

Financial results for the second quarter
of fiscal year 2020

< Supplement >

October 30, 2020

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

(Billions of yen)

| | FY2020 1H actual | FY2020 2H forecast | FY2020 forecast | FY2019 1H actual | FY2019 2H actual | FY2019 actual | Y on Y change | | |
|---|---------------------|-----------------------|--------------------|---------------------|---------------------|------------------|---------------|-------|-----------|
| | | | | | | | 1H | 2H | full-year |
| Revenue | 148.5 | 169.6 | 318.1 | 163.6 | 169.7 | 333.4 | (15.2) | (0.1) | (15.3) |
| <i>change %</i> | <i>(9.3)</i> | <i>(0.1)</i> | <i>(4.6)</i> | - | - | - | | | |
| Operating profit | 55.3 | 77.9 | 133.2 | 63.2 | 67.4 | 130.6 | (7.9) | 10.5 | 2.6 |
| <i>change %</i> | <i>(12.5)</i> | <i>15.5</i> | <i>2.0</i> | - | - | - | | | |
| Profit before tax | 67.2 | 92.4 | 159.6 | 70.7 | 87.9 | 158.5 | (3.5) | 4.5 | 1.1 |
| <i>change %</i> | <i>(4.9)</i> | <i>5.2</i> | <i>0.7</i> | - | - | - | | | |
| Profit attributable to owners of parent | 49.4 | 70.3 | 119.7 | 54.4 | 67.8 | 122.2 | (5.0) | 2.5 | (2.5) |
| <i>change %</i> | <i>(9.2)</i> | <i>3.7</i> | <i>(2.0)</i> | - | - | - | | | |

Note: Change % shows changes from the same period of the previous fiscal year.

2. Revenue by segment

(Billions of yen)

| | FY2020 1H | FY2020 2H | FY2020 | FY2019 1H | FY2019 2H | FY2019 | Y on Y change | | |
|------------------------------|-----------|-----------|----------|-----------|-----------|--------|---------------|--------|-----------|
| | actual | forecast | forecast | actual | actual | actual | 1H | 2H | full-year |
| Prescription drugs | 47.2 | 68.1 | 115.3 | 51.5 | 54.8 | 106.3 | (4.3) | 13.3 | 9.0 |
| <i>change %</i> | (8.3) | 24.3 | 8.5 | - | - | - | | | |
| CYMBALTA | 13.5 | 14.7 | 28.2 | 12.9 | 13.3 | 26.2 | 0.6 | 1.4 | 2.0 |
| INTUNIV | 6.0 | 9.8 | 15.9 | 4.5 | 6.2 | 10.6 | 1.6 | 3.7 | 5.2 |
| VYVANSE | 0.1 | 0.6 | 0.7 | - | 0.0 | 0.0 | 0.1 | 0.6 | 0.6 |
| Infectious Disease Drugs | 4.9 | 17.9 | 22.8 | 7.3 | 8.7 | 16.0 | (2.5) | 9.2 | 6.8 |
| OXYCONTIN Franchise | 2.8 | 2.7 | 5.4 | 3.1 | 2.7 | 5.8 | (0.3) | (0.1) | (0.4) |
| SYMPROIC | 1.1 | 1.6 | 2.7 | 1.1 | 1.1 | 2.1 | 0.0 | 0.6 | 0.6 |
| ACTAIR | 0.1 | 0.2 | 0.3 | 0.1 | 0.2 | 0.3 | 0.0 | 0.0 | 0.1 |
| MULPLETA | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | (0.0) | 0.0 | (0.0) |
| PIRESPA | 2.8 | 2.0 | 4.8 | 3.4 | 3.3 | 6.8 | (0.6) | (1.3) | (1.9) |
| Others | 15.8 | 18.5 | 34.4 | 19.0 | 19.2 | 38.3 | (3.2) | (0.7) | (3.9) |
| CRESTOR | 3.7 | 4.1 | 7.8 | 4.4 | 4.2 | 8.6 | (0.7) | (0.0) | (0.8) |
| IRBETAN Franchise | 1.7 | 1.9 | 3.6 | 2.2 | 2.0 | 4.2 | (0.5) | (0.1) | (0.6) |
| Overseas subsidiaries/Export | 11.0 | 13.0 | 24.0 | 17.5 | 13.3 | 30.8 | (6.5) | (0.2) | (6.8) |
| <i>change %</i> | (37.3) | (1.7) | (21.9) | - | - | - | | | |
| Shionogi Inc. | 3.3 | 2.9 | 6.2 | 6.8 | 3.3 | 10.1 | (3.5) | (0.5) | (3.9) |
| C&O | 4.2 | 6.2 | 10.5 | 7.2 | 6.0 | 13.1 | (2.9) | 0.3 | (2.6) |
| Contract manufacturing | 6.7 | 10.4 | 17.1 | 10.1 | 7.5 | 17.6 | (3.4) | 2.9 | (0.5) |
| <i>change %</i> | (33.7) | 38.2 | (2.9) | - | - | - | | | |
| OTC and quasi-drugs | 5.5 | 6.4 | 11.9 | 4.4 | 5.3 | 9.7 | 1.1 | 1.1 | 2.2 |
| <i>change %</i> | 24.5 | 20.5 | 22.3 | - | - | - | | | |
| Royalty income | 77.3 | 71.0 | 148.3 | 79.1 | 87.8 | 166.9 | (1.7) | (16.8) | (18.6) |
| <i>change %</i> | (2.2) | (19.1) | (11.1) | - | - | - | | | |
| HIV Franchise | 63.9 | 62.4 | 126.3 | 64.9 | 63.2 | 128.1 | (1.0) | (0.8) | (1.8) |
| CRESTOR | 11.1 | 5.7 | 16.9 | 11.3 | 11.0 | 22.3 | (0.1) | (5.3) | (5.4) |
| Others | 2.3 | 2.9 | 5.2 | 2.8 | 13.6 | 16.5 | (0.6) | (10.7) | (11.3) |
| Others | 0.8 | 0.7 | 1.5 | 1.1 | 1.0 | 2.2 | (0.3) | (0.3) | (0.6) |
| <i>change %</i> | (27.1) | (30.1) | (28.5) | - | - | - | | | |
| Total | 148.5 | 169.6 | 318.1 | 163.6 | 169.7 | 333.4 | (15.2) | (0.1) | (15.3) |
| <i>change %</i> | (9.3) | (0.1) | (4.6) | - | - | - | | | |

Note: Change % shows changes from the same period of the previous fiscal year.

Sales of prescription drugs are shown on non-consolidated basis.

Products included in infectious disease drugs are bellow.

•Xofluza •Rapiacta •Brightpoc Flu Neo •Finibax •Flumarin •Flomox
•Seftem •Shiomarin •Vancomycin •Baktar •Flagyl •Fluconazole •Isodine

3. Management index

(Management index trend)

| | | FY2018 | FY2019 | FY2019 1H | FY2020 1H |
|---|-----|--------|--------|-----------|-----------|
| Return on equity attributable to owners of parent (ROE) | % | 17.8 | 15.5 | 6.7 | 6.2 |
| Ratio of profit before tax to total assets (ROA) | % | 19.4 | 17.5 | 7.6 | 7.5 |
| Ratio of operating profit to revenue | % | 39.4 | 39.2 | 38.6 | 37.3 |
| Ratio of profit before tax to revenue | % | 47.3 | 47.5 | 43.2 | 45.3 |
| Total assets turnover | | 0.41 | 0.37 | 0.18 | 0.16 |
| Ratio of equity attributable to owners of parent to total assets | % | 86.2 | 87.7 | 88.5 | 89.9 |
| Dividend payout ratio | % | 21.4 | 26.0 | - | - |
| Ratio of dividends to equity attributable to owners of parent (DOE) | % | 3.8 | 4.0 | - | - |
| Basic earnings per share | yen | 438.47 | 395.71 | 174.66 | 160.83 |
| Diluted earnings per share | yen | 434.71 | 395.28 | 174.43 | 160.77 |

4. Capital investments and Depreciation and Amortization

(Billions of yen)

| | FY2020 1H | FY2020 2H | FY2020 | FY2019 1H | FY2019 2H | FY2019 | Y on Y change | | |
|-------------------------------|-----------|-----------|----------|-----------|-----------|--------|---------------|-------|-----------|
| | actual | forecast | forecast | actual | actual | actual | 1H | 2H | full-year |
| Investments in equipments | 2.8 | 15.0 | 17.9 | 4.3 | 5.7 | 10.0 | (1.4) | 9.4 | 7.9 |
| Depreciation and Amortization | 7.3 | 7.2 | 14.4 | 6.9 | 7.2 | 14.1 | 0.3 | (0.0) | 0.3 |

5. R&D expenses

(Billions of yen)

| | FY2020 1H | FY2020 2H | FY2020 | FY2019 1H | FY2019 2H | FY2019 | Y on Y change | | |
|-----------------|-----------|-----------|----------|-----------|-----------|--------|---------------|-----|-----------|
| | actual | forecast | forecast | actual | actual | actual | 1H | 2H | full-year |
| R&D expenses | 24.9 | 27.2 | 52.0 | 23.3 | 24.6 | 47.9 | 1.5 | 2.6 | 4.1 |
| <i>change %</i> | 6.5 | 10.4 | 8.5 | - | - | - | | | |
| % to revenue | 16.7 | 16.0 | 16.4 | 14.3 | 14.5 | 14.4 | | | |

Note: Change % shows changes from the same period of the previous fiscal year

6. Employees

| | End of FY2018 | End of 2019 1H | End of FY2019 | End of 2020 1H | End of FY2020 | Y on Y change | | |
|-----------|---------------|----------------|---------------|----------------|---------------|---------------|-----|-----------|
| | actual | actual | actual | actual | forecast | 1H | 2H | full-year |
| Employees | 5,233 | 5,261 | 5,222 | 5,313 | 5,506 | 91 | 193 | 284 |

7. Consolidated statement of profit or loss

(Millions of yen)

| | FY2019 1H actual | FY2020 1H actual | Y on Y change | |
|--|---------------------|---------------------|------------------|--|
| Revenue | 163,635 | 148,452 | (15,183) | Increasing/(decreasing) in Prescription drugs: (4.3)billion yen Overseas subsidiaries/Export(6.5)billion yen Contract manufacturing: (3.4)billion yen Royalty income: (1.7)billion yen |
| Cost of sales | (27,704) | (22,857) | (4,847) | |
| Gross profit | 135,930 | 125,594 | (10,336) | |
| Selling, general and administrative expenses | (46,643) | (43,157) | (3,485) | |
| Research and development expenses | (23,327) | (24,854) | 1,526 | |
| Amortization of intangible assets associated with products | (1,618) | (1,611) | (7) | |
| Other income | 245 | 245 | 0 | |
| Other expenses | (1,390) | (909) | (481) | |
| Operating profit | 63,196 | 55,308 | (7,887) | |
| Finance income | 9,713 | 12,805 | 3,092 | Shionogi B.V. Increasing in dividend income from ViiV. |
| Finance costs | (2,254) | (925) | (1,328) | Decreasing in foreign exchange losses |
| Profit before tax | 70,656 | 67,189 | (3,466) | |
| Income tax expense | (16,235) | (17,806) | 1,571 | |
| Profit | 54,420 | 49,382 | (5,038) | |
| Profit attributable to | | | | |
| Owners of parent | 54,382 | 49,381 | (5,001) | |
| Non-controlling interests | 38 | 1 | (36) | |
| Profit | 54,420 | 49,382 | (5,038) | |

8-1. Consolidated statement of financial position (Assets)

(Millions of yen)

| | As of Mar. 31 2020 | As of Sep. 30 2020 | Y on Y change | |
|-------------------------------|-----------------------|-----------------------|------------------|---|
| Assets | | | | |
| Non-Current assets | | | | |
| Property, plant and equipment | 71,350 | 70,350 | (1,000) | |
| Goodwill | 10,854 | 27,234 | 16,379 | Due to the aquisition of Tetra Therapeutics, Inc. |
| Intangible assets | 46,536 | 46,955 | 419 | |
| Right-of-use assets | 4,657 | 4,554 | (103) | |
| Other financial assets | 202,161 | 206,565 | 4,404 | |
| Deferred tax assets | 3,048 | 4,023 | 974 | |
| Other non-current assets | 16,890 | 8,778 | (8,111) | |
| Total non-current assets | 355,500 | 368,461 | 12,961 | |
| Current assets | | | | |
| Inventories | 33,818 | 39,070 | 5,251 | |
| Trade receivables | 79,804 | 79,024 | (780) | |
| Other financial assets | 171,157 | 185,876 | 14,718 | Increased in time deposits over 3 months |
| Income taxes receivable | 192 | 114 | (78) | |
| Other current assets | 22,191 | 17,861 | (4,329) | |
| Cash and cash equivalents | 208,861 | 240,437 | 31,576 | |
| Total current assets | 516,026 | 562,384 | 46,358 | |
| Total assets | 871,526 | 930,846 | 59,319 | |

8-2. Consolidated statement of financial position (Equity/Liabilities)

| | <i>(Millions of yen)</i> | | |
|---|--------------------------|-----------------------|------------------|
| | As of Mar. 31 2020 | As of Sep. 30 2020 | Y on Y change |
| Equity and liabilities | | | |
| Equity | | | |
| Share capital | 21,279 | 21,279 | - |
| Capital surplus | 20,432 | 20,734 | 301 |
| Treasury shares | (77,292) | (7,982) | 69,309 |
| Retained earnings | 708,291 | 707,718 | (573) |
| Other components of equity | 91,848 | 94,713 | 2,865 |
| Equity attributable to owners of parent | 764,560 | 836,463 | 71,903 |
| Non-controlling interests | 51 | 52 | 1 |
| Total equity | 764,611 | 836,516 | 71,905 |
| Liabilities | | | |
| Non-current liabilities | | | |
| Lease liabilities | 4,791 | 4,316 | (475) |
| Other financial liabilities | 4,179 | 3,527 | (651) |
| Retirement benefit liability | 16,089 | 13,730 | (2,358) |
| Deferred tax liabilities | 373 | 343 | (29) |
| Other non-current liabilities | 362 | 334 | (27) |
| Total non-current liabilities | 25,795 | 22,252 | (3,543) |
| Current liabilities | | | |
| Lease liabilities | 3,361 | 3,407 | 46 |
| Trade payables | 10,763 | 9,425 | (1,338) |
| Other financial liabilities | 17,557 | 11,393 | (6,163) |
| Income taxes payable | 21,886 | 24,253 | 2,367 |
| Other current liabilities | 27,551 | 23,597 | (3,954) |
| Total current liabilities | 81,119 | 72,077 | (9,042) |
| Total liabilities | 106,915 | 94,329 | (12,585) |
| Total equity and liabilities | 871,526 | 930,846 | 59,319 |

| | |
|-----------------------|-------------------|
| Due to | |
| Cancellation | +30.9 billion yen |
| Disposal through | |
| third-party allotment | +37.8 billion yen |

9-1. Quarterly trend for FY2019 and FY2020 (Revenue by segment)

Fiscal year ended March 31, 2020 (Billions of yen)

| FY2019 | FY2019 1Q actual | Y on Y change % | FY2019 2Q actual | Y on Y change % |
|------------------------------|---------------------|--------------------|---------------------|--------------------|
| Prescription drugs | 26.3 | - | 25.1 | - |
| CYMBALTA | 6.7 | - | 6.1 | - |
| INTUNIV | 1.8 | - | 2.6 | - |
| VYVANSE | - | - | - | - |
| Infectious Disease Drugs | 3.6 | - | 3.7 | - |
| OXYCONTIN Franchise | 1.7 | - | 1.4 | - |
| SYMPROIC | 0.5 | - | 0.5 | - |
| ACTAIR | 0.1 | - | 0.1 | - |
| MULPLETA | 0.0 | - | 0.0 | - |
| PIRESPA | 1.7 | - | 1.7 | - |
| Others | 10.2 | - | 8.9 | - |
| CRESTOR | 2.4 | - | 2.0 | - |
| IRBETAN Franchise | 1.2 | - | 1.0 | - |
| Overseas subsidiaries/Export | 10.7 | - | 6.8 | - |
| Shionogi Inc. | 5.3 | - | 1.5 | - |
| C&O | 3.8 | - | 3.4 | - |
| Contract manufacturing | 2.4 | - | 7.6 | - |
| OTC and quasi-drugs | 1.8 | - | 2.6 | - |
| Royalty income | 38.9 | - | 40.1 | - |
| HIV Franchise | 31.7 | - | 33.2 | - |
| CRESTOR | 5.7 | - | 5.6 | - |
| Others | 1.5 | - | 1.3 | - |
| Others | 0.5 | - | 0.6 | - |
| Total | 80.8 | - | 82.9 | - |

Note: Sales of prescription drugs are shown on non-consolidated basis.

Fiscal year ending March 31, 2021

| FY2020 | FY2020 1Q actual | Y on Y change % | FY2020 2Q actual | Y on Y change % |
|------------------------------|---------------------|--------------------|---------------------|--------------------|
| Prescription drugs | 22.4 | (15.1) | 24.8 | (1.2) |
| CYMBALTA | 6.9 | 2.9 | 6.6 | 6.8 |
| INTUNIV | 2.6 | 42.2 | 3.4 | 30.1 |
| VYVANSE | 0.0 | - | 0.1 | - |
| Infectious Disease Drugs | 2.1 | (40.7) | 2.7 | (26.5) |
| OXYCONTIN Franchise | 1.4 | (17.3) | 1.4 | (1.5) |
| SYMPROIC | 0.5 | (7.9) | 0.6 | 9.2 |
| ACTAIR | 0.1 | 3.4 | 0.1 | 40.1 |
| MULPLETA | 0.0 | (26.3) | 0.0 | (19.8) |
| PIRESPA | 1.4 | (17.1) | 1.4 | (18.2) |
| Others | 7.3 | (28.4) | 8.5 | (3.5) |
| CRESTOR | 1.5 | (35.3) | 2.1 | 4.7 |
| IRBETAN Franchise | 0.8 | (30.5) | 0.9 | (11.4) |
| Overseas subsidiaries/Export | 5.5 | (49.1) | 5.5 | (18.5) |
| Shionogi Inc. | 1.7 | (68.6) | 1.7 | 11.1 |
| C&O | 2.4 | (37.5) | 1.9 | (44.1) |
| Contract manufacturing | 2.9 | 17.6 | 3.8 | (50.1) |
| OTC and quasi-drugs | 2.3 | 26.1 | 3.2 | 23.4 |
| Royalty income | 38.0 | (2.4) | 39.3 | (2.1) |
| HIV Franchise | 31.0 | (2.4) | 33.0 | (0.7) |
| CRESTOR | 5.6 | (1.6) | 5.6 | (0.8) |
| Others | 1.5 | (3.6) | 0.8 | (40.7) |
| Others | 0.4 | (17.2) | 0.4 | (36.0) |
| Total | 71.4 | (11.6) | 77.1 | (7.0) |

Note: Sales of prescription drugs are shown on non-consolidated basis.

9-2. Quarterly trend for FY2019 and FY2020 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2020 (Billions of yen)

| FY2019 | FY2019 1Q actual | Y on Y change % | FY2019 2Q actual | Y on Y change % |
|---|---------------------|--------------------|---------------------|--------------------|
| Revenue | 80.8 | - | 82.9 | - |
| Cost of sales | 15.7 (12.7) | - | 18.2 (15.0) | - |
| Gross profit | 68.1 | - | 67.8 | - |
| SG & A expenses | 28.6 (23.1) | - | 28.5 (23.6) | - |
| R & D expenses | 14.5 (11.7) | - | 14.1 (11.6) | - |
| Amortization of intangible assets associated with products | 1.0 (0.8) | - | 1.0 (0.8) | - |
| Other income & expenses | (0.9) | - | (0.3) | - |
| Operating profit | 39.2 31.7 | - | 38.0 31.5 | - |
| Finance income & costs | 3.7 | - | 3.8 | - |
| Profit before tax | 43.8 35.3 | - | 42.6 35.3 | - |
| Income tax expense etc. | (8.2) | - | (8.1) | - |
| Profit attributable to owners of parent | 33.6 27.1 | - | 32.9 27.3 | - |

Fiscal year ending March 31, 2021

| FY2020 | FY2020 1Q actual | Y on Y change % | FY2020 2Q actual | Y on Y change % |
|---|-----------------------|--------------------|---------------------|--------------------|
| Revenue | 71.4 | (11.6) | 77.1 | (7.0) |
| Cost of sales | 16.1 (11.5) | (9.3) | 14.8 (11.4) | (24.4) |
| Gross profit | 59.9 | (12.0) | 65.7 | (3.1) |
| SG & A expenses | 29.2 (20.9) | (9.5) | 28.9 (22.3) | (5.5) |
| R & D expenses | 17.0 (12.2) | 4.2 | 16.5 (12.7) | 8.9 |
| Amortization of intangible assets associated with products | 1.1 (0.8) | (0.1) | 1.0 (0.8) | (0.8) |
| Other income & expenses | (0.5) | (49.0) | (0.2) | (17.5) |
| Operating profit | 35.9 (25.6) | (19.1) | 38.5 29.7 | (5.8) |
| Finance income & costs | 4.4 | 21.1 | 7.4 | 96.3 |
| Profit before tax | 42.1 30.1 | (14.9) | 48.2 37.1 | 5.1 |
| Income tax expense etc. | (8.5) | 3.8 | (9.3) | 15.2 |
| Profit attributable to owners of parent | 30.2 21.5 | (20.6) | 36.1 27.8 | 2.2 |

10. Group companies

<Consolidated affiliated companies (as of September 30, 2020)>

| № | Company name | Location | Common stock | Business status | Establish | Closing date | Ownership (%) |
|----|--|------------------------|----------------------|--|--------------|--------------|---------------|
| 1 | Shionogi Pharma Co., Ltd. | Osaka, Japan | JPY 90 million | Mfg., of pharmaceuticals and contract manufacturing, Contract testing and analysis on medicine | Oct.1, 2018 | Mar.31 | 100 |
| 2 | Shionogi Healthcare Co., Ltd. | Osaka, Japan | JPY 10 million | Mfg., and sales of OTC and quasi-drugs | Jan.15, 2016 | Mar.31 | 100 |
| 3 | Shionogi Techno Advance Research Co., Ltd. | Osaka, Japan | JPY 9 million | Contract support services for experimental research | Sep.8, 2010 | Mar.31 | 100 |
| 4 | Shionogi Administration Service Co., Ltd. | Osaka, Japan | JPY 10 million | Real estate rental and shared services | Nov.2, 1992 | Mar.31 | 100 |
| 5 | Shionogi Career Development Center Co., Ltd. | Hyogo, Japan | JPY 10 million | Career development support to the group companies | Apr.3, 2017 | Mar.31 | 100 |
| 6 | Shionogi Digital Science Co., Ltd. | Osaka, Japan | JPY 10 million | ICT solution service to the group companies | Apr.3, 2017 | Mar.31 | 100 |
| 7 | Shionogi Business Partner Co., Ltd. | Osaka, Japan | JPY 10 million | Insurance agency and shared services | Apr.3, 2017 | Mar.31 | 100 |
| 8 | Shionogi Pharmacovigilance Center Co.,Ltd. | Osaka, Japan | JPY 10 million | Pharmacovigilance activity for the group companies | Apr.3, 2017 | Mar.31 | 100 |
| 9 | Shionogi Marketing Solutions Co., Ltd. | Osaka, Japan | JPY 10 million | Market research, Making of the sales promotion materials, Support of the sales department | Apr.3, 2017 | Mar.31 | 100 |
| 10 | UMN Pharma Inc. | Akita, Japan | JPY 1,037 million | Research, development, mfg., and marketing of biopharmaceuticals | Apr.20, 2004 | Dec.31 | 100 |
| 11 | Shionogi Inc. | New Jersey, U.S.A. | USD 12 | Mfg., sale and development of pharmaceuticals | Aug.25, 2008 | Mar.31 | 100 |
| 12 | Tetra Therapeutics, Inc. | Michigan, U.S.A. | USD 37 thousand | Research and development of pharmaceuticals | Jul.21, 2016 | Dec.31 | 100 |
| 13 | Shionogi B.V. | Amsterdam, Netherlands | GBP 630 thousand | Mfg., sale and development of pharmaceuticals | Nov.29, 2018 | Mar.31 | 100 |
| 14 | C&O Pharmaceutical Technology (Holdings) Limited | Shenzhen, China | HKD 165,840 thousand | Mfg., sale and development of pharmaceuticals | Jul.28, 2003 | Dec.31 | 100 |
| 15 | Taiwan Shionogi & Co., Ltd. | Taipei, Taiwan, R.O.C. | TWD 92 million | Mfg., and sale of pharmaceuticals | Dec.26, 1963 | Mar.31 | 100 |
| 16 | Beijing Shionogi Pharmaceutical Technology Limited | Beijing, China | JPY 30 million | Support services for sales | Mar.29, 2013 | Dec.31 | 100 |
| 17 | Shionogi Singapore Pte. Ltd. | Singapore | SGD 9 million | Development of pharmaceuticals | Dec.30, 2013 | Mar.31 | 100 |

Note: Thirty two consolidated affiliated companies are not shown on this table as the scale of their business is very small.

11. Pipeline (as of October 30, 2020)

| Areas | Code No. (Generic name) [Product name] | Mechanism of action (Administration) | Indication | Stage | Origin | Development |
|--------------------|--|---|--|---|-----------------------------------|-------------------------------|
| Infectious disease | S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU:Fetroja®] | Cell-wall synthesis inhibition (injection) | USA:Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia with no or limited treatment options Europe:Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options | Global:PhaseIII (pediatric) USA:Approval (cUTI) (Nov.2019), Approval (Nosocomial pneumonia) (Sep.2020) Europe: Approval (Apr.2020) | In-house | In-house |
| | S-033188 (baloxavir marboxil) [Japan:Xofluza®] | Cap-dependent endonuclease inhibition (oral, granule) | Influenza virus infection | Japan:Approval (body weight \geq 20kg) (Sep.2018) Japan:NDA submission (body weight <20kg) (Aug.2018) Japan:PhaseIII (high dosage for children) | In-house | Shionogi/Roche (Switzerland) |
| | S-033188 (baloxavir marboxil) [Japan:Xofluza®] | Cap-dependent endonuclease inhibition (oral) | Influenza virus infection (prophylaxis) | Japan:NDA submission (Oct.2019) | In-house | Shionogi/Roche (Switzerland) |
| | S-648414 | Not disclosed (oral) | HIV infection | USA,Japan:PhaseI | In-house | In-house |
| Pain/CNS | S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®] | Peripheral opioid receptor antagonist (oral, powder) | Opioid-induced constipation(pediatric) | Europe:PhaseI/II | In-house | In-house |
| | S-297995 (naldemedine tosilate) | Peripheral opioid receptor antagonist (oral) | Postoperative ileus | USA:PhaseII | In-house | In-house |
| | S-120083 | Not disclosed (oral) | Inflammatory pain | Japan:PhaseI USA:PhaseII | Shionogi/Purdue Pharma L.P. (USA) | Shionogi/Purdue Pharma L.P. |
| | S-010887 | Not disclosed (oral) | Neuropathic pain | Japan:PhaseI | In-house | In-house |
| | S-117957 | Not disclosed (oral) | Insomnia | USA:PhaseI | Shionogi/Purdue Pharma L.P. (USA) | Shionogi/Purdue Pharma L.P. |
| | S-600918 | P2X ₃ receptor antagonist (oral) | Neuropathic pain | Japan:PhaseI | In-house | In-house |
| | S-600918 | P2X ₃ receptor antagonist (oral) | Refractory/unexplained chronic cough | Global:PhaseII | In-house | In-house |
| | S-600918 | P2X ₃ receptor antagonist (oral) | Sleep Apnea Syndrome | Japan:PhaseII | In-house | In-house |
| | S-637880 | Not disclosed (oral) | Neuropathic pain | Japan:PhaseI | In-house | In-house |
| | LY248686 (duloxetine hydrochloride) [Cymbalta®] | SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral) | Depression (pediatric) | Japan:PhaseIII | Eli Lilly (USA) | Shionogi/Eli Lilly Japan K.K. |
| | S-812217 (Zuranolone) | GABAA receptor positive allosteric modulator (oral) | Depression | Japan:PhaseII | Sage (USA) | Shionogi/Sage |
| | SDT-001 | Treatment digital application based on cerebral mechanism | Inattention symptom in ADHD patients (pediatric) | Japan:PhaseII | Akili (USA) | Shionogi/Akili |
| | BPN14770 | PDE4D negative allosteric modulator (oral) | Fragile X syndrome | USA:PhaseII | Tetra (USA) | Shionogi/Tetra |
| | BPN14770 | PDE4D negative allosteric modulator (oral) | Alzheimer's disease | USA:PhaseII Japan:PhaseI | Tetra (USA) | Shionogi/Tetra |

| Areas | Code No. (Generic name) [Product name] | Mechanism of action (Administration) | Indication | Stage | Origin | Development |
|--------------------|--|---|--|--|-----------------------------------|-----------------|
| Metabolic disorder | S-237648 | Neuropeptide Y Y5 receptor antagonist (oral) | Obesity | Japan:PhaseII USA:PhaseI | In-house | In-house |
| | S-707106 | Insulin sensitizer (oral) | Type 2 diabetes | USA:PhaseIIa | In-house | In-house |
| | ADR-001 | Human mesenchymal stem cells (injection) | Decompensated liver cirrhosis | Japan:PhaseI/II | Rohto | Shionogi/Rohto |
| Frontier | S-588410 | Cancer peptide vaccine (injection) | Esophageal cancer | Japan:PhaseIII | OncoTherapy Science, Inc. (Japan) | In-house |
| | S-588410 | Cancer peptide vaccine (injection) | Bladder cancer | Japan,Europe:PhaseII | OncoTherapy Science, Inc. (Japan) | In-house |
| | S-488210 | Cancer peptide vaccine (injection) | Head and neck squamous cell carcinoma | Europe:PhaseI/II | OncoTherapy Science, Inc. (Japan) | In-house |
| | S-588210 | Cancer peptide vaccine (injection) | Solid tumor | UK:PhaseI | OncoTherapy Science, Inc. (Japan) | In-house |
| | S-222611 (epertinib) | HER2/EGFR dual inhibitor (oral) | Malignant tumor | Europe:PhaseI/II | In-house | In-house |
| | S-770108 | Antifibrotic (inhalation) | Idiopathic pulmonary fibrosis | Japan:PhaseI | In-house | In-house |
| | SR-0379 | Promote granulation formation (topical) | Cutaneous ulcer (Pressure ulcer, Diabetic ulcer) | Japan:PhaseII | FunPep (Japan) | Shionogi/FunPep |
| | S-005151 (Redasemtide Trifluoroacetate) | Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection) | Stroke | Japan:PhaseII | StemRIM (Japan) | In-house |
| | S-005151 (Redasemtide Trifluoroacetate) | Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection) | Epidermolysis bullosa | Japan:PhaseII (preparing NDA submission) | StemRIM (Japan) | In-house |

<Out-Licensing Activity>

| Code No. (Generic name) [Product name] | Mechanism of action (Administration) | Indication | Stage | Origin | Development |
|--|---|--|---|---------------------------------|--|
| S/GSK1349572 (dolutegravir) | Integrase inhibitor (oral) | For the treatment of HIV infection | (DTG*1/3TC*2 2-drug fixed dose combination tablet) USA:Approval(naïve patients) (Apr.2019) USA:Approval(switch patients) (Aug.2020) Europe:Approval(naïve and switch patients) (Jul.2019) Japan:Approval(naïve patients)(Jan. 2020) | Shionogi-ViiV Healthcare LLC | ViiV Healthcare Ltd. (UK) |
| S/GSK1265744 LAP*3 (cabotegravir) | Integrase inhibitor (injection) | For the treatment and prevention for HIV infection | (CAB*4 LAP+RPV*5 LAP 2-drug regimen for treatment) Canada:Approval(Mar.2020) USA:NDA re-submission(Jul.2020) Europe:MAA submission(Jul.2019) (CAB LAP for prevention) Global:PhaseIII | Shionogi-ViiV Healthcare LLC | ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention |
| S-0373 | Non-peptide mimetic of TRH (oral) | Spinocerebellar ataxia | Japan:PhaseIII | In-house | Kissei Pharmaceutical Co., Ltd. (Japan) |
| S-033188 (baloxavir marboxil) [USA:Xofluza™] | Cap-dependent endonuclease inhibition (oral) | Influenza virus infection | USA:Approval(Oct.2018) USA:Approval(high risk patients) (Oct.2019) USA:NDA submission(pediatric, ≥ 1 year old) (Mar.2020) USA:NDA submission (Granule)(Mar.2020) USA:NDA submission (Prophylaxis) (Mar.2020) Europe:MAA submission(treatment, prophylaxis)(Nov.2019) Global:PhaseIII(severe influenza virus infection) Global:PhaseIII(pediatric, < 1 year old) Global:PhaseIII(transmission) | In-house | Shionogi/Roche (Switzerland) |

*1 Dolutegravir, *2 Lamivudine, *3 Long acting parenteral formulation, *4 Cabotegravir, *5 Rilpivirine

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

| Generic name [Product name] | Mechanism of action (Administration) | Indication | Stage | Origin | Development |
|---|--|--|---------------------------|---|-------------|
| Oxycodone hydrochloride hydrate [OxyContin®] | Natural opium alkaloids (oral) | For the treatment of moderate to severe chronic pain | Japan:Approval (Oct.2020) | Napp Pharmaceuticals Limited (UK) | In-house |

Since Jul 31, 2020

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|-------------------------------|--|
| Change of phase | S-649266:USA NDA submission (Nosocomial pneumonia) →USA Approval (Sep.2020) |
| | S/GSK1349572: USA NDA submission(switch patients)→USA Approval (Aug.2020) Oxycodone hydrochloride hydrate: Japan NDA re-submission (For the treatment of moderate to severe chronic pain)→ Japan Approval (Oct.2020) |
| Compound added to the list | BPN14770(Fragile X Syndrome): USA Phase II (Added due to acquisition of Tetra Therapeutics) |
| | BPN14770(Alzheimer's disease): USA Phase II (Added due to acquisition of Tetra Therapeutics) |
| | BPN14770(Alzheimer's disease): Japan Phase I |