 0.4% | | | |
| Other | 160 | | 104 | (35.0)% | | | |
| Ordinary profit (loss) | 3,476 | 300 | 562 | (83.8)% | 4,400 | 682.1% | (500) |
| Extraordinary income | 4,087 | 16,650 | 16,601 | 306.1% | 9,000 | (45.8)% | 4,500 |
| Extraordinary losses | 87 | 650 | 656 | 649.0% | – | – | – |
| Profit before income taxes | 7,476 | 16,300 | 16,507 | 120.8% | 13,400 | (18.8)% | 4,000 |
| Income taxes - current | 1,510 | 4,700 | 4,017 | 166.0% | 2,800 | (30.3)% | 800 |
| Income taxes - deferred | 587 | (400) | (542) | (192.2)% | 500 | – | 150 |
| Profit attributable to non-controlling interests | 93 | 100 | 110 | 18.6% | 100 | (9.5)% | 50 |
| Profit attributable to owners of parent | 5,285 | 11,900 | 12,921 | 144.5% | 10,000 | (22.6)% | 3,000 |
| Comprehensive income | 30,762 | | (13,764) | (–) | | | |

*1: Forecast values presented in the financial statements for the six months ended September 30, 2021.

*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: 4.0% decrease in net sales Sales of pharmaceuticals decreased. Despite increases in sales of Beova[®], MINIRIN MELT[®], and certain other products, net sales decreased mainly because of the impact of the NHI drug price revisions implemented in April 2021 and a decrease in export sales. Whereas sales of therapeutic and care foods and technical fees decreased, other sales increased.</p> <p>Other businesses: 11.1% decrease in net sales Net sales of the Information Services Business, the Construction Business, and the Merchandising Business decreased 8.8%, 16.7%, and 10.9% respectively.</p> <p>Forecast:</p> <p>Pharmaceutical Business: 5.3% increase in net sales Sales of pharmaceuticals are expected to decrease mainly because of the impact of the NHI drug price revisions implemented in April 2022 despite the Company's ongoing efforts to promote its products, such as Beova[®], P-TOL[®], and MINIRIN MELT[®], and the introduction into the market of TAVNEOS[®] and CAROGRA[®]. Sales of therapeutic and care foods are expected to increase slightly. Technical fees and other sales are also expected to increase.</p> <p>Other businesses: 2.1% decrease in net sales Net sales of the Construction Business are expected to increase. Net sales of the Information Services Business and the Merchandising Business are expected to decrease.</p> |
| Cost of sales | <p>Results: 0.4-percentage-point decrease in cost of sales ratio The cost of sales ratio of the Pharmaceutical Business increased owing mainly to the impact of NHI drug price revisions and the change in the composition of product sales. On the other hand, cost of sales of other businesses decreased owing mainly to the change of the business structure.</p> <p>Forecast: 2.6-percentage-point decrease in cost of sales ratio Although the cost of sales ratio of the Pharmaceutical Business is expected to increase owing mainly to factors such as the impact of NHI drug price revisions and the change in the composition of product sales, this will be offset by revenue from technical fees, and the cost of sales ratio is expected to decrease overall. In addition, cost of sales of other businesses is expected to decrease owing mainly to the change of the business structure.</p> |
| Selling, general and administrative expenses | <p>Results: 4.6% 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. The increase in R&D expenses centered on clinical trial expenses.</p> <p>Forecast: 3.5% decrease YoY Although selling expenses are expected to increase, R&D expenses and general and administrative expenses are expected to decrease. The increase in selling expenses is due to increases in expenses for operating activities and in depreciation and amortization. R&D expenses are expected to decrease mainly due to milestone payments on in-licensed products.</p> |
| Non-operating income and expenses | <p>Results: Main items included increases in interest and dividend income.</p> <p>Forecast: No extraordinary items are expected.</p> |
| Extraordinary income and losses | <p>Results: The main item was a gain on sale of investment securities.</p> <p>Forecast: A gain on sale of investment securities is expected to be recorded as extraordinary income.</p> |

[Other Items (Consolidated)]

(Million yen)

| Item | Fiscal year ended March 31, 2021 | Fiscal year ended March 31, 2022 | | | Fiscal year ending March 31, 2023 (Forecast) | | |
|--------------------------------------|----------------------------------|----------------------------------|----------------------------|-------|----------------------------------------------|---------|----------------------------|
| | | Forecast* | Results | YoY | Full year | YoY | 1st half |
| Depreciation and amortization | 3,148 | 3,700 | 3,730 | 18.5% | 4,300 | 15.3% | 2,100 |
| Capital investment | 1,180 | 1,600 | 1,488 | 26.1% | 780 | (47.6)% | 410 |
| Main items | Production equipment, etc. | Production equipment, etc. | Production equipment, etc. | | Production equipment, etc. | | Production equipment, etc. |
| | 615 | 700 | 428 | | 240 | | 130 |
| | Other | Other | Other | | Other | | Other |
| | 564 | 900 | 1,059 | | 540 | | 280 |
| Number of employees at end of period | 1,863 | — | 1,828 | (35) | — | — | — |

*: Forecast values presented in the financial statements for the six months ended September 30, 2021.

II. Consolidated Balance Sheets

(Million yen)

| Fiscal year | | Fiscal year ended March 31, 2021 | Fiscal year ended March 31, 2022 | Change |
|--------------|------------------------------------------------|-------------------------------------|-------------------------------------|----------|
| Item | | | | |
| Assets | Current assets | 92,965 | 99,342 | 6,376 |
| | Cash and deposits | 20,456 | 30,013 | 9,557 |
| | Notes and accounts receivable - trade | 23,058 | – | (23,058) |
| | Notes receivable - trade | – | 233 | 233 |
| | Accounts receivable - trade | – | 21,723 | 21,723 |
| | Contract assets | – | 850 | 850 |
| | Investments in specified trusts and securities | 27,530 | 26,862 | (668) |
| | Inventories | 20,119 | 18,988 | (1,130) |
| | Other current assets | 1,800 | 669 | (1,131) |
| | Non-current assets | 175,895 | 138,745 | (37,150) |
| | Property, plant and equipment | 24,290 | 24,074 | (215) |
| | Intangible assets | 1,640 | 1,569 | (71) |
| | Investments and other assets | 149,964 | 113,101 | (36,863) |
| | Investment securities | 138,133 | 96,631 | (41,502) |
| | Long-term prepaid expenses | 10,262 | 12,480 | 2,218 |
| | Retirement benefit assets | – | 2,460 | 2,460 |
| | Deferred tax assets | 585 | 524 | (61) |
| | Other | 1,017 | 1,027 | 10 |
| | Allowance for doubtful accounts | (34) | (23) | 11 |
| Total assets | | 268,861 | 238,087 | (30,773) |

| | |
|------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cash and deposits | <ul style="list-style-type: none"> • Main factor: Increase due to profit including gain on sale of investment securities |
| Contract assets | <ul style="list-style-type: none"> • A new account title created as a result of the application of the Accounting Standard for Revenue Recognition, etc. |
| Investments in specified trusts and securities | <ul style="list-style-type: none"> • Main factor: Decrease due to redemption at maturity of investment trusts |
| Inventories | <ul style="list-style-type: none"> • A decrease in products and raw materials in the Pharmaceutical Business and a decrease in work in process in the Information Services Business |
| Other current assets | <ul style="list-style-type: none"> • A decrease in accounts receivable in the Pharmaceutical Business |
| Investment securities | <ul style="list-style-type: none"> • Decreases in sales and 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 |
| Retirement benefit assets | <ul style="list-style-type: none"> • A new account title created as a result of a negative value recorded for retirement benefit liability |

(Million yen)

| Fiscal year | | Fiscal year ended March 31, 2021 | Fiscal year ended March 31, 2022 | Change |
|----------------------------------|----------------------------------------------|-------------------------------------|-------------------------------------|----------|
| Item | | | | |
| Liabilities | Total liabilities | 48,907 | 35,907 | (12,999) |
| | Current liabilities | 18,245 | 18,744 | 499 |
| | Notes and accounts payable - trade | 7,909 | 4,104 | (3,804) |
| | Short-term borrowings | 1,743 | 1,640 | (103) |
| | Income taxes payable | 1,487 | 3,497 | 2,009 |
| | Contract liabilities | – | 2,696 | 2,696 |
| | Other | 7,104 | 6,806 | (298) |
| | Non-current liabilities | 30,662 | 17,163 | (13,498) |
| | Deferred tax liabilities | 28,480 | 16,259 | (12,220) |
| | Retirement benefit liability | 1,234 | – | (1,234) |
| | Other | 946 | 903 | (43) |
| Net assets | Total net assets | 219,953 | 202,180 | (17,773) |
| | Shareholders' equity | 144,941 | 153,854 | 8,912 |
| | Share capital | 24,356 | 24,356 | – |
| | Capital surplus | 24,226 | 24,226 | 0 |
| | Retained earnings | 109,270 | 118,183 | 8,912 |
| | Treasury shares | (12,911) | (12,912) | (0) |
| | Total accumulated other comprehensive income | 74,373 | 47,531 | (26,842) |
| | Non-controlling interests | 638 | 794 | 156 |
| Total liabilities and net assets | | 268,861 | 238,087 | (30,773) |

| | |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notes and accounts payable - trade | <ul style="list-style-type: none"> Decreased in the Pharmaceutical Business and the Information Services Business |
| Income taxes payable | <ul style="list-style-type: none"> Increased due to an increase in income of the Pharmaceutical Business |
| Contract liabilities | <ul style="list-style-type: none"> A new account title created as a result of the application of the Accounting Standard for Revenue Recognition, etc. |
| Deferred tax liabilities | <ul style="list-style-type: none"> Decreased due to a decrease in unrealized gains on investment securities |
| Retirement benefit liability | <ul style="list-style-type: none"> Transferred to a new account title (retirement benefit assets) |
| Retained earnings | <ul style="list-style-type: none"> Cumulative effect of changes in accounting policies (application of the Accounting Standard for Revenue Recognition, etc.): -¥1,472 million; Dividends paid: -¥2,536 million; Profit attributable to owners of parent: +¥12,921 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; an increase in remeasurements of defined benefit plans |

III. Consolidated Statements of Cash Flows

(Million yen)

| Item | Fiscal year ended March 31, 2021 | Fiscal year ended March 31, 2022 | Change |
|-------------------------------------------------------------|-------------------------------------|-------------------------------------|----------|
| Cash flows from operating activities | (2,542) | 1,533 | 4,076 |
| Cash flows from investing activities | (9,329) | 10,776 | 20,105 |
| Cash flows from financing activities | (4,000) | (2,756) | 1,244 |
| Effect of exchange rate change on cash and cash equivalents | 0 | 4 | 3 |
| Net increase (decrease) in cash and cash equivalents | (15,872) | 9,557 | 25,429 |
| Cash and cash equivalents at beginning of period | 59,319 | 43,447 | (15,872) |
| Cash and cash equivalents at end of period | 43,447 | 53,004 | 9,557 |

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

1. Cash flows from operating activities: Increased

Despite factors contributing to cash outflows, such as a decrease in trade payables, net cash provided by operating activities amounted to ¥1,533 million for the fiscal year ended March 31, 2022 as a result of factors contributing to cash inflows, such as decreases in inventories, accounts receivable, and other current assets.

2. Cash flows from investing activities: Increased (higher cash inflows)

Although long-term prepaid expenses were recorded due to purchase of investment securities and purchase of commercialization rights, net cash provided by investing activities amounted to ¥10,776 million for the fiscal year ended March 31, 2022 due to proceeds from sale of investment securities.

3. Cash flow from financing activities: Increased (lower cash outflows)

Net cash used in financing activities was ¥2,756 million for the fiscal year ended March 31, 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 (Forecast) | | |
|--------------------------------------------------------------------------------------|----------------------------------|----------------------------------|---------|---------|----------------------------------------------|---------|----------|
| | | Forecast*1 | Results | YoY | Full year | YoY | 1st half |
| Overactive Bladder Treatment Beova [®] | 7,024 | 8,300 | 8,141 | 15.9% | 11,000 | 35.1% | 4,600 |
| DESMOPRESSIN Formulations MINIRIN MELT [®] , etc.*2 | 3,464 | 4,100 | 3,965 | 14.5% | 3,900 | (1.6)% | 1,900 |
| Dysuria Treatment URIEF [®] | 3,671 | 2,800 | 2,878 | (21.6)% | 2,200 | (23.6)% | 1,100 |
| Hyperphosphatemia Treatment P-TOL [®] | 5,885 | 6,300 | 5,784 | (1.7)% | 6,300 | 8.9% | 3,100 |
| Treatment for Renal Anemia Darbepoetin Alfa BS Injection [JCR] | 4,883 | 4,100 | 3,730 | (23.6)% | 3,600 | (3.5)% | 1,700 |
| Treatment for Renal Anemia Epoetin Alfa BS Injection [JCR] | 4,416 | 3,500 | 3,834 | (13.2)% | 2,200 | (42.6)% | 1,200 |
| Treatment for Diabetes GLUBES [®] | 4,308 | 4,000 | 3,838 | (10.9)% | 3,400 | (11.4)% | 1,700 |
| Treatment for Diabetes GLUFAST [®] | 1,161 | 1,100 | 1,151 | (0.8)% | 1,000 | (13.1)% | 500 |
| Treatment for Diabetes MARIZEV [®] | 1,547 | 1,400 | 1,234 | (20.2)% | 1,200 | (2.8)% | 600 |
| Treatment for MPA ^{*3} and GPA ^{*4} TAVNEOS [®] | – | – | – | – | 700 | – | 200 |
| Treatment for Ulcerative Colitis CAROGRA [®] | – | – | – | – | 350 | – | 150 |
| Treatment for Ulcerative Colitis RECTABUL ^{®*5} | 791 | 800 | 808 | 2.1% | – | – | – |
| Treatment of Dry Mouth Symptoms SALAGEN [®] | 1,526 | 1,500 | 1,412 | (7.5)% | 1,100 | (22.1)% | 550 |

*1: Forecast values presented in the financial statements for the six months ended September 30, 2021.

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

*3: Microscopic polyangiitis

*4: Granulomatosis with polyangiitis

*5: Marketed only by EA Pharma starting in April 2022, with the Company co-promoting.

VI. R&D Pipeline (In-house)

(As of May 2022)

| Product name / Generic name / Development code | Expected indications | Category | Development stage | Development classification |
|------------------------------------------------|--------------------------------------------------------------|--------------------------------------|------------------------|------------------------------------------------------------------------------------------------|
| TAVNEOS® Capsules / Avacopan | Microscopic polyangiitis Granulomatosis with polyangiitis | Selective C5a receptor antagonist | Preparation for launch | In-licensed / Vifor Fresenius Medical Care Renal Pharma (Switzerland) |
| CAROGRA® Tablets / Carotegrast Methyl | Ulcerative colitis | Alpha 4 integrin receptor antagonist | Preparation for launch | In-licensed / Co-development with EA Pharma (Japan) |
| Rovatiirelin / 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 (U.S.) |
| Difelikefalin / MR13A9 | Uremic pruritus in dialysis patients | Kappa opioid receptor agonist | Phase III | In-licensed / Co-development with Maruishi Pharmaceutical (Japan) Primary endpoint achieved |
| CG0070 | Non-muscle-invasive bladder cancer | Oncolytic Viral Therapy | Phase III | In-licensed / CG Oncology (U.S.) |
| Linzagolix / KLH-2109 | Endometriosis | GnRH receptor antagonist | Phase II | Kissei |
| KDT-3594 | Parkinson's disease | Dopamine receptor agonist | Phase II | Kissei |
| KSP-0243 | Inflammatory bowel disease | | Phase I | Kissei |

*Changes from previous release (February 2022): CAROGRA® Tablets: NDA→Preparation for launch
Fostamatinib: Phase III→NDA

VII. R&D Pipeline (Out-licensing)

(As of May 2022)

| Generic name / Development code | Expected indications | Category | Countries & Regions | Development company | Development stage |
|---------------------------------|------------------------------------------------------|-----------------------------------------|---------------------|-------------------------------------|--------------------------------|
| Linzagolix | Uterine fibroids | GnRH receptor antagonist | EU, US | ObsEva SA (Switzerland) | NDA |
| | Endometriosis | | EU, US | | Phase III |
| | Uterine fibroids, Endometriosis | | 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 |
| KDT-3594 | Parkinson's disease | Dopamine receptor agonist | China, etc. | AffaMed (China) | Phase II |
| Bedoradrine | Acute exacerbation of asthma | Beta 2 adrenergic receptor agonist | US | MediciNova (U.S.) | Phase II |
| Fostamatinib | Chronic idiopathic thrombocytopenic purpura | Tyrosine kinase inhibitor | Korea | JW Pharmaceutical (Korea) | NDA preparation |
| | | | China, etc. | Inmagene Biopharmaceuticals (China) | Preparation for clinical trial |

*Changes from previous release (February 2022): None