

Financial Results for the Fiscal Year 2019, Ended December 31, 2019

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- ※ This material is prepared based on Japan GAAP.
- ※ Amounts are rounded down to the nearest million yen.
- ※ The forecasts presented in this material are forward-looking statements. Reflecting assumptions based on information available on the date of publication, these statements are subject to inherent risks and uncertainties. Accordingly, unforeseen factors may cause actual results to differ materially from the projections contained herein.
Torii will not necessarily revise this material regardless of any new information, future events or other results.

February 6, 2020



TORII PHARMACEUTICAL CO., LTD.

I Summary Information

① Financial Results

| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) | FY2020 forecast | Change | Change (%) |
|--|-----------|--------|----------|------------|-----------------|----------|------------|
| | A | B | B-A | (B-A)/A | C | C-B | (C-B)/B |
| Net sales | 62,551 | 42,998 | (19,553) | (31.3) | 41,600 | (1,398) | (3.3) |
| Operating income | 4,951 | 1,430 | (3,520) | (71.1) | 3,000 | 1,569 | 109.7 |
| Ordinary income | 5,080 | 1,691 | (3,388) | (66.7) | 3,300 | 1,608 | 95.0 |
| Net income | 1,164 | 27,367 | 26,202 | – | 2,100 | (25,267) | (92.3) |
| (Reference) | | | | | | | |
| R&D expenses | 4,138 | 2,956 | (1,181) | (28.5) | 1,000 | (1,956) | (66.2) |
| Earnings per share (EPS) | (¥) 41.51 | 974.98 | 933.47 | | 74.80 | (900.18) | |
| Return on equity (ROE) | (%) 1.3 | 27.3 | 26.0 | | | | |
| Ratio of ordinary income to total assets | (%) 4.9 | 1.4 | (3.5) | | | | |
| Ratio of operating income to net sales | (%) 7.9 | 3.3 | (4.6) | | | | |
| Return on assets (ROA) | (%) 1.1 | 22.5 | 21.4 | | | | |

② Financial Conditions

| (Millions of Yen) | December 31, 2018 | December 31, 2019 | Change | Change (%) |
|----------------------------|-------------------|-------------------|--------|------------|
| | A | B | B-A | (B-A)/A |
| Total assets | 103,253 | 139,943 | 36,690 | 35.5 |
| Total equity | 87,092 | 113,125 | 26,033 | 29.9 |
| Equity ratio | (%) 84.3 | 80.8 | (3.5) | |
| Book value per share (BPS) | (¥) 3,103.28 | 4,029.30 | 926.02 | |

③ Statement of Cash Flows

| (Millions of Yen) | FY2018 | FY2019 | Change |
|---|----------|---------|--------|
| | A | B | B-A |
| Net cash provided by operating activities | 8,259 | 42,499 | 34,239 |
| Net cash provided by investing activities | (27,068) | 2,099 | 29,168 |
| Net cash used in financing activities | (1,432) | (1,433) | (1) |
| Cash and cash equivalents, end of period | 15,654 | 58,819 | 43,165 |

④ Capital Expenditures

| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) | FY2020 forecast | Change | Change (%) |
|----------------------|--------|--------|--------|------------|-----------------|--------|------------|
| | A | B | B-A | (B-A)/A | C | C-B | (C-B)/B |
| Capital expenditures | 811 | 330 | (480) | (59.3) | 804 | 473 | 143.3 |
| PP&E | 660 | 203 | (456) | (69.2) | 541 | 337 | 165.4 |
| Intangible assets | 150 | 126 | (24) | (15.9) | 263 | 136 | 107.7 |

⑤ Depreciation/Amortization

| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) | FY2020 forecast | Change | Change (%) |
|--|--------|--------|--------|------------|-----------------|--------|------------|
| | A | B | B-A | (B-A)/A | C | C-B | (C-B)/B |
| Depreciation and amortization of intangible assets | 1,040 | 985 | (54) | (5.2) | 882 | (103) | (10.5) |
| Amortization of long-term prepaid expenses | 965 | 486 | (479) | (49.7) | 552 | 65 | 13.6 |

II Financial Results for the FY2019

① Statement of Income

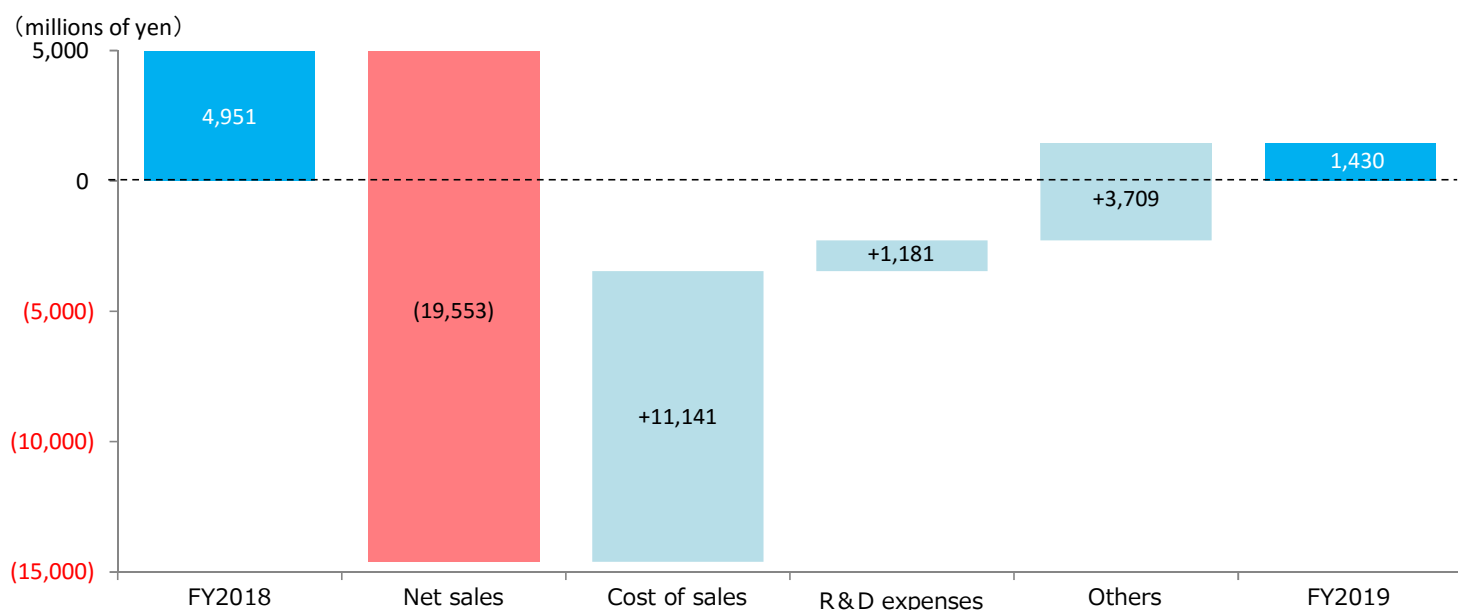
| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) |
|---|---------|--------|----------|------------|
| | A | B | B-A | (B-A)/A |
| Net sales | 62,551 | 42,998 | (19,553) | (31.3) |
| Sales of products | 61,835 | 40,641 | (21,193) | (34.3) |
| Sales of products (Except HIV infection) | 40,386 | 40,641 | 255 | 0.6 |
| Renal disease and hemodialysis | 21,991 | 18,005 | (3,986) | (18.1) |
| Skin disease | 9,126 | 9,049 | (77) | (0.8) |
| Allergens | 3,803 | 7,627 | 3,824 | 100.6 |
| Other | 5,464 | 5,959 | 494 | 9.1 |
| HIV infection | 21,448 | – | (21,448) | (100.0) |
| Other sales | 716 | 2,356 | 1,640 | 229.0 |
| Cost of sales | 31,844 | 20,702 | (11,141) | (35.0) |
| Cost of products sold | 31,781 | 20,588 | (11,193) | (35.2) |
| Other cost | 63 | 114 | 51 | 81.5 |
| Gross profit | 30,707 | 22,295 | (8,411) | (27.4) |
| Selling, general and administrative expenses | 25,755 | 20,864 | (4,890) | (19.0) |
| R&D expenses | 4,138 | 2,956 | (1,181) | (28.5) |
| Others | 21,616 | 17,907 | (3,709) | (17.2) |
| Operating income | 4,951 | 1,430 | (3,520) | (71.1) |
| Non-operating income and expenses | 128 | 261 | 132 | |
| Ordinary income | 5,080 | 1,691 | (3,388) | (66.7) |
| Extraordinary income and loss | (2,049) | 36,008 | 38,058 | |
| Income before income taxes | 3,030 | 37,700 | 34,669 | – |
| Income taxes | 1,865 | 10,333 | 8,467 | |
| Net income | 1,164 | 27,367 | 26,202 | – |

(Reference) Ratio to net sales

| (%) | FY2018 | FY2019 | Change |
|------------------|--------|--------|--------|
| | A | B | B-A |
| Cost of sales | 50.9 | 48.1 | (2.8) |
| SG&A | 41.2 | 48.6 | 7.4 |
| R&D expenses | 6.6 | 6.9 | 0.3 |
| Operating income | 7.9 | 3.3 | (4.6) |
| Ordinary income | 8.1 | 3.9 | (4.2) |
| Net income | 1.9 | 63.6 | 61.7 |

[Factors in increase/decrease compared with the same term of the last fiscal year]

Operating income (¥1,430 million : Decrease ¥3,520 million year-on-year)



Major factors in increase/decrease

| | |
|---------------|--|
| Net sales | : Decrease with the termination of the exclusive rights to market the six anti-HIV drugs in Japan and generic drugs(REMITCH) Increase with the expansion of the products of Allergens and the six anti-HIV drugs distribution fee income ※For sales of products, please refer to the next page |
| Cost of sales | : Decrease in net sales |
| R&D expenses | : Decrease in co-development expenses (JTS-661,JTE-052) |
| Others | : Decrease with sales-linked expenses, personel expenses by business struture reform and cost reduction effect |

Ordinary income (¥1,691 million : Decrease ¥3,388 million year-on-year)

Special remarks: None

Net income (¥27,367 million : Increase ¥26,202 million year-on-year)

| | | |
|---|---|----------------|
| FY2019: Income from the termination of the exclusive rights to market the six anti-HIV drugs in Japan | ¥ | 40,614 million |
| Business structure reform expenses (Extra retirement allowance) | ¥ | 4,504 million |

② Sales of Products

| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) |
|--|--------|--------|----------|------------|
| | A | B | B-A | (B-A)/A |
| Sales of Products | 61,835 | 40,641 | (21,193) | (34.3) |
| Sales of products(Except HIV infection) | 40,386 | 40,641 | 255 | 0.6 |
| [Renal disease and hemodialysis] | | | | |
| REMITCH | 11,598 | 8,693 | (2,904) | (25.0) |
| Oral anti-pruritus agent | | | | |
| Riona | 6,603 | 6,630 | 27 | 0.4 |
| Agent for hyperphosphatemia | | | | |
| KAYEXALATE ※ | 1,963 | 1,907 | (56) | (2.9) |
| Agent for hyperkalemia | | | | |
| Others | 1,826 | 773 | (1,052) | (57.6) |
| Total | 21,991 | 18,005 | (3,986) | (18.1) |
| [Skin disease] | | | | |
| ANTEBATE ※ | 5,536 | 5,439 | (97) | (1.8) |
| Topical corticosteroid | | | | |
| LOCOID ※ | 1,541 | 1,630 | 88 | 5.8 |
| Topical corticosteroid | | | | |
| ZEFNART | 1,454 | 1,454 | (0) | (0.0) |
| Topical antifungal agent | | | | |
| Others | 593 | 524 | (69) | (11.6) |
| Total | 9,126 | 9,049 | (77) | (0.8) |
| [Allergens] | | | | |
| CEDARCURE ※ | 405 | 3,654 | 3,249 | 801.8 |
| Japanese cedar pollinosis (Allergen Immunotherapy) | | | | |
| MITICURE ※ | 1,247 | 2,749 | 1,502 | 120.4 |
| House dust mite allergy (Allergen Immunotherapy) | | | | |
| CEDARTOLEN ※ | 1,859 | 924 | (935) | (50.3) |
| Japanese cedar pollinosis (Allergen Immunotherapy) | | | | |
| Others | 291 | 298 | 7 | 2.6 |
| Total | 3,803 | 7,627 | 3,824 | 100.6 |
| [Other] | | | | |
| BIO-THREE | 2,682 | 2,843 | 161 | 6.0 |
| Viable bacterial preparations | | | | |
| Others | 2,782 | 3,115 | 333 | 12.0 |
| Total | 5,464 | 5,959 | 494 | 9.1 |
| HIV infection | 21,448 | – | (21,448) | (100.0) |

※ In-house products

(References) Sales and ratio of in-house products

| (Millions of Yen) | FY2018 | FY2019 | Change | Change (%) |
|-------------------------------------|--------|--------|--------|------------|
| | A | B | B-A | (B-A)/A |
| Sales of in-house products | 15,855 | 19,068 | 3,212 | 20.3 |
| Ratio of in-house product sales (%) | 25.6 | 46.9 | 21.3 | – |

③ Research and Development

| Development code [Product Name] | Indication | Formulation/ Route of administration | Development stage (domestic) | | | | | Remarks |
|--|--|--|------------------------------|----------|-----------------------------------|-------------|----------|--|
| | | | Phase I | Phase II | Phase III | Application | Approval | |
| Renal disease and hemodialysis | | | | | | | | |
| JTT-751 [Riona® Tablets] | Iron-deficiency anemia | Oral | | | Phase III | | | <ul style="list-style-type: none"> ·Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan ·Co-development with JT(Additional indication) ·Riona filed by JT has been approved as a treatment of hyperphosphatemia in January 2014, and is being promoted and distributed by Torii. |
| JTZ-951 | Anemia associated with chronic kidney disease | Oral | | | | Application | | <ul style="list-style-type: none"> ·JT's original compound ·Licensing agreement signed with JT for development and commercialization ·NDA filing by JT in November, 2019 |
| Skin disease | | | | | | | | |
| JTE-052 [CORECTIM Ointment] | Atopic dermatitis | Topical | | | | | Approval | <ul style="list-style-type: none"> ·JT's original compound ·Licensing agreement signed with JT for development and commercialization ·NDA approval obtained by JT in January, 2020 |
| | Atopic dermatitis in children | Topical | | | Phase III | | | <ul style="list-style-type: none"> ·JT's original compound ·Licensing agreement signed with JT for development and commercialization |
| Allergens | | | | | | | | |
| TO-203 [MITICURE® House Dust Mite Sublingual Tablets] | House dust mite induced allergic asthma (Allergen Immunotherapy) | Sublingual tablet | | | Phase II / III (Study completed※) | | | <ul style="list-style-type: none"> ·Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan ·In-house ※Examining the future development policy |

Updates since the previous announcement on October 31, 2019 :

·JTZ-951 NDA filing for the Treatment of Anemia Associated with CKD by JT on November 29, 2019.

·Manufacturing and marketing approval of JTE-052(CORECTIM Ointment) for the indication of Atopic dermatitis by JT on January 23, 2020.

Additional Information

·In January 2020, Torii signed an exclusive license agreement with JT for co development and commercialization of tapinarof, a topical, therapeutic aryl hydrocarbon receptor modulating agent (TAMA), in Japan. JT signed an exclusive license agreement on January 15, 2020, with Dermavant Sciences GmbH for the development and commercialization of tapinarof for dermatological diseases and conditions in Japan. (Torii and JT will jointly develop tapinarof.)

(Reference)

·In October 2017, JT announced that the company signed an exclusive license agreement with EirGen Pharma Limited for the development and commercialization in Japan of calcifediol extended-release capsules (marketed by OPKO Health, Inc. in the U.S. under the brand name "RAYALDEE®") for the treatment of secondary hyperparathyroidism (SHPT) in chronic kidney disease, and Torii is expected to commercialize the product once it is approved.

Torii and its parent company, JT (specifically, the pharmaceutical division of the company) each leverage their own pharmaceutical product and service strengths. Torii is primarily responsible for manufacturing and marketing functions, while the parent company is responsible for research and development functions. For the clinical research and development of JT, please refer to the following posted on the company's website.

https://www.jt.com/investors/results/S_information/pharmaceuticals/

III Financial Forecasts for the FY2020

① Statement of Income

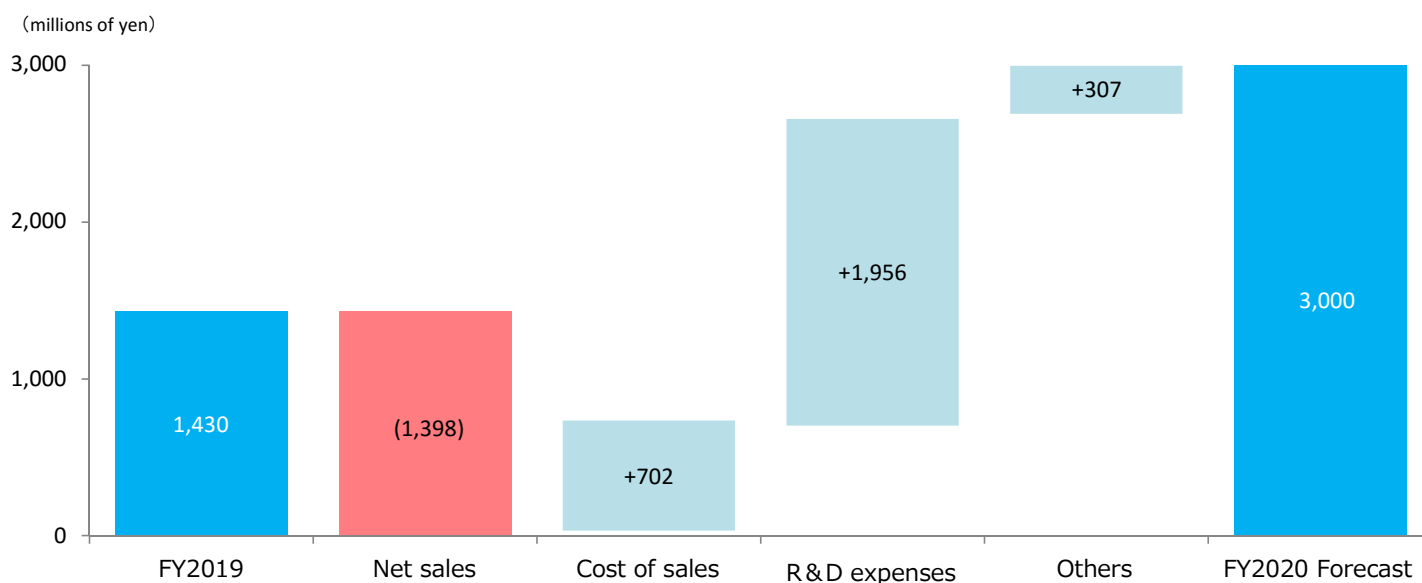
| <i>(Millions of Yen)</i> | FY2019 | FY2020 forecast | Change | Change (%) |
|--------------------------------|--------|--------------------|----------|---------------|
| | A | B | B-A | (B-A)/A |
| Net sales | 42,998 | 41,600 | (1,398) | (3.3) |
| Sales of products | 40,641 | 40,980 | 338 | 0.8 |
| Renal disease and hemodialysis | 18,005 | 14,870 | (3,135) | (17.4) |
| Skin disease | 9,049 | 9,290 | 240 | 2.7 |
| Allergens | 7,627 | 11,050 | 3,422 | 44.9 |
| Other | 5,959 | 5,770 | (189) | (3.2) |
| Other sales | 2,356 | 620 | (1,736) | (73.7) |
| Cost of sales | 20,702 | 20,000 | (702) | (3.4) |
| Gross profit | 22,295 | 21,600 | (695) | (3.1) |
| SG&A | 20,864 | 18,600 | (2,264) | (10.9) |
| R&D expenses | 2,956 | 1,000 | (1,956) | (66.2) |
| Others | 17,907 | 17,600 | (307) | (1.7) |
| Operating income | 1,430 | 3,000 | 1,569 | 109.7 |
| Ordinary income | 1,691 | 3,300 | 1,608 | 95.0 |
| Net income | 27,367 | 2,100 | (25,267) | (92.3) |

(Reference) Ratio to net sales

| <i>(%)</i> | FY2019 | FY2020 forecast | Change |
|------------------|--------|--------------------|--------|
| | A | B | B-A |
| Cost of sales | 48.1 | 48.1 | 0.0 |
| SG&A | 48.6 | 44.7 | (3.9) |
| R&D expenses | 6.9 | 2.4 | (4.5) |
| Operating income | 3.3 | 7.2 | 3.9 |
| Ordinary income | 3.9 | 7.9 | 4.0 |
| Net income | 63.6 | 5.0 | (58.6) |

[Factors in increase/decrease compared with the FY2019]

Operating Income (¥3,000 million : Increase ¥1,569 million year-on-year)



Major factors in increase/decrease

| | |
|---------------|--|
| Net sales | : Decrease with the drug price revision implemented on October 1, 2019 and six anti-HIV drugs distribution fee income Increase with the expansion of the products of Allergens ※For sales of products, please refer to the next page |
| Cost of sales | : Decrease with changes in sales mix among the products(increase in the in-house product ratio) |
| R&D expenses | : Decrease with business structure reform in last fiscal year(organizational reform) and co-development expenses(JTT-751) |
| Others | : Decrease with business structure reform in last fiscal year(personnel optimization, cost reductions, etc.) |

Ordinary Income (¥3,300 million : increase ¥1,608 million year-on-year)

Special remarks: None

Net income (¥2,100 million : Decrease ¥25,267 million year-on-year)

FY2019 Income from the termination of the exclusive rights to market the six anti-HIV drugs in Japan

| | | |
|---|---|----------------|
| | ¥ | 40,614 million |
| Business structure reform expenses (Extra retirement allowance) | ¥ | 4,504 million |

② Sales of Products

| <i>(Millions of Yen)</i> | FY2019 | FY2020 forecast | Change | Change (%) |
|---|--------|--------------------|---------|---------------|
| | A | B | B-A | (B-A)/A |
| Sales of Products | 40,641 | 40,980 | 338 | 0.8 |
| [Renal disease and hemodialysis] | | | | |
| Riona Agent for hyperphosphatemia | 6,630 | 6,620 | (10) | (0.2) |
| REMITCH Oral anti-pruritus agent | 8,693 | 6,350 | (2,343) | (27.0) |
| KAYEXALATE ※ Agent for hyperkalemia | 1,907 | 1,810 | (97) | (5.1) |
| Others | 773 | 90 | (683) | (88.4) |
| Total | 18,005 | 14,870 | (3,135) | (17.4) |
| [Skin disease] | | | | |
| ANTEBATE ※ Topical corticosteroid | 5,439 | 4,920 | (519) | (9.6) |
| LOCOID ※ Topical corticosteroid | 1,630 | 1,490 | (140) | (8.6) |
| ZEFNART Topical antifungal agent | 1,454 | 1,360 | (94) | (6.5) |
| Others | 524 | 1,520 | 995 | 189.6 |
| Total | 9,049 | 9,290 | 240 | 2.7 |
| [Allergens] | | | | |
| CEDARCURE ※ Japanese cedar pollinosis (Allergen Immunotherapy) | 3,654 | 6,340 | 2,685 | 73.5 |
| MITICURE ※ House dust mite allergy (Allergen Immunotherapy) | 2,749 | 4,150 | 1,400 | 50.9 |
| Others | 1,223 | 560 | (663) | (54.2) |
| Total | 7,627 | 11,050 | 3,422 | 44.9 |
| [Other] | | | | |
| BIO-THREE Viable bacterial preparations | 2,843 | 2,990 | 146 | 5.1 |
| Others | 3,115 | 2,780 | (335) | (10.8) |
| Total | 5,959 | 5,770 | (189) | (3.2) |

※ In-house products

(References) Sales and ratio of in-house products

| <i>(Millions of Yen)</i> | FY2019 | FY2020 forecast | Change | Change (%) |
|--|--------|--------------------|--------|---------------|
| | A | B | B-A | (B-A)/A |
| Sales of in-house products | 19,068 | 21,600 | 2,531 | 13.3 |
| Ratio of in-house product sales (%) | 46.9 | 52.7 | 5.8 | – |