# Consolidated Financial Results for the Nine Months Ended September 30, 2023 [IFRS]

November 9, 2023

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Scheduled filing date of quarterly securities report: November 10, 2023
Scheduled starting date of dividend payments: —
Supplementary briefing materials on quarterly financial results: No
Explanatory meeting on quarterly financial results: No

(Amounts of less than one million yen are rounded down)

**1. Consolidated Financial Results for the Nine Months Ended September 30, 2023 (January 1, 2023 to September 30, 2023)**

(1) Consolidated operating results (% indicates changes from the previous corresponding period)

| | Revenue | | Core operating profit | | Operating profit | | Profit before tax | |
|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| **Nine Months Ended September 30, 2023** | 22,543 | 101.1 | 7,042 | - | 6,752 | — | 4,661 | — |
| **Nine Months Ended September 30, 2022** | 11,208 | 43.3 | 143 | (96.4) | (426) | — | (368) | — |

| | Profit attributable to owners of parent | | Total comprehensive income | |
|---|---|---|---|---|
| | Million yen | % | Million yen | % |
| **Nine Months Ended September 30, 2023** | 3,541 | — | 5,920 | — |
| **Nine Months Ended September 30, 2022** | (186) | — | (896) | — |

| | Basic earnings per share | Diluted earnings per share |
|---|---|---|
| | Yen | Yen |
| **Nine Months Ended September 30, 2023** | 27.30 | 27.27 |
| **Nine Months Ended September 30, 2022** | (1.44) | (1.44) |

(2) Consolidated financial position

| | Total assets | Net assets | Equity attributable to owners of parent | Ratio of equity attributable to owners of parent to total assets |
|---|---|---|---|---|
| | Million yen | Million yen | Million yen | % |
| As of September 30, 2023 | 66,103 | 37,461 | 37,461 | 56.7 |
| As of December 31, 2022 | 63,865 | 32,041 | 32,041 | 50.2 |

**2. Payment of Dividends**

| | Annual dividends | | | | |
|---|---|---|---|---|---|
| | 1st quarter-end | 2nd quarter-end | 3rd quarter-end | Year-end | Total |
| | Yen | Yen | Yen | Yen | Yen |
| Fiscal Year ended December 31, 2022 | - | 0.00 | - | 0.00 | 0.00 |
| Fiscal Year ending December 31, 2023 | - | 0.00 | - | | |
| Fiscal Year ending December 31, 2023 (forecast) | | | | 0.00 | 0.00 |

(Note) Revisions to the dividend forecast announced most recently: No

**3. Consolidated Financial Forecasts for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)**

| | Revenue | Core operating profit | Operating profit | Profit before tax | Profit attributable to owners of parent |
|---|---|---|---|---|---|
| | Million yen / % | Million yen / % | Million yen / % | Million yen / % | Million yen / % |
| Fiscal Year ending December 31, 2023 | 30,000 / 11.7 | 6,700 / (30.5) | 6,300 / (29.8) | 3,700 / (44.4) | 2,700 / (64.3) |

(Note) Revisions to the consolidated financial forecast announced most recently: No

Items that are excluded from operating profit to calculate core operating profit include accounting effects of business acquisitions and acquisition-related costs, impairment loss on property, plant and equipment, intangible assets and goodwill, gains or losses on compensation, settlements, non-recurring and significant gains and losses, and amortization of intangible assets from introduction of individual products or developments.

**[Notes]**

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in change in scope of consolidation) :None

(2) Changes in accounting policies and changes in accounting estimates

| | | |
|---|---|---|
| 1) Changes in accounting policies required by IFRS | : | None |
| 2) Changes in accounting policies due to other reasons | : | None |
| 3) Changes in accounting estimates | : | None |

(3) Number of shares issued (common stock)

| | | | | |
|---|---|---|---|---|
| 1) Number of shares issued at the end of the period (including treasury stock) | As of September 30, 2023 | 130,010,400 shares | As of December 31, 2022 | 130,010,400 shares |
| 2) Number of treasury stock at the end of the period | As of September 30, 2023 | 402,647 shares | As of December 31, 2022 | 179,447 shares |
| 3) Average number of shares during the period | Nine months ended September 30, 2023 | 129,731,004 shares | Nine months ended September 30, 2022 | 129,829,104 shares |

(Note) The number of treasury shares at the end of the period includes shares in the Company held by the Custody Bank of Japan, Ltd. (Trust Account E) (179,200 shares as of December 31, 2022 and 402,400 shares as of September 30, 2023). In addition, the shares in the Company held by the Custody Bank of Japan, Ltd. (Trust Account E) are included in treasury shares excluded from calculating the average number of shares during the period (181,098 shares for the nine months ended September 30, 2022 and 279,149 shares for the nine months ended September 30, 2023).

* Quarterly financial results reports are not required to be subjected to quarterly review by a certified public accountant or an audit firm

* Explanation on the appropriate use of operating forecasts and other special instructions

(Caution regarding forward-looking statements)

Financial forecasts and other statements regarding the future presented in these materials are based on information currently available and certain assumptions deemed to be reasonable and are not meant to be taken as commitment of the Company to achieve such results. Actual performance may differ substantially due to various factors.

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## 1. Qualitative Information on Quarterly Financial Results for the Period under Review

### (1) Explanation of Operating Results

During the nine months ended September 30, 2023 (from January 1, 2023 to September 30, 2023), PeptiDream Inc. ("PeptiDream") continued to make excellent progress in leveraging the PDPS (Peptide Discovery Platform System) technology, its proprietary drug finding platform, across its two (2) business segment; Drug Discovery and Development, and Radiopharmaceutical.

**(A) Drug Discovery and Development Business Segment**

The Drug Discovery and Development Business Segment is composed of three businesses: 1) Collaboration Discovery and Development Business, 2) PDPS Technology Transfer Business, 3) In-House/Strategic Discovery and Development Business.

As of September 30, 2023, PeptiDream's pipeline consisted of 130 discovery & development programs. (representing a net increase of 3 programs from the end of the prior fiscal quarter ending June 30, 2023).

The below table is a snapshot of PeptiDream's program(s) across the three drug discovery approaches at the end of the current fiscal quarter.

| 【Number of programs for each drug discovery approach】 | As of June 30, 2023 | As of September 30, 2023 |
|---|---|---|
| Peptide drugs | 66 | 66 |
| Small molecule drugs | | |
| Peptide drug conjugates ("PDCs") | 61 | 64 |
| Multi-functional peptide conjugates ("MPCs") | | |
| Total | 127 | 130 |

The below table is a snapshot of the number of program(s) currently at each stage of the discovery and development process, compared to the end of June.

| 【Number of programs at each stage of the discovery and development process】 | As of June 30, 2023 | As of September 30, 2023 |
|---|---|---|
| Target Validation-to-Hit Stage | 14 | 16 |
| Hit-to-Lead Stage | 70 | 70 |
| Lead-to-GLP-Tox Stage | 29 | 28 |
| GLP-Tox-to-IND Stage | 9 | 10 |
| Phase 1 | 5 | 6 |
| Phase 2 | 0 | 0 |
| Phase 3 | 0 | 0 |
| Total | 127 | 130 |

The figures in the above table include; (i) ALL preclinical and clinical programs in the Collaboration Discovery and Development business and the In-House/Strategic Discovery and Development business, (ii) ONLY clinical programs in the PDPS Technology Transfer business, and (iii) DOES NOT include programs in the Radiopharmaceuticals Business Segment.

The below table is a snapshot of the development status of main programs.

| Program | Indication | Partner | Late-Preclinical | Clinical Ph1 | Clinical Ph2 | Clinical Ph3 | Status |
|---|---|---|---|---|---|---|---|
| GhR<br>AZP-3813<br>Therapeutic Peptide | Acromegaly | Amolyt Pharma | | | | | Ph1 Safety Study Initiated Jun-2023<br>Ph1 Study Results expected 1H-2024 |
| PD-L1<br>BMS-986229<br>RI-PDC (PET diagnostic) | Oncology | Bristol-Myers Squibb | | | | | Ph1 Imaging Study Initiated Nov-2019<br>(NCT04161781) |
| PD-L1<br>Therapeutic Peptide | Oncology | Bristol-Myers Squibb | | | | | Ph1 Safety Study Initiated Apr-2022<br>Ph1 Study Report expected late 1H-2024 |
| CD38<br>BHV-1100 + NK Cells<br>Therapeutic Peptide | Multiple Myeloma | Biohaven | | | | | Ph1a/b Safety/Efficacy Study Initiated Oct-2021<br>(NCT04634435) |
| Undisclosed<br>Therapeutic Peptide | Undisclosed | Merck | | | | | Ph1 Safety Study Initiated Jul-2023 |
| S2-protein<br>PA-001<br>Therapeutic Peptide | COVID-19 | PeptiAID | | | | | Clinical Research Safety Study (jRCTs031210601)<br>Completed – Initiate Ph1 Safety Study in 2024 |
| Glypican-3<br>RYZ801/RYZ811<br>RI-PDC | Liver Cancer | RayzeBio | | | | | IND-enabling studies/human imaging ongoing<br>Anticipate IND filing 1H-2024 |
| CA9<br>PD-32766<br>RI-PDC | Renal cell carcinoma | | | | | | IND-enabling studies ongoing<br>Anticipate human imaging 1H-2024 |
| Undisclosed<br>RI-PDC | Oncology | Novartis | | | | | IND-enabling studies ongoing |
| Undisclosed<br>RI-PDC | Oncology | RayzeBio | | | | | Selected Clinical Candidate – Dec2022 |
| Myostatin<br>Therapeutic Peptide | Obesity/SMA/DMD/<br>Muscle Disorders | | | | | | Selection of Clinical Candidate – 1H-2024 |
| KIT<br>Therapeutic<br>Small Molecule | Mast Cell-Driven<br>Allergic Diseases | Modulus | | | | | Selected Clinical Candidate – Aug-2023 |
| TfR<br>Oligo-PDC | Neuromuscular<br>Disorders | Takeda | | | | | |

Note: As of November 2023, above list not inclusive of all programs

**Clinical Stage Programs:**

1. **GhR Program:** Indication: Acromegaly; Modality: Therapeutic Peptide; Partnered with Amolyt Pharma (Amolyt) (AZP-3813)

   AZP-3813, a macrocyclic peptide growth hormone receptor antagonist (GHRA), is currently being tested in a Phase 1 study (initiated in June 2023), investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AZP-3813 following single and multiple ascending doses in healthy subjects, as a potential add-on to somatostatin analogs for the treatment of acromegaly. Results of the Phase 1 study are expected in the first quarter of 2024.
2. **PD-L1 Bioimaging Agent Program:** Indication: Oncology Imaging; Modality: Diagnostic RI-PDC; Partnered with Bristol-Myers Squibb (BMS) (BMS-986229). 18F-BMS-986229 is currently being tested (ClinicalTrials.gov Identifier: NCT04161781; initiated in November 2019; conducted in US at Memorial Sloan Kettering Cancer Center) as a radioactive tracer to determine if positron emission tomography (PET) imaging is a practical and safe way to both diagnose and track the status of esophageal, stomach, and gastroesophageal junction cancers in patients. 18F-BMS-986229 PET scans may better show a protein located on tumor cells called PD-L1 and help doctors choose treatment options that use PD-L1 to fight cancer compared to the usual approach using fluorodeoxyglucose (FDG) PET scans.
3. **PD-L1 Inhibitor Program:** Indication: Oncology; Modality: Therapeutic Peptide; Partnered with BMS (*see note below*). The macrocyclic peptide PD-L1 (programmed death ligand-1) inhibitor is currently being tested in a Phase 1 study, (ISRCTN17572332; initiated in April 2022; conducted in the UK by Quotient Sciences Limited (code QSC203717)), investigating the safety, tolerability, and pharmacokinetics in 136 healthy volunteers. As announced on October 26, 2023, BMS has decided to not advance this program beyond the ongoing Phase 1 Healthy Volunteer Study, deciding instead to prioritize other programs in the BMS portfolio. The decision was made for business reasons, and not due to any safety concerns. The Phase 1 study is expected to wrap-up in November 2023, with the Clinical Study Report expected by late 1H-2024, at which time PeptiDream will review the clinical data with BMS and explore options to continue the development of this promising program.
4. **CD38-ARM™ Program:** Indication: Multiple Myeloma; Modality: MPC; Partnered with Biohaven, LTD. (Biohaven) (BHV-1100). BHV-1100 (CD38-ARM™) is currently being tested in an open-label single center Phase 1a/1b study (ClinicalTrials.gov Identifier: NCT04634435; initiated in October 2021; conducted in US by Dana-Farber Cancer Institute) with the primary objective of establishing the safety and exploring the efficacy of infusing

the ex-vivo combination product of cytokine induced memory-like (CIML) natural killer (NK) cells with BHV-1100 and immunoglobulin (IVIG) followed by low dose IL-2 to target and kill multiple myeloma cells expressing the cell surface protein CD38 in minimal residual disease positive (MRD+) multiple myeloma (MM) patients in first or second remission. Biohaven reported in March 2023 (March 2023 Corporate Presentation) first patient survival to one year and that two additional patients have been randomized in the ongoing clinical study.

5. **Undisclosed Program**: Indication: Undisclosed; Modality: Therapeutic Peptide; Partnered with Merck & Co., Inc., Rahway, NJ, USA, (MSD, Program Identifier not yet disclosed).
   An undisclosed therapeutic peptide, discovered using PeptiDream's PDPS technology by MSD under the companies' 2018 PDPS technology licensing agreement, is currently being tested in a Phase 1 clinical study (initiated in July 2023). The details of the ongoing Phase 1 study have not yet been released.
6. **S2-Protein Inhibitor Program:** Indication: COVID-19; Modality: Therapeutic Peptide; Partnered with PeptiAID (PA-001). PA-001 was tested in an exploratory single ascending dose clinical study (dRCTs031210601) in 30 healthy Japanese adult male volunteers in accordance with the Clinical Trials Act in Japan, and as reported in August 2022, was found to be safe and well tolerated without any compound related adverse events and demonstrated a clear-dose dependent pharmacokinetic profile. PeptiAID is currently preparing to submit an IND application for PA-001 to the U.S. FDA.

**In the Collaboration Discovery and Development Business;**

During the current fiscal quarter, on July 25, 2023, PeptiDream announced a research collaboration and license agreement to discover novel protein degraders for two targets selected by Astellas. Under the agreement between the two companies, Astellas will have the option to select up to three additional targets to be included in the collaboration. Under the terms of the agreement, the companies plan to combine PeptiDream's PDPS (Peptide Discovery Platform System) technology with Astellas' drug discovery capabilities to discover multiple next-generation protein degraders targeting diverse targets that go beyond existing technologies. Astellas will be responsible for the development and commercialization of products created from this collaborative research. Astellas will provide PeptiDream with an upfront payment of ¥3.0 billion. PeptiDream is eligible to receive discovery, development and commercial sales milestones of up to ¥20.6 billion per target. PeptiDream is also eligible to receive single-digit percent royalty payments on net sales of any products arising from the collaboration.

On September 20, 2023, PeptiDream announced a new multi-target collaboration and license agreement with U.S.-based Genentech, a member of the Roche Group, focused on the discovery and development of novel macrocyclic peptide-radioisotope ("peptide-RI") drug conjugates. Under the agreement, PeptiDream will use its proprietary PDPS technology to discover, optimize, and develop macrocyclic peptide candidates for use as peptide-RI drug conjugates against targets of interest to Genentech. PeptiDream will lead early preclinical development before transitioning peptide-RI drug conjugate products arising from the collaboration to Genentech for further development and commercialization. PeptiDream will retain the right to develop and commercialize such peptide-RI drug conjugate products in Japan. Under the terms of the agreement, PeptiDream will receive an upfront payment of $40 million USD (¥5.9 billion JPY) (1 USD = 147.7 JPY) from Genentech and be eligible for payments based on the achievement of specified development, regulatory, and commercial milestones potentially up to $1 billion USD (¥147.7 billion JPY). In addition, PeptiDream is eligible to receive tiered royalties on net sales (ex-Japan) of any such products arising from the collaboration.

**In the PDPS Technology Transfer Business;**

As of September 30, 2023, PeptiDream has non-exclusively licensed its PDPS technology to 11 companies: BMS (2013), Novartis (2015), Eli Lilly (2016), Genentech (2016), Shionogi (2017), MSD (2018), MiraBiologics (2018), Taiho Pharmaceutical (2020), Janssen (2020), ONO Pharmaceutical (2021) and Fujirebio (2022). PeptiDream continues to receive various technology license and management payments from the licensee companies, in addition to potential preclinical and clinical milestone payments as programs advance.

On July 2023, PeptiDream received a milestone payment from MSD, under the companies' 2018 PDPS technology licensing agreement, for the initiation of a Phase 1 clinical study by MSD for an undisclosed therapeutic macrocyclic peptide discovered at MSD using PeptiDream's PDPS technology.

In accordance with all PDPS technology license agreements, PeptiDream is not informed as to what specific discovery and development programs are being prosecuted by the licensee company until certain initial pre-clinical milestones are achieved. In addition, PeptiDream continues to receive interest from multiple companies interested in licensing the PDPS technology.

**In the In-House/Strategic Discovery and Development Business;**

PeptiDream continues to advance and expand the number of In-House/Strategic Discovery and Development programs. The goal of these efforts is to develop the programs to at least the lead and/or clinical candidate stage or potentially post-Phase 1/2 stage, before seeking to license these programs out to big pharma companies, leveraging PeptiDream's existing network of partners, for significantly higher financials than can be attained from standard discovery and development deals. PeptiDream has continually been expanding its capabilities in turning hit candidates identified from the PDPS technology into 1) peptide therapeutics, 2) small molecule therapeutics, 3) peptide drug conjugates ("PDCs") and 4) multi-functional peptide conjugates ("MPCs"). Programs being developed with Strategic partners, Strategic partners being companies that bring proprietary technology/know-how to combine with PeptiDream's, are often under some type of cost-sharing agreement, in which the costs of discovery and development are shared, allowing PeptiDream to often have a larger share in the program and future revenues if successful. In addition, PeptiDream continues to pursue a number of in-house fully-owned programs and looks forward to providing future updates as these programs progress toward the clinic.

PeptiDream has announced strategic partnerships with JCR Pharmaceuticals Co., Ltd. ("JCR Pharma"), Modulus Discovery, Inc. ("Modulus Discovery"), Heptares Therapeutics Ltd. ("Sosei-Heptares"), Biohaven, POLA Chemical Industries ("POLA"), Kawasaki Medical School, the Bill & Melinda Gates Foundation ("Gates Foundation"), Mitsubishi Corporation ("MC"), in the joint venture, PeptiGrowth Inc. ("PeptiGrowth"), RayzeBio Inc.("RayzeBio"), PeptiAID Inc. ("PeptiAID") and Amolyt.

PeptiDream and **JCR Pharma** have successfully developed a series of constrained peptides that bind to the transferrin receptor (TfR) and are capable of carrying various therapeutic payloads across the blood-brain barrier (BBB) for delivery/targeting to the brain, and for the delivery of therapeutic payloads to muscle, arising from the joint research collaboration between the companies initiated in February 2016. Most therapeutics do not readily cross the BBB into the brain, with only a small fraction of the drug ever entering the central nervous system (CNS), posing a significant challenge to the development of effective therapeutics for the treatment of CNS disorders. The developed peptide carriers, when conjugated to various therapeutic payloads (herein referred to as a peptide-drug conjugates or "PDC"), function to facilitate the transport of the payload across the BBB into the brain, thereby significantly increasing the amount of the therapeutic payload in the brain, and/or can function to deliver the therapeutic payloads specifically to muscle, thereby significantly increasing the amount of therapeutic targeted to muscle. Potential payloads range from antibody and protein therapeutics to nucleic acids, peptides, and small molecule drugs. The two companies are focusing on third-party licensing activities, with PeptiDream leading such activities from execution of agreement to supply of peptide carriers, with the Dec 22, 2020 announced collaborative research and exclusive license agreement to create PDCs for neuromuscular diseases with Takeda Pharmaceutical Company Limited, representing the first of such licensing deals. PeptiDream announced on July 27, 2021, a further expansion of the collaborative research and license agreement with Takeda Pharmaceutical Company extending into CNS Diseases. The companies are looking to conjugate the peptide carriers to a number of Takeda payloads, and the collaboration has the potential to yield a number of therapeutics products in the neuromuscular, muscular, and CNS disease space. PeptiDream continues to discuss additional potential research and license agreements for the TfR carrier peptides with various companies, with PeptiDream and JCR Pharma sharing related revenues from such licensing activities.

PeptiDream and **Modulus Discovery** have been leveraging the expertise of both companies to jointly discover and develop small molecule clinical candidates based on peptide hit candidates identified from the PDPS technology against high value kinase targets. Modulus Discovery is utilizing its computational chemistry technology and expertise to design small molecule candidates

in collaboration with PeptiDream, with the companies jointly sharing the costs and co-owning any resulting products. On August 8, 2023, PeptiDream and Modulus Discovery announced the nomination of the first clinical development candidate arising from the companies' strategic drug discovery partnership (program code: MOD-B). The candidate is highly selective small molecule targeting KIT, a key signaling kinase involved in the Mast cell response pathway, for the potential treatment of Mast-cell driven immuno-inflammatory diseases, including allergic disease. Going forward, Modulus Discovery will be responsible for conducting IND-enabling studies with the aim of moving the MOD-B program into clinical trials, as well as leading all partnering/out-licensing activities for the program. PeptiDream currently holds a less than 5% equity stake in Modulus Discovery.

PeptiDream and **Sosei-Heptares** are working to discover, develop and commercialize novel therapeutics targeting Protease Activated Receptor 2 (PAR2), which is a well validated target for multiple indications in pain, cancer, and inflammatory disease. The strategic partnership brings together two powerful technologies, Sosei-Heptares's StaR platform for GPCR target protein production and PeptiDream's PDPS hit finding technology, in addition to considerable preclinical and clinical development capabilities. Under the agreement, the companies jointly share the costs and will co-own any resulting products. As announced on May 12, 2021, the companies have previously identified high affinity and selective inhibitors against PAR2 and have optimized them to be sufficiently stable in the gut for oral administration, and lead candidates are currently advancing through preclinical studies with the objective of developing a novel oral peptide therapy to treat inflammation and pain in gastrointestinal (GI) disorders, such as Inflammatory Bowel Disease. The companies are continuing preclinical development of the program and are actively discussing a variety of partnering and out-licensing options for the program.

PeptiDream and **Biohaven** are developing BHV-1100 (CD38-ARM™), a bispecific heterodimeric peptide conjugate (a CD38 binding peptide conjugated to an IgG binding peptide), designed to recruit endogenous antibodies to multiple myeloma ("MM") cancer cells, targeting them for destruction via the body's innate antibody-mediated immune mechanisms. BHV-1100 + Autologous NK cells received Orphan Drug Designation on September 8, 2020. BHV-1100 is currently being tested in an open-label single center Phase 1a/1b study (ClinicalTrials.gov Identifier: NCT04634435)(Dana-Farber Cancer Institute) with the primary objective of establishing the safety and exploring the efficacy of infusing the ex vivo combination product of cytokine induced memory-like (CIML) NK cells plus BHV-1100 and low dose IL-2 in newly diagnosed MM patients who have minimal residual disease (MRD+) in first or second remission prior to autologous stem cell transplant (ASCT), with the primary outcome measures being dose limiting toxicities following combination product administration (time frame: 100 days post-combination product administration) and incidence and severity of side effects related to the combination product (time frame: 90 to 100 days post-combination product administration).

PeptiDream and **POLA Chemical Industries** ("POLA") are working on the discovery and development of dermatology focused peptide-based cosmetics, quasi-drugs, and therapeutics. PeptiDream has been identifying candidates using its PDPS technology against applicable dermatological targets based on POLA's extensive expertise in the field and the companies are working together to commercialize such cosmetic products. PeptiDream retains the development and commercialization rights to any therapeutic use for any such products arising from the collaboration. The companies have identified a number of lead candidates that are now being tested in in-vitro and ex-vivo models for efficacy and potential use in cosmetic products.

PeptiDream, initially in collaboration with **Kawasaki Medical School**, has developed a series of potent macrocyclic peptide inhibitors of Myostatin. Myostatin (also known as growth differentiation factor 8, or GDF8) is a protein produced and released by myocytes that acts as a powerful negative regulator of skeletal muscle mass. Numerous preclinical and clinical studies have suggested that myostatin inhibitors can increase lean muscle mass, improve physical strength, reduce visceral fat, and improve metabolic dysfunction, such as insulin-mediated glucose disposal, providing growing evidence that myostatin may be an important therapeutic target for the treatment of a variety of muscular dystrophies, such as Spinal muscular atrophy "SMA", Facioscapulohumeral muscular dystrophy "FSHD", Duchene muscular dystrophy "DMD" and other muscle wasting diseases, as well as a potential treatment for obesity, metabolic syndrome, and type 2 diabetes mellitus. In preclinical animal models,

PeptiDream's myostatin inhibitors show strong suppression of myostatin signaling and high exposure in muscle tissue, resulting in significant improvements in both muscle mass and muscle strength, justifying further development. PeptiDream presented preclinical results of the Myostatin program at World Muscle Society ("WMS") 2023 in October 2023. PeptiDream is currently considering clinical development options for the program as well as discussions with potential partners interested in licensing/partnering the program.

PeptiDream and **the Gates Foundation** have been working on the development of a series of novel macrocyclic peptides for the treatment of Tuberculosis and Nontuberculous Mycobacterial (NTM) diseases, infectious diseases that disproportionately affect people in the world's poorest countries. Bacterial infections are among the leading causes of morbidity and mortality globally. The global burden of tuberculosis is staggering, with up to one-third of the world's population latently-infected, and with 10.4 million new active cases and 1.8 million deaths occurring annually. PeptiDream previously received grant funding in November 2017 for the screening and identification of potential macrocyclic peptide candidates to treat Tuberculosis, and again in November 2019 for optimizing one of the most promising hit candidate series into lead candidates ("hit-to-lead development funding") suitable for future development. In 2022, PeptiDream further optimized the lead candidate series to have oral bioavailability and preclinical efficacy studies continue. Under the terms of the original grant(s), any Gates Foundation-funded products that arise will be made available by PeptiDream at an affordable price in lower middle-income countries (LMIC). PeptiDream is able to commercialize in developed countries on its own and is actively discussing out-licensing/partnering options for the program.

PeptiDream and **MC** established a joint venture company, PeptiGrowth to develop, produce and sell peptide alternatives to growth factors, key ingredients of cell culture, used in the manufacturing of cell therapies, regenerative medicines and other biopharmaceutical areas, including the growing market of lab-grown meat and other products. PeptiGrowth is leveraging the expertise and know-how of both parent companies toward the advancement of cell therapies, regenerative medicines, and other biopharmaceuticals in the pharmaceutical industry. Growth factors are a class of proteins that are widely present in humans and other animals. In addition to playing important roles in cell growth and proliferation, they are crucially involved in induction of differentiation of stem cells (iPS cells, ES cells, etc.) into nerve, blood, and other types of cells. Currently, growth factors are mainly extracted from animal serum or produced by recombination technology, however, their production presents a number of challenges to the pharmaceutical industry, including safety risks due to contamination with impurities, variation in quality among production lots, and high production costs. PeptiDream has been using its proprietary PDPS (Peptide Discovery Platform System) technology, to identify alternative peptides that perform the equivalent function as protein growth factors and utilize chemical synthetic routes that do not use animal serum or recombination technology, and by establishing a commercial manufacturing process, PeptiGrowth can produce homogenous products of high purity, ensuring less lot to lot variation, at lower costs. PeptiGrowth will fully leverage the MC Group's global network and its broad customer base to enhance marketing and sales functions. PeptiGrowth has already launched seven products; PG-001 (a peptide alternative to hepatocyte growth factor (HGF)), PG-002 (a peptide inhibitor of TGFβ1) in 2021, PG-003 (a peptide alternative to brain derived neurotropic factor (BDNF)), PG-004 (a peptide inhibitor of BMP4,7), PG-005 (BMP7 selective inhibitor) , PG-006 (BMP4 selective inhibitor) in 2022, and PG-007 (VEGFR2 agonist) in September 2023. PeptiDream is progressing a number of additional peptide alternative growth factor programs in parallel, with additional products expected to be launched in 2023 and 2024. PeptiDream is in active discussions with multiple potential partners regarding the therapeutic use of these alternative peptides, to which PeptiDream holds the exclusive development and commercialization rights. PeptiDream licensed the global therapeutic development and commercialization rights to PG-001 to Genentech in May 2022. On August 22, 2023, PeptiGrowth and Orizuru Therapeutics (OZTx), a Japanese biopharmaceutical company focused on the research and development of iPSC-derived regenerative medicines, entered into a joint development agreement to create a novel synthetic peptide replacement for a recombinant growth factor used in the manufacturing of regenerative medicine products being developed by OZTx. Under this agreement, PeptiGrowth will develop and supply multiple candidate peptides created by PDPS to OZTx. OZTx will use the provided candidate peptides as part of their in-house evaluation assay system to specify a few candidates that are promising as the growth factor alternative peptide. These candidate peptides will be optimized in terms of bioactivity, chemical stability, solubility, etc., to create novel chemically synthesized peptides that have the equivalent functions as conventional

recombinant growth factors in cell proliferation and differentiation induction. PeptiDream currently holds a 39.5% equity stake in PeptiGrowth, with MC holding the remaining 60.5%.

PeptiDream and **RayzeBio** are working to discover and development peptide-RI conjugates for use as therapeutics ("Peptide Radiotherapeutics"). The two companies have been working on a number of programs against targets of interest, with PeptiDream providing peptide candidates, identified and optimized using its proprietary Peptide Discovery Platform System (PDPS) technology and in-house peptide chemistry capabilities, to RayzeBio for further development as radiotherapeutics and radiodiagnostics. PeptiDream is leading preclinical discovery and optimization efforts, with RayzeBio leading translational biology efforts to further characterize peptide-RI conjugates and advance such conjugates into clinical development. Under the terms of the agreement, PeptiDream received an equity interest in RayzeBio, as an upfront payment in August 2020, and has received subsequent milestone payments in November 2020, June 2021, and September 2022, as multiple programs advance. PeptiDream is eligible to receive certain further milestone payments and royalties on future sales (ex-Japan) of any products that arise from the partnership. As announced on August 9, 2022, RayzeBio granted PeptiDream an option to attain development and commercialization rights in Japan to the companies' joint peptide-RI conjugate programs. PeptiDream and RayzeBio announced the nomination of the first peptide-radioisotope conjugate (RI-PDC) development candidate (target undisclosed) for treating solid tumors in December 2022 and the second RI-PDC development candidate against Glypican-3 (GPC3) for the treatment of liver cancer in March 2023 (Program code: RYZ801/ RYZ811). RYZ801 is a therapeutic development candidate, which has Ac225 as the radioisotope. RYZ811 is a diagnostic imaging agent that has the same binder and chelator as RYZ801. As of August 1, 2023, several clinical sites outside of the United States have imaged a total of 47 HCC patients with our binder using Ga68. Approximately 90% showed uptake of our binder into HCC tumors with a minority of patients showing heterogeneous uptake across HCC lesions. No patients had experienced an SAE. In September 2023, RayzeBio completed an initial public offering ("IPO"), listing its shares on the Nasdaq Global Market ("Nasdaq"). At the time of the IPO, PeptiDream sold a portion of its RayzeBio shares. PeptiDream intends to use a portion of the proceeds of the sale to fund the development of RYZ801 and RYZ811 in Japan. PeptiDream currently holds a roughly 2% equity stake in RayzeBio.

PeptiDream and **PeptiAID**, a joint venture with Fujitsu, Mizuho Capital, Takenaka Corporation, and Kishida Chemical established November 12, 2020, have been working on the development of PA-001, a peptide therapeutic for the treatment of COVID-19. PeptiDream applied its proprietary PDPS technology toward identifying peptide candidates targeting the COVID-19 viral "spike" protein, which is essential for coronavirus to enter human cells, leading to the discovery of PA-001. On March 23, 2021, PeptiAID announced the initiation of preclinical studies of PeptiDream's PA-001 candidate which exhibits highly potent antiviral activity against conventional SARS-CoV-2, as well as all mutant strains identified to date, such as the Alpha, Beta, Gamma, Delta and Omicron mutant strains. An in vitro study also demonstrated high synergistic effectiveness when used in combination with drugs that are currently approved for emergency use against COVID-19. Preclinical studies of PA-001, consisting of toxicity, safety pharmacology, and genotoxicity studies have been completed and confirmed the safety of PA-001. Early-stage exploratory clinical research of PA-001 based on the Clinical Trials Act, was initiated in February 2022 (jRCT (Japan Registry of Clinical Trials) Trial ID: jRCTs031210601). In this clinical research, adverse events, injection site reaction and vital signs of the single ascending dose administration of PA-001 from Step1 (0.3mg/kg) to Step5 (8mg/kg) by intravenous injection for healthy Japanese adult volunteer, were investigated, and as announced on August 10, 2022, PeptiAID confirmed that PA-001 exhibited no compound related adverse events and exhibited a favorable safety profile, along with a clear dose-response pharmacokinetics profile. On May 15, 2023, PeptiAID was selected by the Japan Agency for Medical Research and Development (AMED) to receive a grant to conduct a Phase 1 study of PA-001. PeptiAID is currently preparing to submit an IND application for PA-001 and initiate a Phase 1 clinical trial of PA-001 in 2024. PeptiDream currently holds a 39.4% equity stake in PeptiAID.

PeptiDream and **Amolyt** entered into a strategic partnership and license option agreement, announced March 8, 2020, On September 9, 2021, PeptiDream announced that Amolyt had exercised its option to globally license a portfolio of macrocyclic peptide growth hormone receptor antagonists (GHRA) under the terms of the research collaboration agreement with PeptiDream

announced in March 2020. PeptiDream will be eligible for certain payments associated with development, and commercial success of any GHRA product(s), as well as be eligible for certain royalties on future net sales. The identified, optimized drug candidate, AZP-3813, is being developed as a potential treatment for acromegaly and neuroendocrine tumors (NET), to potentially be used in combination with somatostatin analogues (SSAs), for patients who do not adequately respond to SSAs alone. As presented by Amolyt at the 2023 European Congress of Endocrinology (ECE) in May, 2023, and at the 2023 Endocrine Society Meeting (ENDO) in June, 2023, reported that treatment with AZP-3813 induced enhanced suppression of IGF1 levels in normal Beagle dogs. On June 5, 2023 Amolyt announced the initiation of a Phase 1 clinical trial of AZP-3813 for the treatment of acromegaly. Results of the Phase 1 study are expected in the first quarter of 2024. On September 16, 2021, Amolyt announced the closing of an $80 million Series B round, and on January 10, 2023, the closing of an $138 million Series C round with the funds to be used in part toward the clinical development of AZP-3813.

PeptiDream continues to work on a number of fully-owned in-house programs. PeptiDream's main area of focus is on identifying and optimizing selective high-affinity peptide binding candidates against a number of high value tumor/cancer specific targets, for potential conjugation to radionuclide ("RI") payloads for use as peptide-RI conjugates for the treatment of cancer.

On November 1, 2023, PeptiDream announced its first wholly-owned peptide radiopharmaceutical development candidate arising from PeptiDream's ongoing internal peptide radiopharmaceutical discovery and development efforts. The development candidate ("PD-32766") is a novel and highly-selective macrocyclic peptide-radioisotope (RI) conjugate against Carbonic Anhydrase IX ("CAIX"), a member of the carbonic anhydrase enzyme family, expressed in variety of solid tumors, including renal cell carcinoma ("RCC"), glioblastoma, triple negative breast cancer, ovarian cancer, colorectal cancer, and others. PD-32766 was discovered using PeptiDream's proprietary PDPS technology and further optimized at PeptiDream with in vivo imaging and efficacy studies conducted at PDRadiopharma, our wholly owned subsidiary. PeptiDream is currently conducting IND-enabling studies of PD-32766 and intends to initially develop the therapeutic and paired diagnostic imaging agent for the diagnosis and treatment of RCC. The paired diagnostic imaging agent, which consists of the same peptide and chelator as the therapeutic, will enable us to screen and identify patients, both in clinical trials and in clinical practice, who have CAIX expressing tumors that are most likely to have a favorable clinical response from PD-32766 treatment. PeptiDream is additionally planning to initiate human imaging studies in 1H-2024, prior to the start of a Phase 1 study. RCC is the 9$^{th}$ most common cancer in the United States, representing 2% of all global cancer diagnoses and death, with 5-year survival rates at 12% (worldwide an estimated 431,288 people were diagnosed with kidney cancer in 2020, with roughly 9 out of 10 kidney cancers being renal cell carcinomas). There are largely three main types of RCC, clear cell ("ccRCC"), papillary ("pRCC-type 1 and type 2"), and chromophobe ("chRCC"), with ccRCC representing roughly 70% of RCC cases. CAIX is a highly expressed, specific surface antigen in the majority of ccRCC tumors (>95%), with minimal expression in normal tissues, making it a potentially ideal target for the diagnosis and treatment of ccRCC.

PeptiDream intends to retain Japan commercialization rights to such peptide-RI-PDC programs, while out-licensing ex-Japan commercialization rights to interested pharma companies. PeptiDream is also actively investigating the use of these cancer targeting peptides with other potential payloads in collaboration with various existing and/or new partners.

A second main area of focus for PeptiDream is around the discovery and development of multi-functional peptide conjugates (MPCs), as PeptiDream believes that MPCs may represent a superior modality to bispecific antibodies and other multi-functional molecule classes. PeptiDream has been focused on identifying novel T cell and NK cell targeting peptides, which can be conjugated with the tumor specific targeting peptides above, to generate a new class of T cell and NK cell engagers molecules, an area that holds exciting therapeutic promise.

In addition to T cell and NK cell engager molecules, PeptiDream has selective potent candidates against a variety of pro-inflammatory cytokines, including IL17, and is actively investigating combining various candidates into MPCs, as there is growing clinical evidence that antagonizing multiple pro-inflammatory pathways in parallel may represent a better therapeutic strategy. PeptiDream has a number of other internal programs, outside these main areas of focus, such as PeptiDream's influenza hemagglutinin (HA) program, which exhibits strong broad efficacy against group 1 influenza strains, including the H5N1 strain, and further enhanced potency in combination with existing influenza treatments, such as Tamiflu, in in vivo animal studies, to

which PeptiDream continues to consider a variety of partnering and out-licensing options for the program, as the number of influenza cases make a global resurgence as social contact returns following the COVID-19 pandemic.

PeptiDream has previously announced, along with Shionogi & Co., and Sekisui Chemical Co., Ltd, the formation of PeptiStar Inc., a Contract Development and Manufacturing Organization (“CDMO”) for the research and commercial manufacture of peptide therapeutics. PeptiStar brings together the most cutting-edge technologies and innovations in large-scale peptide production from various companies throughout Japan in order to manufacture peptides of the highest quality and purity, while simultaneously driving down the cost of production. The PeptiStar manufacturing facility is located in Osaka. PeptiDream currently holds less than 15% equity stake in PeptiStar.

On September 17, 2021, PeptiDream announced that it was successful in its bid for Lots 2-11 and 2-12 (Address: 3-chome, Tonomachi, Kawasaki-ku, Kawasaki City, Kanagawa) in the public tender for land that was conducted by the Urban Renaissance Agency as follows: Location: 102-20 and 102-21, 3-chome, Tonomachi, Kawasaki-ku, Kawasaki City, Kanagawa, Land area: 11,635.60 m2, Bid-winning price: 3.2 billion yen. KING SKYFRONT has been designated as an international strategic zone and the Keihin-Rinkai Life Innovation Comprehensive Global Strategic Special Zone. It is an open innovation hub for the creation of new industries based on world-class R&D in the life science fields. PeptiDream plans to expand PeptiDream's head office and research facilities on the land, and with the acquisition of PDRadiopharma, PeptiDream is evaluating the best use of the land, as PeptiDream hopes to add certain functions to further enhance the RI-PDC and radiopharmaceuticals business. Details of the plan will be announced as soon as they are finalized. PeptiDream purchased the land using funds on hand, and the construction of any future buildings will be through funds on hand and/or long-term loans from financial institutions.

**(B) Radiopharmaceutical Business Segment:**

Through the acquisition of PDRadiopharma Inc., which became a 100% subsidiary on March 28, 2022, PeptiDream is engaged in the research, development, manufacture, and sales of radiopharmaceuticals (both radiotherapeutic and radiodiagnostic) products. PDRadiopharma currently markets 22 radiodiagnostic agents for SPECT (Single Photon Emission Computed Tomography), 2 PET (Positron Emission Tomography) imaging agents and 8 radiotherapeutic products (in 3 product categories). PDRadiopharma also develops and provides image analysis software used to assist interpretation of images obtained from these radiodiagnostic agents.

PDRadiopharma's key radiopharmaceutical products are described in the table below.

・**Radiodiagnostic Products (SPECT)**

| Product Name | Therapeutic Category |
|---|---|
| Neurolite® Injection Daiichi | Diagnosis of cerebral blood flow |
| Cardiolite® Daiichi | Diagnosis of cardiac disease, cardiac function and parathyroid diseases |
| Thallium Chloride-Tl 201 Injection | Diagnosis of cardiac disease, tumor, and parathyroid diseases |
| MyoMIBG®-I 123 Injection | Diagnosis of cardiac disease, neuroblastoma and pheochromocytoma |
| Techne® MDP Injection | Diagnosis of bone diseases, brain tumor and cerebrovascular disorders |
| Ultra-Techne Kow® | Diagnosis of brain, thyroid, salivary glands and ectopic gastric mucosal diseases, and regional pulmonary ventilation |
| Octreoscan® Injection | Diagnosis of neuroendocrine neoplasm |

・**Radiodiagnostic Products (PET)**

| Product Name | Therapeutic Category |
|---|---|
| AMYViD® Injection | Amyloid imaging |
| Fludeoxyglucose(F18) Injection FRI | Diagnosis of tumor, ischemic heart disease and epilepsy |

・**Radiotherapeutics Products**

| Product Name | Therapeutic Category |
|---|---|
| Raiatt MIBG-I 131 Injection | Treatment of pheochromocytoma and paraganglioma |
| Sodium Iodide-I 131 Capsules | Treatment of thyroid cancer and diagnosis of thyroid diseases |
| ZEVALIN® Yttrium Injection | Treatment of CD20-positive non-Hodgkin lymphoma and mantle cell lymphoma |

PDRadiopharma currently has four programs in clinical development as described in the table below.

| | Program/ Target | Radio-isotopes | Indication | Clinical Ph1 | Clinical Ph2 | Clinical Ph3 | Marketed | Notes |
|---|---|---|---|---|---|---|---|---|
| Dx | Tauvid® Tau | $^{18}F$ | Alzheimer's disease | Co-development with Eli Lilly in Japan | | | | Approved by US FDA in 2020 |
| | | | | US (Eli Lilly) | | | | |
| Dx | F-1311 PSMA | $^{99m}Tc$ | Prostate Cancer | Japan (PDR) | | | | In-licensed from Lantheus Medical Imaging |
| | | | | US (Lantheus) | | | | |
| Thx | FF-10158 Integrin αvβ3/5 | $^{68}Ga$/ $^{177}Lu$ | Malignant glioma and others | US/ EU (NVS) | | | | Out-licensed ex-Japan rights to Novartis<br>PDR retains Japan rights |
| Thx | PPMX-T002 Cadherin 3 | - | Advanced and recurrent solid tumors | Japan (PPMX) | | | | Co-owned with Perseus Proteomics (PPMX)<br>PPMX leading out-licensing activities |
| | | | | US (PPMX) | | | | |

Note: Dx: Diagnostics, Thx: Theranostics; As of September 2023.

PDRadiopharma, in partnership with Lilly, is co-developing flortaucipir (F18) (Product name in the US: Tauvid®) in Japan, a PET Imaging agent for diagnosing and monitoring the progression of Alzheimer's disease by visualizing neurofibrillary tangles (NFTs) caused by abnormally accumulated tau protein in the brain. PeptiDream expects that the approval of flortaucipir F18, along with PDRadiopharma' s already approved AMYViD®, will greatly expand the use of PET diagnostic reagents in the diagnosis and monitoring of AD.

In March 2023, PDRadiopharma received approval for label expansion of Techne® Phytate Kit for the identification of sentinel lymph node and lymphoscintigraphy in cervical cancer, corpus uteri cancer, vulvar cancer and head and neck cancer (excluding thyroid cancer). In August 2023, PDRadiopharma received regulatory approval for a label expansion of AMYViD®, a PET imaging agent for detecting beta amyloid, to include patients exhibiting even mild cognitive impairment or suspected to have dementia due to Alzheimer's disease, now becoming eligible to receive AMYViD® Injection to confirm the accumulation of beta amyloid plaques in the brain by PET imaging. In October 2023, PDRadiopharma acquired assets in related to four products ("Bridgea GATEWAY", "Bridgea TIMER", "onti" and "ankan") which will enable full automation and digitalization of dose management and contribute to the reduction of medical accident risks by improving operational efficiency of health care providers from RYUKYU ISG. PDRadiopharma will assume responsibilities for manufacturing, commercialization and maintenance service roles for the products.

PeptiDream is active in the discovery and development of RI-PDCs for use as radiodiagnostics and radiotherapeutics both fully-owned internal programs and programs in collaboration with BMS (radiodiagnostics), Bayer (radiodiagnostics), Novartis (radiodiagnostics/ therapeutics), and RayzeBio (radiodiagnostics/therapeutics), and has established itself as one of the major players in this field. Integrating the technologies, know-how and networks of PeptiDream and PDRadiopharma, PeptiDream group aims to expand its radiopharmaceuticals business by developing new radiopharmaceuticals and in-licensing promising radiopharmaceuticals from Companies overseas that are interested in bringing their products into the Japan market.

PeptiDream Group continues its commitment to promoting ESG (Environmental, Social, and Governance) initiatives and its sustainability efforts including focus areas, ten most material issues, relevant policies and data are proactively disclosed on the corporate website and Sustainability Report. In addition, in order to further promote sustainability initiatives as a group, PDRadiopharma established a new "Sustainability Promotion Committee" to review and promote sustainability initiatives at PDRadiopharma.

As GHG (greenhouse gas) emissions (Scope 1+2) produced by our business operations mainly derive from electronic power consumption, PeptiDream has selected an electricity supplier which proactively promotes the shift towards renewable energy. To further take this initiative, PeptiDream has decided to introduce CO2 (carbon dioxide)-free power from its supplier for use at our head office and laboratory. This means that we will achieve our medium-term goal of the realization of "carbon-neutral" business operations 4 years earlier than originally planned.

PeptiDream believes as a R&D-driven innovative company that ensuring diversity is important in gaining a competitive advantage and nurturing innovation in order to fulfill its mission. In particular, PeptiDream values the diversity of expertise and scientific sense of each individual employee, and believes it is important to ensure a framework which allows the managers and senior scientists who play kay roles in R&D and management to engage in science-based discussions and decision-making regardless of their age, gender or cultural background. PeptiDream has set four quantitative indicators which it considers to be constituent elements of the diversity of core human resources (*1). The current status of these indicators and PeptiDream's 2030 targets are as follows; (1) Ratio of doctorate (Ph.D.) holders (end of December 2022: 51.2%, target for 2030: Maintain 50% or more); (2) Female manager ratio (end of December 2022: 18.6%, target for 2030: 30% or more); (3) Ratio of foreign employees or employees with overseas work experience (*2) (end of December 2022: 32.6%, target for 2030: Maintain 30% or more); and (4) Ratio of young employees (in 20s/30s) (end of December 2022: 16.3%, target for 2030: 30% or more).

*1: Managers and senior-ranking specialists (excludes officers)

*2: Employees with overseas research or work experience (excludes periods of less than one year and periods as a student studying abroad)

PeptiDream has received high evaluations from various evaluation organizations through continuous efforts for sustainability. On January 2022, PeptiDream was awarded as a "Top-Rated ESG Performer" for 2022 by Sustainalytics, a global ESG rating agency, and has been identified as top performer within the industry (rated No.2 among the 439 global biotech companies being evaluated). PeptiDream has been recognized by CDP for its leadership in climate change with an A- (A minus) rating. PeptiDream reached the Leadership level, the highest level, as a company that excels in its efforts and information disclosure in climate change. On May 2023, PeptiDream was selected as a constituent of the JPX Prime 150 Index, a new index developed by JPX Market Innovation & Research, Inc., a subsidiary of the Japan Exchange Group. In July 2023, PeptiDream was selected to remain a constituent of the FTSE4Good Index Series and FTSE Blossom Japan Index for the third consecutive year and of the FTSE Blossom Japan Sector Relative Index for the second consecutive year. These indices are constructed by global index provider FTSE Russel. In addition, the FTSE Blossom Japan Index and FTSE Blossom Japan Sector Relative Index are both broad ESG indices and are adopted by the Government Pension Investment Fund (GPIF) of Japan as a core ESG benchmark for its passive investments.

As of September 30, 2023, the Group had a total of 704 employees (716 when including its 12 board members and approximately 26.6% of employees are women). The Company had a total of 207 employees and PDRadiopharma Inc. had a total of 497 employees, including temporary staff.

As a result of the above, for the nine months ended September 30, 2023, the Drug Discovery and Development Business recorded revenue of 10,721,322 thousand yen (a 7,151,499 thousand yen increase year on year), segment profit of 6,573,586 thousand yen (segment loss of 196,580 thousand yen in the same period of the previous fiscal year), the Radiopharmaceutical Business recorded revenue of 11,822,628 thousand yen (a 4,183,910 thousand yen increase year on year), segment profit of 246,760 thousand yen (a 63,829 thousand yen increase year on year), and the Group recorded revenue of 22,543,951 thousand yen (a 11,335,410 thousand yen increase year on year), core operating profit of 7,042,788 thousand yen (a 6,899,536 thousand yen increase year on year ), operating profit of 6,752,846 thousand yen (operating loss of 426,772 thousand yen in the same period of the previous fiscal year), profit before tax of 4,661,920 thousand yen (loss before tax of 368,500 thousand yen in the same period of the previous fiscal year), and profit attributable to owners of parent of 3,541,432 thousand yen (loss attributable to owners of parent of 186,603 thousand yen in the same period of the previous fiscal year).

In addition to IFRS-based results, PeptiDream discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a IFRS basis that are deemed to be non-recurring items by PeptiDream are excluded as non-core items from these financial results on a core basis.

Items that are excluded from operating profit to calculate core operating profit include accounting effects of business acquisitions and acquisition-related costs, impairment loss on property, plant and equipment, intangible assets and goodwill, gains or losses on compensation, settlements, non-recurring and significant gains and losses, and amortization of intangible assets from introduction of individual products or developments.

A reconciliation of core operating income to operating income is as follows:

(Thousands of yen)

| | Results for the nine months ended September 30, 2022 | Results for the nine months ended September 30, 2023 | Change | % |
|---|---|---|---|---|
| Core operating profit | 143,251 | 7,042,788 | 6,899,536 | — |
| Accounting effects of business acquisitions and acquisition-related costs | 546,961 | 255,347 | (291,614) | (53.3) |
| Impairment loss on property, plant and equipment, intangible assets and goodwill | — | — | — | — |
| Gains or losses on compensation, settlements | — | — | — | — |
| Non-recurring and significant gains and losses | — | — | — | — |
| Amortization of intangible assets from introduction of individual products or developments | 23,062 | 34,593 | 11,531 | 50.0 |
| Operating profit (loss) | (426,772) | 6,752,846 | 7,179,619 | — |

In the third quarter ended September 30, 2023, PeptiDream recorded a finance cost of 2,021,149 thousand yen. The reason for this recording is as follows. The March 2022 acquisition of PDRadiopharma included a contingent consideration payment of 4,000,000 thousand yen if an indication expansion for AMYViD®, the PET diagnostic agent for visualizing beta amyloid plaques in the brain of patients with Alzheimer's or other forms of dementia, to include mild cognitive impairment, was approved in Japan by April 30, 2024. PDRadiopharma Inc. received approval for a partial change to the indication of AMYViD® on August 31, 2023. With the new indication for "visualization of beta amyloid plaques in the brain of patients with mild cognitive impairment or suspected to have dementia due to Alzheimer's disease," the contingent payment of 4,000,000 thousand yen to Fujifilm Corporation has been incurred.

(2) Explanation of Financial Position

1) Analysis of financial position

Total assets at the end of the nine months ended September 30, 2023 increased by 2,238,656 thousand yen from the end of the previous fiscal year to 66,103,857 thousand yen. This was mainly because of an increase of 8,323,155 thousand yen in cash and cash equivalents, despite a decrease of 5,765,800 thousand yen in trade and other receivables.

Liabilities decreased by 3,181,242 thousand yen from the end of the previous fiscal year to 28,642,492 thousand yen. This was mainly because of decreases of 1,480,331 thousand yen in income taxes payable, 2,142,576 thousand yen in borrowings, and 2,056,239 thousand yen in other financial liabilities, despite an increase of 2,427,562 thousand yen in trade and other payables.

Equity increased by 5,419,898 thousand yen from the end of the previous fiscal year to 37,461,364 thousand yen. This was mainly because of an increase of 4,478,421 thousand yen in retained earnings due to the recording of profit.

2) Analysis of status of cash flows

Cash and cash equivalents for the nine months ended September 30, 2023 increased by 8,323,155 thousand yen from the end of the previous fiscal year to 13,570,821 thousand yen.

Status of cash flows and related factors during the nine months ended September 30, 2023 are described below.

(Cash flows from operating activities)

Cash flows from operating activities resulted in a cash inflow of 9,186,629 thousand yen (compared with an outflow of 1,408,588 thousand yen in the same period of the previous fiscal year). This was mainly due to the recording of decrease in trade and other receivables of 5,765,800 thousand yen, despite a decrease in income taxes payable of 3,667,008 thousand yen.

(Cash flows from investing activities)

Cash flows from investing activities resulted in a cash inflow of 1,780,966 thousand yen (compared with an outflow of 26,963,720 thousand yen in the same period of the previous fiscal year). This was mainly due to proceeds from sale of investment securities of 2,864,600 thousand yen.

(Cash flows from financing activities)

Cash flows from financing activities resulted in a cash outflow of 2,948,813 thousand yen (compared with an inflow of 20,925,538 thousand yen in the same period of the previous fiscal year). This was mainly due to a decrease in short-term borrowings of 500,000 thousand yen and repayments of long-term borrowings of 1,680,000 thousand yen.

## (3) Explanation of Consolidated Financial Forecasts and Other Forward-looking Information

PeptiDream's key indices are as shown in the table below.

【Key indices】

| | Results for the full year ended December 31, 2021 | Results for the nine months ended September 30, 2022 | Results for the full year ended December 31, 2022 | Results for the nine months ended September 30, 2023 | Forecasts for the full year ending December 31, 2023 |
|---|---|---|---|---|---|
| | 2021/Jan ~ 2021/Dec | 2022/Jan ~ 2022/Sep | 2022/Jan ~ 2022/Dec | 2023/Jan ~ 2023/Sep | 2023/Jan ~ 2023/Dec |
| Capital Expenditures (JPY millions) | 1,300 | 3,530 | 3,913 | 886 | 2,038 |
| Depreciation Expense (JPY millions) | 633 | 1,375 | 1,973 | 1,828 | 2,211 |
| Research and Development Expenses (JPY millions) | 1,654 | 1,888 | 2,915 | 2,259 | 3,830 |
| Year-end headcount (people) | 177 | 682 | 680 | 716 | 736 |

(Notes) 1. The amount that will actually be paid is shown for capital expenditures.
2. Capital Expenditures of fiscal year ended December 31, 2021 includes advance payments (644 million yen) for the purchase of the land.
3. The Group has adopted International Financial Reporting Standards (IFRS) from the results for the first quarter of the fiscal year ended December 31,2022, and major management indicators for the Group as a whole are listed.

PeptiDream announced a new Mid-Term Management Targets on March 25, 2021 for the period from the fiscal year ended March 31, 2021 to the fiscal year ending March 31, 2026. Specifically, PeptiDream anticipates 4 or more new therapeutic drugs (not including diagnostics) to be launched (approved), 32 or more programs to be in clinical development, and 160 or more programs to be in preclinical development, by the end of FY2026. In order to fully support and promote these targets, PeptiDream will continue to actively expand through the hiring of highly skilled and talented professionals. In addition, in order to realize our goal of being a global "Drug Discovery Powerhouse", PeptiDream will continue to expand our partnership network and our leading position as the hub in the global peptide-based drug discovery ecosystem (*1).

| **Mid-Term Targets by the end of FY2026** | | **As of September 30, 2023** |
|---|---|---|
| (1) New drugs*2 launched (approved) | 4 or more | 0 |
| (2) Number of clinical programs | 32 or more | 6 |
| (3) Number of preclinical drug discovery programs | 160 or more | 124 |
| (4) Number of employees | 220 or more | 214 |
| (5) Establishing foundation as a "Drug Discovery Powerhouse" | | |

*1 Mid-Term Targets on a non-consolidated basis.

*2 Diagnostic agents and products other than therapeutics are not included.

Regarding the 5th target, with the aim to solidify PeptiDream's position and reputation as a global "Drug Discovery Powerhouse", we will particularly focus our efforts on the following five initiatives:

① To further lead the expansion of the global peptide-based drug discovery eco-system and our partnership network through expanding our role as the central hub.

② To continue to expand the number of licensees of our proprietary PDPS technology and its position as "the most widely-used peptide-based drug discovery platform in the world".

③ To create a healthy, safe, and diverse work environment where all employees can maximize their abilities, have equal opportunities, and be considered a "best place to work"

④ To strive toward a "transparent, responsive, and balanced corporate governance structure", ensure the highest business ethical standards, and maintain a continuous and open dialogue with all internal and external stakeholders.

⑤ To promote operational efficiency for the sustainable growth of society, minimize our environmental impact with a focus on water, waste, and energy efficiency, and become "carbon neutral" in our operations by 2026.

2. Condensed Quarterly Consolidated Financial Statements and Primary Notes

(1) Condensed Quarterly Consolidated Statements of Financial Position

(Thousands of yen)

| | As of December 31, 2022 | As of September 30, 2023 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | 5,247,665 | 13,570,821 |
| Trade and other receivables | 16,589,145 | 10,823,345 |
| Other financial assets | 6,243 | 6,244 |
| Inventories | 2,678,699 | 2,771,381 |
| Other current assets | 550,958 | 423,584 |
| Total current assets | 25,072,713 | 27,595,378 |
| Non-current assets | | |
| Property, plant and equipment | 18,125,415 | 17,231,614 |
| Goodwill | 8,370,677 | 8,370,677 |
| Intangible assets | 2,232,554 | 2,163,692 |
| Investments accounted for using equity method | 399,728 | 263,942 |
| Other financial assets | 6,122,214 | 6,895,057 |
| Deferred tax assets | 3,435,235 | 3,461,879 |
| Retirement benefit asset | 65,441 | 69,535 |
| Other non-current assets | 41,218 | 52,079 |
| Total non-current assets | 38,792,486 | 38,508,478 |
| Total assets | 63,865,200 | 66,103,857 |

| | As of December 31, 2022 | As of September 30, 2023 |
|---|---|---|
| Liabilities and equity | | |
| Liabilities | | |
| Current liabilities | | |
| Trade and other payables | 4,080,097 | 6,507,659 |
| Borrowings | 2,690,653 | 2,194,629 |
| Other financial liabilities | 344,882 | 275,957 |
| Income taxes payable | 2,325,030 | 844,699 |
| Provisions | 27,649 | 26,273 |
| Contract liabilities | 669,757 | 985,407 |
| Other current liabilities | 892,332 | 643,813 |
| Total current liabilities | 11,030,403 | 11,478,440 |
| Non-current liabilities | | |
| Borrowings | 18,357,797 | 16,711,244 |
| Other financial liabilities | 2,327,082 | 339,768 |
| Retirement benefit liability | 108,450 | 113,038 |
| Total non-current liabilities | 20,793,330 | 17,164,051 |
| Total liabilities | 31,823,734 | 28,642,492 |
| Equity | | |
| Share capital | 3,956,738 | 3,956,738 |
| Capital surplus | 4,524,436 | 4,502,054 |
| Treasury shares | (607,334) | (1,085,546) |
| Retained earnings | 23,848,337 | 28,326,759 |
| Other components of equity | 319,287 | 1,761,359 |
| Total equity attributable to owners of parent | 32,041,465 | 37,461,364 |
| Total equity | 32,041,465 | 37,461,364 |
| Total liabilities and equity | 63,865,200 | 66,103,857 |

(2) Condensed Quarterly Consolidated Statements of Profit or Loss

Nine months ended September 30, 2022 and September 30, 2023

(Thousands of yen, unless otherwise stated)

| | Nine months ended September 30, 2022 | Nine months ended September 30, 2023 |
|---|---|---|
| Revenue | 11,208,540 | 22,543,951 |
| Cost of sales | 5,686,909 | 8,313,715 |
| Gross profit | 5,521,631 | 14,230,236 |
| Selling, general and administrative expenses | 4,056,806 | 5,197,317 |
| Research and development expenses | 1,888,515 | 2,259,523 |
| Other income | 5,694 | 3,963 |
| Other expenses | 8,776 | 24,511 |
| Operating profit (loss) | (426,772) | 6,752,846 |
| Finance income | 320,426 | 264,058 |
| Finance costs | 129,168 | 2,194,524 |
| Share of profit (loss) of investments accounted for using equity method | (132,986) | (160,460) |
| Profit (loss) before tax | (368,500) | 4,661,920 |
| Income tax expense | (181,896) | 1,120,488 |
| Profit (loss) | (186,603) | 3,541,432 |
| | | |
| Profit attributable to: | | |
| Owners of parent | (186,603) | 3,541,432 |
| Profit (loss) | (186,603) | 3,541,432 |
| | | |
| Earnings (loss) per share | | |
| Basic earnings (loss) per share (Yen) | (1.44) | 27.30 |
| Diluted earnings (loss) per share (Yen) | (1.44) | 27.27 |

(3) Condensed Quarterly Consolidated Statements of Comprehensive Profit or Loss

Nine months ended September 30, 2022 and September 30, 2023

(Thousands of yen)

| | Nine months ended September 30, 2022 | Nine months ended September 30, 2023 |
|---|---|---|
| Profit (loss) | (186,603) | 3,541,432 |
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss: | | |
| Financial assets measured at fair value through other comprehensive income | (709,440) | 2,379,061 |
| Total of items that will not be reclassified to profit or loss | (709,440) | 2,379,061 |
| Other comprehensive income | (709,440) | 2,379,061 |
| Comprehensive income | (896,044) | 5,920,493 |
| Comprehensive income attributable to: | | |
| Owners of parent | (896,044) | 5,920,493 |
| Comprehensive income | (896,044) | 5,920,493 |

(Note) The above statement items are disclosed net of tax.

(4) Condensed Quarterly Consolidated Statements of Changes in Equity

Nine months ended September 30, 2022

(Thousands of yen)

| | Equity attributable to owners of parent | | | | | | Total equity |
|---|---|---|---|---|---|---|---|
| | Share capital | Capital surplus | Treasury shares | Retained earnings | Other components of equity | Total equity attributable to owners of parent | |
| Balance at January 1, 2022 | 3,956,738 | 4,452,358 | (620,123) | 16,372,687 | 1,188,589 | 25,350,250 | 25,350,250 |
| Profit (loss) | – | – | – | (186,603) | – | (186,603) | (186,603) |
| Other comprehensive income | – | – | – | – | (709,440) | (709,440) | (709,440) |
| Total comprehensive income | – | – | – | (186,603) | (709,440) | (896,044) | (896,044) |
| Purchase of treasury shares | – | – | (87) | – | – | (87) | (87) |
| Disposal of treasury shares | – | – | 12,956 | – | – | 12,956 | 12,956 |
| Share-based payment transactions | – | 5,502 | – | – | – | 5,502 | 5,502 |
| Total transactions with owners | ― | 5,502 | 12,868 | ― | ― | 18,371 | 18,371 |
| Balance at September 30, 2022 | 3,956,738 | 4,457,861 | (607,255) | 16,186,083 | 479,149 | 24,472,577 | 24,472,577 |

Nine months ended September 30, 2023

(Thousands of yen)

| | Equity attributable to owners of parent | | | | | | Total equity |
|---|---|---|---|---|---|---|---|
| | Share capital | Capital surplus | Treasury shares | Retained earnings | Other components of equity | Total equity attributable to owners of parent | |
| Balance at January 1, 2023 | 3,956,738 | 4,524,436 | (607,334) | 23,848,337 | 319,287 | 32,041,465 | 32,041,465 |
| Profit (loss) | — | — | — | 3,541,432 | — | 3,541,432 | 3,541,432 |
| Other comprehensive income | — | — | — | — | 2,379,061 | 2,379,061 | 2,379,061 |
| Total comprehensive income | — | — | — | 3,541,432 | 2,379,061 | 5,920,493 | 5,920,493 |
| Purchase of treasury shares | — | — | (513,842) | — | — | (513,842) | (513,842) |
| Disposal of treasury shares | — | — | 35,630 | — | — | 35,630 | 35,630 |
| Transfer from other components of equity to retained earnings | — | — | — | 936,989 | (936,989) | — | — |
| Share-based payment transactions | — | (22,382) | — | — | — | (22,382) | (22,382) |
| Total transactions with owners | — | (22,382) | (478,212) | 936,989 | (936,989) | (500,594) | (500,594) |
| Balance at September 30, 2023 | 3,956,738 | 4,502,054 | (1,085,546) | 28,326,759 | 1,761,359 | 37,461,364 | 37,461,364 |

(5) Condensed Quarterly Consolidated Statements of Cash Flows

(Thousands of yen)

| | Nine months ended September 30, 2022 | Nine months ended September 30, 2023 |
|---|---|---|
| Cash flows from operating activities | | |
| Profit (loss) before tax | (368,500) | 4,661,920 |
| Depreciation and amortization | 1,375,987 | 1,828,986 |
| Interest and dividend income | (1,238) | (6,021) |
| Interest expenses | 129,168 | 173,374 |
| Foreign exchange loss (gain) | (262,984) | (304,372) |
| Share of loss (profit) of investments accounted for using equity method | 132,986 | 160,460 |
| Decrease (increase) in trade and other receivables | (989,246) | 5,765,800 |
| Decrease (increase) in inventories | (364,419) | (92,682) |
| Increase (decrease) in trade and other payables | 598,370 | 2,474,844 |
| Increase (decrease) in defined benefit asset and liability | 5,452 | 495 |
| Other | (1,144,271) | (1,679,237) |
| Subtotal | (888,695) | 12,983,567 |
| Interest and dividends received | 1,238 | 6,021 |
| Interest paid | (101,220) | (135,951) |
| Income taxes paid | (441,013) | (3,667,008) |
| Income taxes refund | 21,102 | — |
| Net cash provided by (used in) operating activities | (1,408,588) | 9,186,629 |
| Cash flows from investing activities | | |
| Proceeds from sale of investment securities | — | 2,864,600 |
| Payments for purchase of investment securities | — | (200,000) |
| Payments for acquisition of subsidiaries | (23,460,335) | — |
| Collection of loans receivable | 67,486 | 4,682 |
| Purchase of property, plant and equipment | (3,449,779) | (779,660) |
| Purchase of intangible assets | (110,328) | (104,609) |
| Other | (10,763) | (4,046) |
| Net cash provided by (used in) investing activities | (26,963,720) | 1,780,966 |
| Cash flows from financing activities | | |
| Net increase (decrease) in short-term borrowings | — | (500,000) |
| Proceeds from long-term borrowings | 22,400,000 | — |
| Repayments of long-term borrowings | (1,120,000) | (1,680,000) |
| Payments of borrowing fee | (212,800) | — |
| Repayments of lease liabilities | (141,573) | (254,258) |
| Purchase of treasury shares | (87) | (514,554) |
| Net cash provided by (used in) financing activities | 20,925,538 | (2,948,813) |
| Effect of exchange rate change on cash and cash equivalents | 262,984 | 304,372 |
| Net increase (decrease) in cash and cash equivalents | (7,183,786) | 8,323,155 |
| Cash and cash equivalents at beginning of period | 11,746,529 | 5,247,665 |
| Cash and cash equivalents at end of period | 4,562,743 | 13,570,821 |

## (6) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes regarding going concern assumption)

Not applicable.

(Notes in case of significant changes in equity)

Not applicable.

(Segment information)

(1) Outline of reportable segments

On March 28, 2022 in the three months ended March 31, 2022, PeptiDream acquired the entire shares of a newly established company, PDRadiopharma Inc., which succeeded the radiopharmaceutical business of Fujifilm Toyama Chemical Co., Ltd. through an absorption-type split. As a result of this transaction, effective from the second quarter ended June 30, 2022, the Board of Directors of PeptiDream is monitoring the two reportable segments of the Drug Discovery and Development Business Segment and the Radiopharmaceutical Business Segment to determine the allocation of management resources and evaluate financial results. Therefore, from the second quarter ended June 30, 2022, the Group reorganizes its reportable segments to the above two segments of the Drug Discovery and Development Business Segment and the Radiopharmaceutical Business Segment.

[Description of reportable segments]

| Reportable Segment | Business description |
|---|---|
| Drug Discovery and Development Business Segment (Collaboration, PDPS Licensing, In-House/Strategic) | The Drug discovery and development business centers around the use of PDPS, PeptiDream's proprietary drug discovery platform system. This segment engages primarily in the discovery, research and development of new therapeutics and diagnostics through collaborative research and development with pharmaceutical companies in Japan and overseas, PDPS technology licensing, and in-house/strategic partnering and compound licensing. |
| Radiopharmaceutical Business Segment | The Radiopharmaceutical business engages in the research and development, manufacturing, and sale of diagnostic radiopharmaceuticals (diagnostic agents for SPECT and PET) used to examine blood flow of the heart and brain and bone metastasis of cancers; and therapeutic radiopharmaceuticals that address unmet medical needs, such as pheochromocytoma. |

(2) Segment revenues and performance

Revenues and performance for each of the Group's reportable segments were as follows. Inter-segment revenues are based on prevailing market prices.

Nine months ended September 30, 2022 (January 1, 2022 to September 30, 2022)

(Thousands of yen)

| | Reportable Segment | | | Adjustment | Consolidated Statement |
|---|---|---|---|---|---|
| | Drug Discovery and Development Business Segment | Radiopharmaceutical Business Segment | Total | | |
| Revenue | | | | | |
| External revenue | 3,569,822 | 7,638,717 | 11,208,540 | — | 11,208,540 |
| Inter-segment revenue | — | 8,332 | 8,332 | (8,332) | — |
| Total | 3,569,822 | 7,647,049 | 11,216,872 | (8,332) | 11,208,540 |
| Segment profit (loss) | (196,580) | 182,930 | (13,649) | — | (13,649) |
| (Adjustments) | | | | | |
| Business combination-related expenses (Note) | | | | | 413,122 |
| Operating profit (loss) | | | | | (426,772) |
| Finance income | | | | | 320,426 |
| Finance costs | | | | | 129,168 |
| Share of profit (loss) of associates accounted for using the equity method | | | | | (132,986) |
| Profit (loss) before income taxes | | | | | (368,500) |

(Note) Business combination-related expenses include acquisition-related expenses of 368,122 thousand yen and amortization expenses of 45,000 thousand yen for intangible assets newly acquired through the business combination.

Nine months ended September 30, 2023 (January 1, 2023 to September 30, 2023)

(Thousands of yen)

| | Reportable Segment | | | Adjustment | Consolidated Statement |
|---|---|---|---|---|---|
| | Drug Discovery and Development Business Segment | Radiopharmaceutical Business Segment | Total | | |
| Revenue | | | | | |
| External revenue | 10,721,322 | 11,822,628 | 22,543,951 | — | 22,543,951 |
| Inter-segment revenue | — | 62,820 | 62,820 | (62,820) | — |
| Total | 10,721,322 | 11,885,448 | 22,606,771 | (62,820) | 22,543,951 |
| Segment profit | 6,573,586 | 246,760 | 6,820,346 | — | 6,820,346 |
| (Adjustments) | | | | | |
| Business combination-related expenses (Note) | | | | | 67,500 |
| Operating profit | | | | | 6,752,846 |
| Finance income | | | | | 264,058 |
| Finance costs | | | | | 2,194,524 |
| Share of profit (loss) of associates accounted for using the equity method | | | | | (160,460) |
| Profit before income taxes | | | | | 4,661,920 |

(Note) Amortization expenses of 67,500 thousand yen for intangible assets newly acquired through the business combination.