Consolidated Financial Results for the Six Months Ended June 30, 2024 [IFRS]

Aug 8, 2024

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Scheduled date to file semi-annual securities report: Aug 9, 2024
Scheduled starting date of dividend payments: —
Preparation of supplementary material on financial results: No
Holding of financial results briefing: Yes (for institutional investors)

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

1. Consolidated Financial Results for the Six Months Ended June 30, 2024 (January 1, 2024 to June 30, 2024)

(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	%
Six Months Ended June 30, 2024	36,133	283.3	24,772	—	24,649	—	24,742	—
Six Months Ended June 30, 2023	9,426	87.6	(793)	—	(986)	—	(1,110)	—

	Profit attributable to owners of parent		Total comprehensive income	
	Million yen	%	Million yen	%
Six Months Ended June 30, 2024	17,925	—	18,394	—
Six Months Ended June 30, 2023	(729)	—	(516)	—

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Six Months Ended June 30, 2024	138.30	138.11
Six Months Ended June 30, 2023	(5.62)	(5.62)

(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 June 30, 2024	95,881	58,770	58,770	61.3
As of December 31, 2023	69,464	40,349	40,349	58.1

2. Payment of Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal Year Ended December 31, 2023	—	0.00	—	0.00	0.00
Fiscal Year Ending December 31, 2024	—	0.00			
Fiscal Year Ending December 31, 2024 (forecast)			—	0.00	0.00

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

3. Consolidated Financial Forecasts for the Fiscal Year Ending December 31, 2024 (January 1, 2024 to December 31, 2024)

	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, 2024	45,000 / 56.7	20,500 / 186.1	20,100 / 196.8	19,900 / 357.1	14,000 / 361.2

(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 June 30, 2024	130,010,400 shares	As of December 31, 2023	130,010,400 shares
2) Number of treasury stock at the end of the period	As of June 30, 2024	398,628 shares	As of December 31, 2023	402,647 shares
3) Average number of shares during the period	Six months ended June 30, 2024	129,608,551 shares	Three months ended June 30, 2023	129,793,651 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) (402,400 shares as of December 31, 2023 and 398,300 shares as of June 30, 2024). In addition, the shares in the Company held by the Custody Bank of Japan, Ltd. (Trust Account E) are included in treasury shares excluded from calculating the average number of shares during the period (216,502 shares for the six months ended June 30, 2023 and 401,566 shares for the six months ended June 30, 2024).

* Semi-annual financial results reports are exempt from review conducted by certified public accountants 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 six months ended June 30, 2024 (from January 1, 2024 to June 30, 2024), PeptiDream ("the Company") continued to make excellent progress in both its Radiopharmaceuticals and Non-Radiopharmaceutical Drug Discovery Businesses.

(A) Radiopharmaceuticals Business:

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

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

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

- **Sodium Iodide-^{131}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 ^{131}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 ^{111}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 ^{90}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 ^{111}In, used for the diagnosis of patients with neuroendocrine tumors by scintigraphy. *Product licensed from Curium Pharma.*

- **Techne® DMSA Kit:** Kit for the preparation of technetium (^{99m}Tc) dimercaptosuccinic acid injection used for the diagnosis of renal diseases by renal scintigraphy.

- **Techne® DTPA Kit:** Kit for the preparation of technetium (^{99m}Tc) diethylenetriamine pentaacetatic acid injection used for the diagnosis of renal diseases by renal scintigraphy.

- **Techne® MAA Kit:** Kit for the preparation of technetium (^{99m}Tc) macroaggregated human serum albumin injection for use in lung perfusion scintigraphy

- **Techne® MAG3 Injection:** Imaging agent containing technetium (^{99m}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}Tc) methylenediphosphonate injection used for the diagnosis of skeletal diseases by bone scintigraphy and cerebral tumor or cerebral vessel disorders by cerebral scintigraphy. Also available in kit form.

- **Techne® Pyrophosphate Kit:** Kit for the preparation of technetium (^{99m}Tc) pyrophosphate injection for use in cardiac or bone scintigraphy to diagnose cardiac or skeletal diseases.

- **Techne® Phytate Kit:** Kit for the preparation of technetium (^{99m}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}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}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-iodobynzylguanidine radiolabeled with ^{123}I used for the diagnosis of heart diseases by cardiac scintigraphy and neuroblastoma and pheochromocytoma by tumor scintigraphy. In December 2023, MyoMIBG-I123 was approved for 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}Tc from ^{99}Mo. Extracted ^{99m}Tc in the form of sodium pertechnetate (^{99m}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}F) Injection FRI:** Imaging agent used for the diagnosis of patients with malignant tumors, heart disease, intractable partial epilepsy, and large-vessel vasculitis.

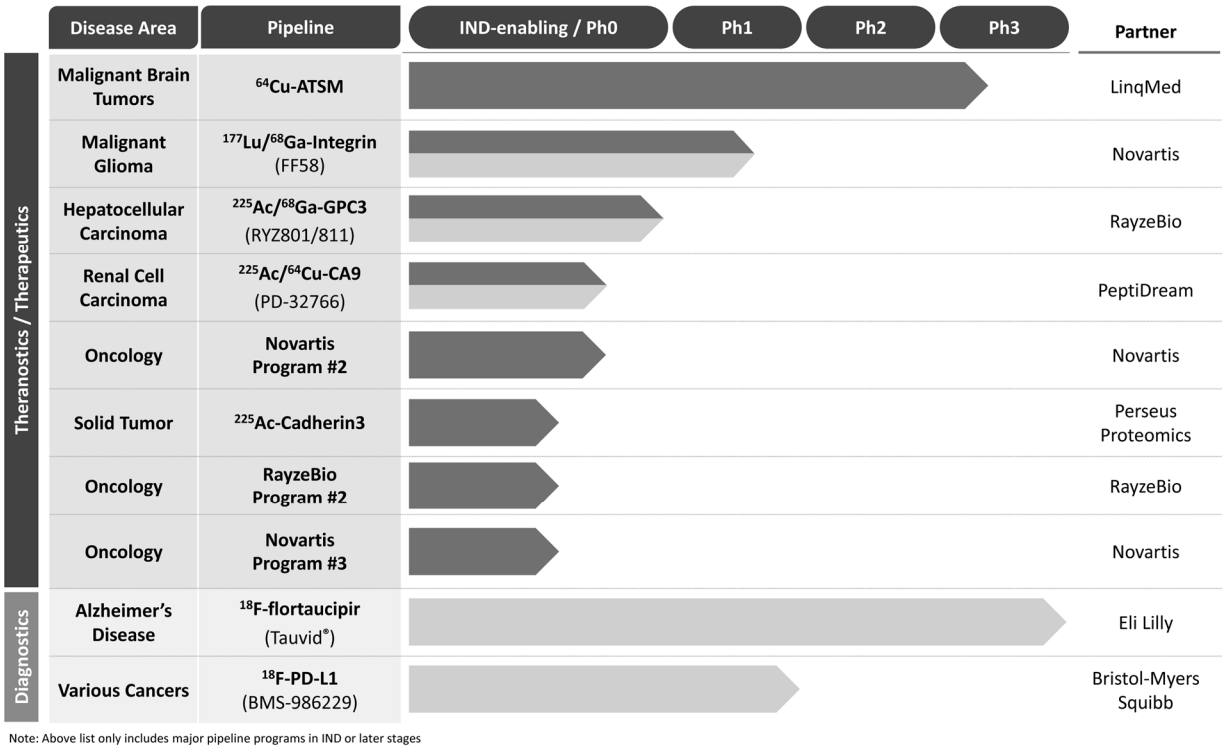
- **Adosterol®-I131 Injection:** Product consists of iodinated (^{131}I) methylnorcholestenol used for localization of adrenal diseases by adrenal scintigraphy.

- **Iofetamine (^{123}I) Injection Daiichi:** Product consists of the small molecule N-isopropyl-4-iodoamphetamine radiolabeled with ^{123}I, used for regional cerebral blood perfusion scintigraphy.

- **AMYViD® Injection**: Product consists of the small molecule florbetapir radiolabeled with ^{18}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. In May 2024, AMYViD became listed in the National Health Insurance Drug Price List. *Product licensed from Eli Lilly and Company.*

(A)-2: Radiopharmaceutical Development Programs & Pipeline

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



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

- **^{64}Cu-ATSM Program:** *Indication:* Glioma and other malignant brain cancers; *Modality:* small molecule diacetyl-bis(N4-methylthiosemicarbazone) conjugated to a chelator radiolabeled with ^{64}Cu (^{64}Cu-ATSM); *Partner:* **LinqMed**. *Current Status:* ^{64}Cu-ATSM is currently being tested in a Phase 3 randomized, comparative, investigator-initiated clinical trial (STEP-64 study, study number NCCH2301) to verify whether ^{64}Cu-ATSM treatment extends survival time compared to the 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}Cu-ATSM as a radiotherapeutic for severe brain tumors.

  In June 2024, LinqMed announced the completion of the Phase 1 investigator-initiated clinical trial (STAR-64 study; study identifier NCCH1711) of ^{64}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, and that 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}Cu-ATSM was well tolerated, and that the recommended dosing of ^{64}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}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}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}Cu-ATSM localizes to these hypoxic tumor microenvironments, delivering the therapeutic ^{64}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. As announced 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}Cu-ATSM in Japan. LinqMed will continue to lead development activities of ^{64}Cu-ATSM and PDRadiopharma will lead regulatory filing and commercialization activities in Japan.

- **^{177}Lu/^{68}Ga-Integrin (FF58) Program:** *Indication:* Advanced Solid Tumors (Pancreatic Ductal Adenocarcinoma, Gastroesophageal Adenocarcinoma, Glioblastoma Multiforme); *Modality:* small molecule (FF58) targeting Integrin αvβ3/5 conjugated to a chelator radiolabeled with ^{177}Lu (for the therapeutic) or ^{68}Ga (for the diagnostic); *Partner:* **Novartis**; Novartis holds worldwide (ex-Japan) commercialization rights, with PeptiDream/PDRadiopharma holding Japan commercialization rights. *Current Status:* ^{177}Lu-FF58 is currently being tested in a Phase 1, open-label, multi-center study to evaluate the safety, tolerability, dosimetry and preliminary activity of ^{177}Lu-FF58 in patients with selected advanced solid tumors (NCT05977322).

  Additional program details: The purpose of the Phase 1 study is to test the safety and dosing of ^{177}Lu-FF58, a radioligand therapy for patients with advanced or metastatic tumors that express proteins known as integrins: alpha-v beta-3 integrin (αvβ3) and alpha-v beta-5 integrin (αvβ5). The study will also further characterize the radioligand imaging agent ^{68}Ga-Integrin including its ability to identify tumor lesions and its safety profile. The study will be done in two parts. The first part is called "escalation" and the second part is called "expansion". In both parts of the study, patients will be screened with a ^{68}Ga-FF58 positron emission tomography (PET)/computed tomography (CT) or PET/magnetic resonance imaging (MRI) scan to assess eligibility for treatment with ^{177}Lu-FF58. In the escalation part, different doses of ^{177}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}Lu-FF58 at the recommended dose determined during the escalation part. The end of study will occur when at least 80% of the patients 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, or the study is terminated early in which case all patients would also be followed up for safety.

- **^{225}Ac/^{68}Ga-GPC3 (RYZ-801/RYZ-811) Program:** *Indication:* Hepatocellular Carcinoma ("HCC"); *Modality:* macrocyclic peptide targeting glypican-3 (GPC3) conjugated to a chelator radiolabeled with ^{225}Ac (for the therapeutic RYZ-801) or Ga^{68} (for the diagnostic RYZ-811); *Partner:* **RayzeBio**, **a Bristol Myers Squibb** ("**BMS**") **company** (RayzeBio was acquired by BMS in February 2024**)**; RayzeBio/BMS holds worldwide (ex-Japan) commercialization rights, with PeptiDream/PDRadiopharma holding an option to attain Japan commercialization rights. *Current Status:* RYZ-811 is currently being tested in a Ph 0 study, being conducted at several clinical sites outside the United States (as reported in

September 2023, more than 47 HCC patients have been imaged using RYZ-811, with approximately 90% showing specific tumor uptake, and no series adverse events (SAEs) reported). In parallel, RYZ-801 and RYZ-811 are currently undergoing IND-enabling studies, with the plan to file INDs in 2024, followed by the initiation of a Phase 1 safety study for RYZ-801/RYZ-811 in HCC patients.

Additional program details: 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}Ac for the treatment of hepatocellular carcinoma "HCC". In preclinical studies of HCC xenograft models, the GPC3 binding peptide showed specific tumor uptake, and significant tumor growth inhibition including regression with single doses delivering ^{225}Ac or ^{177}Lu. RYZ-811, is a paired diagnostic imaging agent with the same peptide binder and chelator as RYZ801 but with ^{68}Ga as the radioisotope. 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.

- **^{225}Ac/^{64}Cu-CA9 (PD-32766T/PD-32766D) Program**: *Indication:* Clear Cell Renal Cell Carcinoma ("ccRCC") and other cancers; *Modality:* macrocyclic peptide targeting Carbonic Anhydrase IX ("CAIX") conjugated to a chelator radiolabeled with ^{225}Ac (for the therapeutic PD-32766T) or ^{64}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. As announced in April 2024, the clinical research for the Ph0 human imaging study of ^{64}Cu-PD-32766 in patients with ccRCC was approved by the National Cancer Center Japan's clinical review board, and as announced in June 2024, the first patient was enrolled in the now ongoing Ph0 study. Additionally, in April 2024, PeptiDream presented preclinical results of 64Cu-PD-32766/177Lu-PD-32766 at the 2024 American Association for Cancer Research (AACR) Annual Meeting.

  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.

- **Novartis Program #2:** *Indication:* Solid Tumors; *Modality:* 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:* The undisclosed program is currently undergoing IND-enabling studies, initiated in October 2023.

Additional program details: Program has certain partner limitations on disclosable information. PeptiDream anticipates further announcements regarding this program in 2024.

- **^{225}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 ^{90}Y (now changing to ^{225}Ac) (for the therapeutic); *Partner:* **Perseus Proteomics ("PPMX").** *Current Status:* PPMX is in the process of changing the radioisotope conjugated to the antibody from ^{90}Y to ^{225}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 July 2024, PPMX announced that ^{225}Ac-PPMX-T002 showed greater efficacy in a mouse model of pancreatic cancer compared to ^{90}Y-PPMX-T002 and would be reporting the results at the European Association of Nuclear Medicine (EANM) 2024 Meeting.

  Additional program details: 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.

- **RayzeBio/BMS Program #2:** *Indication:* Solid Tumors; *Modality:* macrocyclic peptide targeting undisclosed target conjugated to a chelator radiolabeled with ^{225}Ac (for the therapeutic) or ^{68}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: PeptiDream anticipates further announcements regarding this program in 2024.

- **Novartis Program #3:** *Indication:* Solid Tumors; *Modality:* 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 on July 30, 2024, the program has now entered into IND-enabling studies.

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

- **^{18}F-Flortaucipir (Tauvid®) Program:** *Indication:* Brain imaging of aggregated tau neurofibrillary tangles (NFTs) in patients with cognitive impairment being evaluated for Alzheimer's disease (AD); *Modality:* small molecule flortaucipir radiolabeled with ^{18}F for PET imaging; *Partner:* **Eli Lilly and Company ("Lilly")**. *Current Status:* ^{18}F-Flortaucipir has completed the Japan Phase 3 study and the partners are now proceeding with seeking regulatory approval.

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

- **^{18}F-PD-L1 (^{18}F-BMS-986229) Program:** *Indication:* Oncology Imaging; *Modality:* macrocyclic peptide targeting PD-L1 (programmed death ligand-1) radiolabeled with ^{18}F for PET imaging (^{18}F-BMS-986229); *Partner:* **BMS**. *Current Status:* ^{18}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 recently published in the **Journal of Nuclear Medicine** (May 2024: Volume 65:5: Cytryn et al., *^{18}F-BMS-986229 PET to Assess Programmed-Death Ligand 1 Status in Gastroesophageal Cancer*). The results showed that PET imaging with ^{18}F-BMS-986229 is a safe and feasible noninvasive tool for assessing PD-L1 expression in patients with GEC and may provide a more comprehensive picture of PD-L1 expression, capturing spatial heterogeneity that single-site biopsies may miss. Patients who showed ^{18}F-BMS-986229 accumulation in any lesions by PET imaging had longer progression-free survival ("PFS")(any accumulation*; median PFS 28.4 months vs* no accumulation*; median PFS 9.9 months*) when treated with frontline PD-1 inhibitors, suggesting that PET imaging with ^{18}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), RayzeBio (2020; now a BMS company), and Genentech (2023), in addition to a growing number of fully-owned internal peptide-RI conjugate programs. **In April 2024, PeptiDream announced the further expansion of its discovery collaboration with Novartis, adding additional peptide-RI conjugate and other programs to the existing collaboration.** 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 already executed two partnering deals, in 2022 with Eli Lilly for the development and commercialization of the radiotracer ^{18}F-Flortaucipir in Japan, and in 2023 with LinqMed for the development and commercialization of the radiotherapeutic Cu^{64}-ATSM 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 also commercialize their products in Japan. The strategic in-licensing/partnering of high-value programs represents an important complementary strategy to PeptiDream 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 October 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. PDRadiopharma will assume responsibilities for manufacturing, commercialization, and maintenance service roles for the products.

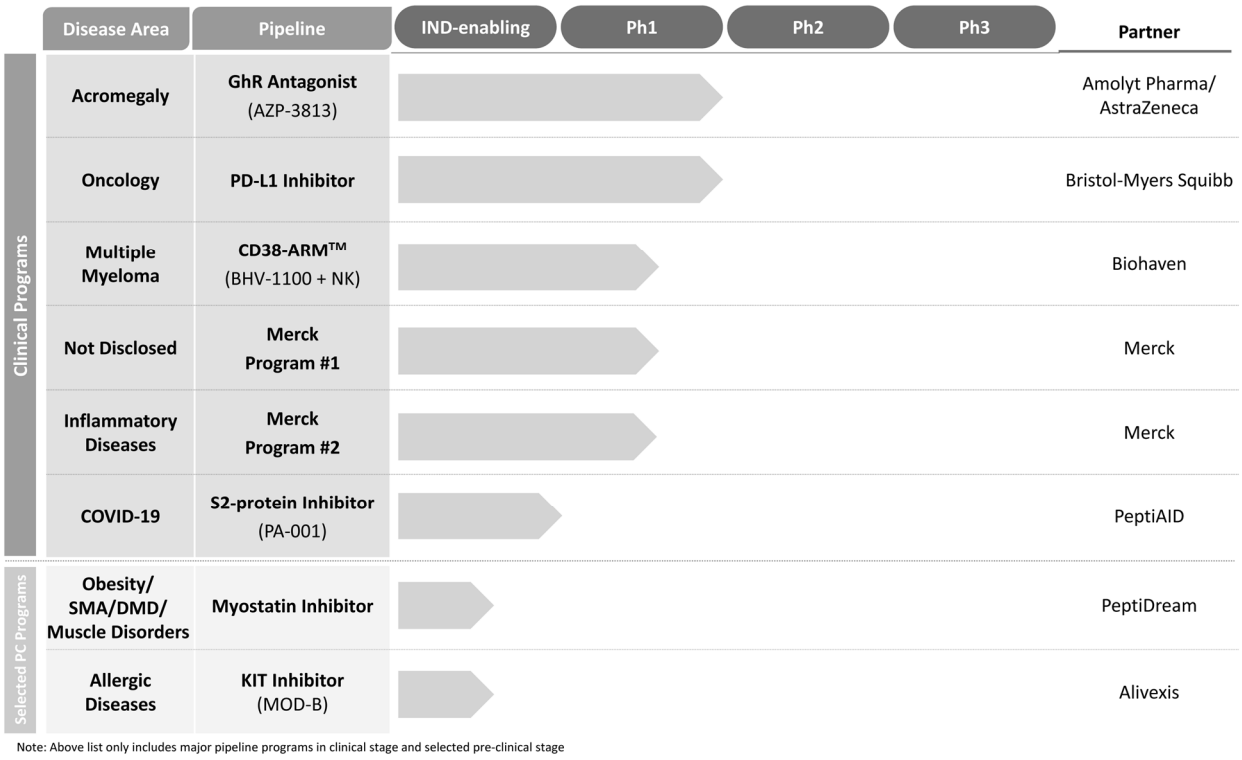
(B) Non-Radiopharmaceuticals Drug Discovery Business:

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.



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

- **GhR antagonist Program (AZP-3813):** *Indication:* Acromegaly; *Modality:* AZP-3813 is a macrocyclic peptide growth hormone receptor antagonist ("GHRA"); *Partner:* **Amolyt Pharma ("Amolyt"; Acquired by AstraZeneca in July 2024)**. *Current Status:* AZP-3813 recently completed a Phase 1 study investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AZP-3813 in a randomized double-blind placebo-controlled single and multiple ascending dose studies (SAD and MAD, respectively). In the SAD study, 5 subjects received a single subcutaneous administration of 3 mg AZP-3813 or placebo (3:2) and 8 subjects received 10, 20, 40, 60, 90, 120 mg AZP-3813 or placebo (6:2). In the MAD study, 8 subjects received 10, 20, 40, 60, 90, 120 mg AZP-3813 or placebo (6:2) QD for 14 consecutive days. Treatment was well tolerated in all subjects with no safety concerns. Cmax and AUC increased in a dose-proportional manner. The half-life of AZP-3813 was estimated to be 20-22 hours. In the SAD study, AZP-3813 induced a dose-related decrease in circulating IGF-1 levels at doses of 10 mg and above with a more prolonged reduction up to 72 hours at higher doses. In the MAD study, AZP-3813 induced a gradual and sustained dose-related decrease in circulating IGF-1 levels, with a larger effect after 2 weeks of dosing as compared to single administration at the same dose, consistent with a cumulative effect of repeated administration. Amolyt Pharma reported that these data clearly demonstrate that the novel GHRA, AZP-3813, substantially decreases circulating IGF-1 levels in healthy individuals, thereby supporting further testing in patients with acromegaly.

  Additional program details: PeptiDream and **Amolyt** 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 recently reported by Amolyt Pharma at the 26th 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), with the presentation materials now available on the Amolyt Pharma website (www.amolytpharma.com). Acromegaly is a rare, chronic endocrine disorder typically caused by a benign growth hormone (GH)-secreting pituitary adenoma that stimulates over-production of insulin-like growth factor-1 (IGF1) from the liver. The goal in treating acromegaly is to normalize IGF-1 levels to alleviate the symptoms and manage the potential medical complications caused by its excess. Treatment with somatostatin analog (SSA) monotherapy does not provide optimal control of circulating IGF-1 levels in the majority of patients. AZP-3813 is a 16-amino acid, bicyclic peptide that binds to the Growth Hormone ("GH") Receptor and prevents circulating GH from stimulating the production of IGF1. Studies have shown that AZP-3813 potently decreases circulating levels of IGF-1 and further suppressive effects are observed when combined with the SSA, octreotide. Therefore, AZP-3813 is being developed as an add-on therapy for the treatment of acromegaly in patients insufficiently controlled with SSAs.

- **PD-L1 Inhibitor Program:** *Indication:* Oncology; *Modality:* A macrocyclic peptide PD-L1 inhibitor (Program Identifier not disclosed); *Partner:* **BMS** (*see note below*). *Current Status:* The macrocyclic peptide PD-L1 inhibitor recently completed a Phase 1 safety study, (ISRCTN17572332), investigating the safety, tolerability, and pharmacokinetics in healthy volunteers, and a Clinical Study Report is currently being prepared.

  Additional program details: As announced in October 2023, BMS has decided to not advance this program beyond the ongoing Phase 1 Healthy Volunteer Study, deciding instead to prioritize other programs in the BMS portfolio. The decision was made for business reasons, and not due to any safety concerns. Once PeptiDream receives the Clinical Study Report from the Phase 1 Study, PeptiDream will review the clinical data with BMS and explore alternative options to continue the development of this promising program.

- **CD38-ARM™ (BHV-1100) Program:** *Indication:* Multiple Myeloma; *Modality:* BHV-1100 (CD38-ARM™) is a heterodimeric peptide conjugate composed of a macrocyclic peptide targeting CD38 conjugated to a macrocyclic peptide targeting IgG; *Partner:* **Biohaven, LTD. ("Biohaven")**. *Current Status:* BHV-1100 is currently being tested in 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.

  Additional program details: BHV-1100 + Autologous NK cells received Orphan Drug Designation on September 8, 2020.

- **Merck Program #1**: *Indication:* Undisclosed; *Modality:* Therapeutic 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 undisclosed). The details of the ongoing Phase 1 study have not been released.

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

- **Merck Program #2**: *Indication:* Inflammatory Disease; *Modality:* Therapeutic 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 undisclosed). 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 macrocyclic peptide inhibitor of the S2-protein expressed on the surface of the COVID-19 virus; *Partner:* **PeptiAID**. *Current Status:* In June 2024, an IND application was submitted to the FDA for the initiation of a Phase 1 clinical safety study of PA-001. In July 2024, PeptiAID received clearance to initiate a Phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of PA-001 in healthy elderly volunteers.

  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:* Macrocyclic peptide inhibitor of Myostatin; *Partner:* **PeptiDream**. *Current Status:* Clinical candidate selection based on ongoing preclinical testing in obesity animal models in combination with GLP-1 dual agonists.

  Additional program details: Myostatin (also known as growth differentiation factor 8, or GDF8) is a protein produced and released by myocytes that acts as a powerful negative regulator of skeletal muscle mass. Numerous preclinical and clinical studies have suggested that myostatin inhibitors can increase lean muscle mass, improve physical strength, reduce visceral fat, and improve metabolic dysfunction, such as insulin-mediated glucose disposal, providing growing evidence that myostatin may be an important therapeutic target for the treatment of a variety of muscular dystrophies, such as Spinal muscular atrophy "SMA", Facioscapulohumeral muscular dystrophy "FSHD", Duchene muscular dystrophy "DMD" and other muscle wasting diseases, as well as a potential treatment for obesity, metabolic syndrome, and type 2 diabetes mellitus. PeptiDream presented preclinical results of the Myostatin program at World Muscle Society ("WMS") 2023 in October 2023.

- **cKIT Inhibitor (MOD-B) Program:** *Indication:* Mast-cell driven immune-inflammatory and allergic diseases; *Modality:* Small molecule inhibitor of 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 will be conducting IND-enabling studies with the aim of moving the cKIT inhibitor program into clinical trials.

  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 already has two MPC programs in partnerships with **Biohaven** (BHV-1100) and **Santen**, in addition to a growing pipeline of internal MPC programs. Additionally, PeptiDream continues to expand the uses of its macrocyclic peptides, announcing a collaboration with **Astellas** (2023) in the field of targeted degraders.

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

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

- **March 2024:** Amolyt Enters into Definitive Agreement to be Acquired by AstraZeneca
- **March 2024:** PeptiGrowth Inc., PeptiDream Affiliated Company, Announces Product Launch of TPO-alternative peptide (TPOR agonist) – PG-010.
- **June 2024:** PeptiAID Submits IND for a Phase 1 Clinical Trial of PA-001
- **June 2024:** Merck Initiates a Phase 1 Clinical Trial of Second PDPS Program (2nd Merck program to enter the clinic).
- **July 2024:** Phase 1 Clinical Trial of AZP-3813, Partnered with Amolyt, Meets Study Endpoints

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

As of March 31, 2024, 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 June 30, 2024.

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

PeptiGrowth (*Tokyo, Japan*) was established in 2020 as a joint venture between **PeptiDream** and **Mitsubishi Corporation**, with the aim to develop, produce and sell peptide alternatives to growth factors, key ingredients of cell culture, used in the manufacturing of cell therapies, regenerative medicines and other biopharmaceutical areas, including the growing market of lab-grown meat and other products. Growth factors are a class of proteins that are widely present in humans and other animals. In addition to playing important roles in cell growth and proliferation, they are crucially involved in induction of differentiation of stem cells (iPS cells, ES cells, etc.) into nerve, blood, and other types of cells. Currently, growth factors are mainly extracted from animal serum or produced by recombination technology, however, their production presents a number of challenges to the pharmaceutical industry, including safety risks due to contamination with impurities, variation in quality among production lots,

and high production costs. PeptiDream has been using its proprietary PDPS® technology, to identify alternative peptides that perform the equivalent function as protein growth factors and utilize chemical synthetic routes that do not use animal serum or recombination technology, and by establishing a commercial manufacturing process, PeptiGrowth can produce homogenous products of high purity, ensuring less lot-to-lot variation, at lower costs. Mitsubishi Corporation is actively involved in the sales and marketing of PeptiGrowth's growing lineup of products. PeptiGrowth has launched nine (10) 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 neurotropic 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, and PG-010（TPOR agonist as an alternative to TPO, in 2024. The companies aim to continue to launch additional products in the future.

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

PeptiAID (*Kanagawa, Japan*) was established in 2020 as a joint venture between **PeptiDream, Fujitsu, Mizuho Capital, Takenaka Corporation**, and **Kishida Chemical**, with the aim to discover and develop a peptide therapeutic for the treatment of COVID-19. PeptiDream applied its proprietary PDPS® technology toward identifying peptide candidates targeting the COVID-19 viral "spike" protein, which is essential for coronavirus to enter human cells, leading to the discovery of PA-001. In May 2023, PeptiAID was selected by the Japan Agency for Medical Research and Development (AMED) to receive a grant to conduct a Phase 1 study of PA-001. On June 4, 2024, PeptiAID submitted an IND application to the FDA to conduct a Phase 1 safety study, and in July 2024, the IND application was accepted, paving the way for the Phase 1 safety study to begin in 2H-2024.

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

PeptiStar (*Osaka, Japan*) was established in 2017 as a joint venture between **PeptiDream, Shionogi**, and **Sekisui Chemical Co., Ltd**, with the aim to create a Contract Development and Manufacturing Organization ("CDMO") for the research and commercial manufacture of peptide therapeutics. PeptiStar brings together the most cutting-edge technologies and innovations in large-scale peptide production from various companies throughout Japan in order to manufacture peptides of the highest quality and purity, while simultaneously driving down the cost of production. PeptiStar's CDMO manufacturing facility is located in Osaka, Japan.

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

LinqMed (*Chiba, Japan*) was established in 2022, as a bioventure arising from the National Institutes for Quantum Sciences and Technology ("QST"), with the aim to bring innovative "visible" anti-cancer drugs to patients. As announced in December 2023, PeptiDream participated in LinqMed's Series A equity financing.

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

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

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

PeptiDream's corporate offices and state of the art research labs (*~7,950 sq m^2 of office and lab space*) are located in Kawasaki, Japan. PDRadiopharma's corporate, sales, and marketing offices are located in Tokyo, Japan, with its main manufacturing site located in Chiba, Japan (*~25,200 sq m^2 of research and manufacturing facilities*), and PET laboratories located in Osaka, Japan and Kawasaki, Japan (*each with ~2,200 sq $m^2$of office and lab space*). As of June 30, 2024, the Group had a total headcount of 733 employees (745 when including its 12 board members), (PeptiDream Inc; 215 employees, PDRadiopharma Inc., 518 employees).

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

- PeptiDream Group continues its commitment to promoting ESG (Environmental, Social, and Governance) initiatives and its sustainability efforts including focus areas, ten most material issues, relevant policies and data are proactively disclosed on the corporate website 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 the shift towards renewable energy. To further take this initiative, PeptiDream has decided to introduce CO2 (carbon dioxide)-free power from its supplier for use at our head office and laboratory. This means that we will achieve our medium-term goal of the realization of "carbon-neutral" business operations 4 years earlier than originally planned.

- PeptiDream believes as a R&D-driven innovative company that ensuring diversity is important in gaining a competitive advantage and nurturing innovation in order to fulfill its mission. In particular, PeptiDream values the diversity of expertise and scientific sense of each individual employee, and believes it is important to ensure a framework which allows the managers and senior scientists who play kay roles in R&D and management to engage in science-based discussions and decision-making regardless of their age, gender or cultural background. PeptiDream has set four quantitative indicators which it considers to be constituent elements of the diversity of core human resources (*1). The current status of these indicators and PeptiDream's 2030 targets are as follows; (1) Ratio of doctorate (Ph.D.) holders (end of December 2023: 54.0%, target for 2030: Maintain 50% or more); (2) Female manager ratio (end of December 2023: 16.0%, target for 2030: 30% or more); (3) Ratio of foreign employees or employees with overseas work experience (*2) (end of December 2023: 32.0%, target for 2030: Maintain 30% or more); and (4) Ratio of young employees (in 20s/30s) (end of December 2023: 24.0%, 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 for sustainability. On January 2022, PeptiDream was awarded as a "Top-Rated ESG Performer" for 2022 by Sustainalytics, a global ESG rating agency, and has been identified as top performer within the industry (rated No.2 among the 439 global biotech companies being evaluated). PeptiDream has been recognized by CDP for its leadership in climate change with an A- (A minus) rating for the second consecutive year in 2023. PeptiDream reached the Leadership level, the highest level, as a company that excels in its efforts and information disclosure in climate change. On May 2023, PeptiDream was selected as a constituent of the JPX Prime 150 Index, a new index developed by JPX Market Innovation & Research, Inc., a subsidiary of the Japan Exchange Group. In July 2024, PeptiDream was selected to remain a constituent of the FTSE4Good Index Series and FTSE Blossom Japan Index for the FOURTH consecutive year and of the FTSE Blossom Japan Sector Relative Index for the THIRD consecutive year. These indices are constructed by global index provider FTSE Russel. In addition, the FTSE Blossom Japan Index and FTSE Blossom Japan Sector Relative Index are both broad ESG indices and are adopted by the Government Pension Investment Fund (GPIF) of Japan as a core ESG benchmark for its passive investments.

As a result of the above, for the six months ended June 30, 2024, the Drug Discovery and Development Business recorded revenue of 28,480,960 thousand yen (a 27,019,593 thousand yen increase year on year), segment profit of 24,740,819 thousand yen (segment loss of 1,168,739 thousand yen in the same period of the previous fiscal year), the Radiopharmaceutical Business recorded revenue of 7,652,665 thousand yen (a 312,018 thousand yen decrease year on year), segment loss of 46,535 thousand yen (segment profit of 227,641 thousand yen in the same period of the previous fiscal year), and the Group recorded revenue of 36,133,625 thousand yen (a 26,707,575 thousand yen increase year on year), core operating profit of 24,772,986 thousand yen (core operating loss of 793,562 thousand yen in the same period of the previous fiscal year), operating profit of 24,649,283 thousand yen (operating loss of 986,098 thousand yen in the same period of the previous fiscal year), profit before tax of 24,742,228 thousand yen (loss before tax of 1,110,932 thousand yen in the same period of the previous fiscal year), and profit attributable to owners of parent of 17,925,302 thousand yen (loss attributable to owners of parent of 729,014 thousand yen).

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 income to operating income is as follows:

(Thousands of yen)

	Results for the six months ended June 30, 2023	Results for the six months ended June 30, 2024	Change	%
Core operating profit (loss)	(793,562)	24,772,986	25,566,549	-
Accounting effects of business acquisitions and acquisition-related costs	169,472	100,640	(68,832)	(40.6)
Impairment loss on property, plant and equipment, intangible assets and goodwill	―	―	―	―
Gains or losses on compensation, settlements	―	―	―	―
Non－recurring and significant gains and losses	―	―	―	―
Amortization of intangible assets from introduction of individual products or developments	23,062	23,062	―	―
Operating profit (loss)	(986,098)	24,649,283	25,635,381	―

(2) Explanation of Financial Position

1) Analysis of financial position

Total assets at the end of the six months ended June 30, 2024 increased by 26,417,228 thousand yen from the end of the previous fiscal year to 95,881,241 thousand yen. This was mainly because of increases of 5,969,618 thousand yen in cash and cash equivalents, 27,795,103 thousand yen in trade and other receivables, and 2,367,714 thousand yen in deferred tax assets, despite a decrease of 10,287,137 thousand yen in other financial assets.

Liabilities increased by 7,996,303 thousand yen from the end of the previous fiscal year to 37,110,606 thousand yen. This was mainly because of increases of 8,794,648 thousand yen in income taxes payable, and 814,377 thousand yen in other financial liabilities, despite decreases of 1,292,459 thousand yen in borrowings, and 385,837 thousand yen in deferred tax liabilities.

Equity increased by 18,420,924 thousand yen from the end of the previous fiscal year to 58,770,634 thousand yen. This was mainly because of increases of 17,925,302 thousand yen in retained earnings due to the recording of profit, and an increase of 469,448 thousand yen in other components of equity due to the recording of other comprehensive income.

2) Analysis of status of cash flows

Cash and cash equivalents for the six months ended June 30, 2024 increased by 5,969,618 thousand yen from the end of the previous fiscal year to 25,477,479 thousand yen.

Status of cash flows and related factors during the six months ended June 30, 2024 are described below.

(Cash flows from operating activities)

Cash flows from operating activities resulted in a cash outflow of 2,659,911 thousand yen (compared with an inflow of 8,769,521 thousand yen in the same period of the previous fiscal year). This was mainly due to the recording of increase in trade and other receivables of 27,795,103 thousand yen, and income taxes paid of 1,015,740 thousand yen, despite the recording of profit before tax of 24,742,228 thousand yen, and recording of depreciation and amortization of 1,154,343 thousand yen.

(Cash flows from investing activities)

Cash flows from investing activities resulted in a cash inflow of 9,956,370 thousand yen (compared with an outflow of 797,543 thousand yen in the same period of the previous fiscal year). This was mainly due to proceeds from sale of investment securities of 10,935,460 thousand yen.

(Cash flows from financing activities)

Cash flows from financing activities resulted in a cash outflow of 1,485,160 thousand yen (an 816,789 thousand yen decrease in outflow year on year). This was mainly due to repayments of long-term borrowings of 1,320,000 thousand yen.

(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, 2022	Results for the six months ended June 30, 2023	Results for the full year ended December 31, 2023	Results for the six months ended June 30, 2024	Forecasts for the full year ending December 31, 2024
	2022/Jan ~ 2022/Dec	2023/Jan ~ 2023/ Jun	2023/Jan ~ 2023/Dec	2024/Jan ~ 2024/Jun	2024/Jan ~ 2024/Dec
Capital Expenditures (JPY millions)	3,913	617	1,668	1,026	3,174
Depreciation Expense (JPY millions)	1,973	1,221	2,433	1,154	2,163
Research and Development Expenses (JPY millions)	2,915	1,506	3,155	1,471	4,110
Year-end headcount (people)	680	704	725	745	765

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

2. Condensed Semi-annual Consolidated Financial Statements and Primary Notes

(1) Condensed Semi-annual Consolidated Statements of Financial Position

(Thousands of yen)

	As of December 31, 2023	As of June 30, 2024
Assets		
Current assets		
Cash and cash equivalents	19,507,861	25,477,479
Trade and other receivables	4,970,860	32,765,963
Other financial assets	6,245	6,245
Inventories	2,404,156	2,789,939
Income taxes receivable	—	14,565
Other current assets	335,959	727,377
Total current assets	27,225,082	61,781,570
Non-current assets		
Property, plant and equipment	17,358,317	17,286,634
Goodwill	8,370,677	8,370,677
Intangible assets	2,211,452	2,141,261
Investments accounted for using equity method	81,067	—
Other financial assets	11,801,205	1,514,067
Deferred tax assets	2,337,218	4,704,933
Retirement benefit asset	32,146	34,357
Other non-current assets	46,845	47,739
Total non-current assets	42,238,930	34,099,671
Total assets	69,464,013	95,881,241

	As of December 31, 2023	As of June 30, 2024
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	3,203,559	3,486,439
Borrowings	2,586,259	2,589,645
Other financial liabilities	255,987	1,025,603
Income taxes payable	1,003,852	9,798,501
Provisions	31,583	16,268
Contract liabilities	823,011	674,858
Other current liabilities	712,834	658,563
Total current liabilities	8,617,088	18,249,879
Non-current liabilities		
Borrowings	19,634,447	18,338,602
Other financial liabilities	323,160	367,921
Deferred tax liabilities	385,837	—
Retirement benefit liability	97,647	95,046
Provisions	56,120	59,157
Total non-current liabilities	20,497,214	18,860,727
Total liabilities	29,114,303	37,110,606
Equity		
Share capital	3,956,738	3,956,738
Capital surplus	4,550,372	4,566,129
Treasury shares	(1,085,546)	(1,075,128)
Retained earnings	27,804,689	52,269,245
Other components of equity	5,123,456	(946,349)
Total equity attributable to owners of parent	40,349,709	58,770,634
Total equity	40,349,709	58,770,634
Total liabilities and equity	69,464,013	95,881,241

(2) Condensed Semi-annual Consolidated Statements of Profit or Loss

Six months ended June 30, 2023 and June 30, 2024

(Thousands of yen, unless otherwise stated)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Revenue	9,426,049	36,133,625
Cost of sales	5,464,694	6,172,764
Gross profit	3,961,355	29,960,861
Selling, general and administrative expenses	3,429,071	3,804,852
Research and development expenses	1,506,241	1,471,800
Other income	3,939	29
Other expenses	16,079	34,954
Operating profit (loss)	(986,098)	24,649,283
Finance income	103,153	335,214
Finance costs	124,756	136,342
Share of profit (loss) of investments accounted for using equity method	(103,231)	(105,927)
Profit (loss) before tax	(1,110,932)	24,742,228
Income tax expense	(381,918)	6,816,926
Profit (loss)	(729,014)	17,925,302
Profit (loss) attributable to:		
Owners of parent	(729,014)	17,925,302
Profit (loss)	(729,014)	17,925,302
Earnings (loss) per share		
Basic earnings (loss) per share (Yen)	(5.62)	138.30
Diluted earnings (loss) per share (Yen)	(5.62)	138.11

(3) Condensed Semi-annual Consolidated Statements of Comprehensive Profit or Loss

Six months ended June 30, 2023 and June 30, 2024

(Thousands of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Profit (loss)	(729,014)	17,925,302
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Financial assets measured at fair value through other comprehensive income	212,258	469,448
Total of items that will not be reclassified to profit or loss	212,258	469,448
Other comprehensive income	212,258	469,448
Comprehensive income	(516,755)	18,394,750
Comprehensive income attributable to:		
Owners of parent	(516,755)	18,394,750
Comprehensive income	(516,755)	18,394,750

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

(4) Condensed Quarterly Consolidated Statements of Changes in Equity

Six months ended June 30, 2023

(Thousands of yen)

	Equity attributable to owners of parent						Total equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	Total equity attributable to owners of parent	
Balance at January 1, 2023	3,956,738	4,524,436	(607,334)	23,848,337	319,287	32,041,465	32,041,465
Profit (loss)	–	–	–	(729,014)	–	(729,014)	(729,014)
Other comprehensive income	–	–	–	–	212,258	212,258	212,258
Total comprehensive income	–	–	–	(729,014)	212,258	(516,755)	(516,755)
Purchase of treasury shares	–	–	(513,842)	–	–	(513,842)	(513,842)
Disposal of treasury shares	–	–	35,630	–	–	35,630	35,630
Share-based payment transactions	–	(25,873)	–	–	–	(25,873)	(25,873)
Total transactions with owners	–	(25,873)	(478,212)	–	–	(504,085)	(504,085)
Balance at June 30, 2023	3,956,738	4,498,562	(1,085,546)	23,119,323	531,546	31,020,624	31,020,624

Three months ended June 30, 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)	—	—	—	17,925,302	—	17,925,302	17,925,302
Other comprehensive income	—	—	—	—	469,448	469,448	469,448
Total comprehensive income	—	—	—	17,925,302	469,448	18,394,750	18,394,750
Purchase of treasury shares	—	—	(143)	—	—	(143)	(143)
Disposal of treasury shares	—	—	10,562	—	—	10,562	10,562
Transfer from other components of equity to retained earnings	—	—	—	6,539,253	(6,539,253)	—	—
Share-based payment transactions	—	15,756	—	—	—	15,756	15,756
Total transactions with owners	—	15,756	10,418	6,539,253	(6,539,253)	26,174	26,174
Balance at June 30, 2024	3,956,738	4,566,129	(1,075,128)	52,269,245	(946,349)	58,770,634	58,770,634

(5) Condensed Semi-annual Consolidated Statements of Cash Flows

(Thousands of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Cash flows from operating activities		
Profit (loss) before tax	(1,110,932)	24,742,228
Depreciation and amortization	1,221,011	1,154,343
Interest and dividend income	(5,792)	(481)
Interest expenses	116,872	136,342
Foreign exchange loss (gain)	(270,895)	(128,293)
Share of loss (profit) of investments accounted for using equity method	103,231	105,927
Decrease (increase) in trade and other receivables	12,060,426	(27,795,103)
Decrease (increase) in inventories	33,568	(385,782)
Increase (decrease) in trade and other payables	(1,186,090)	436,504
Increase (decrease) in defined benefit asset and liability	2,175	(4,813)
Other	208,303	178,365
Subtotal	11,171,878	(1,560,762)
Interest and dividends received	5,792	481
Interest paid	(91,717)	(108,802)
Income taxes paid	(2,316,431)	(1,015,740)
Income taxes refund	-	24,912
Net cash provided by (used in) operating activities	8,769,521	(2,659,911)
Cash flows from investing activities		
Proceeds from sale of investment securities	-	10,935,460
Payments for purchases of investment securities	(200,000)	-
Collection of loans receivable	3,121	3,122
Purchase of property, plant and equipment	(547,145)	(928,858)
Purchase of intangible assets	(53,632)	(75,699)
Other	112	22,345
Net cash provided by (used in) investing activities	(797,543)	9,956,370
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	(500,000)	-
Repayments of long-term borrowings	(1,120,000)	(1,320,000)
Repayments of lease liabilities	(167,395)	(183,766)
Purchase of treasury shares	(514,554)	(143)
Proceeds from issuance of share acquisition rights	-	18,750
Net cash provided by (used in) financing activities	(2,301,949)	(1,485,160)
Effect of exchange rate change on cash and cash equivalents	270,895	158,319
Net increase (decrease) in cash and cash equivalents	5,940,923	5,969,618
Cash and cash equivalents at beginning of period	5,247,665	19,507,861
Cash and cash equivalents at end of period	11,188,589	25,477,479

(6) Notes to Condensed Semi-annual 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.

(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.

Six months ended June 30, 2023 (January 1, 2023 to June 30, 2023)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	1,461,366	7,964,683	9,426,049	—	9,426,049
Inter-segment revenue	—	29,910	29,910	(29,910)	—
Total	1,461,366	7,994,593	9,455,959	(29,910)	9,426,049
Segment profit (loss)	(1,168,739)	227,641	(941,098)	—	(941,098)
(Adjustments)					
Business combination-related expenses (Note)					45,000
Operating profit (loss)					(986,098)
Finance income					103,153
Finance costs					124,756
Share of profit (loss) of associates accounted for using the equity method					(103,231)
Profit (loss) before income taxes					(1,110,932)

(Note) Amortization expenses of 45,000 thousand yen for intangible assets newly acquired through the business combination.

Six months ended June 30, 2024 (January 1, 2024 to June 30, 2024)

(Thousands of yen)

	Reportable Segment			Adjustment	Consolidated Statement
	Drug Discovery and Development Business Segment	Radiopharmaceutical Business Segment	Total		
Revenue					
External revenue	28,480,960	7,652,665	36,133,625	—	36,133,625
Inter-segment revenue	—	177,534	177,534	(177,534)	—
Total	28,480,960	7,830,199	36,311,160	(177,534)	36,133,625
Segment profit (loss)	24,740,819	(46,535)	24,694,283	—	24,694,283
(Adjustments)					
Business combination-related expenses (Note)					45,000
Operating profit (loss)					24,649,283
Finance income					335,214
Finance costs					136,342
Share of profit (loss) of associates accounted for using the equity method					(105,927)
Profit (loss) before income taxes					24,742,228

(Note) Amortization expenses of 45,000 thousand yen for intangible assets newly acquired through the business combination.