The Mochida Pharmaceutical Group's "22-24 Medium-Term Management Plan"

This material is an English translation of the press release issued on May 13, 2022 in Japanese, and the Japanese release is given priority regarding content and interpretation.

May 13, 2022

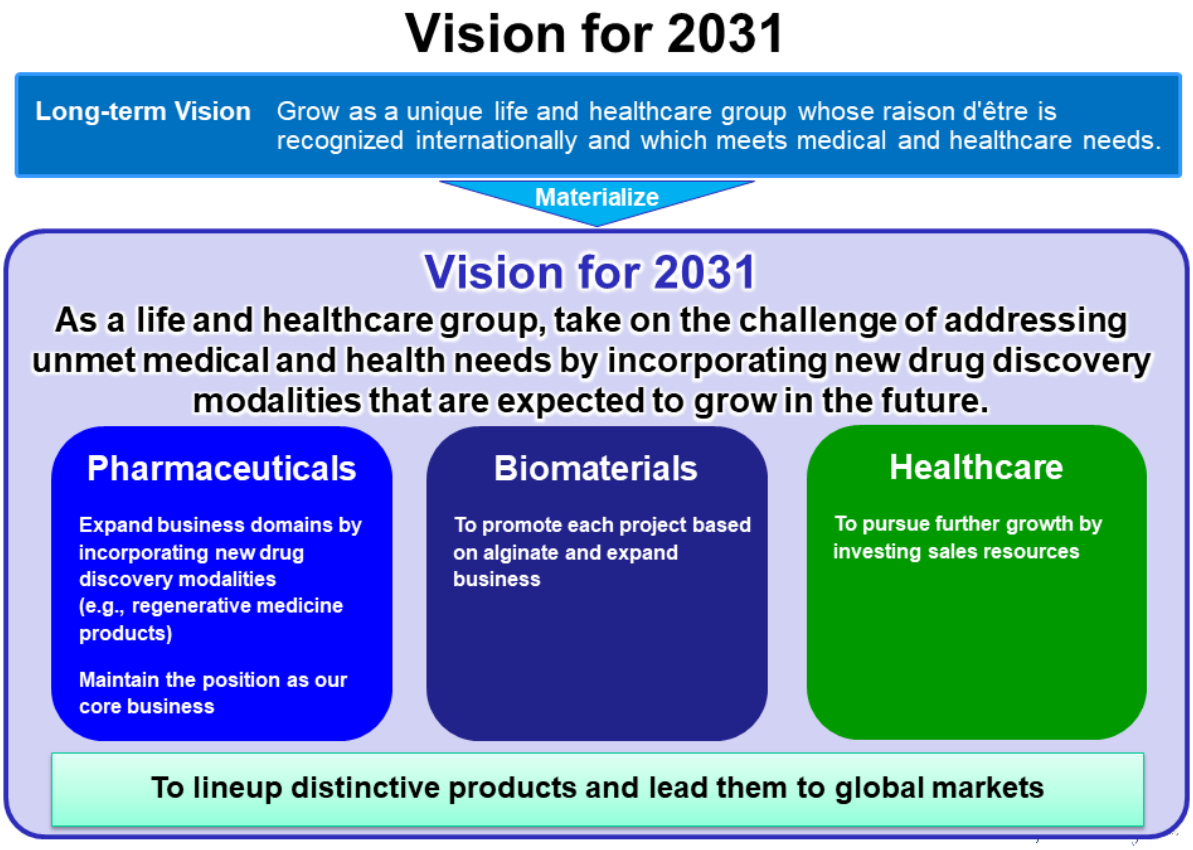
Dear All,

Mochida Pharmaceutical Group(Mochida Pharmaceutical Co., Ltd., TSE: 4534, Prime section) is pleased to announce that it has developed its "Vision for 2031" and the three-year "22-24 Medium-term Management Plan", which begins in FY 2022.

1. Vision for 2031

Mochida Pharmaceutical Group has developed its business activities based on the fundamental mission of "contributing to human health and well-being," as stated in its corporate philosophy. To expand on our past efforts and achieve sustainable growth by overcoming a business environment that is expected to become increasingly severe in the future, we have materialized our existing long-term vision and developed the "Vision for 2031" that the Group aims to realize in 2031, a milestone year 10 years from now.

- Amid the diversification and sophistication of medical care, such as addressing intractable and rare diseases that have been difficult to treat with conventional small molecules and antibody drugs alone, to take on the challenge of addressing unmet medical and health needs by incorporating new drug discovery modalities that are expected to grow in the future;
- In addition to the current mainstay pharmaceutical and healthcare businesses, to work to position the biomaterials business as one of the pillars of the next generation.



[Efforts toward 2031]

Pharmaceutical business

- To incorporate new drug discovery modalities, such as cells, nucleic acids, and genes, to enhance our drug discovery pipeline and maintain the position as a core business;
- Among them, to position regenerative medicine products as one of our focus areas and give priority to projects using mesenchymal stem cells;
- To launch products from our pipeline that incorporate new drug discovery modalities, including regenerative medicine products, by FY2031.

Biomaterials Business

- To promote each project based on alginate, which is expected to have various medical applications, and work for an early launch and business expansion. Also, to promote development with a view to global expansion.

(See Figure 2)

Healthcare business

To focus on developing high-performance, value-added dermatological skin care products through communications with physicians, pharmacists, and nurses etc.

- To steadily expand the scale of our business by improving our business structure via the investment of sales resources, etc., focusing on new areas, and introducing new and renewed products.

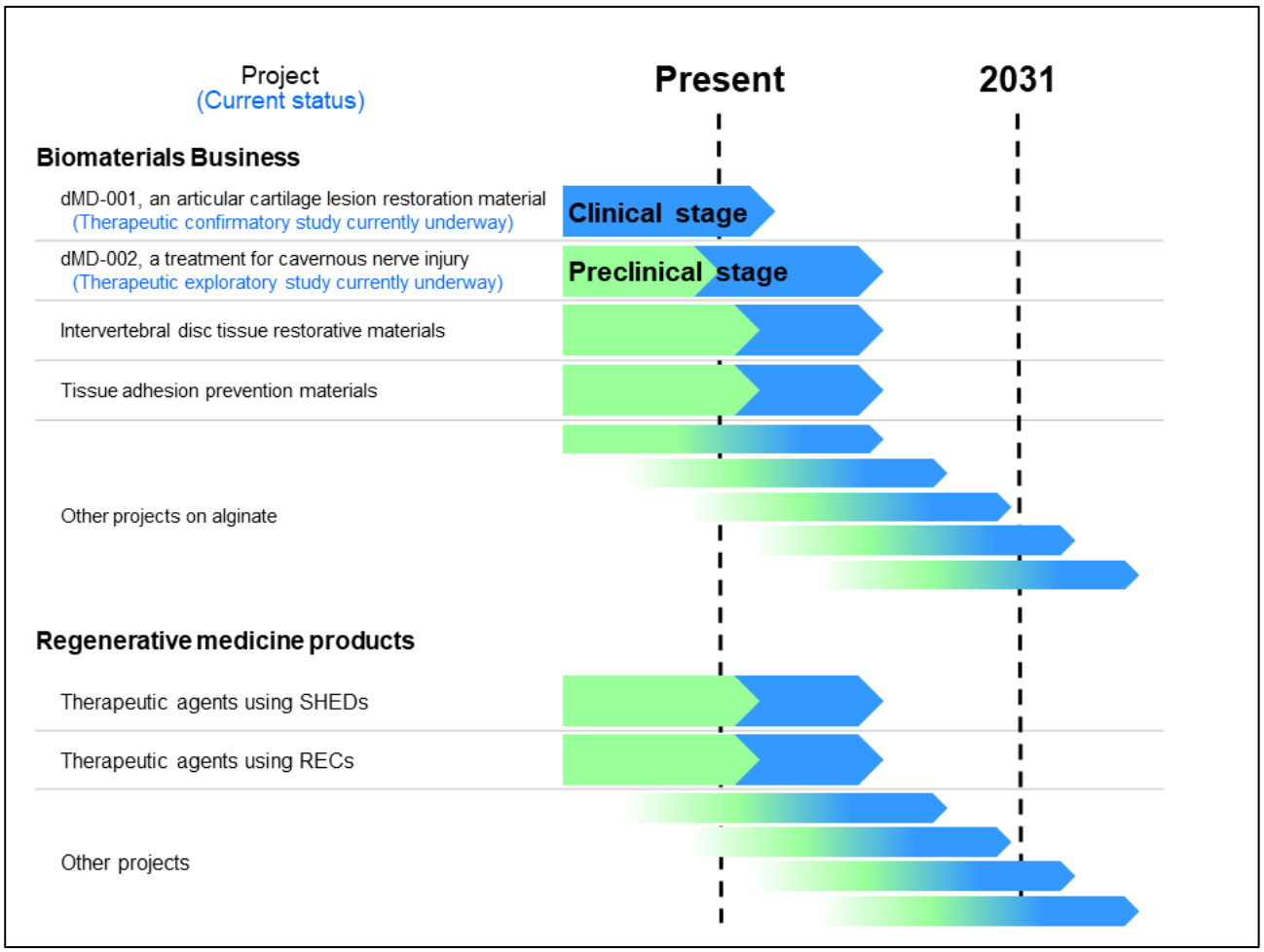
Global expansion

- To expand into overseas markets by offering a lineup of distinctive products that meet the needs in each business segment;
- To launch highly purified EPA drugs in Vietnam, China, the U.S., and other countries, subsequently to Thailand;
- Also, to promote the development of medical devices in our biomaterials business and regenerative medicine products in our pharmaceuticals business, which we aim to launch in the future, with a view to global expansion.

[Scale of business targeted for 2031]

- We aim to achieve sales of approximately 40 billion yen, including product fields such as the biomaterials business products and regenerative medicine products in the pharmaceutical business(see Fig. 1), which are positioned as one of the pillars of the next generation.
- With these new businesses as growth drivers, we aim to develop our business to achieve total net sales of 140 billion yen and an operating margin of 15%.

Figure 1: New business development



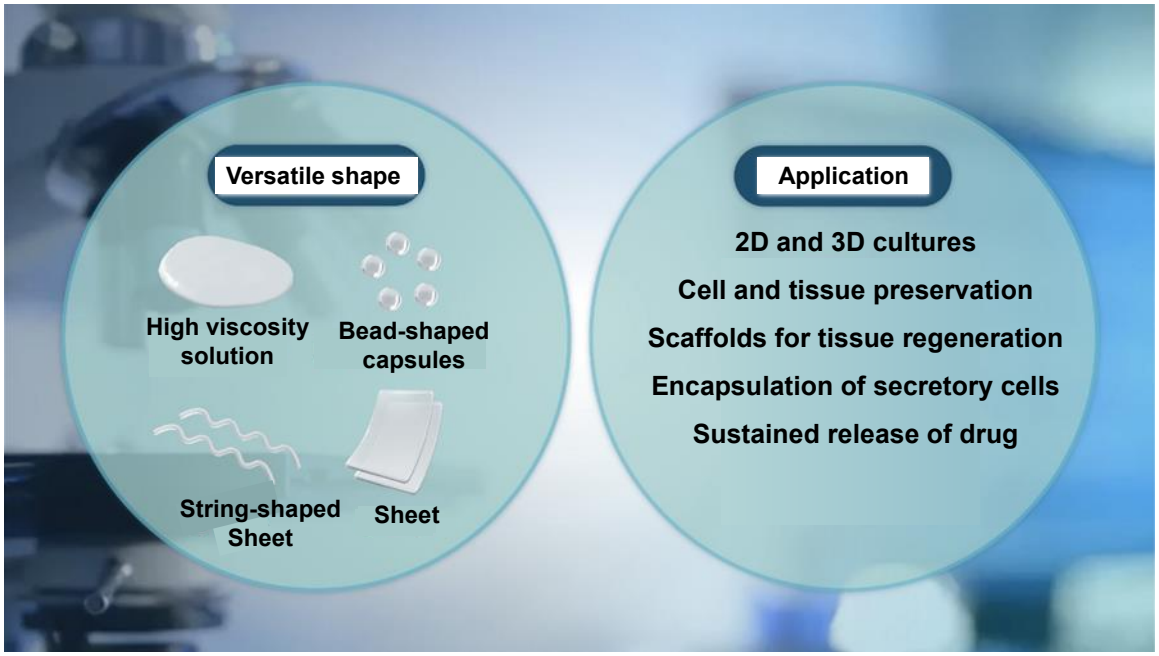
What are SHEDs (stem cells from human exfoliated deciduous teeth)?

SHEDs are stem cells taken from the pulp cavity inside the tooth and are a type of mesenchymal stem cell. Stem cells collected from deciduous teeth are particularly active and have a high capacity for tissue repair and regeneration. As they can be collected from deciduous teeth, collection can be performed at any time, reducing the invasiveness on the donor. Therefore, it is expected to be utilized in the future as a raw material for regenerative medicine products that can be stably supplied domestically.

What are RECs (Rapidly Expanding Cells)?

RECs are high purity mesenchymal stem cells isolated from human bone marrow fluid. These cells are obtained by a proprietary isolation and culture method, and have significantly superior proliferative, differentiation, and migratory capacities compared to mesenchymal stem cells isolated by conventional methods.

Figure 2: Properties and potential applications of alginate



- Sodium alginate is a natural product molecule derived from brown algae. It becomes a highly viscous aqueous solution, and it becomes a gel with calcium ions, which are divalent cations, being added. This property can be used to process the material into various forms and hardness during gelation.

- Possible applications of alginate in the biotechnological and medical fields include 2D and 3D culture, cell and tissue preservation, scaffolds for tissue regeneration, encapsulation of secretory cells, and sustained release of drugs.

- We are working on various applications of endotoxin-free sodium alginate that can be used in living organisms. Alginate, which is a polysaccharide, can be a nutrient source for cells. In addition, when a gel is formed on the affected area, the alginate gel remains in the implanted area for a certain period of time because no enzymes exist in the body to break it down. Also, it does not harm cells due to its similarity to biological components. The relationship of alginate to native cells when implanted in a wound or other sites is also currently being studied: we expect further potential applications

2. 22-24 Medium-term Management Plan

To realize its “Vision for 2031,” Mochida Pharmaceutical Group has adopted the 22-24 Medium-term Management Plan as an action plan for issues to be addressed over the next three years from the perspective of the sustainable enhancement of corporate value and in alignment with its Group’s Basic Sustainability Policy.

The business environment surrounding the pharmaceutical industry is expected to become even more challenging going forward, given the continued promotion of policies to curb drug costs against the backdrop of the problem of securing financial resources for social security expenses. The Group will continue to invest in growth to realize its “Vision for 2031,” in spite of the expectation of a temporary deterioration in earnings during the 22-24 Medium-term Management Plan period.

Similarly to last fiscal year, we have decided not to prepare or announce management target values for the final year of the Medium-Term Management Plan, which we had announced every year until the 20-22 Medium-term Management Plan, because it continues to be extremely difficult to predict how much and how quickly the future reform of the drug price system and other factors could affect the industry environment.

2.1. Basic policy

We will respond to medical and healthcare needs with concentration of the total power of the Group covering research and development, manufacturing and marketing, pursue sustainable growth by promoting selection and focusing processes, and restructure the earnings structure to respond to further environmental changes.

2.2. Key issues to be addressed

We will focus on the following issues under the theme of innovation creation and productivity improvement.

1) Maximization of profits in targeted areas with a focus on new drugs
- To concentrate our resources on the targeted areas (cardiovascular medicine, obstetrics and gynecology, psychiatry, and gastroenterology) to maintain our prominence and maximize earnings from new drugs in our core pharmaceutical business;
- To continually work to maintain a stable supply and proper quality of our products, while promoting improvements in our cost structure by reducing procurement costs and reviewing our product lineup.

2) Continuous investment in growth to realize the “Vision for 2031”

To pursue investments in business activities that will lead to future competitiveness;
- To work to expand and promote the biomaterials business and aim for an early launch;
- To incorporate new drug discovery modalities, such as cells, nucleic acids, and genes. To give priority to development especially in the field of regenerative medicine products.

3) Strengthening of the corporate organization to create innovation and improve productivity

- To harmonize and coordinate four approaches: optimization of business processes and business quality level, promotion of digital transformation, institutional reform, and the promotion of facility management, in order to achieve efficient organizational operations and increase corporate value;
- To continue to support capacity development to improve performance and promote the development of human resources that will drive innovation;
- To focus on strengthening our human resource management system to ensure development and vitalization of human resources;
- To work to improve our organizational capabilities by optimizing our personnel strategy and allocation, while strengthening interdepartmental cooperation.

2.3. Business Strategies

1) Pharmaceutical business

i) Pharmaceutical research

- To enhance our drug discovery pipeline by promoting open innovation and incorporating new modalities through drug discovery utilizing external resources;
- To prioritize and advance drug discovery using mesenchymal stem cells.

ii) Development

- To optimize organizational structuring and to allocate resources for accelerating drug development and improving accuracy, in close cooperation with our partners;
- To obtain approval during the 22-24 Medium-term Management Plan period for MND-2119, a new highly purified EPA drug, MD-711, an inhaled form of a treatment drug for pulmonary arterial hypertension, the pediatric indication of Lialda, an ulcerative colitis treatment drug, the pediatric indication of Lexapro, an antidepressant, ACT-541468, a treatment for insomnia, and MD-120, an antidepressant;
- To promote the development of MND-21, a treatment for hypertriglyceridemia, in China;
- To promote the addition of drug indications and dosage forms to the drugs under development and products on the market;
- To enhance the strategies for the in-licensing of the products in development so as to expand the pipeline in the fields in which we specialize;
- To promote the in-licensing and development of biosimilars.

iii) Marketing

- To develop medical representatives who can capably cover all targeted areas, and to optimize information provision activities through the acceleration of both online and offline efforts channels;
- In the gastrointestinal field, to maximize sales of Lialda, an ulcerative colitis treatment drug which is the mainstay of our revenue, aiming to be the No. 1 5-aminosalicylic acid drug; In addition, to improve the position of Goofice and Movicol, chronic constipation treatment drugs in the constipation market;
- In the psychiatry area, to maintain the market position of Lexapro, an antidepressant, and further, to focus on the early maximization of sales of MD-120, an antidepressant, and ACT-541468,a therapeutic agent for insomnia;
- In the cardiovascular area, to promote propagation of the value of Urece, a treatment for hyperuricemia in gout; Also, to focus on early maximization of sales of MND-2119, a highly purified EPA drug, by leveraging our experience as a leading manufacturer of highly purified EPA drug;
- In the field of obstetrics and gynecology, to contribute to women's health more broadly through the treatment of endometriosis, adenomyosis, and dysmenorrhea with Dienogest, and continue to be a leader in this field;
- For the treatment of pulmonary arterial hypertension, which is an intractable disease, to launch a new inhalant in addition to Treprost, and promote its proper use by frequently providing information to medical facilities;
- To work on the generic drug business to focus on lines with strong business potential such as the authorized generic drug of Dinagest and biosimilars in cooperation with Mochida Pharmaceutical Sales Co., Ltd. and other business partners;
- To work toward increasing the prominence of the Epadel-OTC drug as a pioneer in the manufacture and sales of an EPA drug.

2) Biomaterials Business

We will promote and develop the biomaterials business based on sodium alginate.

- To launch dMD-001, an articular cartilage lesion restoration material, during the 22-24 Medium-term Management Plan period;
- To promote the development of dMD-002, a treatment for cavernous nerve injury;
- To work on the development of intervertebral disc tissue restorative materials using alginate gelation technology in the affected area;
- To work on the development of tissue adhesion prevention materials for tissue resection using alginate sheets;
- To consider alginate as a pharmaceutical material.

3) Mochida Pharmaceutical Plant Co., Ltd.

Mochida Pharmaceutical Plant will continually work to maintain a stable operation, a stable supply, and proper quality of its products, while aiming to reduce the manufacturing cost ratio. The plant will promote contract manufacturing business of medical products with high reliability and efficiency in response to diverse needs of our customers, using both state-of-the-art manufacturing facilities and leading-edge technologies that meet global standards.

4) Mochida Healthcare Co., Ltd.

- To strengthen its sales capabilities by deploying sales resources and promoting sales activities that utilize digital technology;
- To strengthen marketing based on its high rate of support and popularity among dermatologists, obstetricians and gynecologists;
- To work to strengthen relationships with partner companies and expand sales channels;
- To aim for the continued growth of the Collage Repair series and the Collage Furfur series.

2.4. Shareholder returns

Mochida Pharmaceutical Group considers it an important management issue to continuously strive to increase corporate value by developing business performance and to return appropriate profits to shareholders. Our basic policy is to maintain stable dividends while enhancing internal reserves for future business development, and we will determine dividends based on an awareness of the importance of returning profits to shareholders according to revenues.

The business environment is expected to become more severe as mentioned above, but we intend to maintain a dividend of at least 80 yen per share during the 22-24 Medium-term Management Plan period.

In addition, we will flexibly respond to changes in the business environment with respect to the acquisition of treasury stock.

2.5. Sustainability

Under its Basic Sustainability Policy, Mochida Pharmaceutical Group will continue to grow sustainably as a company playing a necessary role in society, by providing value as a pharmaceutical company; in other words, by “contributing to human health and well-being.” In doing so, it will contribute to the realization of a sustainable society that will also help achieve the SDGs.

From the perspective of the sustainable enhancement of corporate value, we have developed the 22-24 Medium-term Management Plan in alignment with the Basic Sustainability Policy. We will continue to step up our efforts in sustainability issues and the promotion system in accordance with our basic policy.

Mochida Pharmaceutical Group Basic Sustainability Policy

Mochida Pharmaceutical Group aims to grow as a unique life and healthcare group which meets medical and healthcare needs, gaining global recognition for its raison d’être, in accordance with its corporate philosophy “Actively contributing to human health and well-being in the field of medicine, totally committed to the development of innovative products.”
For the sustainable enhancement of corporate value, we will strive to provide value as a pharmaceutical company “contributing to human health and well-being” under appropriate corporate governance in accordance with the Code of Conduct of Mochida Pharmaceutical Group. We will also contribute to the realization of a sustainable society while giving due consideration to our impact on the global environment.

Disclaimer

- The information provided in this document contains some “forward-looking statements”. These forward-looking statements are based on the judgments of the Company derived from the information available to us at this time, and include known and unknown risks and uncertain elements. Accordingly, the actual results may differ materially from these statements due to a variety of factors.
- These risks and uncertainties include general economic conditions in Japan and worldwide, such as the general situation in the industry and markets, interest rates and currency exchange rate fluctuations. The risks and uncertainties exist in forward-looking statements relating to products in particular. These product-related risks and uncertainties include, but are not limited to, technological advancements, granting of patents to our competitors, completion of clinical trials, claims or concerns relating to safety or efficacy of products, acquisition of approval from regulatory authorities, reform of health insurance systems inside and outside Japan, trends toward the containment of health care cost, government law and regulations that affect the Company’s business inside and outside Japan, and issues pertaining to development of new products.
- Approved products contain risks relating to manufacturing and marketing which include, but not are limited to, situations in which the Company may face deficiencies in manufacturing capacity needed to meet demand, difficulties in securing the supplies of raw materials, and demand not created in markets.
- We do not intend to, and assume no obligation to, update or modify any forward-looking statements even if such updating or modification is desirable due to the emergence of new information, future events or other reasons.
- The information contained in this document regarding pharmaceutical products (including those which are being developed) is not intended to act as a promotion or advertisement, or to provide medical advice.