We aspire to be a “Global Specialized Player” with the ability to meet increasingly diversified healthcare needs.

Under our Mid-term Business Plan 2022 (fiscal 2018 –2022), Sumitomo Dainippon Pharma is working to reshape our business foundation through the “establishment of growth engines,” and the “building of a flexible and efficient organization.” We will reduce the impact that the approaching expiry of the exclusive marketing period for LATUDA® in North America is expected to have on our business performance, and recover as soon as possible through such measures as aggressive research and development, pipeline expansion, and the launch of a frontier business to achieve sustained growth. We will continue striving to create innovative drugs and provide diverse solutions, as we aspire to establish ourselves as a “Global Specialized Player” by 2033 with the ability to meet increasingly diversified healthcare needs.

Hiroshi Nomura
Representative Director, President and Chief Executive Officer
Looking back over fiscal 2018 (the year ended March 31, 2019), how would you rate the Group’s business performance?

We experienced declines in revenue and profit due to lower sales in Japan and impairment losses in North America.

The fiscal 2018 consolidated performance saw a year-on-year decline in sales and profit, attributed to a decrease in sales in Japan and the recording of impairment loss on intangible assets in North America, among other factors. While the North America segment recorded revenue growth due to an increase in sales of LATUDA® and APTIOM®, the Japan segment recorded a decline in sales due to the impact of NHI drug price revisions implemented in April 2018, as well as lower sales of long-listed products. As a result, revenue was ¥459.3 billion, down ¥7.6 billion year-on-year, and core operating profit was ¥77.3 billion, down ¥13.3 billion. In addition to the decline in core operating profit, we recorded impairment losses on R&D and marketing rights in North America, and incurred structural reform expenses associated with the consolidation of our production sites. Consequently, the operating profit was ¥57.9 billion, down ¥30.3 billion.

In terms of R&D, we received approval in July 2018 for our partial change application for an additional indication of Parkinsonism in dementia with Lewy bodies for TRERIEF® in Japan. We also obtained approval in March 2019 for RETHIO® in pediatric malignant solid tumors. With regards to LATUDA®, we obtained approval of the drug for the treatment of schizophrenia in China in January 2019, while we also applied for approval of the drug for schizophrenia and bipolar depression in Japan in July 2019. In July 2018, we submitted an application for approval of the LONASEN® transdermal patch for schizophrenia in Japan and obtained approval in June 2019. We received Complete Response Letters (CRLs) from the U.S. Food and Drug Administration (FDA) indicating that approval is not possible at present for dasotraline for ADHD and apomorphine hydrochloride for OFF episodes associated with Parkinson’s disease, for which we have pending applications for approval in the U.S. However, we are preparing to resubmit the application for apomorphine hydrochloride. At present, we are reviewing the development plans for dasotraline for ADHD, and SB623 for chronic stroke, which failed to achieve the primary endpoints in the Phase 2b study.

Thus, while we recorded declines in revenue and profit on the business performance front in fiscal 2018, core operating profit, which is our focus, was in line with the initial forecast due to appropriate cost controls and the results of structural reform. On the other hand, we consider delays in R&D and market launch plans to be

### Financial Results for Fiscal 2018
(Billions of yen)

<table>
<thead>
<tr>
<th></th>
<th>FY2017</th>
<th>FY2018</th>
<th>YOY change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>466.8</td>
<td>459.3</td>
<td>-7.6 (-1.6%)</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>90.6</td>
<td>77.3</td>
<td>-13.3 (-14.7%)</td>
</tr>
<tr>
<td>Operating profit</td>
<td>88.2</td>
<td>57.9</td>
<td>-30.3 (-34.4%)</td>
</tr>
<tr>
<td>Net profit attributable to owners of the parent</td>
<td>53.4</td>
<td>48.6</td>
<td>-4.8 (-9.0%)</td>
</tr>
</tbody>
</table>

### Major topics of Fiscal 2018

**Japan**
- Improved efficiency in manufacturing (consolidated 4 production sites into 2 sites)
- Declines in revenue and profit due to NHI price revisions and decreases in revenue for long-listed products

**North America**
- LATUDA® ANDA lawsuits concluded through settlement, except for one lawsuit pending, with condition of settlement that generic versions of LATUDA® may enter the market commencing February 20, 2023
- Launched LONHALA® MAGNAR®
- Revenue shortfall in respiratory portfolio

**China/Others**
- Achieved steady growth

**R&D**
- Success in 3 approvals, 1 NDA submission
- Received Complete Response Letters for dasotraline (ADHD) and apomorphine from FDA
- Success in pivotal study: Schizophrenia for lurasidone (Japan)
- Success in POC*1 study: Schizophrenia for SEP-363856 (US) / Not successful in POC study: Chronic stroke for SB623 (US)
- Initiated clinical studies for 4 assets / Initiated Phase 2 study for 1 asset

*1 Proof of Concept (POC): confirmation of expected safety and efficacy in humans
How do you regard the future environment for pharmaceutical companies?

We believe that it will be an era of diversified healthcare needs requiring not only new drug development, but also contributions to disease prevention and global health.

Sumitomo Dainippon Pharma in April 2019 announced the Mid-term Business Plan (MTBP) 2022, which runs from fiscal 2018 to fiscal 2022. Its release was delayed due to the timing of the LATUDA® ANDA lawsuits. In the formulation of the plan, we considered the changes in the environment for pharmaceutical companies that are expected over the next 15 years.

Although it is difficult to forecast the future accurately, the acceleration of the 4th Industrial Revolution on a global scale, together with the aging society and the decline in the working population mainly in developed countries, particularly Japan, can be considered to be macro-trends. It is also expected that the status of Japan and Europe in the global economy will fall due to the rise of China and other emerging countries. Moreover, we expect that society’s demand for contributions to global health issues, such as infectious disease control, will increase even more due to rising populations in Asia and Africa. In addition to advancing healthcare, the need for disease prevention is expected to rise further in the future.

In the world of medicine, we expect to see progress with respect to understanding disease mechanisms, early diagnosis, and prevention and intervention methods, making more diseases treatable. In addition, we also expect commercialization of new treatment methods, particularly the use of new modalities such as regenerative medicine and precision medicine. Furthermore, the use of digital technology, such as big data, artificial intelligence (AI), and the Internet of Things (IoT), will facilitate more advanced and efficient services in the medical and healthcare sector.

In this environment, the role of pharmaceuticals will remain important, and pharmaceuticals will continue to be the major part of the solution we will provide for unmet medical needs. We anticipate that the pharmaceutical companies of the future will increasingly be expected to play a societal role, which will include enhancing preventative healthcare services and contributing to global health, in addition to creating new drugs as innovative treatments. The message of our MTBP is that the next 15 years will be a time of accelerated changes that will require pharmaceutical companies to adapt and evolve in order to meet the needs of our increasingly complex and aging population.

Changes in environment surrounding pharma (Anticipated changes over the next 15 years)

**Society**
- Acceleration of the 4th Industrial Revolution
- Aging society with fewer working population
- Rise of China and other emerging countries, relatively lower positioning of Japan and Europe
- Increasing corporate social responsibilities for contribution to global health

**Healthcare/ Healthcare System**
- Further aging society
- Higher pressure on healthcare costs
- More disease-prevention measures available and more diseases treatable
- Realization of new modalities such as regenerative medicine
- Greater use of big data and AI technologies

**Healthcare Industry**
- Solution to unmet medical needs
  - Pharmaceutical products remain at the core of solutions
  - Digital technologies become available
  - Preventive medical care becomes available
years will be a “Time for Change.” It is our aim to establish a new business model that can achieve sustained growth over the medium-to-long term by embracing these changes in social needs and advances in medical technology and information technology to proactively transform our business.

*2 Modality traditionally referred to the use of medicines, such as low molecular compounds, biopharmaceuticals, and nucleic acid medicine, but here we include therapies using digital technology.

*3 Precision medicine refers to a new approach involving a shift from conventional genome research to clinical medicine that includes stratification of individual patients in an effort to deliver more effective treatment.

Please explain your medium-to-long term corporate vision.

We aspire to establish ourselves as a “Global Specialized Player” by 2033 with the ability to meet increasingly diversified healthcare needs.

Under our MTBP, we have formulated our new vision, “For Longer and Healthier Lives: We unlock the future with cutting-edge technology and ideas,” in view of the changes in the external environment. We have also set a position we aspire to establish in 2033 as a “Global Specialized Player” with the ability to meet increasingly diversified healthcare needs. While 15 years may appear to be a long period of time, it encompasses three 5-year plans that will pass quickly considering the time required for pharmaceutical R&D. We recognize that during this period, setting priorities and demonstrating strengths in our specialty fields is important.

As the “Global Specialized Player” that we aspire to become, we will be a company that provides diverse healthcare solutions demanded by society through our new frontier business, in addition to being a global leader in psychiatry and neurology, oncology, and regenerative medicine/cell therapy, which are our three focus areas.

In the psychiatry and neurology area, where we already have a high profile in the global market, we aim to continue to be an innovator with the ability to make high quality contributions to patients through development of new drugs and provision of treatment options for diseases that continue to be difficult to treat. We will position the oncology area as a new engine to drive sustained growth for Sumitomo Dainippon Pharma with the anticipated introduction of several global products and the establishment of a global “DSP oncology” brand. In the regenerative medicine/cell therapy area, our cell culturing and differentiation technology is extremely advanced, and we are confident that exhibiting our uniqueness through the pursuit of sophisticated production technology and state-of-the-art science based on open innovation will allow us to establish an unrivaled position. We aim to turn a profit in this area during the period of the next MTBP (2023-2027), and to expand it into a business worth around ¥200 billion on the global scale by 2033. We plan to launch initially in Japanese markets products that are currently under development in the neurology and ophthalmology areas, and in overseas markets during the
Under this MTBP, we will significantly reshape our business foundation through the “establishment of growth engines” and the “building of a flexible and efficient organization.” As for the reason why we believe it is necessary to reshape our business foundation, it would be a major challenge to forecast our growth in the next MTBP, assuming that there was no LATUDA®. We are aware that our sense of urgency should not be diminished because we currently have revenue from LATUDA®, and we want to demonstrate the changes needed to “reshape our business foundation”, using revenue and cash flow during the exclusive marketing period for LATUDA® for our future growth. Going forward, we plan to reinforce this awareness through dialogue with our employees to ensure continued alignment and unity.

In terms of the “establishment of growth engines,” we will not only continue to focus on R&D and business growth in our three focus areas, but also promote drug discovery utilizing external networks, primarily at our sites in Japan and the U.S. In addition, we will also work to strengthen our innovation base through new approaches to drug discovery, such as the realization of precision medicine by leveraging cutting edge research results and biomarkers. Moreover, in order to obtain results even in highly uncertain areas, we will focus on improving the probability of success and efficiency in research and development through targets that anticipate changes in the scientific and medical environment; evidence-based and objective evaluation and decision-making; thorough risk management; biomarkers; and big data.

In the psychiatry and neurology area, we are prioritizing the global development of SEP-363856, a new generation anti-psychotic agent which does not bind to dopamine 2 (D2) receptor. With a target launch in fiscal 2023, we hope to grow SEP-363856 into a product with growth potential beyond LATUDA®. In the oncology area, we are prioritizing the speedy development of napabucasin and early stage assets for the early establishment of an

next MTBP period. Furthermore, we aim to expand into next-generation medical treatments, such as genome editing, peripheral organ regeneration, and autologous cell therapy, by 2033. We already have employees around the world who are actively engaged in our three focus areas, and we expect that the reinforced focus on these areas will boost their motivation.

In addition to our three focus areas, we will promote R&D in the infectious disease area through collaboration with academia. At present, we are promoting research projects that include drugs to treat antimicrobial resistant bacterial infections, and a universal influenza vaccine and malaria vaccine using our vaccine adjuvant, with a target launch in the 2020s. In addition to fulfilling our aspiration to contribute to global health, the planned drugs to treat antimicrobial resistant bacterial infections and the universal influenza vaccine are projected to become blockbuster products.

The frontier business is rooted in our desire to not just treat already sick people, but also help people stay healthy amid an expansion of future healthcare needs that will extend from prevention through convalescence. We laid the groundwork in the current MTBP period by setting up the Frontier Business Office in April 2019. We will strive to commercialize healthcare solutions that provide new value to society, focusing on areas where we can anticipate synergies with our existing pharmaceutical operations with the objective of creating a business worth ¥100 billion on the global scale by 2030. During the current MTBP period, we will evaluate internal and external projects under development and new opportunities at an early stage, and commercialize those that are promising. During the next MTBP period, we plan to establish the frontier business as a new growth engine worth tens of billions in yen.

Please explain the specific growth strategies in the Mid-term Business Plan 2022.

We will focus on the establishment of new growth engines and the reinforcement of the organizational foundation to support them, as part of efforts to prepare for post-LATUDA® revenue replacement*4.

*4 After the expiry of the exclusive marketing period for LATUDA® in the U.S.
In addition to focusing on the early establishment of new products in the psychiatry and neurology area such as LONASEN® and LATUDA®, and working on the simultaneous development of SEP-363856 in Japan and China. We will further implement compliance education in China to promote a culture that prioritizes compliance over everything else. In Southeast Asia, we will reinforce the functions of our subsidiaries in Singapore and Thailand, and strengthen the business infrastructure as growth markets after China.

Another strategy pillar of the MTBP is strengthening the organizational foundation to support these growth engines. We will use digital innovation to enable our organization and talent to identify changes in the external environment and adapt proactively and flexibly, while maintaining the ability to do things diligently, which is called “CHANTO” in Japanese.

It is not uncommon for pharmaceutical projects to extend over a long period of five to ten years. However, we expect to create better products by keeping a watchful eye on changes in the external environment and incorporating advances in social systems and technology.

Our concept of “CHANTO” refers to the capability to continuously foster and deliver innovation to patients and other customers, while transforming our organization in flexible ways to adapt to changes in the world.

Pharmaceutical R&D may not always proceed as expected. However, obtaining approval for and launching our pipeline of products in a timely manner is essential for future growth. Even in difficult circumstances, we have to complete our oncology franchise.

In terms of our regional strategy, we will reinforce business infrastructure, with China as the third pillar after the leading markets of Japan and North America. We will also position Asia as a future growth market and reinforce the functions of our Southeast Asian subsidiaries. In Japan, we will work on a turnaround to a growth trajectory during the current MTBP period by launching new products, including LATUDA® and LONASEN® tape promoting the development of SEP-363856 and napabucasin, which are global development compounds; and expanding in-licensed products in the diabetes area by leveraging our solid Japan marketing base. These and other measures will lay the groundwork to achieve ¥200 billion in revenue during the next MTBP period. The environment for medical representatives (MRs) in Japan has changed, but we will focus on education of MRs more than in the past, and expect to be able to return to a growth trajectory by introducing new products.

In North America, we will pursue profit maximization for LATUDA®, while continuing our focus on growing LONHALA® MAGNAIR®, promoting development of SEP-363856, which is a priority, and obtaining approval for napabucasin. We will also focus on obtaining approval for and launching dasotraline and apomorphine, in preparation for LATUDA® revenue replacement. In addition, we also plan to secure compounds in the psychiatry and neurology area that will drive growth in the first half of the next MTBP period through M&As.

In China, we will continue to expand MEROPEN®, in addition to focusing on the early establishment of new products in the psychiatry and neurology area such as LONASEN® and LATUDA®, and working on the simultaneous development of SEP-363856 in Japan and China.

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R&D and deliver innovative treatments to patients. As expected, our employees have always performed their jobs professionally in the past. Just as in the world of professional athletes there are various levels ranging from novices to top players, there are also various levels for delivering complete performance as professionals in the workplace. Going forward, we would like all employees to ask themselves what “CHANTO” means for their job and to further develop their skills to produce the highest quality results as true professionals. It is also important to constantly discuss “CHANTO” and instill the concept across the organization.

**Q5** Please explain your business goals and financial strategy.

**A5**

We will aim for ¥600 billion in revenue and ¥120 billion in core operating profit in fiscal 2022 through proactive R&D investment and strategic M&As. In terms of the business goals for fiscal 2022, the final year of the current MTBP, we are targeting ¥600 billion in revenue and ¥120 billion in core operating profit. In achieving these goals, we are also aiming for ROIC of 10% and ROE of 12% as the KPIs of capital efficiency. With regards to streamlining expenses, we recognize that we implemented adequate retrenchment in fiscal 2016 through fiscal 2017. Going forward, we will aim to enhance capital efficiency primarily through the expansion of core operating profit.

We will continue utilizing profit earned for strategic investment, including M&As and aggressive investment in R&D. We expect the cumulative profit of core segments to be more than ¥850 billion between fiscal 2018 and fiscal 2022, of which we plan to allocate ¥450 billion for R&D investment. We have also set an M&A range of ¥300 billion to ¥600 billion using cash generated and financial leverage. In terms of our M&A and in-licensing strategy, we will prioritize product pipeline enhancement, rather than corporate expansion. We believe that a certain level of large-scale investment is necessary as we will target late-stage assets for pipeline acquisitions in the psychiatry and neurology area, which will contribute to profit from fiscal 2023 onward. We also plan to prioritize investment aimed at the acquisition of pipeline products and technologies in the three focus areas, which will contribute to profit from fiscal 2028 onward.

**Financial goals and dividend policy**

**FY2022 Business goals**

<table>
<thead>
<tr>
<th>Revenue</th>
<th>¥600 billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core operating profit</td>
<td>¥120 billion</td>
</tr>
<tr>
<td>ROIC</td>
<td>10%</td>
</tr>
<tr>
<td>ROE</td>
<td>12%</td>
</tr>
</tbody>
</table>

**Dividend policy**

Maintain a consistent payment policy but also consider reflecting any improvement in the Company’s performance in the dividend payment

5-year average payout ratio: 20% or higher

**ROE (Return on Equity)**

Aim to achieve ROE of 10% or more over the long term

Note: Business goals are based on the Company’s assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such goals and involve both known and unknown risks and uncertainties. Accordingly, goals may not be realized as described.
In fiscal 2019 (the year ending March 31, 2020), we are forecasting revenue of ¥475 billion, up ¥15 billion year-on-year, and core operating profit of ¥77 billion, as North America will offset the decline in revenue and profit in Japan.

Regarding dividends, we place emphasis on the appropriate distribution of results backed by performance, and our policy is to provide stable dividends, in addition to offering increases in the dividend linked to any improvement in performance. Further, we aim for a five-year average payout ratio of at least 20% under the MTBP. Based on these policies, we plan to pay an annual dividend of ¥28 per share in fiscal 2019, which is unchanged from the previous fiscal year.

Based on the Mid-term Business Plan 2022, we will reshape our business foundation through the “establishment of growth engines” and the “building of a flexible and efficient organization.” Fiscal 2019, which is the second year of the plan, will be an important year for creating the foundation, which is aimed at achieving ¥200 billion in future revenue in Japan, establishing a path for growth in North America in preparation for post-LATUDA® revenue replacement, and laying the groundwork for growth markets in China and the rest of Asia. As a professional organization, we are committed to instilling company-wide awareness of “CHANTO,” and steadily achieving our financial and non-financial goals. We aspire to establish ourselves as a “Global Specialized Player” in order to realize sustained growth and enhance corporate value over the medium- to long-term. We look forward to the ongoing support of all our stakeholders.

Representative Director, President and Chief Executive Officer

Financial Policy: Ensure Strategic Investment with Financial Leverage

\[
\text{Expected incremental cash flow of ¥100 billion or more}
\]

\[
\text{Cash on hand}
\]

\[
\text{Strategic investment ¥300 - 600 billion in five years}
\]

\[
\text{Profit in core segments (cumulative from fiscal 2018–fiscal 2022): at least ¥850 billion (forecast)}
\]

\[
\text{R&D investment: ¥450 billion}
\]

\[
\text{Loans repayment}
\]

\[
\text{Dividends}
\]

\[
\text{Income taxes}
\]

\[
\text{Payment of contingent consideration, etc.}
\]