

# Consolidated Financial Results for the Fiscal Year Ended December 31, 2024 [IFRS]

February 13, 2025

Company name: PeptiDream Inc. Tokyo Stock Exchange  
 Stock code: 4587 URL <https://www.peptidream.com/>  
 Representative: Patrick C. Reid, President & Chief Executive Officer  
 Inquiries: Yuko Okimoto, Head of Investor Relations  
 Scheduled date of Ordinary General Meeting of Shareholders: March 27, 2025  
 Scheduled filing date of securities report: March 28, 2025  
 Scheduled starting date of dividend payments: —  
 Supplementary briefing materials on financial results: No  
 Explanatory meeting on financial results: Yes (for securities analysts and institutional investors)

TEL: +81-44-223-6612

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

## 1. Consolidated Financial Results for the Fiscal Year Ended December 31, 2024 (January 1, 2024 to December 31, 2024)

### (1) Consolidated operating results

(% indicates year-on-year changes.)

	Revenue		Core operating profit		Operating profit		Profit before tax	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Fiscal Year Ended December 31, 2024	46,676	62.6	21,225	196.2	21,113	211.7	20,888	379.8
Fiscal Year Ended December 31, 2023	28,712	6.9	7,165	(25.6)	6,773	(24.6)	4,353	(34.6)

	Profit attributable to owners of parent		Total comprehensive income	
	Million yen	%	Million yen	%
Fiscal Year Ended December 31, 2024	15,014	394.6	16,216	85.1
Fiscal Year Ended December 31, 2023	3,035	(59.8)	8,760	32.6

	Basic earnings per share	Diluted earnings per share	Return on equity attributable to owners of parent	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	Yen	Yen	Yen	Yen	Yen
Fiscal Year Ended December 31, 2024	115.85	115.68	30.9	25.8	45.2
Fiscal Year Ended December 31, 2023	23.41	23.38	8.4	6.5	23.6

(Reference) Share of profit (loss) of investments accounted for using equity method

Fiscal year ended December 31, 2024: ¥22 million

Fiscal year ended December 31, 2023: ¥(357) million

### (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	Equity attributable to owners of parent per share
	Million yen	Million yen	Million yen	%	Yen
As of December 31, 2024	92,769	56,762	56,762	61.2	437.63
As of December 31, 2023	69,464	40,349	40,349	58.1	311.16

(3) Consolidated cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal Year Ended December 31, 2024	23,844	8,370	(2,994)	48,117
Fiscal Year Ended December 31, 2023	12,420	1,302	264	19,507

2. Payment of Dividends

	Annual dividends per share					Total dividends (Annual)	Dividend payout ratio (Consolidated)	Ratio of dividends to equity attributable to owners of parent (Consolidated)
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal Year Ended December 31, 2023	-	0.00	-	0.00	0.00	-	-	-
Fiscal Year Ended December 31, 2024	-	0.00	-	0.00	0.00	-	-	-
Fiscal Year Ending December 31, 2025 (Forecast)	-	0.00	-	0.00	0.00		-	

3. Consolidated Financial Forecasts for the Fiscal Year Ending December 31, 2025 (January 1, 2025 to December 31, 2025)

	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, 2025	49,000 / 5.0	21,700 / 2.2	21,600 / 2.3	21,200 / 1.5	15,100 / 0.6

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) Significant changes in the scope of consolidation during the period :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)
- 2) Number of treasury stock at the end of the period
- 3) Average number of shares during the period

As of December 31, 2024	130,010,400 shares	As of December 31, 2023	130,010,400 shares
As of December 31, 2024	398,635 shares	As of December 31, 2023	402,647 shares
Fiscal year ended December 31, 2024	129,610,167 shares	Fiscal year ended December 31, 2023	129,699,938 shares

(Note) The number of treasury stock at the end of the period includes shares in the Company held by the Custody Bank of Japan, Ltd. (Trust Account E) (402,400 shares as of December 31, 2023 and 398,300 shares as of December 31, 2024). 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 (310,215 shares for the fiscal year ended December 31, 2023 and 399,924 shares for the fiscal year ended December 31, 2024).

**[Reference] Overview of Non-consolidated Financial Results**

**1. Non-consolidated Financial Results for the Fiscal Year Ended December 31, 2024 (January 1, 2024 to December 31, 2024)**

**(1) Non-consolidated operating results**

(% indicate year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Fiscal Year Ended December 31, 2024	31,313	146.5	21,040	228.4	20,519	223.1	21,074	262.2
Fiscal Year Ended December 31, 2023	12,702	(17.5)	6,406	(29.6)	6,351	(28.1)	5,817	35.4

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Fiscal Year Ended December 31, 2024	162.60	—
Fiscal Year Ended December 31, 2023	44.85	—

**(2) Non-consolidated financial position**

	Total assets	Net assets	Equity-to-asset ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of December 31, 2024	89,669	55,608	62.0	428.73
As of December 31, 2023	68,157	40,574	59.5	312.89

(Reference) Equity As of December 31, 2024: ¥55,567 million  
As of December 31, 2023: ¥40,552 million

\* These financial results are outside the scope of audit 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.

(Obtaining supplementary briefing materials on financial results)

The Company plans to hold an explanatory meeting on financial results for institutional investors on Thursday 13, 2025 and intends to publish the presentation materials on its website on the same day.

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

### (1) Explanation of Operating Results

During the twelve (12) months ended December 31, 2024 (from January 1, 2024 to December 31, 2024), PeptiDream (“the Company”) continued to make excellent progress in both its Radiopharmaceuticals and Non-Radiopharmaceutical Drug Discovery Businesses.

#### **(A) Radiopharmaceuticals Business:**

PeptiDream operates a fully integrated Radiopharmaceutical Business, from discovery and development to commercialization, marketing, and sales in Japan. Through its wholly-owned subsidiary PDRadiopharma, PeptiDream currently markets and sells a number of approved radiotherapeutics and radiodiagnostics in Japan, as well as providing other services and products supporting the radiopharmaceutical market in Japan. Additionally, PeptiDream and PDRadiopharma have a growing discovery and development pipeline of innovative radiotherapeutic and radiodiagnostic programs, both fully owned internal programs as well as partnered programs, currently in development. As macrocyclic peptides are increasingly proving ideal for the targeted delivery of tumor killing radioisotope payloads, integrating the technologies, know-how and networks of PeptiDream and PDRadiopharma, the PeptiDream Group aims to expand its radiopharmaceuticals business by developing and commercializing novel high-value radiopharmaceuticals, in addition to in-licensing promising radiopharmaceuticals from Companies overseas that are interested in bringing their products into the Japan market.

#### **(A)-1: Currently Marketed Radiotherapeutic and Radiodiagnostic Products**

Below is a brief description of the Products currently marketed and sold by PeptiDream, through its subsidiary PDRadiopharma, in Japan. *All products originally developed by PDRadiopharma unless otherwise noted.*

- ◆ **Sodium Iodide-<sup>131</sup>I Capsules:** Product used for the treatment of patients with hyperthyroidism, thyroid cancer and its metastases, as well as the diagnosis of metastasis of thyroid cancer by scintigraphy. Product available in different strengths ranging from 37 MBq to 1.85 GBq.
- ◆ **Raiatt MIBG-I131 Injection:** Product consists of the small molecule compound 3-iodobenzylguanidine radiolabeled with <sup>131</sup>I used for the treatment of patients with MIBG avid, unresectable pheochromocytoma and paraganglioma.
- ◆ **Zevalin® Indium Injection:** Product consists of a CD20-targeting antibody, ibritumomab tiuxetan, radiolabeled with <sup>111</sup>In and used to confirm the accumulation sites of ibritumomab tiuxetan. *Japan Marketing Authorization holder is Mundipharma and product is sold by PDRadiopharma.*
- ◆ **Zevalin® Yttrium Injection:** Product consists of a CD20-targeting antibody, ibritumomab tiuxetan, radiolabeled with <sup>90</sup>Y and used for the treatment of patients with low-grade B-cell non-Hodgkin’s lymphoma or mantle cell lymphoma. *Japan Marketing Authorization holder is Mundipharma and product is sold by PDRadiopharma*
- ◆ **Octreoscan® Injection:** Product consists of the somatostatin receptor targeting peptide, pentetreotide, radiolabeled with <sup>111</sup>In, used for the diagnosis of patients with neuroendocrine tumors by scintigraphy. *Product licensed from Curium Pharma.*
- ◆ **Technetium® DMSA Kit:** Kit for the preparation of technetium (<sup>99m</sup>Tc) dimercaptosuccinic acid injection used for the diagnosis of renal diseases by renal scintigraphy.
- ◆ **Technetium® DTPA Kit:** Kit for the preparation of technetium (<sup>99m</sup>Tc) diethylenetriamine pentaacetic acid injection used for the diagnosis of renal diseases by renal scintigraphy.

- ◆ **Techne® MAA® Kit:** Kit for the preparation of technetium ( $^{99m}\text{Tc}$ ) macroaggregated human serum albumin injection for use in lung perfusion scintigraphy
- ◆ **Techne® MAG3 Injection:** Imaging agent containing technetium ( $^{99m}\text{Tc}$ ) mercaptoacetyltriglycine used for the diagnosis of renal and urinary tract diseases by renal scintigraphy and renography. Also available in kit form.
- ◆ **Techne® MDP Injection:** Imaging agent containing technetium ( $^{99m}\text{Tc}$ ) methylenediphosphonate injection used for the diagnosis of skeletal diseases by bone scintigraphy and cerebral tumor or cerebral vessel disorders by cerebral scintigraphy. Also available in kit form.
- ◆ **Techne® Pyrophosphate Kit:** Kit for the preparation of technetium ( $^{99m}\text{Tc}$ ) pyrophosphate injection for use in cardiac or bone scintigraphy to diagnose cardiac or skeletal diseases. In August 2024 PDRadiopharma received approval for a new formulation of the Techne® Pyrophosphate Kit.
- ◆ **Techne® Phytate Kit:** Kit for the preparation of technetium ( $^{99m}\text{Tc}$ ) phytate used to diagnose liver and spleen diseases by hepatosplenic scintigraphy, and to identify sentinel lymph nodes and for lymphoscintigraphy in patients with breast cancer or malignant melanoma. 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.
- ◆ **Neurolite® Injection Daiichi:** Imaging agent containing N, N'-ethylenedi-L-cysteinate(3-)] oxotechnetium ( $^{99m}\text{Tc}$ )-diethyl ester used for regional cerebral blood perfusion scintigraphy. Also available in kit form. *Product licensed from Lantheus Holdings, Inc.*
- ◆ **Cardiolite® Injection Daiichi:** Imaging agent containing technetium ( $^{99m}\text{Tc}$ ) hexakis(2-methoxy-isobutyl isonitrile) used in the diagnosis of heart disorders by myocardial perfusion scintigraphy, assessment of ventricular function by first pass technique, and localization of hyperparathyroidism by parathyroid scintigraphy. Also available in kit form. *Product licensed from Lantheus Holdings, Inc.*
- ◆ **MyoMIBG®-I123 Injection:** Product consists of 3-iodobenzylguanidine radiolabeled with  $^{123}\text{I}$  used for the diagnosis of heart diseases by cardiac scintigraphy and neuroblastoma and pheochromocytoma by tumor scintigraphy. In December 2023, the MyoMIBG-I123 label was expanded to include the diagnosis of Parkinson's disease and dementia with Lewy bodies by cardiac scintigraphy.
- ◆ **Thallium Chloride-Tl201 Injection:** Imaging agent used for the diagnosis of cardiac diseases by myocardial scintigraphy, cerebral, thyroid, pulmonary, bone, soft tissue and mediastinal tumors by tumor scintigraphy and parathyroid diseases by parathyroid scintigraphy.
- ◆ **Ultra-Techne Kow®:** Generator to extract  $^{99m}\text{Tc}$  from  $^{99}\text{Mo}$ . Extracted  $^{99m}\text{Tc}$  in the form of sodium pertechnetate ( $^{99m}\text{Tc}$ ) is used for the diagnosis of brain tumors, cerebrovascular disorders, thyroid diseases, salivary gland diseases and ectopic gastric mucosa. Also used to assess regional pulmonary ventilation function in combination with Techne Gas Generator.
- ◆ **Fludeoxyglucose ( $^{18}\text{F}$ ) Injection FRI:** Imaging agent used for the diagnosis of patients with malignant tumors, heart disease, intractable partial epilepsy, and large-vessel vasculitis.

- ◆ **Adosterol®-I131 Injection:** Product consists of iodinated (<sup>131</sup>I) methylnorcholestenol used for localization of adrenal diseases by adrenal scintigraphy.
- ◆ **Iofetamine (<sup>123</sup>I) Injection Daiichi:** Product consists of the small molecule N-isopropyl-4-iodoamphetamine radiolabeled with <sup>123</sup>I, used for regional cerebral blood perfusion scintigraphy.
- ◆ **AMYViD® Injection:** Product consists of the small molecule florbetapir radiolabeled with <sup>18</sup>F and indicated for the visualization of beta amyloid plaques in the brain of patients with suspected mild cognitive impairment or patients with cognitive impairment with suspected Alzheimer’s type dementia and for the visualization of beta amyloid plaques in the brain of the patients administered monoclonal antibodies directed against beta amyloid. In May 2024, AMYViD® became listed in the National Health Insurance Drug Price List. In September 2024, PDRadiopharma received approval of Partial Change to the Indication of AMYViD®. In November 2024, AMYViD® have been updated, resulting in an expanded scope of insurance coverage. *Product licensed from Eli Lilly and Company.*

#### **(A)-2: Radiopharmaceutical Development Programs & Pipeline**

Below is a table of PeptiDream/ PDRadiopharma’s current clinical-stage radiopharmaceutical pipeline. **Disease Area, Pipeline, Clinical-stage** (Investigational New Drug enabling studies “IND-enabling”/ human imaging Phase 0 studies “Ph 0”; Phase 1 “Ph 1”; Phase 2 “Ph 2”; Phase 3 “Ph 3”, **Partner** are listed. Following the table is a brief description of each program.

	Disease Area	Pipeline	IND-enabling / Ph0	Ph1	Ph2	Ph3	Partner
Theranostics / Therapeutics	Malignant Brain Tumors	<sup>64</sup> Cu-ATSM					LinqMed
	Postate Cancer	<sup>177</sup> Lu/ <sup>64</sup> Cu-PSMA I&T					Curium
	Malignant Glioma	<sup>177</sup> Lu-Integrin (FF58)					PeptiDream
	Hepatocellular Carcinoma	<sup>225</sup> Ac/ <sup>68</sup> Ga-GPC3 (RYZ801/811)					RayzeBio
	PDAC/NSCLC/BC/CRC	<sup>177</sup> Lu/ <sup>68</sup> Ga Program (NNS309)					Novartis
	Renal Cell Carcinoma	<sup>225</sup> Ac/ <sup>64</sup> Cu-CA9 (PD-32766)					PeptiDream
	Oncology	Novartis (Not disclosed)					Novartis
	Gastric cancer	<sup>225</sup> Ac/ <sup>64</sup> Cu-CLDN18.2 (PD-29875)					PeptiDream
	Oncology	RayzeBio (Not disclosed)					RayzeBio
	Solid Tumor	<sup>225</sup> Ac-Cadherin3					Perseus Proteomics
Diagnostics	Alzheimer’s Disease	<sup>18</sup> F-flortaucipir (Tauvid™)					Eli Lilly
	Various Cancers	<sup>18</sup> F-PD-L1 (BMS-986229)					Bristol-Myers Squibb

Note: Above list only includes major pipeline programs in IND or later stages

- ◆ **<sup>64</sup>Cu-ATSM Program:**  
Indication: Gliomas and other malignant brain cancers;  
Modality: LinqMed discovered small molecule diacetyl-bis(N4-methylthiosemicarbazone) conjugated to a chelator radiolabeled with <sup>64</sup>Cu (<sup>64</sup>Cu-ATSM);  
Partner: LinqMed  
Current Status:

<sup>64</sup>Cu-ATSM is currently being tested in a Phase 3 randomized, comparative, investigator-initiated clinical trial (STEP-64 study, study number NCCH2301; jRCT2031240090) to verify whether <sup>64</sup>Cu-ATSM treatment extends survival time compared to conventional standard treatment in patients with recurrent and refractory malignant gliomas, the most difficult to treat types of malignant brain tumors. The STEP-64 study is aimed at seeking accelerated approval of <sup>64</sup>Cu-ATSM as a radiotherapeutic for severe brain tumors.

LinqMed announced the completion of the Phase 1 investigator-initiated clinical trial (STAR-64 study; study identifier NCCH1711) of <sup>64</sup>Cu-ATSM in patients with malignant brain tumors, including malignant gliomas, central nervous system malignant lymphomas, and metastatic brain tumors, representing rare and refractory brain cancers, in June 2024, and the study results were presented at the American Society of Clinical Oncology (ASCO2024). Results of the Phase 1 showed a favorable safety profile, and that <sup>64</sup>Cu-ATSM was well tolerated, and that the recommended dosing of <sup>64</sup>Cu-ATSM for patients with malignant brain tumors is 99 MBq/kg, administered four times every seven days. In terms of efficacy, while overall survival was only a secondary readout, 14 out of 18 patients (77.8%) who received <sup>64</sup>Cu-ATSM survived for more than 6 months, and 12 (66.7%) survived for more than 1 year. Specifically, in patients with glioblastoma, 5 out of 9 patients (55.6%) survived for more than 1 year. In general, only 30-40% of patients survive for more than 1 year after the recurrence of glioblastoma, with these highly promising early results serving as the basis for moving <sup>64</sup>Cu-ATSM directly from Ph1 into a Ph3/registrational study. The studies are supported by the Clinical Research Support Department of the National Cancer Center Hospital and is the first investigator-initiated clinical trial to progress from Phase 1 to Phase 3 with research funding from the Japan Agency for Medical Research and Development (AMED).

Additional program details:

Most tumors are known to create a hypoxic microenvironment within and around the tumor, due to increased oxygen consumption by rapidly proliferating tumor cells and an inadequate oxygen supply due to abnormal tumor angiogenesis, and <sup>64</sup>Cu-ATSM localizes to these hypoxic tumor microenvironments, delivering the therapeutic <sup>64</sup>Cu payload, which induces irreversible DNA damage and results in tumor cell death. In Japan, there are approximately 4,000 – 5,000 new cases of gliomas reported each year, with the 5-year overall survival (OS) rate at 15.5%, a median OS of 18 months, and a recurrence rate of 51%. There are currently no effective or established treatments for patients with these recurrent malignant brain tumors to which standard treatments, surgical excision, stereotactic irradiation, or chemotherapy, proved ineffective.

In December 2023, PeptiDream entered into a strategic partnership and license agreement with Japan-based LinqMed, under which the companies will share costs and profits for the development and commercialization of <sup>64</sup>Cu-ATSM in Japan. LinqMed will continue to lead development activities of <sup>64</sup>Cu-ATSM and PDRadiopharma will lead regulatory filing and commercialization activities in Japan.

◆ <sup>177</sup>Lu/<sup>64</sup>Cu-PSMA I&T Program:

Indication: Prostate Cancer (metastatic castration-resistant prostate cancer);

Modality: **Curium discovered small molecule** (PSMA I&T) targeting prostate specific membrane antigen (PSMA) conjugated to a chelator radiolabeled with <sup>177</sup>Lu (for the therapeutic <sup>177</sup>Lu-PSMA-I&T) or <sup>64</sup>Cu (for the diagnostic <sup>64</sup>Cu-PSMA-I&T);

Partner: **Curium Pharma;** Curium holds worldwide (ex-Japan) commercialization rights, with Curium and PeptiDream/PDRadiopharma sharing Japan commercialization rights.

Current Status:

<sup>177</sup>Lu-PSMA-I&T is currently being tested by Curium in a global pivotal Phase 3 ECLIPSE trial (ClinicalTrials.gov identifier; NCT05204927). ECLIPSE was a multi-center, open-label, randomized clinical trial comparing the safety and efficacy of <sup>177</sup>Lu-PSMA-I&T versus hormone therapy in patients with metastatic castration-resistant prostate cancer. The ECLIPSE trial enrolled over 400 patients, across 51 trial sites in the United States and Europe.

Curium reported in November 2024 the global pivotal Phase 3 ECLIPSE Trial has met primary endpoint. <sup>64</sup>Cu-PSMA-I&T PET is currently being investigated in 2 multicenter Phase 3 trials; SOLAR RECUR testing the diagnostic performance in men with biochemical recurrence of prostate cancer (ClinicalTrials.gov identifier NCT06235099) and SOLAR STAGE



testing the diagnostic performance in men with newly diagnosed unfavorable intermediate- to high-risk prostate cancer (ClinicalTrials.gov identifier; NCT06235151). Curium reported the completion of enrollment of SOLAR-RECUR clinical trial in November 2024. The first in human Phase 1/2 SOLAR trial met the co-primary endpoints of region-level correct localization rate and patient-level correct detection rate in patients with histologically-proven metastatic prostate cancer.

On October 1, 2024, PeptiDream announced a strategic partnership between its wholly-owned subsidiary PDRadiopharma and Curium for the clinical development, regulatory filing, and commercialization of Curium's  $^{177}\text{Lu}$ -PSMA-I&T and  $^{64}\text{Cu}$ -PSMA-I&T products in Japan. Under the terms of the partnership, Curium and PDRadiopharma will jointly collaborate on clinical development activities of  $^{177}\text{Lu}$ -PSMA-I&T and  $^{64}\text{Cu}$ -PSMA-I&T in Japan, with PDRadiopharma leading regulatory filing, manufacturing, commercialization, and distribution activities in Japan. Curium will continue to lead global development of the two agents and support PDRadiopharma through technology transfer to support the set-up of manufacturing lines in Japan – including a high throughput Copper 64 manufacturing line based on Curium's proprietary technology. The partners will share costs of development of the two products and share profits upon Japan commercialization.

Additional program details:

Prostate cancer continues to be widely prevalent in Japan. Annually, there are approximately 90,000 - 100,000 new cases, with patients with metastatic castration resistant prostate cancer having an overall survival rate of approximately three years in clinical trial settings, and even shorter in the real-world, and there remains a significant unmet medical need for therapies. The diagnostic agent  $^{64}\text{Cu}$ -PSMA-I&T developed with the Copper 64 isotope with its longer radionuclide half-life (12.7 hours) compared to other commercially available solutions based on Gallium 68 (68 minutes) and/or Fluorine 18 (110 minutes) and is expected to offer logistics and patient workflow management flexibility to clinicians across Japan.

♦  **$^{177}\text{Lu}/^{68}\text{Ga}$ -Integrin (FF58) Program:**

Indication: Advanced Solid Tumors (Pancreatic Ductal Adenocarcinoma, Gastroesophageal Adenocarcinoma, Glioblastoma Multiforme);

Modality: **FUJIFILM/PDRadiopharma-discovered small molecule (FF58)** targeting Integrin  $\alpha\text{v}\beta 3/5$  conjugated to a chelator radiolabeled with  $^{177}\text{Lu}$  (for the therapeutic) or  $^{68}\text{Ga}$  (for the diagnostic);

Partner: **FUJIFILM/PDRadiopharma** (see additional program details below);

Current Status: A Clinical Study Report from the partially completed Phase 1 study (ClinicalTrials.gov identifier: NCT05977322) to evaluate the safety, tolerability, dosimetry and preliminary activity of  $^{177}\text{Lu}$ -FF58 in patients with selected advanced solid tumors is being prepared.

Additional program details:

The purpose of the first-in-human Phase 1 study is to test the safety and dosing of  $^{177}\text{Lu}$ -FF58, a radioligand therapy for patients with advanced or metastatic tumors that express proteins known as integrins: alpha-v beta-3 integrin ( $\alpha\text{v}\beta 3$ ) and alpha-v beta-5 integrin ( $\alpha\text{v}\beta 5$ ). While both  $\alpha\text{v}\beta 3$  and  $\alpha\text{v}\beta 5$  integrins are reported to be expressed in a variety of tumor types, their expression can vary significantly between individual tumors and even within different areas of the same tumor, and the roles of these integrins in tumor progression remains unclear. The study will also further characterize the radioligand imaging agent  $^{68}\text{Ga}$ -Integrin including its ability to identify tumor lesions and its safety profile. The study will be done in two parts. The first part is called "escalation" and the second part is called "expansion". In both parts of the study, patients will be screened with a  $^{68}\text{Ga}$ -FF58 positron emission tomography (PET)/computed tomography (CT) or PET/magnetic resonance imaging (MRI) scan to assess eligibility for treatment with  $^{177}\text{Lu}$ -FF58. In the escalation part, different doses of  $^{177}\text{Lu}$ -Integrin will be tested to identify the recommended dose. The expansion part of the study will examine the safety and preliminary efficacy of  $^{177}\text{Lu}$ -FF58 at the recommended dose determined during the escalation part.

The FF58 is a radiolabeled small molecule discovered by FUJIFILM and FUJIFILM RI Pharma (which in 2018 became FUJIFILM Toyama Chemical (FFTC), currently PDRadiopharma). In 2018, FFTC entered into an Option and License Agreement ("OLA") with Advanced Accelerator Applications International ("ADACAP"), an entity wholly-owned by Novartis (hereinafter referred to as "Novartis"), under which Novartis would be responsible for development of the diagnostic

$^{68}\text{Ga}$ -FF58 up to Phase 1/2a and the therapeutic  $^{177}\text{Lu}$ -FF58 up to Phase 1, with an exercisable option to continue development beyond these stages under the terms of the OLA. As Novartis decided to not exercise its option to take the FF58 program forward, the program will be transferred back to PDRadiopharma and FUJIFILM, and once the Clinical Study Report is received and reviewed, next steps will be determined.

♦  **$^{225}\text{Ac}/^{68}\text{Ga}$ -GPC3 (RYZ-801/RYZ-811) Program:**

Indication: Hepatocellular Carcinoma (“HCC”);

Modality: PDPS®-originating macrocyclic peptide targeting glypican-3 (GPC3) conjugated to a chelator radiolabeled with  $^{225}\text{Ac}$  (for the therapeutic RYZ-801) or  $^{68}\text{Ga}$  (for the diagnostic RYZ-811);

Partner: RayzeBio, a Bristol Myers Squibb (“BMS”) company (RayzeBio was acquired by BMS in 2024); RayzeBio/BMS holds worldwide (ex-Japan) commercialization rights, with PeptiDream/PDRadiopharma holding an option to attain Japan commercialization rights.

Current Status:

As announced on January 28, 2025, initiated a Phase 1/1b, open-label, multi-center study to investigate the safety, tolerability, dosimetry and preliminary efficacy of RYZ-801 and the safety, tolerability, and biodistribution of RYZ-811 in HCC patients (ClinicalTrials.gov identifier; NCT06726161).

Additional program details:

The Phase 1 study will be conducted in two parts. The first part is called "escalation" and the second part is called "expansion". In both parts of the study, patients will initially be imaged with a  $^{68}\text{Ga}$ -RYZ811 positron emission tomography (PET)/ computed tomography (CT) or PET/magnetic resonance imaging (MRI) scans and will be evaluated for eligibility for  $^{225}\text{Ac}$ -RYZ801 treatment. In the escalation part, different doses of  $^{225}\text{Ac}$ -RYZ801 will then be tested to identify recommended dose(s) (RD(s)) for further evaluation. The expansion part of the study will examine the safety and preliminary efficacy of  $^{225}\text{Ac}$ -RYZ801 at the RD(s) determined during the escalation part.

Liver cancer is the sixth most common cause of cancer death in United States, with an estimated 29,380 deaths per year. The five-year survival rate for all liver cancer patients is approximately 20% and the survival rate of patients with advanced stage liver cancer is significantly lower. GPC3 is an oncofetal protein that is overexpressed in up to 75% of hepatocellular tumors, with minimal to no expression in normal tissues. RYZ-801, the therapeutic development candidate, is a novel proprietary peptide which targets GPC3 for delivery of  $^{225}\text{Ac}$  for the treatment of hepatocellular carcinoma “HCC”. As a diagnostic imaging agent, RYZ-811 is designed to enable us to screen and identify patients, both in clinical trials and commercially, who have GPC3 expressing HCC tumors that are most likely to have a favorable clinical response from treatment with RYZ-801.

♦  **$^{177}\text{Lu}/^{68}\text{Ga}$ -NNS309 Program:**

Indication: Solid Tumors (Locally Advanced or Metastatic Pancreatic Ductal Adenocarcinoma, Non-small Cell Lung Cancer, Hr+/HER2- Breast Cancer, Triple Negative Breast Cancer, Colorectal Cancer);

Modality: PDPS®-originating macrocyclic peptide (NNS309) targeting an undisclosed target conjugated to a chelator radiolabeled with  $^{177}\text{Lu}$  (for the therapeutic) or  $^{68}\text{Ga}$  (for the diagnostic);

Partner: Novartis, with Novartis holding worldwide commercialization rights to the program.

Current Status:

As announced on December 17, 2024, initiated a Phase 1, open-label, multi-center study to evaluate the safety, tolerability, dosimetry and preliminary efficacy of  $^{177}\text{Lu}$ -NNS309 and the safety and imaging properties of  $^{68}\text{Ga}$ -NNS309 in patients with selected solid tumors (ClinicalTrials.gov identifier; NCT06562192).

Additional program details:

The Phase 1 study will be conducted in two parts. The first part is called "escalation" and the second part is called "expansion". In both parts of the study, patients will initially be imaged with a  $^{68}\text{Ga}$ -NNS309 positron emission tomography (PET)/ computed tomography (CT) or PET/magnetic resonance imaging (MRI) scans and will be evaluated for eligibility for

<sup>177</sup>Lu-NNS309 treatment. In the escalation part, different doses of <sup>177</sup>Lu-NNS309 will then be tested to identify recommended dose(s) (RD(s)) for further evaluation. The expansion part of the study will examine the safety and preliminary efficacy of <sup>177</sup>Lu-NNS309 at the RD(s) determined during the escalation part. The end of study will occur when at least 80% of the patients per disease group in the expansion part have completed the follow-up for disease progression or discontinued from the study for any reason, and all patients have completed treatment and the 36-month long-term follow-up period.

♦ **<sup>225</sup>Ac/<sup>64</sup>Cu-CA9 (PD-32766T/PD-32766D) Program:**

Indication: Clear Cell Renal Cell Carcinoma (“ccRCC”) and other cancers;

Modality: PDPS®-originating macrocyclic peptide (PD-32766) targeting Carbonic Anhydrase IX (“CAIX”) conjugated to a chelator radiolabeled with <sup>225</sup>Ac (for the therapeutic PD-32766T) or <sup>64</sup>Cu (for the diagnostic PD-32766D);

Partner: PeptiDream holds worldwide commercialization rights to the program.

Current Status:

PD-32766T and PD-32766D are currently undergoing IND-enabling studies, in anticipation of initiating Phase 1 safety, tolerability, and dosimetry studies in 2025. Additionally, in 2024, a Phase 0 first-in-human imaging study of <sup>64</sup>Cu-PD-32766D in patients with ccRCC was conducted at the National Cancer Center Japan (NCC). The Phase 0 Study enrolled a total of five ccRCC patients, that were each administered <sup>64</sup>Cu-PD-32766D followed by imaging by PET/CT. Administration of <sup>64</sup>Cu-PD-32766D was safe and well tolerated, with no observed safety/adverse events, and showed clear accumulation in the tumors of all five patients, supporting continued development of the program. As announced in December 2024, the results of the Ph0 study will be presented at the upcoming American Society of Clinical Oncology’s (ASCO) Genitourinary Cancers Symposium (ASCO-GU 2025) in February.

Additional program details:

CAIX is a member of the carbonic anhydrase enzyme family, expressed in a variety of solid tumors, including renal cell carcinoma (“RCC”), glioblastoma, triple negative breast cancer, ovarian cancer, colorectal cancer, and others. RCC is the 9th 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. In preclinical studies of RCC xenograft models, the CAIX binding peptide showed specific tumor uptake, and significant tumor growth inhibition including regression with single dose administrations. 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-32766T treatment.

A key advantage in the development of targeted radiopharmaceuticals over conventional cancer drugs, is the ability to generate early human imaging data (referred to as a Phase 0 study) using the paired diagnostic agent directly in the target patient population, thereby obtaining an early look at the biodistribution, pharmacokinetics, and tumor targeting ability of the agent, thus providing an early look at the diagnostic usefulness of the agent, the likelihood of therapeutic benefit when labeled with a therapeutic radioisotope, and additional critical information that can be used in designing subsequent Phase 1 and 2 studies, thereby significantly accelerating clinical development.

♦ **Undisclosed Novartis Program:**

Indication: Solid Tumors;

Modality: PDPS®-originating macrocyclic peptide targeting undisclosed target conjugated to a chelator radiolabeled with undisclosed radioisotope;

Partner: Novartis, with Novartis holding worldwide commercialization rights to the program.

Current Status:

As announced in July, 2024, the program is currently undergoing IND-enabling studies.

Additional program details:

Program has certain partner limitations on disclosable information.

♦ **<sup>225</sup>Ac/<sup>64</sup>Cu-CLDN18.2 (PD-29875T/PD-29875D) Program:**

Indication: Solid Tumors (Gastric Cancer, Pancreatic Cancer, Biliary Cancer, Genitourinary Tract Cancers, Colorectal Cancer, and other cancers);

Modality: PDPS®-originating macrocyclic peptide (PD-29875) targeting Claudin 18.2 (“CLDN18.2”) conjugated to a chelator radiolabeled with <sup>225</sup>Ac (for the therapeutic PD-29875T) or <sup>64</sup>Cu (for the diagnostic PD-29875D);

Partner: PeptiDream holds worldwide commercialization rights to the program.

Current Status:

As announced on December 12, 2024, PD-29875T and PD-29875D are currently undergoing IND-enabling studies in anticipation of initiating future Phase 1 safety, tolerability, and dosimetry studies. A human Ph0 imaging study of <sup>64</sup>Cu-PD-29875D is also currently in the planning stages for 2025.

Additional program details:

CLDN18.2 is a member of the claudin family of proteins that are integral components of tight junctions found in epithelial tissues. CLDN18.2 is expressed in a variety of solid tumors, including gastric cancer, pancreatic cancer, biliary cancer, genitourinary tract cancers, colorectal cancer, as well as other cancers. PD-29875 was discovered using PeptiDream’s proprietary PDPS® technology and further optimized at PeptiDream with in vivo imaging and efficacy studies conducted at PDRadiopharma. PeptiDream intends to initially develop the therapeutic (<sup>225</sup>AcPD-29875) and paired diagnostic imaging agent (<sup>64</sup>Cu-PD-29875) for the diagnosis and treatment of gastric cancer. 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 CLDN18.2 expressing tumors that are most likely to have a favorable clinical response from PD29875 treatment.

Gastric cancer is the 5th most common cancer in and the 4th leading cause of cancer death worldwide in 2020, representing 7% of all global cancer diagnoses, with an approximate 5-year survival rate of 32% (worldwide an estimated 1.1 million people were diagnosed with gastric cancer in 2020, with 770,000 deaths), with the incidence expected to increase to ~1.8 million new cases per year by 2040.

♦ **Undisclosed RayzeBio/BMS Program:**

Indication: Solid Tumors;

Modality: PDPS®-originating macrocyclic peptide targeting undisclosed target conjugated to a chelator radiolabeled with <sup>225</sup>Ac (for the therapeutic) or <sup>68</sup>Ga (for the diagnostic);

Partner: RayzeBio, a Bristol Myers Squibb (“BMS”) company; RayzeBio/BMS holds worldwide (ex-Japan) commercialization rights, with PeptiDream/PDRadiopharma holding an option to attain Japan commercialization rights.

Current Status:

The program is continuing toward IND-enabling efforts.

Additional program details:

Program has certain partner limitations on disclosable information.

♦ **<sup>225</sup>Ac-Cadherin3 (PPMX-T002) Program:**

Indication: Solid Tumors;

Modality: monoclonal antibody targeting Cadherin 3 (referred to as P-cadherin or CDH3) conjugated to a chelator originally radiolabeled with <sup>90</sup>Y (now changing to <sup>225</sup>Ac) (for the therapeutic);

Partner: Perseus Proteomics (“PPMX”).

Current Status:

PPMX is in the process of changing the radioisotope conjugated to the antibody from  $^{90}\text{Y}$  to  $^{225}\text{Ac}$ . PPMX-T002 showed specific tumor accumulation in the expansion phase of a Phase 1 study in cancer patients, validating the targeting ability of the CDH3 targeting antibody, and supporting continued efforts. In 2024, PPMX announced that  $^{225}\text{Ac}$ -PPMX-T002 showed greater efficacy in a mouse model of pancreatic cancer compared to  $^{90}\text{Y}$ -PPMX-T002 and reported the results at the European Association of Nuclear Medicine (EANM) 2024 Meeting.

Additional program details:

The PPMX-T002 program originated from a partnership between PPMX and FUJIFILM Toyama Chemical (FFTC), and therefore the rights were transferred to PeptiDream/PDRadiopharma post-acquisition. The CDH3 targeting antibody was discovered by PPMX. PPMX is currently leading all research, development and partnering efforts for the program. CDH3 is known to be overexpressed in a number of cancers, including ovarian cancer, biliary tract cancer, and head and neck squamous cell cancer, with low expression in most normal tissues.

♦  **$^{18}\text{F}$ -Flortaucipir (Tauvid™) Program:**

Indication: Brain imaging of aggregated tau neurofibrillary tangles (NFTs) in patients with cognitive impairment being evaluated for Alzheimer's disease (AD);

Modality: small molecule flortaucipir radiolabeled with  $^{18}\text{F}$  for PET imaging;

Partner: **Eli Lilly and Company ("Lilly")**.

Current Status:

As announced in December 2024, PDRadiopharma received approval from the Ministry of Health, Labour and Welfare for the regulatory approval of TAUVID™ in Japan for the indication of supporting the proper use of donanemab in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease.

Additional program details:

$^{18}\text{F}$ -Flortaucipir is the first and only FDA-approved radioactive PET tracer for imaging aggregated tau NFT deposition in the brain.  $^{18}\text{F}$ -Flortaucipir was approved in the United States in 2020 for use with PET imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for AD. PeptiDream expects that the approval of  $^{18}\text{F}$ -Flortaucipir, along with PDRadiopharma's already approved AMYVID®, will greatly expand the use of PET diagnostic reagents in the diagnosis and monitoring of AD.

♦  **$^{18}\text{F}$ -PD-L1 ( $^{18}\text{F}$ -BMS-986229) Program:**

Indication: Oncology Imaging;

Modality: PDPS®-originating macrocyclic peptide targeting PD-L1 (programmed death ligand-1) radiolabeled with  $^{18}\text{F}$  for PET imaging ( $^{18}\text{F}$ -BMS-986229);

Partner: **BMS**.

Current Status:

$^{18}\text{F}$ -BMS-986229 (ClinicalTrials.gov Identifier: NCT04161781) recently completed a Phase 1 observation study, conducted at Memorial Sloan Kettering Cancer Center, in which it was being investigated 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 gastroesophageal cancers ("GEC") in patients. The Phase 1 study met both its primary safety and feasibility endpoints, and the results were published in the Journal of Nuclear Medicine (May 2024; Volume 65:5: Cytryn et al.,  *$^{18}\text{F}$ -BMS-986229 PET to Assess Programmed-Death Ligand 1 Status in Gastroesophageal Cancer*). The results showed that PET imaging with  $^{18}\text{F}$ -BMS-986229 is a safe and feasible noninvasive tool for assessing PD-L1 expression in patients with GEC and may provide a more comprehensive picture of PD-L1 expression, capturing spatial heterogeneity that single-site biopsies may miss.

Patients who showed  $^{18}\text{F}$ -BMS-986229 accumulation in any lesions by PET imaging had longer progression-free survival ("PFS")(any accumulation; median PFS 28.4 months vs no accumulation; median PFS 9.9 months) when treated with frontline PD-1 inhibitors, suggesting that PET imaging with  $^{18}\text{F}$ -BMS-986229 has the potential to improve patient

selection and predict outcomes for anti-PD-1 therapy, which could ultimately lead to better treatment decisions and improved clinical outcomes for patients with GEC.

Additional program details:

Program has certain partner limitations on disclosable information.

**(A)-3: Preclinical Discovery & Development Radiopharmaceutical Programs:**

In addition to the clinical-stage programs described above, PeptiDream has an extensive targeted peptide-RI conjugate discovery pipeline, with multi-program peptide-RI conjugate discovery collaborations with Novartis (2019 & 2024), RayzeBio (2020; now a BMS company), and Genentech (2023), in addition to a growing number of fully-owned internal peptide-RI conjugate programs. As programs arising from these efforts reach the clinical candidate selection/initiation of IND-enabling studies stage, they will be added to the above pipeline table/list. PeptiDream holds options to Japan commercialization rights for all peptide-RI collaboration programs with RayzeBio/BMS and Genentech.

**(A)-4: In-licensed Clinical Stage Radiopharmaceutical Programs:**

PeptiDream/PDRadiopharma are actively searching for attractive high-value radiotherapeutic and radiodiagnostic programs to in-license/partner to develop and commercialize in Japan. Since PeptiDream's 2022 acquisition of PDRadiopharma, the companies have now executed three partnering/in-licensing deals; in 2022 with Eli Lilly for the development and commercialization of the radiotracer <sup>18</sup>F-Flortaucipir in Japan, in 2023 with LinQMed for the development and commercialization of the radiotherapeutic <sup>64</sup>Cu-ATSM in Japan, and in 2024 with Curium for the development and commercialization of <sup>177</sup>Lu-PSMA-I&T and <sup>64</sup>Cu-PSMA-I&T in Japan. As the number of global companies developing targeted radiopharmaceuticals continues to grow rapidly, with the vast majority of those companies focused on the US market, PeptiDream/PDRadiopharma are uniquely positioned to be the partner of choice for those companies wishing to commercialize their products in Japan. The strategic partnering/ in-licensing of high-value programs represents an important complementary strategy to PeptiDream's own internal and partnered discovery efforts.

**(A)-5: Other Notable Items in the Radiopharmaceutical Business:**

PDRadiopharma provides various additional products and services to support the radiopharmaceutical sector in Japan. In 2023, PDRadiopharma acquired assets related to four products ("Bridgea GATEWAY", "Bridgea TIMER", "onti" and "ankan") from RYUKYU ISG, enabling full automation and digitalization of dose management, both of which will contribute to the reduction of medical accident risks by improving operational efficiency of healthcare providers.

On September 2024, PDRadiopharma announced the launch of two additional medical digital transformation (DX) systems, "Bridgea TIMER Guide" and "onti-d" to provide further operational support for healthcare professionals by leveraging data and digital technologies. The Bridgea TIMER Guide is time management system for PET (Positron Emission Tomography) examination. The "Bridgea TIMER Guide" is an optional enhancement to the "Bridgea TIMER" system, which facilitates the sharing of PET scan time management information among healthcare professionals, enabling real-time monitoring of patient status throughout the examination. The "Bridgea TIMER Guide" provides patients with step-by-step instructions through audio and visual displays, guiding them from preparation and administration to imaging and the completion of the examination. This system offers remote patient guidance, improving operational efficiency for healthcare professionals and helping reduce radiation exposure.

The onti-d: Radiopharmaceutical Operational Support System is an advanced information platform designed to support the electronic recording, management, and optimization of radiation exposure doses. The "onti" includes operational support features such as patient information acquisition, prevention of administration errors, automatic calculation of administered doses, and the creation of radiopharmaceutical usage records, those are not equipped with conventional radiation dose management systems.

**(B) Non-Radiopharmaceuticals Drug Discovery Business:**

In addition to PeptiDream’s radiopharmaceutical business, with our proprietary Peptide Discovery Platform System (PDPS®) at its core, PeptiDream operates as one of the leading companies in the discovery of (1) **peptide-based therapeutics**, (2) **peptide-drug conjugates (“PDCs”)** and (3) **multi-functional peptide conjugates (“MPCs”)**, through collaboration and license agreements with a large network of global pharmaceutical and strategic partners, in addition to a growing internal pipeline of programs, with the aim of discovery and developing the next-generation of innovative peptide-based therapeutics.

#### **B)-1: Non-Radiopharmaceutical Development Programs & Pipeline**

Below is a table of PeptiDream’s current clinical-stage Non-Radiopharmaceutical pipeline. **Disease Area, Pipeline, Clinical-stage** (Investigational New Drug enabling studies “**IND-enabling**”; Phase 1 “**Ph 1**”; Phase 2 “**Ph 2**”; Phase 3 “**Ph 3**”), **Partner** are listed. Following the table is a brief description of each program.

	Disease Area	Pipeline	Pre-clinical/ IND-enabling	Ph1	Ph2	Ph3	Partner
Clinical Programs	Acromegaly	GhR Antagonist (AZP-3813)					AstraZeneca
	Oncology	PD-L1 Inhibitor					Bristol-Myers Squibb
	Multiple Myeloma	CD38-ARM™ (BHV-1100 + NK)					Biohaven
	Not Disclosed	Merck (Not disclosed)					Merck
	Inflammatory Diseases	Merck (Not disclosed)					Merck
	COVID-19	S2-protein Inhibitor (PA-001)					PeptiAID
Selected PC Programs	Allergic Diseases	KIT Inhibitor (MOD-B)					Alivexis
	Obesity/ Muscle Disorders	Oral Myostatin Inhibitor					PeptiDream
	Not Disclosed	Oral Peptide Therapeutics					PeptiDream
	Not Disclosed	Oligo/cytotoxic-PDC					Not Disclosed
	Not Disclosed	Peptide Therapeutics					Not Disclosed

Note: Above list only includes major pipeline programs in clinical stage and selected pre-clinical stage

#### ♦ **GhR antagonist Program (AZP-3813):**

Indication: Acromegaly;

Modality: AZP-3813 is a **PDPS®-originating macrocyclic peptide** growth hormone receptor antagonist (“GHRA”);

Partner: **Alexion/AstraZeneca (Amolyt Pharma was acquired by AstraZeneca in July 2024).**

Current Status:

AZP-3813 completed a Phase 1 study in May 2024 investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AZP-3813 in a randomized double-blind placebo-controlled single and multiple ascending dose studies (SAD and MAD, respectively). In the SAD study, 5 subjects received a single subcutaneous administration of 3 mg AZP-3813 or placebo (3:2) and 8 subjects received 10, 20, 40, 60, 90, 120 mg AZP-3813 or placebo (6:2). In the MAD study, 8 subjects received 10, 20, 40, 60, 90, 120 mg AZP-3813 or placebo (6:2) QD for 14 consecutive days. Treatment was well tolerated in all subjects with no safety concerns. Cmax and AUC increased in a dose-proportional manner. The half-life of AZP-3813 was estimated to be 20-22 hours. In the SAD study, AZP-3813 induced a dose-related decrease in circulating IGF-1 levels at doses of 10 mg and above with a more prolonged reduction up to 72 hours at higher doses. In the MAD study, AZP-3813 induced a gradual and sustained dose-related decrease in circulating IGF-1 levels, with a larger effect after 2 weeks of dosing as compared to single administration at the same dose, consistent with a cumulative effect of repeated administration. Amolyt Pharma reported that these data clearly demonstrate that the novel GHRA, AZP-3813, substantially

decreases circulating IGF-1 levels in healthy individuals, thereby supporting further testing in patients with acromegaly.

Additional program details:

PeptiDream and Amolyt (now AstraZeneca) entered into a strategic partnership and license option agreement in December 2020, to which Amolyt exercised its option to globally license a portfolio of macrocyclic peptide GHRA in September 2021. The results of the Phase 1 safety study were reported by Amolyt Pharma at the 26<sup>th</sup> European Congress of Endocrinology (ECE; May 11-14, 2024, Stockholm, Sweden) and at the 2024 Endocrine Society Meeting (ENDO; June 1-4, 2024, Boston, USA). Acromegaly is a rare, chronic endocrine disorder typically caused by a benign growth hormone (GH)-secreting pituitary adenoma that stimulates over-production of insulin-like growth factor-1 (IGF1) from the liver. The goal in treating acromegaly is to normalize IGF-1 levels to alleviate the symptoms and manage the potential medical complications caused by its excess. Treatment with somatostatin analog (SSA) monotherapy does not provide optimal control of circulating IGF-1 levels in the majority of patients. AZP-3813 is a 16-amino acid, bicyclic peptide that binds to the Growth Hormone (“GH”) Receptor and prevents circulating GH from stimulating the production of IGF1. Studies have shown that AZP-3813 potentially decreases circulating levels of IGF-1 and further suppressive effects are observed when combined with the SSA, octreotide. Therefore, AZP-3813 is being developed as an add-on therapy for the treatment of acromegaly in patients insufficiently controlled with SSAs.

♦ **PD-L1 Inhibitor Program:**

Indication: Oncology;

Modality: PDPS®-originating macrocyclic peptide PD-L1 inhibitor (Program Identifier not disclosed);

Partner: PeptiDream.

Current Status:

PeptiDream has received the synoptic Clinical Study Report from BMS and is reviewing the results from the Phase 1 Study (ISRCTN17572332) that investigated the safety, tolerability, and pharmacokinetics in healthy volunteers of the oral PD-L1 inhibitor program, while exploring next options for the program.

Additional program details:

As announced in October 2023, BMS decided to not advance this program beyond the 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.

♦ **CD38-ARM™ (BHV-1100) Program:**

Indication: Multiple Myeloma;

Modality: BHV-1100 (CD38-ARM™) is a heterodimeric peptide conjugate composed of a PDPS®-originating macrocyclic peptide targeting CD38 conjugated to a macrocyclic peptide targeting IgG;

Partner: Biohaven, LTD. (“Biohaven”).

Current Status:

BHV-1100 recently completed an open-label single center interventional Phase 1a/1b study (ClinicalTrials.gov Identifier: NCT04634435; 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. A total of 7 MM patients were enrolled in the Phase 1 study.

Additional program details:

Program has certain partner limitations on disclosable information.

♦ **Merck Undisclosed Program:**

Indication: Undisclosed;



Modality: **PDPS®-originating macrocyclic peptide** targeting an undisclosed target (Program Identifier not disclosed);

Partner: **Merck & Co., Inc., Rahway, NJ, USA, (“MSD”).**

Current Status:

The undisclosed therapeutic macrocyclic 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 study to investigate the safety, tolerability, and pharmacokinetics in healthy volunteers (initiated in July 2023, Identifier: no clinical trial identifier obtained due to the fact that the study is being conducted in healthy volunteers). The details of the ongoing Phase 1 study have not been released.

Additional program details: Program has certain partner limitations on disclosable information.

♦ **Merck Undisclosed Program:**

Indication: Inflammatory Disease;

Modality: **PDPS®-originating macrocyclic peptide** targeting an undisclosed target (Program Identifier not disclosed);

Partner: **Merck & Co., Inc., Rahway, NJ, USA, (“MSD”).**

Current Status:

The undisclosed therapeutic macrocyclic 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 study to investigate the safety, tolerability, and pharmacokinetics in healthy volunteers (initiated in June 2024, Identifier: no clinical trial identifier obtained due to the fact that the study is being conducted in healthy volunteers). The details of the ongoing Phase 1 study have not been released.

Additional program details:

Program has certain partner limitations on disclosable information.

♦ **S2-Protein Inhibitor (PA-001) Program:**

Indication: COVID-19;

Modality: PA-001 is a **PDPS®-originating macrocyclic peptide** inhibitor of the S2-protein expressed on the surface of the COVID-19 virus;

Partner: **PeptiAID.**

Current Status:

As announced on October 9, 2024, PeptiAID announced that the dosing of the first subject in the Phase 1 study being conducted to evaluate the safety, tolerability, and pharmacokinetics of PA-001 in healthy elderly volunteers (initiated in October 2024, Identifier: no clinical trial identifier obtained due to the fact that the study is being conducted in healthy volunteers). The Phase 1 results are anticipated in H2-2025.

Additional program details:

PA-001 was adopted by the Japan Agency for Medical Research and Development (AMED) as part of the “Research Program on Emerging and Re-emerging Infectious Diseases” (Project Name: Pre-clinical and Phase 1 studies of PA-001 to pursue treatment agent for COVID-19) and received funding support from AMED to conduct clinical development activities. PeptiAID previously conducted Specified Clinical Research of PA-001 in accordance with the Clinical Trials Act in Japan in 30 healthy Japanese adult male volunteers and confirmed that PA-001 was safe and well tolerated and demonstrated a clear dose-dependent pharmacokinetics profile, as reported August 10, 2022.

♦ **Myostatin Inhibitor Program:**

Indication: Obesity, DMD, SMA, and other muscular diseases;

Modality: **PDPS®-originating macrocyclic peptide** inhibitor of Myostatin;

Partner: **PeptiDream.**

Current Status:

Ongoing preclinical development activities while exploring clinical development options for this exciting program, including discussions with potential partners interested in licensing/partnering the program. PeptiDream presented a portion of the preclinical results at its R&D Day event on December 12, 2024 (R&D Day presentation materials are available on the PeptiDream website).

Additional program details:

PeptiDream has discovered a series of potent macrocyclic and bridged-macrocyclic peptide inhibitors of Myostatin. Myostatin (also known as growth differentiation factor 8, or GDF8), along with GDF11 and Activin, are members of the transforming growth factor-beta (TGFbeta) superfamily, and function in a complex process that regulates muscle growth and function. 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 more recently the potential treatment for obesity, metabolic syndrome, and type 2 diabetes mellitus. In preclinical DMD mice models, PeptiDream previously reported weekly administration of its peptide myostatin inhibitors, via subcutaneous or oral administration, resulted in both strong suppression of myostatin signaling and high exposure in muscle, yielding significant improvements in four-limb grip strength in treated animals. These extremely promising findings strongly supported their continued development for potential use in DMD, and given the results, PeptiDream initiated additional studies to investigate the use of its oral myostatin peptide inhibitors in obesity, where there is growing evidence that myostatin inhibitors can preserve lean body mass in individuals living with obesity and taking a GLP-1 receptor agonist (such as semaglutide). To this end, peptides from this series were tested in a diet-induced obesity (“DIO”) model where mice were given either a high-fat (60%) diet plus semaglutide (0.12 mg/kg, daily injection), or a high-fat diet (60%) plus semaglutide (0.12 mg/kg, daily injection) in combination with PeptiDream’s peptides orally administered (0.5, 1.5, 4.5 mg/kg; daily dose or 3, 10, 30 mg/kg; weekly dose). Body weight of the animals was measured every 2 days and Echo MRI was utilized to analyze changes in both Fat Mass and Lean Body Mass at 14 and 28 days of treatment. Key findings of the studies: **Significant weight loss:** Mice receiving the combination of oral peptide myostatin inhibitor with semaglutide showed a significant reduction in body weight compared to controls, with weight loss maintained over the study period. **Lean mass preservation:** Unlike many traditional weight-loss therapies that lead to a loss of both fat and lean muscle mass, both daily and weekly administration of PeptiDream’s oral peptide myostatin inhibitor successfully preserved lean body mass when administered in combination with semaglutide, highlighting its potential for improving body composition. **Enhanced therapeutic potential:** The results suggest that the synergistic effects of myostatin inhibition and semaglutide could be an effective strategy for patients with obesity, offering a novel approach to weight management that avoids muscle loss, a common drawback of many current obesity treatments.

◆ **cKIT Inhibitor (MOD-B) Program:**

Indication: Mast-cell driven immune-inflammatory and allergic diseases;

Modality: Small molecule inhibitor of KIT whose discovery was enabled by a PDPS®-originating macrocyclic peptide targeting KIT;

Partner: **Alivexis** (previously known as Modulus Discovery).

Current Status:

The nominated clinical development candidate, announced in August 2023, is a novel potent and selective small molecule inhibitor of 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. Alivexis continues to conduct IND-enabling studies with the aim of moving the cKIT inhibitor program into clinical trials in the future.

Additional program details:

Alivexis is actively engaged in partnering/out-licensing activities for the MOD-B program.

### **(B)-2: Preclinical Discovery & Development Non-Radiopharmaceutical Programs:**

In addition to the clinical-stage programs described above, PeptiDream also has an extensive preclinical pipeline of programs, both partnered and fully owned, across the following three modalities: **(1) peptide-based therapeutics**, **(2) peptide-drug conjugates (“PDCs”)** and **(3) multi-functional peptide conjugates (“MPCs”)**, providing PeptiDream with an exceptionally robust and highly diverse preclinical pipeline from which to generate clinical development candidates to advance into the clinical-stage, which will undoubtedly serve as an important engine for growth for the company. As programs arising from these efforts reach the clinical candidate selection/initiation of IND-enabling studies stage, they will be added to the above pipeline table.

In the **peptide-based therapeutics space**; as one of the leading peptide discovery companies in the world, PeptiDream has announced a number of collaborations with large global pharma and a diverse array of strategic partners, with a multitude of programs spanning a wide variety of disease areas, therapeutic mechanisms, and administration routes. In 2024, PeptiDream continues to see exceptional progress across our peptide therapeutic programs, in particular, making significant advances in the oral delivery of peptide therapeutics.

In the **PDC space**; with macrocyclic peptides increasingly proving to be the ideal agents for the targeted delivery of a wide variety of therapeutic payloads, from tumor killing radioisotopes (programs and partnerships described in the Radiopharmaceutical section above) and cytotoxic payloads to tissue modifying oligonucleotide drugs, PeptiDream has established a strong leading position in the field, with a broad array of preclinical programs across announced collaborations with **Shionogi** (2019; tissue targeting PDCs), **Takeda** (2020/2021; muscle and CNS targeting PDCs incorporating PeptiDream’s Transferrin Receptor targeting peptides discovered with JCR Pharma), **Alnylam Pharmaceuticals, Inc.** (2021; tissue targeting PDCs), **Lilly** (2022; tissue targeting PDCs), **Merck** (2022; tumor targeting PDCs) and **Novartis** (2024; tissue targeting PDCs).

In the **MPC space**; the past decade has seen a number of bispecific antibodies therapeutics approved, and more recently, the advent of newer trispecific/ multispecific antibodies, capable of binding multiple antigens simultaneously, providing for a spectacular array of potential formats and thus exciting new ways to treat disease never before possible. Macrocyclic peptides can also be combined into such multifunctional molecules through the simple conjugation of two or more peptides. PeptiDream has a growing preclinical pipeline of highly promising internal MPC programs. Additionally, PeptiDream continues to expand the uses of its macrocyclic peptides, announcing a collaboration with **Astellas** (2023) in the field of targeted degraders.

### **(B)-3: Select Highlights from the Non-Radiopharmaceutical Business in FY2024:**

*(Please see the relevant Press Releases for additional information on each highlight)*

- ♦ **March 2024:** Amolyt Enters into Definitive Agreement to be Acquired by AstraZeneca.
- ♦ **March 2024:** PeptiGrowth Inc., PeptiDream Affiliated Company, Announces Product Launch of TPO-alternative peptide (TPOR agonist) – PG-010.
- ♦ **June 2024:** PeptiAID Submits IND for a Phase 1 Clinical Trial of PA-001.
- ♦ **June 2024:** Merck Initiates a Phase 1 Clinical Trial of Second PDPS® Program (2<sup>nd</sup> Merck program to enter the clinic).
- ♦ **July 2024:** Phase 1 Clinical Trial of AZP-3813, Partnered with Amolyt, Meets Study Endpoints.
- ♦ **August 2024:** Development Milestone in Collaboration with POLA CHEMICAL INDUSTRIES.
- ♦ **September 2024:** PeptiGrowth Inc., PeptiDream Affiliated Company, Announces Product Launch of FGF2-alternative peptide (FGFR1c agonist) – PG-011.
- ♦ **October 2024:** PeptiAID Announces Dosing of First Subject in Phase 1 Clinical Trial of PA-001.
- ♦ **December 2024:** PeptiDream Announces Preclinical Results Demonstrating Efficacy of Oral Myostatin Inhibitors in Preventing Loss of Lean Muscle Mass Associated with Semaglutide Treatment.
- ♦ **December 2024:** PeptiDream Announces Achievement of Development Milestone in Discovery Alliance with Johnson & Johnson.

### **(B)-4: PDPS® Technology Transfer Business:**

PeptiDream has non-exclusively licensed its PDPS® technology to 11 companies: **BMS** (2013), **Novartis** (2015), **Lilly** (2016),

**Genentech** (2016), **Shionogi and Co.** ("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. 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.

**(C) PeptiDream Equity Shareholdings:**

Below is a brief description of PeptiDream Equity Shareholdings as of December 31, 2024.

**PeptiGrowth:** *At the time of reporting, PeptiDream holds an approximately 39.5% equity stake in PeptiGrowth.*

PeptiGrowth (*Tokyo, Japan*) was established in 2020 as a joint venture between **PeptiDream** and **Mitsubishi Corporation**, with the aim 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. 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® 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. Mitsubishi Corporation is actively involved in the sales and marketing of PeptiGrowth's growing lineup of products.

PeptiGrowth has launched eleven (11) products to date; 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 neurotrophic factor (BDNF)), PG-004 (a peptide alternative to Noggin), PG-005 (a BMP7 selective inhibitor), PG-006 (a BMP4 selective inhibitor) in 2022, PG-007 (a VEGFR2 agonist as an alternative to VEGF), PG-008 (a β-catenin pathway agonist as an alternative to Wnt3a), PG-009 (a synthetic version of EGF) in 2023, PG-010 (TPOR agonist as an alternative to TPO, and PG-011 (FGFR1c agonist as an alternative to FGF2) in 2024. The companies aim to continue to launch additional products in the future.

**PeptiAID:** *At the time of reporting, PeptiDream holds an approximately 39.4% equity stake in PeptiAID.*

**PeptiAID** (*Kanagawa, Japan*) was established in 2020 as a joint venture between **PeptiDream**, **Fujitsu**, **Mizuho Capital**, **Takenaka Corporation**, and **Kishida Chemical**, with the aim to discover and develop 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. In May 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. On June 4, 2024, PeptiAID submitted an IND application to the FDA to conduct a Phase 1 safety study, and in July 2024, the IND application was accepted, paving the way for the Phase 1 safety study, with the first subject dosed in October 2024.

**PeptiStar:** *At the time of reporting, PeptiDream holds less than 20% equity stake in PeptiStar.*

PeptiStar (*Osaka, Japan*) was established in 2017 as a joint venture between **PeptiDream, Shionogi, and Sekisui Chemical Co., Ltd.**, with the aim to create 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. PeptiStar’s CDMO manufacturing facility is located in Osaka, Japan.

**LinqMed:** *At the time of reporting, PeptiDream holds a less than 15% equity stake in LinqMed.*

LinqMed (*Chiba, Japan*) was established in 2022, as a bioventure arising from the National Institutes for Quantum Sciences and Technology (“QST”), with the aim to bring innovative “visible” anti-cancer drugs to patients. PeptiDream participated in LinqMed’s Series A equity financing (December 2023) and again in LinqMed’s recent Series B equity financing (January 2025).

**Alivexis:** *At the time of reporting, PeptiDream holds a less than 5% equity stake in Modulus Discovery.*

Alivexis, originally Modulus Discovery (*Tokyo, Japan & Boston, USA*), was established in 2016 with the aim of pursuing a technology and computational-driven approach to drug discovery.

#### **(D) PeptiDream and PDRadiopharma (PeptiDream Group) Locations, Facilities, and Employee Headcount:**

PeptiDream’s corporate offices and state-of the-art research labs (~7,950 *sqm*<sup>2</sup> of office and lab space) are located in (Tonomachi) Kawasaki, Japan. PDRadiopharma’s corporate, sales, and marketing offices are located in Tokyo, Japan with 8 branch offices, PDRadiopharma’s main manufacturing site located in (Sanmu City) Chiba, Japan (~25,200 *sqm*<sup>2</sup> of research and manufacturing facilities), and PET laboratories located in (Ibaraki City) Osaka, Japan and (Tonomachi) Kawasaki, Japan (*each with ~2,200 sqm*<sup>2</sup> of office and lab space).

On December 17, 2024, PeptiDream/PDRadiopharma announced plans to construct a new state-of the-art manufacturing facility at Kazusa Akademia Park in Chiba, Japan, for the clinical supply and commercial production of the company’s next generation targeted radiopharmaceuticals (*utilizing the radionuclides Lu-177, Ac-225, Cu-64*). The new to-be-built manufacturing facility will sit on a 14-acre (57,000 *sqm*<sup>2</sup>) site within Kazusa Akademia Park, an industrial park located in central Chiba (~45min drive west to PeptiDream/Kawasaki PET lab/ Haneda Airport and ~1hr drive north to Chiba Sanmu site/Narita Airport) and will focus on manufacturing the Group’s growing pipeline of targeted radiotherapeutic and theranostic product offerings. Additionally, its proximal location to both Haneda and Narita Airports, will allow the Group to potentially export products out of Japan to other markets within the Asia-Pacific region as the radiopharmaceutical field continues to grow. Construction of the new facility is scheduled to start in 2026 and become fully operational in 2028. The project is expected to cost approximately 10 billion JPY and will be completely funded by cash on hand.

As of December 31, 2024, the Group had a total headcount of 732 employees (743 when including its 11 board members), (PeptiDream Inc; 217 employees, PDRadiopharma Inc., 515 employees).

#### **(E) ESG (Environmental, Social, and Governance) Initiatives and Goals:**

PeptiDream Group continues its commitment to promoting ESG (Environmental, Social, and Governance) initiatives as well as its sustainability efforts, with the Group’s focus areas, top material issues, relevant policies and data proactively disclosed on the corporate website in the Group’s 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 electric power consumption, PeptiDream selected an electricity supplier which proactively promotes a shift towards renewable energy. Additionally, PeptiDream has introduced CO<sub>2</sub> (carbon dioxide)-free power from its supplier to power both PeptiDream’s head office and R&D facilities. These efforts should allow PeptiDream to realize its medium-term goal of “carbon-neutral”

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 key roles in R&D and management to engage in science-based discussions and decision-making regardless of their age, gender or cultural background. Toward that end, PeptiDream has set four metrics as quantitative indicators of a diverse human workforce (\*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 2024: 45.0%, target for 2030: Maintain 50% or more); (2) Female manager ratio (end of December 2024: 18.3%, target for 2030: 30% or more); (3) Ratio of foreign employees or employees with overseas work experience (\*2) (end of December 2024: 31.7%, target for 2030: Maintain 30% or more); and (4) Ratio of young employees (in 20s/30s) (end of December 2024: 20.0%, 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 toward sustainability. In January 2022, PeptiDream was awarded 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 for the third consecutive year in 2023. PeptiDream reached the Leadership level, the highest level, as a company that excels in its efforts and information disclosure in climate change. In July 2024, PeptiDream was selected to remain a constituent of the FTSE4Good Index Series and FTSE Blossom Japan Index for the FOURTH consecutive year and of the FTSE Blossom Japan Sector Relative Index for the THIRD 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. In January 2025, PeptiDream awarded Prime Status in ISS ESG Corporate Rating for the first time

As a result of the above, for the Fiscal Year Ended December 31, 2024, the Drug Discovery and Development Business recorded revenue of 31,313,392 thousand yen (a 18,610,427 thousand yen increase year on year), segment profit of 20,957,312 thousand yen (a 14,569,410 thousand yen increase year on year), the Radiopharmaceutical Business recorded revenue of 15,363,130 thousand yen (a 646,097 thousand yen decrease year on year), segment profit of 246,528 thousand yen (a 228,616 thousand yen decrease year on year), and the Group recorded revenue of 46,676,523 thousand yen (a 17,964,329 thousand yen increase year on year), core operating profit of 21,225,338 thousand yen (a 14,094,378 thousand yen increase year on year), operating profit of 21,113,841 thousand yen (a 14,340,793 thousand yen increase year on year), profit before tax of 20,888,805 thousand yen (a 16,535,336 thousand yen increase year on year), and profit attributable to owners of parent of 15,014,922 thousand yen (a 11,979,089 thousand yen increase year on 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 Fiscal Year Ended December 31, 2023	Results for the Fiscal Year Ended December 31, 2024	Change	%
Core operating profit	7,165,554	21,225,338	14,094,378	196.2
Accounting effects of business acquisitions and acquisition- related costs	346,381	111,497	(234,884)	(67.8)
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	46,125	—	(46,125)	(100.0)
Operating profit	6,773,047	21,113,841	14,340,793	211.7

## (2) Overview of Financial Position for the Fiscal Year Under Review

Total assets at the end of the Fiscal Year Ended December 31, 2024 increased by 23,305,812 thousand yen from the end of the previous fiscal year to 92,769,826 thousand yen. This was mainly because of increases of 28,610,071 thousand yen in cash and cash equivalents, and 2,395,333 thousand yen in deferred tax assets, despite a decrease of 9,242,214 thousand yen in other financial assets.

Liabilities increased by 6,893,224 thousand yen from the end of the previous fiscal year to 36,007,527 thousand yen. This was mainly because of increases of 7,035,492 thousand yen in income taxes payable, and 2,128,476 thousand yen in trade and other payables, despite a decrease of 2,586,259 thousand yen in borrowings.

Equity increased by 16,412,588 thousand yen from the end of the previous fiscal year to 56,762,298 thousand yen. This was mainly because of increases of 1,201,444 thousand yen in other components of equity due to the recording of other comprehensive income, and 15,014,922 thousand yen in retained earnings due to the recording of profit.

### (3) Overview of Cash Flows for the Fiscal Year Under Review

Cash and cash equivalents for the Fiscal Year Ended December 31, 2024 increased by 28,610,071 thousand yen from the end of the previous fiscal year to 48,117,933 thousand yen.

Status of cash flows and related factors during the Fiscal Year Ended December 31, 2024 are described below.

#### (Cash flows from operating activities)

Cash flows from operating activities resulted in a cash inflow of 23,844,988 thousand yen (a 11,424,019 thousand yen increase in inflow year on year). This was mainly due to the recording of profit before tax of 20,888,805 thousand yen, depreciation and amortization of 2,248,471 thousand yen, and an increase in trade and other payables of 1,747,189 thousand yen, despite income taxes paid of 2,178,823 thousand yen.

#### (Cash flows from investing activities)

Cash flows from investing activities resulted in a cash inflow of 8,370,789 thousand yen (a 7,068,249 thousand yen increase in inflow year on year). This was mainly due to proceeds from sale of investment securities of 10,935,460 thousand yen, despite payments for purchases of investment securities of 377,000 thousand yen, and purchase of property, plant and equipment of 2,076,502 thousand yen.

#### (Cash flows from financing activities)

Cash flows from financing activities resulted in a cash outflow of 2,994,633 thousand yen (compared with an inflow of 264,191 thousand yen in the same period of the previous fiscal year). This was mainly due to repayments of long-term borrowings of 2,640,000 thousand yen, and repayments of lease liabilities of 373,220 thousand yen.

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

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

#### 【Company performance】

	Results for the full year ended December 31, 2022	Results for the full year ended December 31, 2023	Results for the full year ended December 31, 2024	Forecasts for the full year ending December 31, 2025
	2022/Jan ~ 2022/Dec	2023/Jan ~ 2023/Dec	2024/Jan ~ 2024/Dec	2025/Jan ~ 2025/Dec
Net sales (JPY millions)	26,852	28,712	46,676	49,000
Changes from the previous corresponding period (%)	185.0	6.9	62.6	5.0
Core operating profit (JPY millions)	9,637	7,165	21,259	21,700
Changes from the previous corresponding period (%)	135.5	(25.6)	196.7	2.2
Operating profit (JPY millions)	8,980	6,773	21,113	21,600
Changes from the previous corresponding period (%)	120.8	(24.6)	211.7	2.3



【Key indices】

	Results for the full year ended December 31, 2022	Results for the full year ended December 31, 2023	Results for the full year ended December 31, 2024	Forecasts for the full year ending December 31, 2025
	2022/Jan ~ 2022/Dec	2023/Jan ~ 2023/ Dec	2024/Jan ~ 2024/ Dec	2025/Jan ~ 2025/Dec
Capital Expenditures (JPY millions)	3,913	1,668	2,618	5,046
Depreciation Expense (JPY millions)	1,973	2,433	2,248	2,081
Research and Development Expenses (JPY millions)	2,915	3,155	4,002	5,652
Year-end headcount (people)	680	725	743	780

- (Notes) 1. The amount that will actually be paid is shown for capital expenditures.  
2. Capital Expenditures of fiscal year ended December 31, 2022, include balance for the purchase of the land (2,586 million yen).

(5) Basic Policy for Profit Distribution and Dividends for the Fiscal Year under Review and the Following Fiscal Year

The PeptiDream Group recognizes that returning profits to shareholders is an important management issue and will consider profit distributions while taking into account operating results and financial conditions. However, the Group believes that at present it is of the utmost importance to focus on the Group's research and development programs and prioritize internal reserves from the viewpoint of maintaining the necessary research and development funds to do so.

## 2. Management Policies

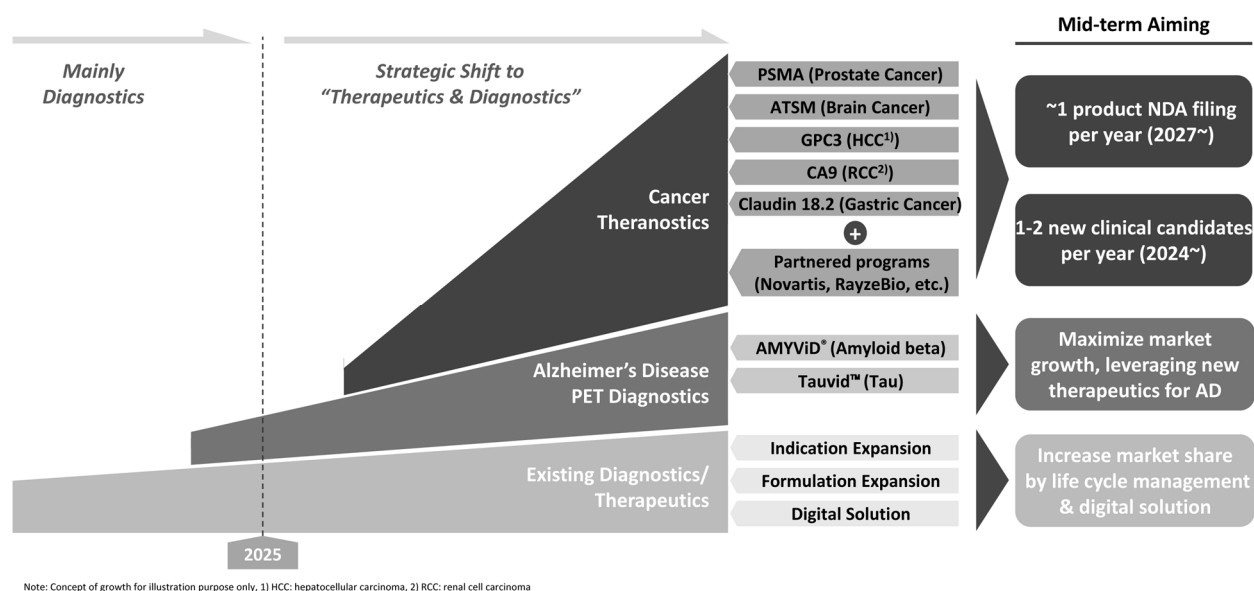
### (1) Basic Management Policy

The PeptiDream Group's mission is to discover the next-generation of transformational medicines that will bring about significant improvements in both medical care and the lives of patients worldwide. Utilizing our proprietary PDPS® technology, one of the world's most advanced drug discovery platform systems, we will lead the discovery, research and development of innovative pharmaceuticals, and through the integration of PDRadiopharma, work to transform the radiopharmaceutical/ radiodiagnostic field toward our goal of bringing the most transformational and impactful pharmaceuticals to patients worldwide.

## (2) Medium- to Long-term Management Strategies and Areas of Focus Issues to be Addressed

### (A) Radiopharmaceutical Business

The Group's Radiopharmaceutical Business is focused on 1) maximizing the value of existing marketed products and services, 2) expanding our product use and offerings in the growing field of brain imaging, and 3) developing new radiotherapeutic products that will drive medium- to long-term growth, mainly in the oncology field.



As shown in the above illustration, the Group is focused in the near term on growing the revenue of our existing products, most of which are radiodiagnostic agents, through the indication expansion, formulation expansion, and offering improved digital solutions for those products. The Group is focused on growing its two Alzheimer's disease PET imaging products, AMYViD<sup>®</sup> and TAUVID<sup>™</sup>, used for the imaging of beta amyloid plaques and neurofibrillary tangles (NFTs), respectively. AMYViD<sup>®</sup> is already on the market, has had its use label expanded, and is covered by insurance. TAUVID<sup>™</sup> was approved in December 2024 and will be on the market earlier in 2025.

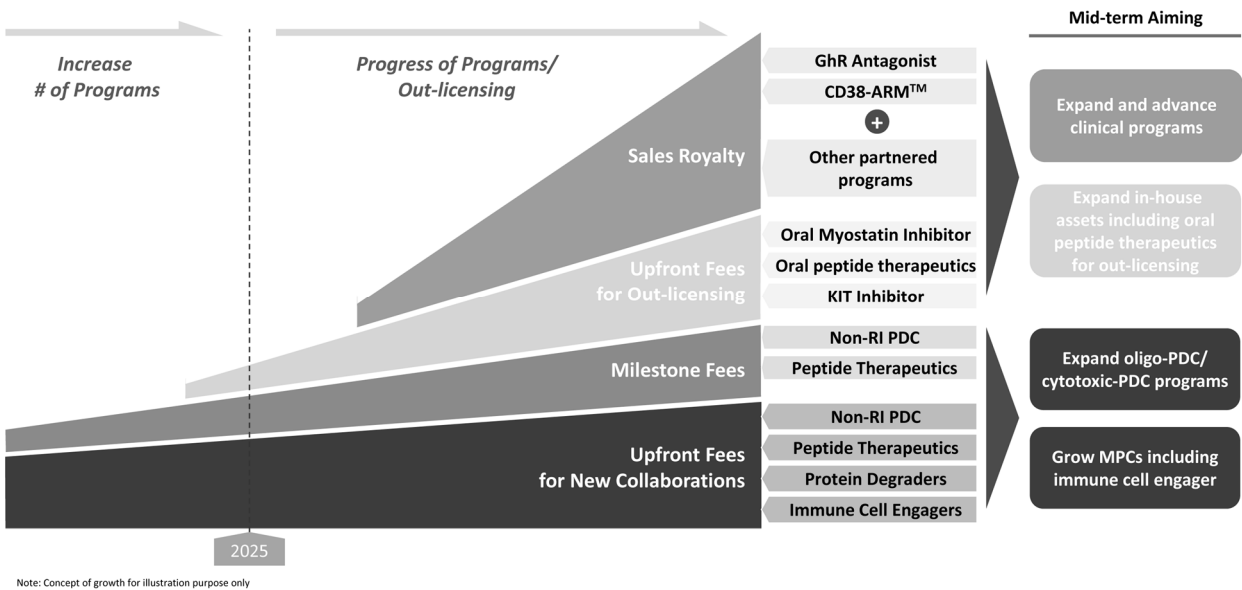
With the approvals of the Alzheimer's therapeutics lecanemab and donanemab in Japan, the Group will be in a position to offer 2 of the major brain imaging agents and provide physicians in Japan with meaningful information on the presence of both pathologies to determine the best treatment regimens for patients suspected of having Alzheimer's disease and/or other forms of dementia.

In the mid-to- long-term, we believe that the development of novel radiotherapeutic products, mainly in the area of oncology, will be a key driver of future growth. We are building a business model that will enable us to continuously expand our pipeline and product portfolio by leveraging the Group's expertise in developing and commercializing radiopharmaceutical products in Japan, the Group's expertise in discovering and developing novel radiotherapeutics, along with the Group's strong business development capabilities and broad global network of collaboration and development partner companies. Until recently, the radiopharmaceutical market has largely been dominated by diagnostic agents, but as we enter a new era of targeted-radiopharmaceuticals, driven by the discovery and development of a growing number of novel and innovative radiotherapeutic and radiodiagnostic products, the Group is ideally positioned for both future growth and to significantly contribute to this renaissance and become the leading radiopharmaceutical company in Japan. Toward this aim, 2024 was a very successful year in growing our clinical-stage pipeline. Our LinqMed partnered ATSM program advanced into Ph3 testing. We announced a new licensing deal with Curium to bring their therapeutic <sup>177</sup>Lu-PSMA-I&T and diagnostic <sup>64</sup>Cu-PSMA-I&T products for prostate cancer into the Japan market. Both our Novartis partnered NNS-309 program and our RayzeBio partnered GPC3 program entered Ph1 studies. We also announced a second development candidate from our collaboration with Novartis in 2024. The Group's own CA9 program completed a Ph0 study in kidney

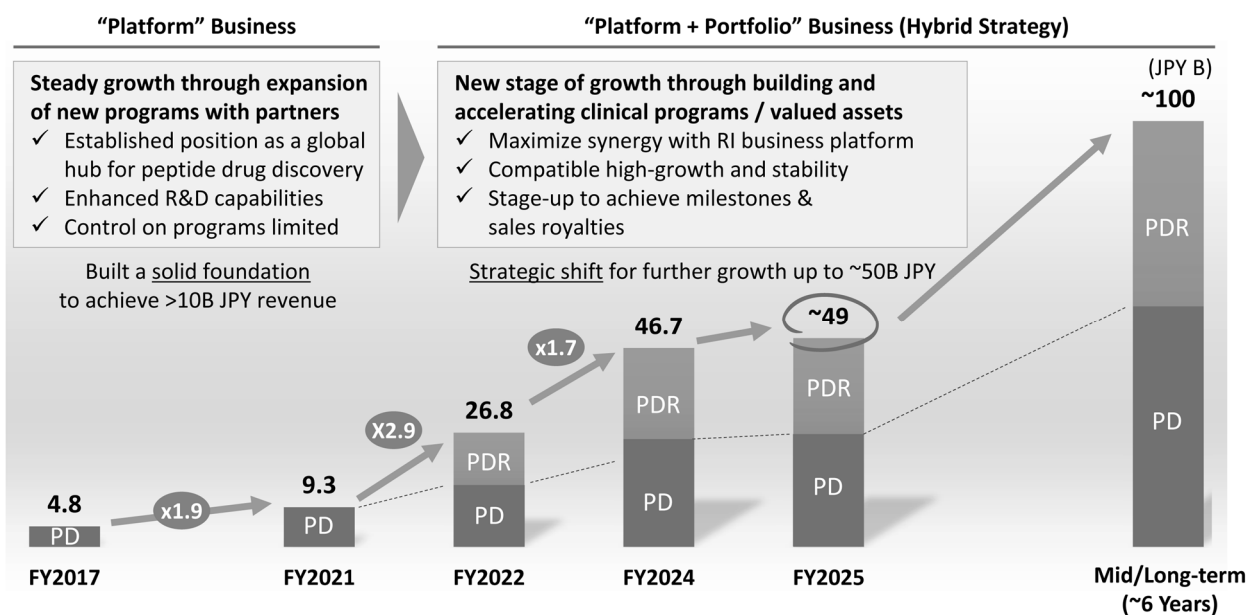
cancer, with positive results paving the way toward moving this program into a Ph1 study in 2025, and we also announced our second wholly owned program targeting CLDN18.2 for gastric cancer, which is now in IND-enabling studies and being planned for a Ph0 study. We anticipate 2025 will also be another excellent year in continuing to grow and expand our radiopharmaceutical clinical pipeline.

**(B) Non-Radiopharmaceutical Drug Discovery Business**

PeptiDream’s Non-Radiopharmaceutical Drug Discovery Business is focused on leveraging its proprietary PDPS® platform to discover (1) peptide therapeutics, (2) PDCs, and (3) MPCs candidates, either internally or in collaboration with wide variety of partners, with the aim of advancing these programs through preclinical development into clinical stage development and toward the market.



As shown in the above illustration, PeptiDream is focused on working across its many partnerships to advance programs from the early discovery/preclinical stages into the clinical-stage and commercialization, thereby unlocking a greater number of growth drivers, all of which represent potential key contributors toward future revenue growth and profitability of the Group. Toward this aim, 2024 was another successful year for PeptiDream. Amolyt reported positive Ph1 results for our GhR program, with Amolyt acquired by Astra Zeneca in 2024. MSD brought their second program into the clinic and PeptiAID also initiated a Ph1 study of PA-001. PeptiDream announced results from its preclinical oral Myostatin program, demonstrating exciting weight loss with lean body mass preservation in obese animal models treated with semaglutide and our oral myostatin inhibitor, and we continue to progress a number of promising internal preclinical programs that we look forward to speaking more about in 2025. We also announced a number of milestones achieved across a number of its partners over the course of 2024, and we anticipate many more to come in 2025. In the medium to long term, PeptiDream will continue to look to maximize the value of the programs it works, and advance programs from discovery/early development into the clinical-stage pipeline.



Note: Financial numbers prior to FY2021 are based on J-GAAP, IFRS applied after FY2022. Revenue for FY2025 and beyond are future outlook.

As shown in the above illustration, following the acquisition of PDRadiopharma, PeptiDream has matured from being a company focused only on early-stage discovery (“platform”), into a company with commercial products and a growing clinical-stage pipeline, in addition to its extensive early-stage discovery efforts (“**platform + portfolio**”). With its unique position in the radiopharmaceutical space in Japan and its extensive discovery pipeline fueling a growing number of clinical-stage programs, the Group believes this new hybrid model brings greater stability to the Group and unlocks a greater number of potential growth drivers, putting the Group on a faster trajectory to future revenue growth and higher profitability.

### 3. Basic Approach to Accounting Standards

The Group has voluntarily adopted the International Financial Reporting Standards (IFRS) with the aim of facilitating international comparisons of financial data in capital markets and further improving the level of business management, among others from the first quarter of the fiscal year ended December 31, 2022.

#### 4. Consolidated Financial Statements and Primary Notes

##### (1) Consolidated Statements of Financial Position

(Thousands of yen)

	As of December 31, 2023	As of December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	19,507,861	48,117,933
Trade and other receivables	4,970,860	5,282,889
Other financial assets	6,245	6,246
Inventories	2,404,156	2,671,658
Other current assets	335,959	1,130,906
Total current assets	27,225,082	57,209,634
Non-current assets		
Property, plant and equipment	17,358,317	17,526,094
Goodwill	8,370,677	8,370,677
Intangible assets	2,211,452	2,142,969
Investments accounted for using equity method	81,067	64,796
Other financial assets	11,801,205	2,558,989
Deferred tax assets	2,337,218	4,732,551
Retirement benefit asset	32,146	73,115
Other non-current assets	46,845	90,996
Total non-current assets	42,238,930	35,560,191
Total assets	69,464,013	92,769,826

	As of December 31, 2023	As of December 31, 2024
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	3,203,559	5,332,036
Borrowings	2,586,259	2,592,935
Other financial liabilities	255,987	320,940
Income taxes payable	1,003,852	8,039,345
Provisions	31,583	26,521
Contract liabilities	823,011	1,105,984
Other current liabilities	712,834	989,009
Total current liabilities	8,617,088	18,406,773
Non-current liabilities		
Borrowings	19,634,447	17,041,512
Other financial liabilities	323,160	398,758
Deferred tax liabilities	385,837	—
Retirement benefit liability	97,647	78,328
Provisions	56,120	59,334
Other non-current liabilities	—	22,821
Total non-current liabilities	20,497,214	17,600,754
Total liabilities	29,114,303	36,007,527
Equity		
Share capital	3,956,738	3,956,738
Capital surplus	4,550,372	4,736,195
Treasury shares	(1,085,546)	(1,075,148)
Retained earnings	27,804,689	49,393,469
Other components of equity	5,123,456	(248,956)
Total equity attributable to owners of parent	40,349,709	56,762,298
Total equity	40,349,709	56,762,298
Total liabilities and equity	69,464,013	92,769,826

## (2) Consolidated Statements of Profit or Loss and Consolidated Statements of Comprehensive Profit or Loss

## Consolidated Statements of Profit or Loss

(Thousands of yen, unless otherwise stated)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Revenue	28,712,194	46,676,523
Cost of sales	11,493,476	12,172,599
Gross profit (loss)	17,218,717	34,503,824
Selling, general and administrative expenses	7,256,195	9,109,710
Research and development expenses	3,155,366	4,002,674
Other income	5,084	1,012
Other expenses	39,192	278,610
Operating profit (loss)	6,773,047	21,113,841
Finance income	190,981	411,243
Finance costs	2,253,012	658,895
Share of profit (loss) of investments accounted for using equity method	(357,547)	22,615
Profit (loss) before tax	4,353,469	20,888,805
Income tax expense	1,317,636	5,873,882
Profit (loss)	3,035,832	15,014,922
Profit (loss) attributable to:		
Owners of parent	3,035,832	15,014,922
Profit (loss)	3,035,832	15,014,922
Earnings (loss) per share		
Basic earnings (loss) per share (Yen)	23.41	115.85
Diluted earnings (loss) per share (Yen)	23.38	115.68

# Consolidated Statements of Comprehensive Profit or Loss

(Thousands of yen)

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Profit (loss)	3,035,832	15,014,922
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Financial assets measured at fair value through other comprehensive income	5,741,157	1,166,840
Remeasurements of defined benefit plans	(16,470)	34,603
Total of items that will not be reclassified to profit or loss	5,724,687	1,201,444
Other comprehensive income	5,724,687	1,201,444
Comprehensive income	8,760,519	16,216,367
Comprehensive income attributable to:		
Owners of parent	8,760,519	16,216,367
Comprehensive income	8,760,519	16,216,367

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



### (3) Consolidated Statements of Changes in Equity

Fiscal year ended December 31, 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)	—	—	—	3,035,832	—	3,035,832	3,035,832
Other comprehensive income	—	—	—	—	5,724,687	5,724,687	5,724,687
Total comprehensive income	—	—	—	3,035,832	5,724,687	8,760,519	8,760,519
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	—	—	—	920,518	(920,518)	—	—
Share-based payment transactions	—	25,936	—	—	—	25,936	25,936
Total transactions with owners	—	25,936	(478,212)	920,518	(920,518)	(452,275)	(452,275)
Balance at December 31, 2023	3,956,738	4,550,372	(1,085,546)	27,804,689	5,123,456	40,349,709	40,349,709

Fiscal year ended December 31, 2024

(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, 2024	3,956,738	4,550,372	(1,085,546)	27,804,689	5,123,456	40,349,709	40,349,709
Profit (loss)	—	—	—	15,014,922	—	15,014,922	15,014,922
Other comprehensive income	—	—	—	—	1,201,444	1,201,444	1,201,444
Total comprehensive income	—	—	—	15,014,922	1,201,444	16,216,367	16,216,367
Purchase of treasury shares	—	—	(163)	—	—	(163)	(163)
Disposal of treasury shares	—	—	10,562	—	—	10,562	10,562
Transfer from other components of equity to retained earnings	—	—	—	6,573,857	(6,573,857)	—	—
Share-based payment transactions	—	185,822	—	—	—	185,822	185,822
Total transactions with owners	—	185,822	10,398	6,573,857	(6,573,857)	196,221	196,221
Balance at December 31, 2024	3,956,738	4,736,195	(1,075,148)	49,393,469	(248,956)	56,762,298	56,762,298

## (4) Consolidated Statements of Cash Flows

	(Thousands of yen)	
	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Cash flows from operating activities		
Profit (loss) before tax	4,353,469	20,888,805
Depreciation and amortization	2,433,182	2,248,471
Interest and dividend income	(6,172)	(263,663)
Interest expenses	231,862	288,061
Foreign exchange loss (gain)	(272,495)	611,072
Share of loss (profit) of investments accounted for using equity method	357,547	(22,615)
Decrease (increase) in trade and other receivables	11,618,285	(312,029)
Decrease (increase) in inventories	274,542	(267,501)
Increase (decrease) in trade and other payables	(1,101,880)	1,747,189
Increase (decrease) in defined benefit asset and liability	22,493	(60,288)
Other	(1,647,423)	1,136,967
Subtotal	16,263,411	25,994,469
Interest and dividends received	6,172	263,663
Interest paid	(181,606)	(234,320)
Income taxes paid	(3,667,008)	(2,178,823)
Net cash provided by (used in) operating activities	12,420,969	23,844,988
Cash flows from investing activities		
Proceeds from sale of investment securities	2,864,600	10,935,460
Payments for purchases of investment securities	(200,000)	(377,000)
Collection of loans receivable	6,243	6,245
Purchase of property, plant and equipment	(1,212,857)	(2,076,502)
Purchase of intangible assets	(156,105)	(141,767)
Other	659	24,353
Net cash provided by (used in) investing activities	1,302,539	8,370,789
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	(500,000)	—
Proceeds from long-term borrowings	4,000,000	—
Repayments of long-term borrowings	(2,340,000)	(2,640,000)
Payments of borrowing fee	(38,000)	—
Repayments of lease liabilities	(343,254)	(373,220)
Purchase of treasury shares	(514,554)	(163)
Proceeds from issuance of share acquisition rights	—	18,750
Net cash provided by (used in) financing activities	264,191	(2,994,633)
Effect of exchange rate change on cash and cash equivalents	272,495	(611,072)
Net increase (decrease) in cash and cash equivalents	14,260,196	28,610,071
Cash and cash equivalents at beginning of period	5,247,665	19,507,861
Cash and cash equivalents at end of period	19,507,861	48,117,933

(5) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes regarding going concern assumption)

Not applicable.

(Segment information)

(1) Outline of reportable segments

Since the Group operated in a single business segment, for the fiscal year ended December 31, 2021, the description of segment information is omitted.

On March 28, 2022 in the first quarter of the previous fiscal year, the Company 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 the Company 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 reorganized 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®, the Company'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 Junket prices.

Fiscal Year Ended December 31, 2023 (January 1, 2023 to December 31, 2023)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	12,702,965	16,009,228	28,712,194	—	28,712,194
Inter-segment revenue	—	86,960	86,960	(86,960)	—
Total	12,702,965	16,096,188	28,799,154	(86,960)	28,712,194
Segment profit (loss)	6,387,902	475,145	6,863,047	—	6,863,047
(Adjustments)					
Business combination-related expenses (Note)					90,000
Operating profit (loss)					6,773,047
Finance income					190,981
Finance costs					2,253,012
Share of profit (loss) of associates accounted for using the equity method					(357,547)
Profit (loss) before income taxes					4,353,469

(Note) Amortization expenses for intangible assets newly acquired through the business combination.

Fiscal Year Ended December 31, 2024 (January 1, 2024 to December 31, 2024)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	31,313,392	15,363,130	46,676,523	—	46,676,523
Inter-segment revenue	—	740,691	740,691	(740,691)	—
Total	31,313,392	16,103,821	47,417,214	(740,691)	46,676,523
Segment profit (loss)	20,957,312	246,528	21,203,841	—	21,203,841
(Adjustments)					
Business combination-related expenses (Note)					90,000
Operating profit (loss)					21,113,841
Finance income					411,243
Finance costs					658,895
Share of profit (loss) of associates accounted for using the equity method					22,615
Profit (loss) before income taxes					20,888,805

(Note) Amortization expenses for intangible assets newly acquired through the business combination.

(Revenue)

In the Drug Discovery and Development Business Segment, the Company has traditionally used PDPS®, its proprietary drug discovery and development platform system, and is pursuing a three-pronged business strategy: 1) the discovery, research and development of new therapeutics and diagnostics through collaborative research and development with pharmaceutical companies in Japan and overseas, 2) PDPS® technology licensing, and 3) strategic partnering/in-house drug discovery. The three-pronged business strategy uses the PDPS® licensing. The main sources of revenue for the Drug Discovery and Development Business Segment are upfront payments, milestone payments and royalties related to the PDPS® licensing, and R&D support payments for the provision of R&D services. In the Radiopharmaceutical Business Segment, the Group's main source of revenue is from the sale of products such as diagnostic radiopharmaceuticals (diagnostic agents for SPECT and PET) and therapeutic radiopharmaceuticals.

Based on the above, the table below discloses revenue for each of the reportable segments and revenue disaggregated by source of revenue.

Fiscal year ended December 31, 2023 (January 1, 2023 to December 31, 2023)

(Thousands of yen)					
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total	Adjustment	Consolidated Statement
Disaggregation of revenue					
Manufacturing, sale and distribution of products	153,634	15,183,343	15,336,978	—	15,336,978
Upfront payments, milestone payments and royalties	10,934,177	11,451	10,945,629	—	10,945,629
R&D support payments	1,299,140	901,393	2,200,533	(86,960)	2,113,573
Other	316,013	—	316,013	—	316,013
Total	12,702,965	16,096,188	28,799,154	(86,960)	28,712,194
Timing of revenue recognition					
Goods and services transferred at a point in time	11,164,831	14,138,646	25,303,478	(86,960)	25,216,518
Services transferred over time	1,538,133	1,957,541	3,495,675	—	3,495,675
Total	12,702,965	16,096,188	28,799,154	(86,960)	28,712,194

(Note) "Other" includes a technology update fee and other fees.

Fiscal year ended December 31, 2024 (January 1, 2024 to December 31, 2024)

(Thousands of yen)					
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total	Adjustment	Consolidated Statement
Disaggregation of revenue					
Manufacturing, sale and distribution of products	185,587	15,191,749	15,377,337	—	15,377,337
Upfront payments, milestone payments and royalties	29,519,322	11,150	29,530,472	—	29,530,472
R&D support payments	1,260,931	900,921	2,161,853	(740,691)	1,421,162
Other	347,550	—	347,550	—	347,550
Total	31,313,392	16,103,821	47,417,214	(740,691)	46,676,523
Timing of revenue recognition					
Goods and services transferred at a point in time	29,739,601	14,345,141	44,084,743	(740,691)	43,344,052
Services transferred over time	1,573,791	1,758,679	3,332,471	—	3,332,471
Total	31,313,392	16,103,821	47,417,214	(740,691)	46,676,523

(Note) “Other” includes a technology update fee and other fees.

(Per-share information)

Basic earnings per share and diluted earnings per share are calculated based on the following information.

(1) Basis for calculation of basic earnings per share

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Profit attributable to owners of parent (Thousands of yen)	3,035,832	15,014,922
Profit not attributable to common shareholders of parent (Thousands of yen)	—	—
Profit attributable to owners of parent used for calculating basic earnings per share (Thousands of yen)	3,035,832	15,014,922
Average number of shares of common stock during the period (Shares)	129,699,938	129,610,167
Basic earnings per share (Thousands of yen)	23.41	115.85

(2) Basis for calculation of diluted earnings per share

	Fiscal year ended December 31, 2023	Fiscal year ended December 31, 2024
Profit used for calculating basic profit per share (Thousands of yen)	3,035,832	15,014,922
Adjusted amount of profit (Thousands of yen)	—	—
Profit used for calculating diluted earnings per share (Thousands of yen)	3,035,832	15,014,922
Average number of shares of common stock during the period (Shares)	129,699,938	129,610,167
Increase in shares of common stock used for calculating diluted earnings per share		
Share acquisition rights (Shares)	—	—
Share benefit trust (Shares)	141,356	182,902
Average number of shares of common stock during the period for dilutive effects (Shares)	129,841,294	129,793,069
Diluted earnings per share (Yen)	23.38	115.68
Overview of dilutive shares not included in calculation of diluted earnings per share due to their dilutive effect	Eighth series share acquisition rights (Number of share acquisition rights: 30,700)	Eighth series share acquisition rights (Number of share acquisition rights: 30,700) Ninth series share acquisition rights (Number of share acquisition rights: 37,500)

(Significant subsequent events)

Not applicable.