

# Consolidated Financial Results for the Three Months Ended March 31, 2025 [IFRS]

May 13, 2025

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 Supplementary briefing materials on quarterly financial results: No  
 Explanatory meeting on quarterly financial results: No

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

## 1. Consolidated Financial Results for the Three Months Ended March 31, 2025 (January 1, 2025 to March 31, 2025)

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

	Revenue		Core operating profit		Operating profit		Profit before tax	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Three Months Ended March 31, 2025	4,233	0.2	(1,355)	—	(1,367)	—	(1,433)	—
Three Months Ended March 31, 2024	4,225	(14.9)	(993)	—	(1,098)	—	(1,104)	—

	Profit attributable to owners of parent		Total comprehensive income	
	Million yen	%	Million yen	%
Three Months Ended March 31, 2025	(1,033)	—	(1,033)	—
Three Months Ended March 31, 2024	(842)	—	(373)	—

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Three Months Ended March 31, 2025	(7.97)	(7.97)
Three Months Ended March 31, 2024	(6.50)	(6.50)

## (2) Consolidated financial position

	Total assets	Net assets	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent to total assets
	Million yen	Million yen	Million yen	%
As of March 31, 2025	80,734	54,787	54,787	67.9
As of December 31, 2024	92,769	56,762	56,762	61.2

## 2. Payment of Dividends

	Annual dividends per share				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal Year Ended December 31, 2024	—	0.00	—	0.00	0.00
Fiscal Year Ending December 31, 2025	—				
Fiscal Year Ending December 31, 2025 (Forecast)		0.00	—	0.00	0.00

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

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

(% indicates year-on-year changes.)

	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

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

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

#### [Notes]

(1) 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)	As of March 31, 2025	130,010,400 shares	As of December 31, 2024	130,010,400 shares
2) Number of treasury stock at the end of the period	As of March 31, 2025	852,035 shares	As of December 31, 2024	398,635 shares
3) Average number of shares during the period	Three months ended March 31, 2025	129,606,727 shares	Three months ended March 31, 2024	129,607,735 shares

(Note) The number of treasury shares at the end of the period includes shares in the Company held by the Custody Bank of Japan, Ltd. (Trust Account E) (398,300 shares as of December 31, 2024 and 851,700 shares as of March 31, 2025). 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 (402,400 shares for the three months ended March 31, 2024 and 403,337 shares for the three months ended March 31, 2025).

\* These quarterly financial results reports are not subject to quarterly review by a certified public accountant or an audit firm

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

(Caution regarding forward-looking statements)

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

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

### (1) Explanation of Operating Results

During the three (3) months ended March 31, 2025 (from January 1, 2025 to March 31, 2025), 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.*
- ◆ **Techne® 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 (<sup>99m</sup>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 Injection:** Imaging agent containing technetium ( $^{99m}\text{Tc}$ ) pyrophosphate injection used for the diagnosis of bone diseases by bone scintigraphy
- ◆ **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 ( $^{131}\text{I}$ ) 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.*
- ◆ **Tauvid™ Injection:** Imaging agent that contains radioactive fluorine (<sup>18</sup>F) to label florotauhipir and indicated for " To support proper use of donanemab (genetical recombination) in patients with mild cognitive impairment and mild dementia due to Alzheimer's disease". PDRadiopharma signed a co-development deal with Eli Lilly in November, and received approval from the Ministry of Health, Labour and Welfare for the regulatory approval of Tauvid™ in Japan in December 2024.

#### **(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
	Prostate 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-FAP (FXX489/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
Diagnos tics	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  $^{64}\text{Cu}$  ( $^{64}\text{Cu}$ -ATSM);

Partner: **LinqMed**

Current Status:

$^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -ATSM was well tolerated, and that the recommended dosing of  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -ATSM localizes to these hypoxic tumor microenvironments, delivering the therapeutic  $^{64}\text{Cu}$  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  $^{64}\text{Cu}$ -ATSM in Japan. LinqMed will continue to lead development activities of  $^{64}\text{Cu}$ -ATSM and PDRadiopharma will lead regulatory filing and commercialization activities in Japan.

◆  **$^{177}\text{Lu}/^{64}\text{Cu}$ -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  $^{177}\text{Lu}$  (for the therapeutic  $^{177}\text{Lu}$ -PSMA-I&T) or  $^{64}\text{Cu}$  (for the diagnostic  $^{64}\text{Cu}$ -PSMA-I&T);

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

Current Status:

$^{177}\text{Lu}$ -PSMA-I&T completed the global pivotal Phase 3 ECLIPSE trial in 2024. (ClinicalTrials.gov identifier; NCT05204927). The ECLIPSE trial, run by Curium, was a multi-center, open-label, randomized clinical trial comparing the safety and efficacy of  $^{177}\text{Lu}$ -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 had met its primary endpoint, demonstrating a statistically significant and clinically meaningful benefit for patients with PSMA-positive metastatic castration resistant prostate cancer.

<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.

In October 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 <sup>177</sup>Lu-PSMA-I&T and <sup>64</sup>Cu-PSMA-I&T products in Japan. Under the terms of the partnership, Curium and PDRadiopharma will jointly collaborate on clinical development activities of <sup>177</sup>Lu-PSMA-I&T and <sup>64</sup>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 <sup>64</sup>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.

♦ **<sup>177</sup>Lu/<sup>68</sup>Ga-Integrin (FF58) Program:**

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

Modality: FUJIFILM/PDRadiopharma-discovered small molecule (FF58) targeting Integrin  $\alpha\beta3/5$  conjugated to a chelator radiolabeled with <sup>177</sup>Lu (for the therapeutic) or <sup>68</sup>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 <sup>177</sup>Lu-FF58 in patients with selected advanced solid tumors has been prepared and is under review.

Additional program details:

The purpose of the first-in-human Phase 1 study is to test the safety and dosing of <sup>177</sup>Lu-FF58, a radioligand therapy for patients with advanced or metastatic tumors that express proteins known as integrins: alpha-v beta-3 integrin ( $\alpha\beta3$ ) and alpha-v beta-5 integrin ( $\alpha\beta5$ ). While both  $\alpha\beta3$  and  $\alpha\beta5$  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 <sup>68</sup>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 <sup>68</sup>Ga-FF58 positron emission tomography (PET)/computed tomography (CT) or PET/magnetic resonance imaging (MRI) scan to assess eligibility for treatment with <sup>177</sup>Lu-FF58. In the escalation part, different doses of <sup>177</sup>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.

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 for the FF58 program.

♦  **$^{225}\text{Ac}/^{68}\text{Ga}$ -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.

♦  **$^{177}\text{Lu}/^{68}\text{Ga}$ -FAP (FXX489) 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 fibroblast activation protein (FAP) conjugated to a chelator radiolabeled with  $^{177}\text{Lu}$  (for the therapeutic;  $^{177}\text{Lu}$ -NNS309 ) or  $^{68}\text{Ga}$  (for the diagnostic;  $^{68}\text{Ga}$ -NNS309);

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).

The best-in-class potential of the FXX489 program was recently presented by Novartis at the American Association for Cancer Research (AACR) Annual Meeting on April 27, 2025.

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  $^{177}\text{Lu}$ -NNS309 treatment. In the escalation part, different doses of  $^{177}\text{Lu}$ -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  $^{177}\text{Lu}$ -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.

♦  **$^{225}\text{Ac}/^{64}\text{Cu}$ -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  $^{225}\text{Ac}$  (for the therapeutic; PD-32766T) or  $^{64}\text{Cu}$  (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  $^{64}\text{Cu}$ -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  $^{64}\text{Cu}$ -PD-32766D followed by imaging by PET/CT. Administration of  $^{64}\text{Cu}$ -PD32766D 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. The results of the Ph0 study were presented at the American Society of Clinical Oncology's (ASCO) Genitourinary Cancers Symposium (ASCO-GU 2025) in February 2025.

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 under consideration and in the planning stages for 2025. PeptiDream presented preclinical results for the PD-29875 CLDN18.2 Program at the recent American Association for Cancer Research (AACR) Annual Meeting 2025 on April 27, 2025 in Chicago.

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>Ac-PD-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 <sup>90</sup>Y to <sup>225</sup>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 <sup>225</sup>Ac-PPMX-T002 showed greater efficacy in a mouse model of pancreatic cancer compared to <sup>90</sup>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.

♦ **<sup>18</sup>F-PD-L1 (<sup>18</sup>F-BMS-986229) Program:**

Indication: Oncology Imaging;

Modality: **PDPs®-originating macrocyclic peptide** targeting PD-L1 (programmed death ligand-1) radiolabeled with <sup>18</sup>F for PET imaging (<sup>18</sup>F-BMS-986229);

Partner: **BMS.**

Current Status:

<sup>18</sup>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., *<sup>18</sup>F-BMS-986229 PET to Assess Programmed-Death Ligand 1 Status in Gastroesophageal Cancer*). The results showed that PET imaging with <sup>18</sup>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 <sup>18</sup>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 <sup>18</sup>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  $^{18}\text{F}$ -Flortaucipir in Japan, in 2023 with LinqMed for the development and commercialization of the radiotherapeutic  $^{64}\text{Cu}$ -ATSM in Japan, and in 2024 with Curium for the development and commercialization of  $^{177}\text{Lu}$ -PSMA-I&T and  $^{64}\text{Cu}$ -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.

In September 2024, PDRadiopharma announced the launch of two additional medical digital transformation (DX) systems, "Bridgea TIMER Guide" and "onti" 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. As announced in March and April 2025, PDRadiopharma continues to add additional features and functionality to the onti platform, including the automatic calculation of appropriate dosage for pediatric nuclear medicine examinations feature, which allows the onti platform to interface with the hospital's test scheduling system and automatically calculate the appropriate dosages in accordance with government guidelines, helping prevent calculation errors and improving operational efficiency.

#### **(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 (ALXN2420)					AstraZeneca
	Oncology	PD-L1 Inhibitor					PeptiDream
	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					Various Partners
	Not Disclosed	Oligo/cytotoxic-PDC					Various Partners
	Not Disclosed	MPCs (Immune Engagers, etc.)					PeptiDream

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

#### ♦ GhR antagonist Program (AZP-3813; now referred to as ALXN2420):

Indication: Acromegaly;

Modality: ALXN2420 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:

Planning is underway for a future Phase 2 study of ALXN2420. ALXN2420 completed a Phase 1 study in May 2024 investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of ALXN2420 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 ALXN2420 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 ALXN2420 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, ALXN2420 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, ALXN2420, substantially decreases circulating IGF-1 levels in healthy individuals, thereby supporting further testing in patients with acromegaly.

Additional program details:

PeptiDream and **Amolyt** (now a subsidiary of **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 ALXN2420 potentially decreases circulating levels of IGF-1 and further suppressive effects are observed when combined with the SSA, octreotide, with results published in the *European Journal of Endocrinology* in March 2025). Therefore, ALXN2420 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 not to 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 completed in early 2025 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. Biohaven is considering next steps for the program.

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 pharmas 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 FY2025:**

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

- ♦ **April 2025:** PeptiGrowth Inc., PeptiDream Affiliated Company, Announces Product Launch of KGF-alternative peptide (FGFR2b agonist) – PG-012.

#### **(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 March 31, 2025.

**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 twelve (12) 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, and PG-012 (FGFR2b agonist as an alternative for KGF) in 2025. 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. A Phase 1 safety study of PA-001 is currently ongoing in the United States.

**PeptiStar:** *At the time of reporting, PeptiDream holds less than a 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 less than a 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 & April 2025).

**Alivexis:** *At the time of reporting, PeptiDream holds less than a 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).

In December 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.

In March 2025, PeptiDream announced plans to construct a new state-of-the-art research building next to its current location in Tonomachi (the land between PeptiDream and the recently completed Tama River Sky Bridge was acquired by PeptiDream in 2021 with a view toward future expansion). The new facility will expand office space as well as lab space to host additional pre-clinical POC and CMC/formulation functions and capabilities. The project is expected to be completely funded by cash on hand and become fully operational in 2028. The project is currently in the early planning phase and more details will be disclosed, including expected costs, as they become available.

As of March 31, 2025, the Group had a total headcount of 736 employees (746 when including its 10 board members), (PeptiDream Inc; 223 employees, PDRadiopharma Inc., 513 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 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 2024. PeptiDream reached the Leadership level, the highest level, as a company that excels in its efforts and information disclosure in climate change. In 2024, PeptiDream was selected to remain a constituent of the FTSE4Good Index Series and FTSE Blossom Japan Index for the FOURTH consecutive year and to remain a constituent 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 was awarded Prime Status in ISS ESG Corporate Rating for the first time

As a result of the above, for the three months ended March 31, 2025, the Drug Discovery and Development Business recorded revenue of 407,109 thousand yen (a 114,064 thousand yen decrease year on year), segment loss of 1,428,378 thousand yen (a 473,154 thousand yen increase year on year), the Radiopharmaceutical Business recorded revenue of 3,826,137 thousand yen (a 122,144 thousand yen increase year on year), segment profit of 83,511 thousand yen (segment loss of 121,164 thousand yen in the same period of the previous fiscal year), and the Group recorded revenue of 4,233,246 thousand yen (a 8,080 thousand yen increase year on year), core operating loss of 1,355,709 thousand yen (a 361,862 thousand yen increase year on year), operating loss of 1,367,367 thousand yen (a 268,478 thousand yen increase year on year), loss before tax of 1,433,378 thousand yen (a 329,324 thousand yen increase year on year), and loss attributable to owners of parent of 1,033,379 thousand yen (a 190,836 thousand yen increase year on year).

In addition to IFRS-based results, the Company 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 the Company 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 profit to operating profit is as follows:

(Thousands of yen)

	Results for the three months ended March 31, 2024	Results for the three months ended March 31, 2025	Change	%
Core operating profit (loss)	(993,847)	(1,355,709)	(361,862)	—
Accounting effects of business acquisitions and acquisition- related costs	93,509	11,657	(81,852)	(87.5)
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	11,531	—	(11,531)	—
Operating profit (loss)	(1,098,888)	(1,367,367)	(268,478)	—

## (2) Explanation of Financial Position

### 1) Analysis of financial position

Total assets at the end of the three months ended March 31, 2025 decreased by 12,034,836 thousand yen from the end of the previous fiscal year to 80,734,989 thousand yen. This was mainly because of a decrease of 12,641,087 thousand yen in cash and cash equivalents.

Liabilities decreased by 10,060,199 thousand yen from the end of the previous fiscal year to 25,947,328 thousand yen. This was mainly because of decreases of 1,036,956 thousand yen in trade and other payables, and 8,027,064 thousand yen in income taxes payable.

Equity decreased by 1,974,637 thousand yen from the end of the previous fiscal year to 54,787,660 thousand yen. This was mainly because of a decrease of 1,033,379 thousand yen in retained earnings due to the recording of loss and an increase of 960,908 thousand yen in treasury shares due to repurchases.

### 2) Analysis of status of cash flows

Cash and cash equivalents for the three months ended March 31, 2025 decreased by 12,641,087 thousand yen from the end of the previous fiscal year to 35,476,845 thousand yen.

Status of cash flows and related factors during the three months ended March 31, 2025 are described below.

#### (Cash flows from operating activities)

Cash flows from operating activities resulted in a cash outflow of 9,825,033 thousand yen (a 7,901,973 thousand yen increase in outflow year on year). This was mainly due to the recording of loss before tax of 1,433,378 thousand yen, and income taxes paid of 8,060,195 thousand yen.

(Cash flows from investing activities)

Cash flows from investing activities resulted in a cash outflow of 1,046,060 thousand yen (compared with an inflow of 10,395,130 thousand yen in the same period of the previous fiscal year). This was mainly due to payments for purchases of investment securities of 300,000 thousand yen, and purchase of property, plant and equipment of 682,994 thousand yen.

(Cash flows from financing activities)

Cash flows from financing activities resulted in a cash outflow of 1,720,389 thousand yen (a 962,990 thousand yen increase in outflow year on year). This was mainly due to repayments of long-term borrowings of 660,000 thousand yen, and an outflow of 960,908 thousand yen for purchase of treasury shares.

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

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

#### 【Key indices】

	Results for the full year ended December 31, 2023	Results for the three months ended March 31, 2024	Results for the full year ended December 31, 2024	Results for the three months ended March 31, 2025	Forecasts for the full year ending December 31, 2025
	2023/Jan ~ 2023/Dec	2024/Jan ~ 2024/ Mar	2024/Jan ~ 2024/Dec	2025/Jan ~ 2025/ Mar	2025/Jan ~ 2025/Dec
Capital Expenditures (JPY millions)	1,668	692	2,618	400	5,046
Depreciation Expense (JPY millions)	2,433	631	2,248	550	2,081
Research and Development Expenses (JPY millions)	3,155	690	4,002	987	5,652
Year-end headcount (people)	725	712	743	746	780

(Note) The amount that will actually be paid is shown for capital expenditures.

## 2. Condensed Quarterly Consolidated Financial Statements and Primary Notes

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

(Thousands of yen)

	As of December 31, 2024	As of March 31, 2025
Assets		
Current assets		
Cash and cash equivalents	48,117,933	35,476,845
Trade and other receivables	5,282,889	4,706,632
Other financial assets	6,246	6,246
Inventories	2,671,658	2,962,629
Income taxes receivable	—	383,385
Other current assets	1,130,906	1,411,265
Total current assets	57,209,634	44,947,005
Non-current assets		
Property, plant and equipment	17,526,094	17,410,929
Goodwill	8,370,677	8,370,677
Intangible assets	2,142,969	2,107,776
Investments accounted for using equity method	64,796	53,808
Other financial assets	2,558,989	2,864,197
Deferred tax assets	4,732,551	4,782,296
Retirement benefit asset	73,115	73,114
Other non-current assets	90,996	125,183
Total non-current assets	35,560,191	35,787,983
Total assets	92,769,826	80,734,989



	As of December 31, 2024	As of March 31, 2025
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	5,332,036	4,295,080
Borrowings	2,592,935	2,594,546
Other financial liabilities	320,940	318,391
Income taxes payable	8,039,345	12,280
Provisions	26,521	22,816
Contract liabilities	1,105,984	935,359
Other current liabilities	989,009	609,745
Total current liabilities	18,406,773	8,788,220
Non-current liabilities		
Borrowings	17,041,512	16,392,114
Other financial liabilities	398,758	384,512
Retirement benefit liability	78,328	73,681
Provisions	59,334	59,424
Other non-current liabilities	22,821	249,375
Total non-current liabilities	17,600,754	17,159,107
Total liabilities	36,007,527	25,947,328
Equity		
Share capital	3,956,738	3,956,738
Capital surplus	4,736,195	4,755,846
Treasury shares	(1,075,148)	(2,036,056)
Retained earnings	49,393,469	48,360,089
Other components of equity	(248,956)	(248,956)
Total equity attributable to owners of parent	56,762,298	54,787,660
Total equity	56,762,298	54,787,660
Total liabilities and equity	92,769,826	80,734,989

(2) Condensed Quarterly Consolidated Statements of Profit or Loss

Three months ended March 31, 2024 and March 31, 2025

(Thousands of yen, unless otherwise stated)

	Three months ended March 31, 2024	Three months ended March 31, 2025
Revenue	4,225,166	4,233,246
Cost of sales	2,746,491	2,764,627
Gross profit (loss)	1,478,674	1,468,619
Selling, general and administrative expenses	1,881,453	1,843,583
Research and development expenses	690,664	987,309
Other income	19	168
Other expenses	5,464	5,261
Operating profit (loss)	(1,098,888)	(1,367,367)
Finance income	149,798	143,280
Finance costs	64,636	198,304
Share of profit (loss) of investments accounted for using equity method	(90,328)	(10,987)
Profit (loss) before tax	(1,104,054)	(1,433,378)
Income tax expense	(261,511)	(399,999)
Profit (loss)	(842,543)	(1,033,379)
Profit (loss) attributable to:		
Owners of parent	(842,543)	(1,033,379)
Profit (loss)	(842,543)	(1,033,379)
Earnings (loss) per share		
Basic earnings (loss) per share (Yen)	(6.50)	(7.97)
Diluted earnings (loss) per share (Yen)	(6.50)	(7.97)

(3) Condensed Quarterly Consolidated Statements of Comprehensive Profit or Loss  
Three months ended March 31, 2024 and March 31, 2025

(Thousands of yen)

	Three months ended March 31, 2024	Three months ended March 31, 2025
Profit (loss)	(842,543)	(1,033,379)
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Financial assets measured at fair value through other comprehensive income	469,448	—
Total of items that will not be reclassified to profit or loss	469,448	—
Other comprehensive income	469,448	—
Comprehensive income	(373,094)	(1,033,379)
Comprehensive income attributable to:		
Owners of parent	(373,094)	(1,033,379)
Comprehensive income	(373,094)	(1,033,379)

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

(4) Condensed Quarterly Consolidated Statements of Changes in Equity  
Three months ended March 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)	—	—	—	(842,543)	—	(842,543)	(842,543)
Other comprehensive income	—	—	—	—	469,448	469,448	469,448
Total comprehensive income	—	—	—	(842,543)	469,448	(373,094)	(373,094)
Purchase of treasury Shares	—	—	(58)	—	—	(58)	(58)
Transfer from other components of equity to retained earnings	—	—	—	6,539,253	(6,539,253)	—	—
Share-based payment transactions	—	8,170	—	—	—	8,170	8,170
Total transactions with owners	—	8,170	(58)	6,539,253	(6,539,253)	8,111	8,111
Balance at March 31, 2024	3,956,738	4,558,543	(1,085,605)	33,501,400	(946,349)	39,984,726	39,984,726

Three months ended March 31, 2025

(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, 2025	3,956,738	4,736,195	(1,075,148)	49,393,469	(248,956)	56,762,298	56,762,298
Profit (loss)	—	—	—	(1,033,379)	—	(1,033,379)	(1,033,379)
Other comprehensive income	—	—	—	—	—	—	—
Total comprehensive income	—	—	—	(1,033,379)	—	(1,033,379)	(1,033,379)
Purchase of treasury shares	—	—	(960,908)	—	—	(960,908)	(960,908)
Share-based payment transactions	—	19,650	—	—	—	19,650	19,650
Total transactions with owners	—	19,650	(960,908)	—	—	(941,257)	(941,257)
Balance at March 31, 2025	3,956,738	4,755,846	(2,036,056)	48,360,089	(248,956)	54,787,660	54,787,660

## (5) Condensed Quarterly Consolidated Statements of Cash Flows

(Thousands of yen)

	Three months ended March 31, 2024	Three months ended March 31, 2025
Cash flows from operating activities		
Profit (loss) before tax	(1,104,054)	(1,433,378)
Depreciation and amortization	631,660	550,763
Interest and dividend income	(294)	(143,280)
Interest expenses	64,636	84,503
Foreign exchange loss (gain)	(82,624)	49,604
Share of loss (profit) of investments accounted for using equity method	90,328	10,987
Decrease (increase) in trade and other receivables	242,281	576,256
Decrease (increase) in inventories	(334,221)	(290,970)
Increase (decrease) in trade and other payables	(158,656)	(383,555)
Increase (decrease) in defined benefit asset and liability	(2,291)	(4,646)
Other	(211,950)	(852,110)
Subtotal	(865,186)	(1,835,826)
Interest and dividends received	294	143,280
Interest paid	(50,663)	(72,290)
Income taxes paid	(1,007,503)	(8,060,195)
Net cash provided by (used in) operating activities	(1,923,059)	(9,825,033)
Cash flows from investing activities		
Proceeds from sale of investment securities	10,935,460	—
Payments for purchases of investment securities	—	(300,000)
Collection of loans receivable	1,561	1,561
Purchase of property, plant and equipment	(484,412)	(682,994)
Purchase of intangible assets	(62,428)	(67,852)
Other	4,948	3,224
Net cash provided by (used in) investing activities	10,395,130	(1,046,060)
Cash flows from financing activities		
Repayments of long-term borrowings	(660,000)	(660,000)
Repayments of lease liabilities	(97,340)	(99,481)
Purchase of treasury shares	(58)	(960,908)
Net cash provided by (used in) financing activities	(757,399)	(1,720,389)
Effect of exchange rate change on cash and cash equivalents	112,650	(49,604)
Net increase (decrease) in cash and cash equivalents	7,827,322	(12,641,087)
Cash and cash equivalents at beginning of period	19,507,861	48,117,933
Cash and cash equivalents at end of period	27,335,184	35,476,845

(6) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes regarding going concern assumption)

Not applicable.

(Notes in case of significant changes in equity)

Not applicable.

(Segment information)

(1) Outline of reportable segments

The Group's reportable segments are components of the Group for which separate financial information is available and which are regularly reviewed by the Board of Directors of the Company to determine the allocation of management resources and evaluate financial results.

The Group organizes its reportable segments to the two segments of the Drug Discovery and Development Business Segment and the Radiopharmaceutical Business Segment to formulate and determine its group strategies.

[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 market prices.

Three months ended March 31, 2024 (January 1, 2024 to March 31, 2024)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	521,173	3,703,992	4,225,166	—	4,225,166
Inter-segment revenue	—	75,230	75,230	(75,230)	—
Total	521,173	3,779,222	4,300,396	(75,230)	4,225,166
Segment profit (loss)	(955,223)	(121,164)	(1,076,388)	—	(1,076,388)
(Adjustments)					
Business combination-related expenses (Note)					22,500
Operating profit (loss)					(1,098,888)
Finance income					149,798
Finance costs					64,636
Share of profit (loss) of associates accounted for using the equity method					(90,328)
Profit (loss) before income taxes					<u>(1,104,054)</u>

(Note) Includes amortization expenses of 22,500 thousand yen for intangible assets newly acquired through the business combination.

Three months ended March 31, 2025 (January 1, 2025 to March 31, 2025)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	407,109	3,826,137	4,233,246	—	4,233,246
Inter-segment revenue	—	184,864	184,864	(184,864)	—
Total	407,109	4,011,001	4,418,111	(184,864)	4,233,246
Segment profit (loss)	(1,428,378)	83,511	(1,344,867)	—	(1,344,867)
(Adjustments)					
Business combination-related expenses (Note)					22,500
Operating profit (loss)					(1,367,367)
Finance income					143,280
Finance costs					198,304
Share of profit (loss) of associates accounted for using the equity method					(10,987)
Profit (loss) before income taxes					<u>(1,433,378)</u>

(Note) Includes amortization expenses of 22,500 thousand yen 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.

Three months ended March 31, 2024 (January 1, 2024 to March 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	46,990	3,703,892	3,750,883	—	3,750,883
Upfront payments, milestone payments and royalties	30,246	100	30,346	—	30,346
R&D support payments	358,250	75,230	433,480	(75,230)	358,250
Other	85,685	—	85,685	—	85,685
Total	521,173	3,779,222	4,300,396	(75,230)	4,225,166
Timing of revenue recognition					
Goods and services transferred at a point in time	95,928	3,373,637	3,469,565	(75,230)	3,394,335
Services transferred over time	425,245	405,585	830,830	—	830,830
Total	521,173	3,779,222	4,300,396	(75,230)	4,225,166

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

Three months ended March 31, 2025 (January 1, 2025 to March 31, 2025)

(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	23,586	3,800,937	3,824,524	—	3,824,524
Upfront payments, milestone payments and royalties	—	1,232	1,232	—	1,232
R&D support payments	294,595	208,831	503,427	(184,864)	318,563
Other	88,926	—	88,926	—	88,926
Total	407,109	4,011,001	4,418,111	(184,864)	4,233,246
Timing of revenue recognition					
Goods and services transferred at a point in time	72,186	3,594,018	3,666,204	(184,864)	3,481,340
Services transferred over time	334,922	416,983	751,906	—	751,906
Total	407,109	4,011,001	4,418,111	(184,864)	4,233,246

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

(Subsequent events)

Not applicable.