

Medium-Term Business Plan  
Year End March 31, 2019 through Year End March 31, 2021

# M1 TRUST 2021

May 15, 2018


**sawai**



1. Review of Previous Medium-Term Business Plan
2. Recognition of Market Conditions
3. Medium- to Long-Term Vision and outline of Medium-Term Business Plan
4. Medium-Term Business Plan
5. Financial Targets

# Review of Previous Medium-Term Business Plan

## Summary of M1 TRUST 2018 Results

|   |  |
|---|--|
| <p><b>Vision</b></p>  | <p>To transform into a company that can continue to grow in the midst of rapidly changing market conditions</p>  |
| <p><b>Period Covered</b></p>                                | <p>April 2015 through March 2018</p>   |
| <p><b>Financial targets for year end March 31, 2018</b></p> | <p>Net Sales: ¥157 billion (target), <u>¥168 billion</u> (actual)*<br/>         Operating income: ¥26 billion(target), <u>¥22 billion</u> (actual)</p>   |
| <p><b>What “M1 TRUST 2018” Will achieve</b></p>             |  <ol style="list-style-type: none"> <li>1. Firmly maintain the number 1 market share in the generics industry             <ul style="list-style-type: none"> <li>• Share within the generics market on volume basis: 16.0% (target), 14.9% (actual)</li> <li>• Revenue growth rate (annual average): 14.1% (target), 16.8% (actual)</li> </ul> </li> <li>2. Strengthen our ability to provide stable supplies and manage costs in response to the “80% Generic Era” (substitution rate)             <ul style="list-style-type: none"> <li>• Production Capacity: 15.5 billion tablets (target), 15.5 billion tablets (actual)</li> <li>• Capital Expenditure for 3 years: 55 billion yen (target), 49.3 billion yen</li> </ul> </li> <li>3. Build an operating foundation for future growth through new business opportunities             <ul style="list-style-type: none"> <li>• Total purchase price of Upsher-Smith Laboratories, LLC (USL) ¥116.5 billion (20% stake has been sold to Sumitomo Corporation of Americas)</li> </ul> </li> </ol> |

\*Net Sales and Profit in Year ended March 2018 is based on IFRS

# Review of Previous Medium-Term Business Plan

## Summary of M1 TRUST 2018 Results

- Net sales were above target due to the acquisition of USL
- Operating income was below target due to fierce competition in the domestic market

Unit: ¥ million

|  | Year End<br>March 31, 2016 |                   | Year End<br>March 31, 2017 |                   | Year End<br>March 31, 2018 |                   |                   |
|--|----------------------------|-------------------|----------------------------|-------------------|----------------------------|-------------------|-------------------|
|  | Results                    | Target            | Results                    | Target            | Results                    | Target            |                   |
| Net sales                                    | 105,454                    | 124,000           | 123,492                    | 143,000           | 132,428                    | 157,000           | 168,127           |
| Cost of sales                                | 60,047                     | 71,900            | 71,858                     | 85,000            | 80,308                     | 96,500            | 98,394            |
| Gross profit                                 | 45,406<br>(43.1%)          | 52,100<br>(42.0%) | 51,634<br>(41.8%)          | 58,000<br>(40.6%) | 52,119<br>(39.4%)          | 60,500<br>(38.5%) | 69,734<br>(41.5%) |
| SG&A expenses                                | 24,718                     | 30,100            | 28,448                     | 33,000            | 31,484                     | 34,500            | 48,639            |
| Operating income<br>(Operating income ratio) | 20,688<br>(19.6%)          | 22,000<br>(17.7%) | 23,185<br>(18.8%)          | 25,000<br>(17.5%) | 20,633<br>(15.6%)          | 26,000<br>(16.6%) | 21,095<br>(12.5%) |
| Ordinary income<br>(Ordinary income ratio)   | 20,619<br>(19.6%)          | 21,700<br>(17.5%) | 23,025<br>(18.6%)          | 24,700<br>(17.3%) | 20,557<br>(15.5%)          | 25,500<br>(16.2%) | 19,188<br>(11.4%) |
| Net income<br>(net income ratio)             | 14,053<br>(13.3%)          | 15,500<br>(12.5%) | 17,155<br>(13.9%)          | 18,500<br>(12.9%) | 15,914<br>(12.0%)          | 18,500<br>(11.8%) | 10,633<br>(6.3%)  |

\* Japanese GAAP basis

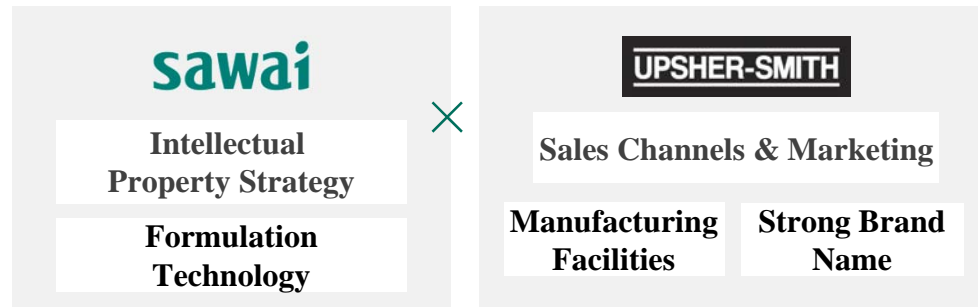
# Review of Previous Medium-Term Business Plan

## Acquisition of Upsher-Smith Laboratories

- In May 2017, the acquisition of Upsher-Smith Laboratories was completed to establish a business foundation in the US market
- Integration at the strategic level is in progress at present

### Full-fledged US Market Entry through USL

US market



**Provide high-quality and value-added generic pharma products to patients both in Japan and the US**

### Acquisition price

- JPY 116.5 billion in total
- 20% stake was sold to Sumitomo Corporation of Americas

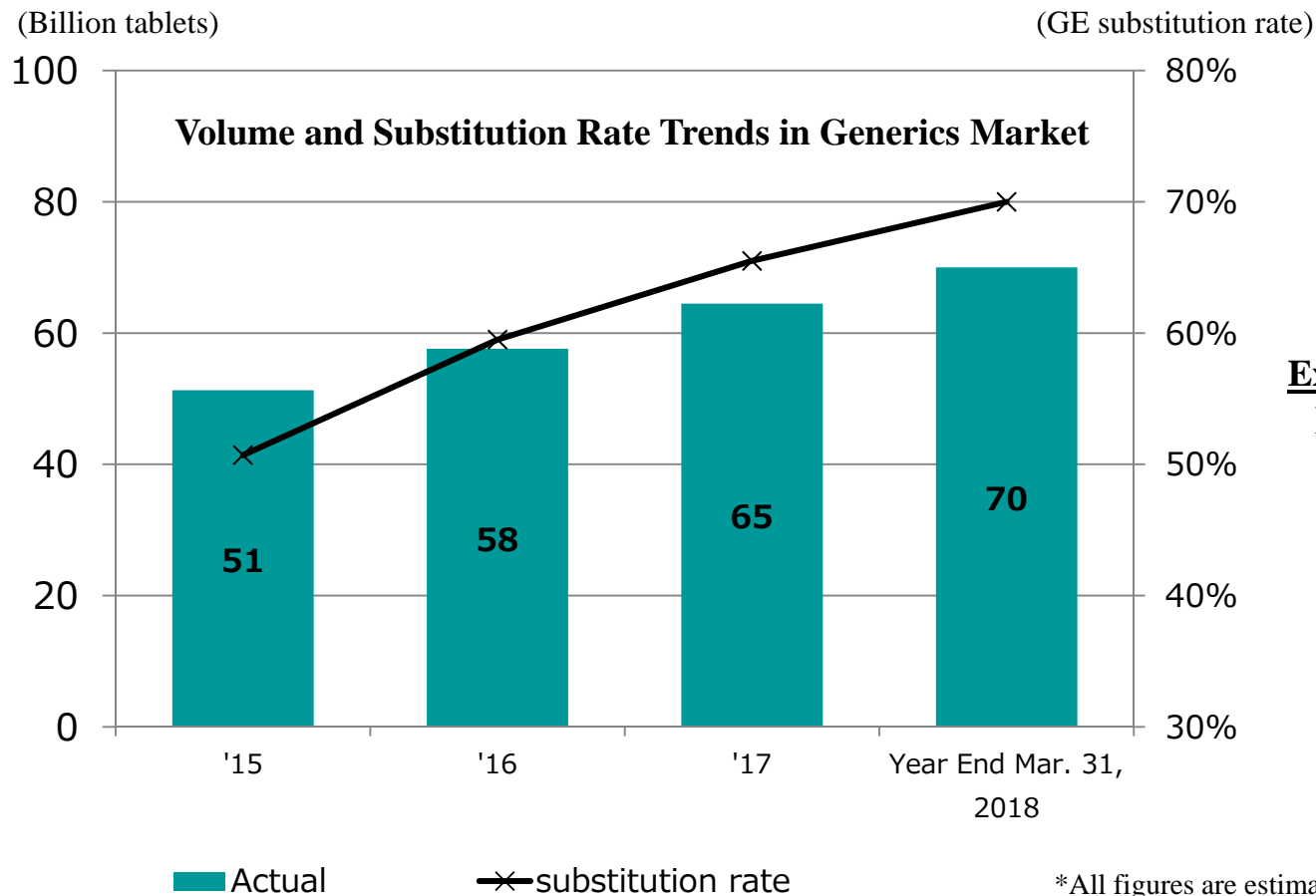
### Funding

- Transaction financed by bank loans and equity finance

# Review of Previous Medium-Term Business Plan

## Trends in the Generics Market

The substitution rate trend was as originally anticipated, but the market expanded to only 19 billion tablets, approximately 1 billion tablets short



### Expansion of the Generics market

Forecast +20 bil. tabs/3 years\*  
 Actual Results +19 bil. tabs/3 years\*

\*All figures are estimated by Sawai Pharmaceutical Co., Ltd.

# Review of Previous Medium-Term Business Plan

## Status of achieving priority measures of M1 TRUST 2018

- In the domestic market, volume share target was not achieved mainly due to our fair price strategy\* in the increasingly competitive environment
- Operating foundation for future growth has been steadily built as planned

### 1. Firmly maintain the number 1 share in the generics industry in Japan

- ▶ • **Volume share target within the Generics market was not achieved**
- **Intensifying price competition due to commoditization and increase in AG**

- Target share was not achieved due to a larger-than-anticipated increase in the number of AG products launched.
- Intensifying price competition due to increased price pressure from major dispensing pharmacies and drug chains.
- Although existing products grew steadily, the use of generics at DPC\*\* facilities stabilized and the sales volume of existing products did not increase as much as we had expected.

### 2. Strengthen stable supply and cost control capabilities in response to changing market conditions

- ▶ • **Maintain high quality and continue stable supply**
- **Cost rate worsened in contrast with initial plan**

- Sales and quantity targets were not achieved, as a result, the cost rate was worse than the initial plan.
- Gross profit target was not achieved, however, optimizing Selling, General, & Administrative (SG&A) expenses curbed profit decline.

### 3. Build an operating foundation for future growth through new business opportunities

- ▶ • **Complete establishing the foundation in the US market through USL acquisition**
- **Development and application of Pitavastatin (PIV) products are on track**

- Acquisition of USL created a foundation for US market penetration. Efforts underway for synergy creation.
- Three Paragraph IV candidate products are on track and PIV product is expected to launch by FY2023.
- Sawai is the sixth market entrant to domestic biosimilar market. Although sales are not significant, certain knowledge was acquired.

\*Sawai tries to maintain price with high quality and stable supply rather than lowering price to gain the share

\*\*Diagnosis Procedure Combination



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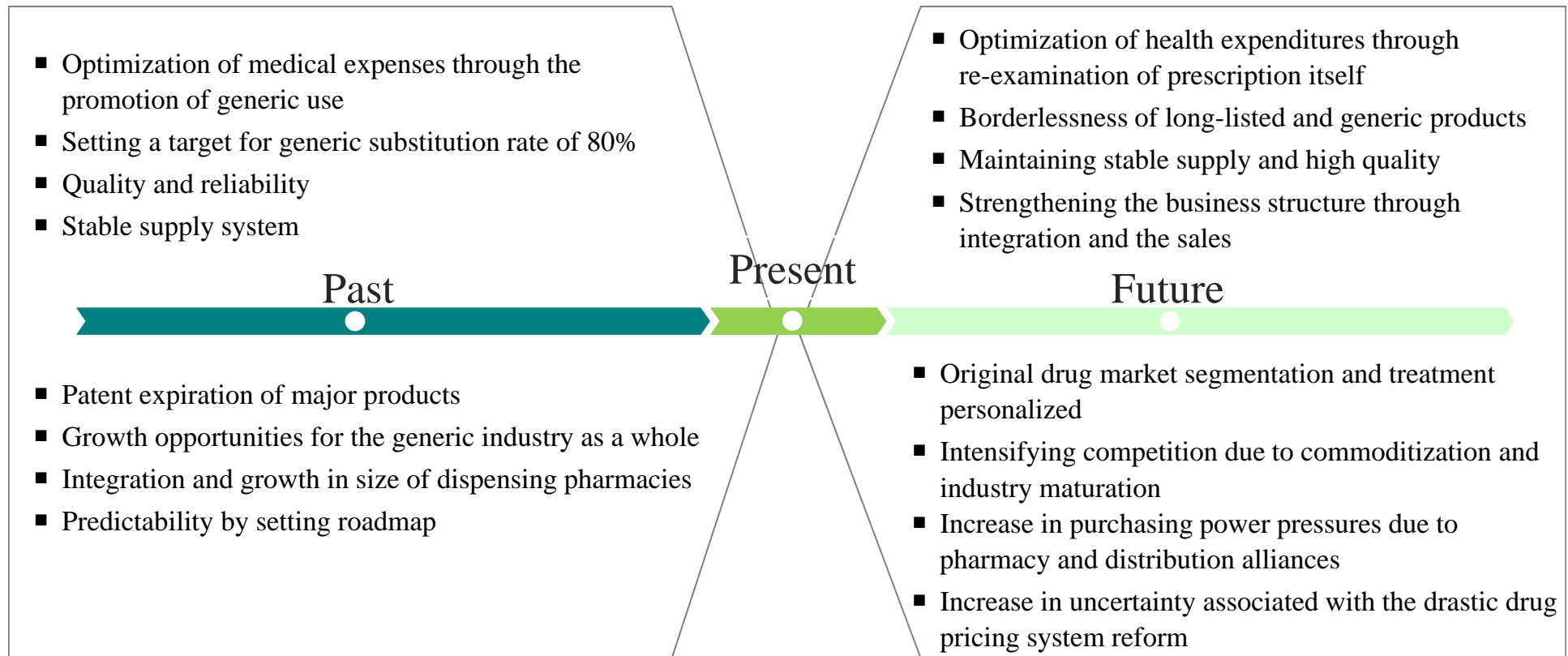


# Recognition of Market Conditions

## Changes in the Micro/Macro Environment

- The domestic market will substantially change due to fundamental reform in the drug pricing system
- A move toward industry reorganization has begun in the generics industry

### Macro environment changes

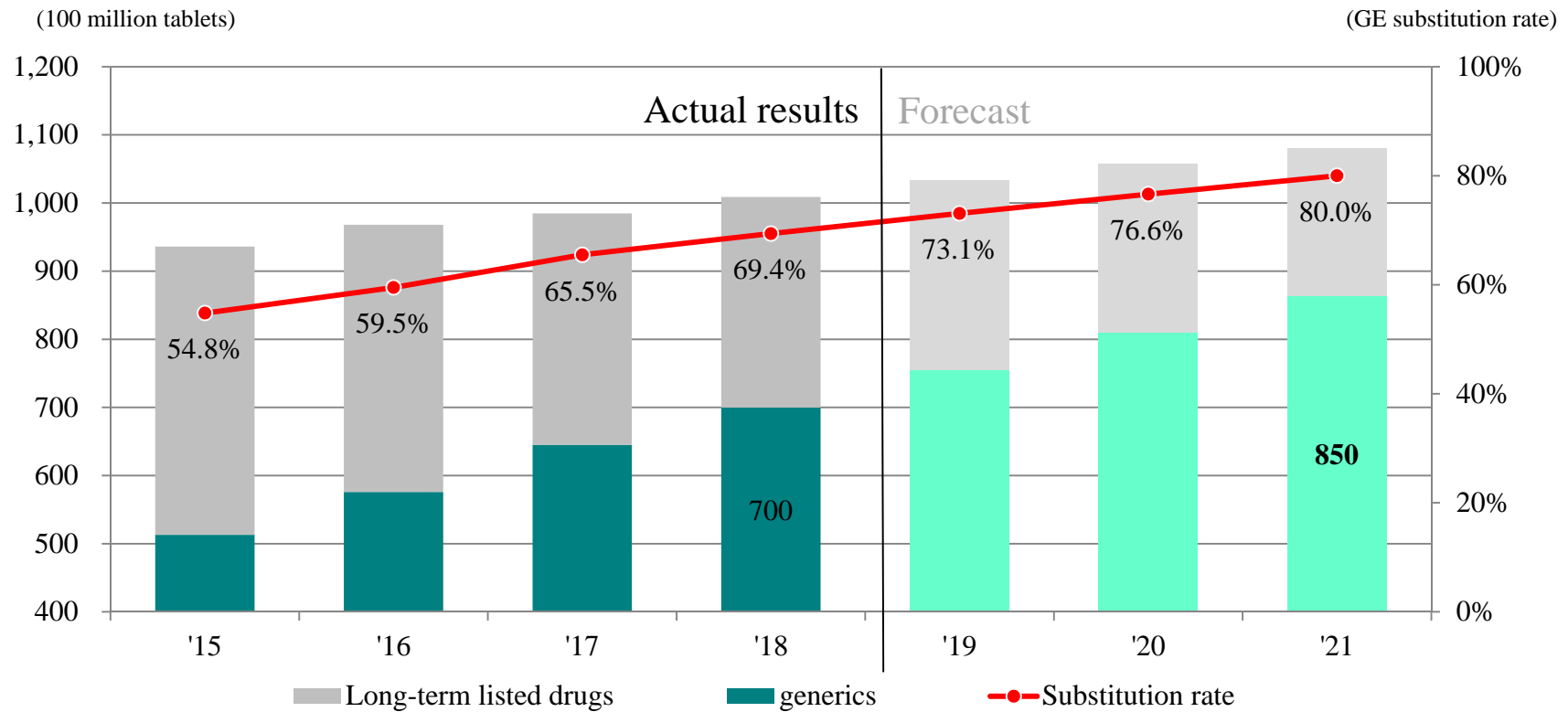


### Micro environment changes

# Recognition of Market Conditions

## Volume Forecast in Generics Market

- Generics market will continue to grow to reach 80% substitution rate by September 2020
- Generics market size will grow to 85 billion tablets in fiscal year 2020 due to promotion of proper use of pharmaceuticals



\*All figures are estimated by Sawai Pharmaceutical Co., Ltd.



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# Medium- to Long-Term Vision

## Medium-to Long-Term Vision

Establish a dominant position in the domestic generics market,  
and transform into a world-leading generic company  
by accelerating growth of USL

Further expand generic business  
and invest in future growth

Build foundation for a greater  
jump forward

Improve growth efficiency by  
strengthening cooperation  
with USL

Transformation  
into a global company

Year end March 31, 2015

Year end March 31, 2018

Year end March 31, 2021

# Medium-to Long-Term Vision Management Theme During M1 TRUST 2021

## Sawai's strengths

- Secured productive capacity prepared ahead of time and the solid financial ground
- Industry-leading product lineup and high capabilities of R&D, production and sales
- Business platform in overseas markets through the acquisition of USL

Build an intra-industry network through potential strategic alliances;  
Accelerate globalization through USL

- Slower growth due to the 80% generic substitution achievement and the promotion of prescription optimization
- Decrease in profitability due to annual drug price revisions and intensified price competition
- Increase in uncertainty, such as a price consolidation of all listed generics into one-price, etc.

Changes in the Japanese market

# Medium-to Long-Term Vision

## Priority Measures During M1 TRUST 2021

### Key tasks in the Japanese market

**Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness**

1. Maintain stable supply and high quality, while simultaneously pursuing cost competitiveness
2. Shift to a product-development and sales structure that meets the “80% Generic Era” status
3. Pursue higher efficiency by building alliances proactively

Build an intra-industry network with a view to strategic alliances;  
Accelerate globalization through USL

**Cooperation that leverages the strengths of both companies**

### Key tasks in the US market

1. Expand the US product lineup and enhance the intellectual property strategy
2. Continue to develop Paragraph IV application products
3. Realize a growth strategy utilizing USL's unique characteristics



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# Medium-Term Business Plan

## Sales-Related Initiatives

Cooperation that leverages the strengths of both companies

**Key tasks in the US market**

**Key tasks in the Japanese market**

Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness

### Action Items

### Key Initiatives

|   |  |
|---|--|
| <p>Improve efficiency through Selection and concentration</p> | <ol style="list-style-type: none"> <li>1. Build an organizational structure that responds to the medical sphere changes by community-based integrated care systems</li> <li>2. Improve sales efficiency through diversification of communication channels</li> <li>3. Search for business and sales alliances</li> </ol> |
| <p>Optimize Distribution</p>                                  | <ol style="list-style-type: none"> <li>1. Gain recommendations by strengthening layer-separated communication with wholesalers and distributors</li> <li>2. Review rebate and allowance system to align with distribution rationalization</li> </ol>   |



# Medium-Term Business Plan

## R&D-Related Initiatives

Cooperation that leverages the strengths of both companies

**Key tasks in the US market**

**Key tasks in the Japanese market**

Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness

### Action Items

### Key Initiatives

|   |   |
|---|---|
| Product development focused on added value and cost effectivity | <ol style="list-style-type: none"> <li>1. Develop value-added products that meet market needs</li> <li>2. Product development with an awareness of manufacturing costs from early stages</li> </ol> |
| Obtain approvals in an effective and secured* manner            | <ol style="list-style-type: none"> <li>1. Optimization of development processes through enhanced collaboration</li> <li>2. Formulation design based on the latest scientific findings</li> </ol>    |

\*Greatest possibility of success

# Medium-Term Business Plan

## Production-Related Initiatives

Cooperation that leverages the strengths of both companies

**Key tasks in the US market**

**Key tasks in the Japanese market**

Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness

### Action Items

### Key Initiatives

Establish manufacturing systems to improve efficiency and flexibility

1. Pursuing efficient production by clarifying the role of each factory
2. Establish a flexible production system that will respond to environment changes, such as consolidation in generics industry
3. Realization of low-cost production and stable supply by utilizing the surplus production capacity from other companies including other generic manufacturers (i.e., contract manufacturing services)

Strengthen purchasing power

1. Establish standard specification requirements and further strengthen bargaining power through centralized purchasing of material and equipment
2. Reduce purchasing price through strengthening of API searching methods

# Medium-Term Business Plan

## Reliability Assurance-Related Initiatives

Cooperation that leverages the strengths of both companies

**Key tasks in the US market**

**Key tasks in the Japanese market**

Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness

### Action Items

### Key Initiatives

Strengthen cooperation in quality assurance

1. Maintain a stable supply system through thorough management, evaluation and auditing of suppliers
2. Strengthen QA at factories and strengthen cooperation with GQP
3. Build an organic, cooperative structure with USL

Strengthen regulatory affairs management system, including USL

1. Strengthen the domestic regulatory affairs audit system
2. Establish QA/PV/RA system for sales in the US

QA : Quality Assurance, GQP : Good Quality Practice, PV : Pharmacovigilance, RA : Regulatory Affairs

# Medium-Term Business Plan Initiatives in the US Market

Cooperation that leverages the strengths of both companies

**Key tasks in the US market**

Key tasks in the Japanese market

Build a structure capable of responding to changes in the industry structure and strengthen cost competitiveness

| Action Items  | Key Initiatives  |
|---|--|
| <p><b>Create synergies between Sawai and USL</b></p>                | <ol style="list-style-type: none"> <li>1. Bring products approved in Japan to the US market</li> <li>2. Collaboratively develop new products</li> <li>3. Implement cooperative, new product development strategies for patent-challenging opportunities</li> </ol> |
| <p><b>Expand pipeline by strengthening in-house development</b></p> | <ol style="list-style-type: none"> <li>1. Aggressively invest in R&amp;D</li> <li>2. Promote better efficiency of R&amp;D operations</li> </ol>  |
| <p><b>Achieve product diversification by in-licensing</b></p>       | <ol style="list-style-type: none"> <li>1. Strategically add products with higher barriers to entry</li> <li>2. Focus on products that could utilize USL sales capabilities</li> </ol>  |

# Medium-Term Business Plan

## Planned New Launches

In the Japanese market, Sawai plans to launch 34 new products during M1 TRUST 2021.

| Japanese market                                 | Year End March 31, 2019          | Year End March 31, 2020       | Year End March 31, 2021         |
|---|----------------------------------|-------------------------------|---------------------------------|
| Generics of major branded products are expected | AIMIX®<br>Strattera®<br>TRAMCET® | URIEF®<br>Lonasen®<br>Iressa® | Feburic®<br>Celecox®<br>MEMORY® |
| Original product estimated market size          | Approx. ¥240 billion             | Approx. ¥90 billion           | Approx. ¥430 billion            |
| Number of newly listed active ingredients       | 11                               | 7                             | 16                              |



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# Financial Targets P/L for the Year Ended March 2019

- As the predictability of the Japanese generics market environment is low and it is difficult to foresee the outcome for the second year and beyond, consolidated P/L is only shown for a single year
- Expected increase in sales and profit in FY ended March 31, 2019

Unit: ¥million

|  | Fiscal year end March 31, 2018<br>(Actual) |            |        | Fiscal year end March 31, 2019<br>(Target) |            |        | Year on Year Change |       |
|--|--|------------|--------|--|------------|--------|---------------------|-------|
|  | Total                                      | By segment |        | Total                                      | By segment |        | Amount              | Rates |
|  |  | Japan      | US     |  | Japan      | US     |                     |       |
| <b>Net sales</b>                                   | 168,068                                    | 134,720    | 33,347 | 172,500                                    | 136,600    | 35,900 | 4,432               | 2.6%  |
| <b>Gross profit</b>                                | 69,440                                     | 51,309     | 18,131 | 69,600                                     | 49,300     | 20,300 | 160                 | 0.2%  |
| <b>Operating income</b>                            | 22,209                                     | 21,903     | 303    | 24,000                                     | 21,300     | 2,700  | 1,791               | 8.1%  |
| <b>Income before income taxes</b>                  | 20,251                                     | —          | —      | 23,700                                     | —          | —      | 3,449               | 17.0% |
| <b>Profit attributable to owners of the parent</b> | 14,017                                     | —          | —      | 17,400                                     | —          | —      | 3,383               | 24.1% |

※ IFRS basis

# Financial Target

## USL P/L plan

- Approximately 25 products are planned to be launched in the US market over the next three years.
- Five to 10 products are expected to come to market every year for the next five years.

Unit: ¥million

|  | Year End<br>March 31, 2018<br>(10 month) | Year End<br>March 31, 2019 | Year End<br>March 31, 2020 | Year End<br>March 31, 2021 | Year End<br>March 31, 2022 | Year End<br>March 31, 2023 | CAGR<br>Year Ended March<br>31, 2019<br>Year Ended March<br>31, 2023 |
|--|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|--|
| <b>Net sales</b>                         | 33,347                                   | 35,900                     | 37,600                     | 44,700                     | 47,300                     | 56,900                     | 12.3%  |
| <b>Existing products</b>                 | 33,347                                   | 31,800                     | 28,900                     | 29,700                     | 25,500                     | 25,400                     | -  |
| <b>Pipeline</b>                          | -  | 4,100                      | 8,700                      | 15,000                     | 21,700                     | 31,500                     | -  |
| <b>Operating income<br/>(before PPA)</b> | 7,486                                    | 7,600                      | 8,500                      | 13,000                     | 13,000                     | 18,500                     | 27.5%  |
| <b>Operating income</b>                  | 1,874                                    | 2,700                      | 3,000                      | 7,500                      | 7,500                      | 13,000                     | 45.5%  |
| <b>EBITDA</b>                            | 9,463                                    | 8,700                      | 9,500                      | 14,500                     | 14,000                     | 19,500                     | 22.4%  |

※ \$1=¥105 (2019/3 or later)

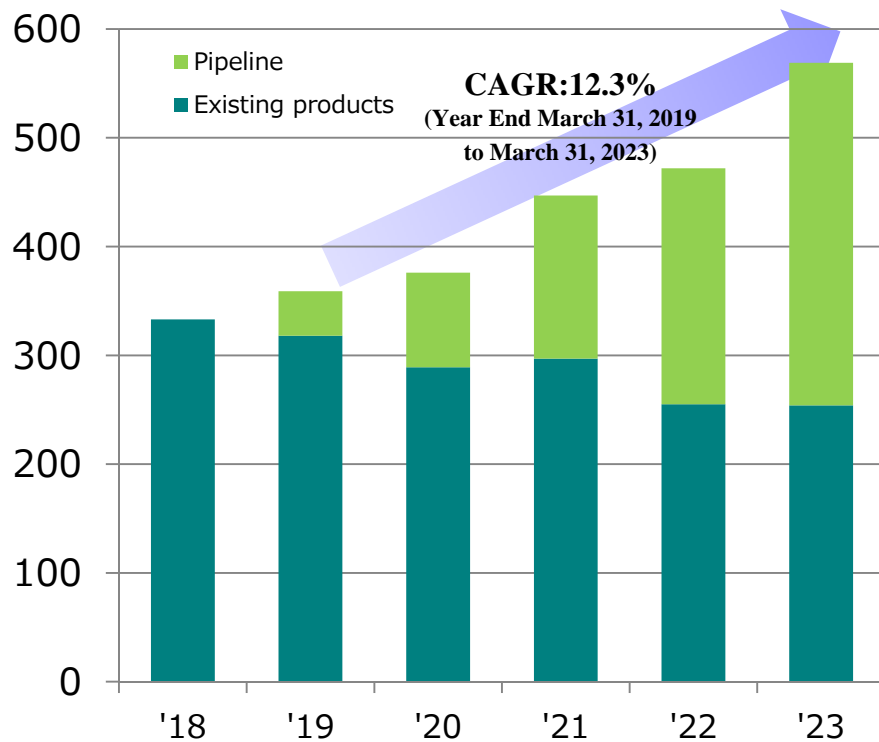


# Financial Target

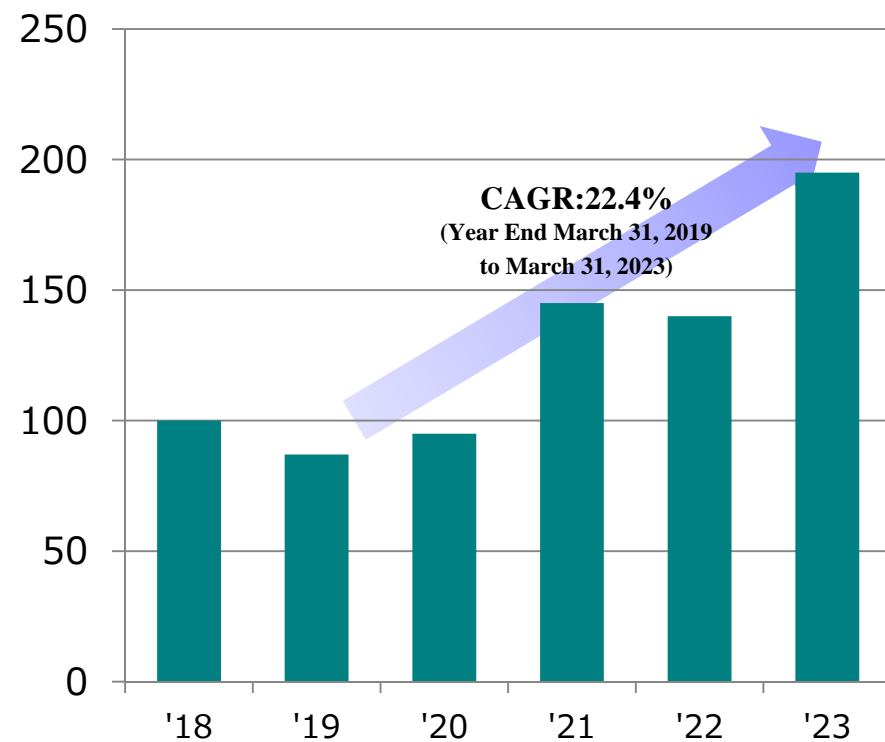
## USL P/L plan

- Estimated to grow 12.3% per year on net sales and 22.4% per year on EBITDA from fiscal year ended March 31, 2019.

**USL: Net Sales (¥100 million)**



**USL: EBITDA (¥100 million)**





- The plans, forecasts, strategy and other information regarding the Sawai Group contained in this presentation are based on the Company's assumptions and judgements using information available at the time of publication. Therefore, due to potential risks and uncertainties, there is no guarantee as to accuracy of this information.
- Potential risks and uncertainties include, but are not limited to, the economic environment for prescription drugs, which is the main operating domain of the Sawai group, market competition and services offered by the Group.

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