Consolidated Financial Results for the Six months Ended June 30, 2024 (IFRS)

August 9, 2024

Company name: Nxera Pharma Co., Ltd (formerly Sosei Group Corporation) — Listing: Tokyo Stock Exchange
Security code: 4565 URL: https://www.nxera.life
Representative: Christopher Cargill, Representative Executive Officer, CEO
Contact person: Hironoshin Nomura, Executive Officer, CFO — Tel: +81-3-5962-5718
Scheduled date of Semi-annual Securities Report filing: August 9, 2024
Scheduled date of dividend payments: -
Supplementary materials for financial results: Yes
Financial results briefing session: Yes

(Rounded million yen)

1. Consolidated Financial Results for the 6 month period ended June 30, 2024 (from January 1, 2024 to June 30, 2024)

(1) Consolidated Operating Results (cumulative)

(Percentages are shown as year-on-year changes)

	Revenue		Core operating profit		Operating profit		Profit before income taxes		Net profit	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
6 month period ended June 30, 2024	12,720	492.7	1,176	-	(3,654)	-	(3,158)	-	(4,703)	-
6 month period ended June 30, 2023	2,146	(12.7)	(2,720)	-	(4,168)	-	(3,760)	-	(2,060)	-

	Net profit attributable to owners of the parent		Total comprehensive income		Earnings per share – basic	Earnings per share – diluted
	Million yen	%	Million yen	%	Yen	Yen
6 month period ended June 30, 2024	(4,703)	-	1,539	-	(52.51)	(52.51)
6 month period ended June 30, 2023	(2,060)	-	4,369	-	(25.13)	(25.13)

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the parent	Ratio of equity attributable to owners of the parent to total assets
	Million yen	Million yen	Million yen	%
At June 30, 2024	156,484	68,980	68,980	44.1
At December 31, 2023	157,198	66,810	66,810	42.5

2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen	Yen	Yen	Yen	Yen
FY2023	-	0.00	-	0.00	0.00
FY2024	-	0.00			
FY2024 (E)			-	0.00	0.00

(Note) There is no change in the dividend forecast from the previous disclosure.

3. Forecast for the year from January 1, 2024 to December 31, 2024

A financial results forecast for the year ended December 31, 2024 has not been provided because it is difficult to forecast a reasonable estimate of the full-year results. Details concerning the reasons thereof, business policy and cost estimates are provided in “1. Analysis of Operating Results and Financial Position (3) Future outlook“ on page 13 of this document.

* Notes

(1) Significant changes in scope of consolidation for the six month period ended June 30, 2024: None

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

1) Changes in accounting policies required by IFRS: None
2) Changes due to changes in accounting policies other than those of item 1: None
3) Changes in accounting estimates: None

(3) Number of common shares issued

1) Number of shares issued at period end (including treasury shares)	At June 30, 2024	89,902,858 shares	At December 31, 2023	89,446,777 shares
2) Number of treasury shares at period end	At June 30, 2024	1,274 shares	At December 31, 2023	335 shares
3) Average number of shares in issue in period	6 month period ended June 30,2024	89,561,090 shares	6 month period ended June 30, 2023	82,023,480 shares

* Semi-annual consolidated financial results reports are not subject to audit.

** Explanation regarding the appropriate use of forecasts of business results and other points to be noted*

Note concerning forward-looking statements:

The financial forecast is based on judgements and estimates that have been prepared on the basis of information available as of the time of disclosure of this material. The actual business results may differ materially from our forecasts due to various factors.

The Company is scheduled to hold a webinar presentation for all existing and potential investors as well as sell-/buy-side analysts which will consist of a presentation followed by a Q&A session on August 9, 2024. Presentation slides will be made available on August 9, 2024 through the investor section of the Company's Home Page.

○ Contents of Attached Materials

1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

Nxera Pharma ("the Group" or "the Company") is a technology-powered biopharma company, in pursuit of new specialty medicines to improve the lives of patients with unmet needs in Japan and globally. Its core activities are drug discovery, drug development and the commercialization of pharmaceutical products. Within the Group, Nxera Pharma UK Limited (formerly Heptares Therapeutics Ltd), a wholly owned subsidiary based in UK, mainly engages in drug discovery, translational medicine, preclinical and early clinical development; Nxera Pharma Japan Co., Ltd. (formerly Idorsia Pharmaceuticals Japan Ltd.), a wholly owned subsidiary based in Japan, and Nxera Pharma Korea Co., Ltd. (formerly Idorsia Pharmaceuticals Korea Co., Ltd.; hereinafter referred to as "NPK"), a wholly owned subsidiary based in South Korea, mainly engage in clinical development and product commercialization in Japan and South Korea, respectively, with potential to expand into other Asia-Pacific ("APAC") regions.

In drug discovery, the Group's core scientific focus is to discover transformative new medicines for important unmet medical needs, including novel small molecules, peptides and therapeutic antibodies targeting G Protein-Coupled Receptors ("GPCRs"). Its proprietary GPCR-targeted structure-based drug discovery ("SBDD") platform ("NxWave™") has enabled the Group to become a world leader in designing new drugs to target GPCRs and to develop an extensive pipeline of over 30 active in-house and partnered programs with the potential to deliver first-in-class or best-in-class medicines targeting important therapeutic areas, including neurology, gastroenterology, and immunology and inflammation.

In late-stage development and commercialization, the Group owns the Japan and APAC (excluding China) territory rights to PIVLAZ® (launched in Japan in 2022 to treat cerebral vasospasm and approved in South Korea with launch planned for 2025) and daridorexant (filed in Japan in 2023 to treat insomnia), as well as exclusive options to license Japan and APAC (ex-China) rights from Idorsia Pharmaceuticals to its cenerimod (autoimmune diseases) and lucerastat (Fabry disease) programs, both of which are in Phase 3 development.

In addition, the Group generates royalty revenues from the global sales of respiratory disease products Seebri® Breezhaler®, Ultibro® Breezhaler® and Enerzair® Breezhaler® from Novartis International AG ("Novartis"). These royalties provide the Group with a significant and stable source of capital.

In conjunction with the Group's name change to Nxera Pharma from Sosei Group, enacted on April 1, 2024, its strategy has been further evolved and refined, focusing on leveraging the NxWave™ platform, pipeline and discovery, development and commercialization capabilities to provide multiple options to advance its own and externally sourced candidates to patients in Japan and globally. This strategy is based on three key strategic pillars:

(i) Delivering Life-Changing Medicines to Patients in Japan

Leveraging the Group's extensive clinical development and commercialization business in Japan using a lean, agile and scalable model to deliver new medicines to patients in this large and growing market and providing a platform to expand into broader APAC markets.

(ii) Progressing High-Value Programs by Design

Advancing and expanding the Group's extensive pipeline of novel and potentially life-changing medicines in-house and with partners, generating multiple opportunities for value-creation targeting fast-growing areas of unmet medical need in Japan and globally.

(iii) Leveraging Cutting-Edge Science and Technology

Extending and enhancing the competitive advantages of the NxWave™ platform through internal innovation and collaboration – accelerating the identification/selection of new programs for development in-house and/or through partnerships.

The Group's progress across these three key areas during the first half of 2024 is as follows:

(i) Delivering Life-Changing Medicines to Patients in Japan

One of the Group's driving ambitions is to become a leading biopharma company in Japan applying cutting-edge science to deliver life-changing medicines for patients. Japan is the third largest pharma market behind the US and China and has a large aging population and universal health care system. The Group's three priorities under this strategic goal are:

- In-house development and commercialization of select wholly owned programs for Japan/APAC
- Late-stage clinical development and commercialization for in-licensed assets in Japan/APAC
- Partnering assets with early clinical POC for global commercialization, retaining Japan/APAC rights

In 2024, the Group aims to achieve PIVLAZ® Sales (NHI basis) of JPY 16,000 million or more, gain JNDA approval and launch daridorexant in Japan, and acquire/in-license at least one late-stage medicine for the Japan/APAC (ex-China) region, focusing on strengthening the Japan/APAC business to achieve its strategic goals.

On April 15, 2024, the Company announced that its operating business NPK had entered into an exclusive supply and distribution agreement with Handok Inc. ("Handok") to commercialize PIVLAZ® (clazosentan sodium) 150 mg in South Korea. Under the terms of the agreement, NPK will provide drug product to Handok at an agreed price and Handok will be exclusively responsible for the promotion, marketing, sales and distribution of PIVLAZ® in South Korea. The Group received a one-off upfront payment from Handok upon signing the agreement and is eligible to receive further commercial milestone payments plus sales revenues coming from product supply.

(ii) Progressing High-Value Programs by Design

Partnering with global biopharmaceutical companies around specific candidates/programs that the Group has developed or for the discovery and development of candidates against partner-nominated targets using its NxWave™ platform has long been a successful strategy for the Group. Many of these partnerships provide the Group with an economic interest in programs advancing in some of the most exciting and fastest growing areas of medicine, such as metabolic diseases and neuropsychiatric disorders.

Success with this strategic goal provides significant industry validation and has generated nearly USD 1 billion in revenues to date from upfront and milestone payments from partners, with the potential for significant ongoing revenues as further milestones are reached.

In parallel, a key objective of the Group has been to transform its own in-house R&D, applying a program-centric operational model to accelerate progress of high-quality candidates into and through clinical development. This is intended to provide both a pipeline of opportunities that the Group can develop through to market itself in select indications in Japan and APAC, as well as via potentially more profitable out-licensing deals.

Partnered programs

On March 11, 2024, the Group announced it had entered a global collaboration and exclusive option-to-license agreement with Boehringer Ingelheim. At the center is a joint mission to develop and commercialize the Group's portfolio of first-in-class GPR52 agonists with the intent to improve patient outcomes by simultaneously addressing positive, negative, and cognitive symptoms of schizophrenia.

The Group received an upfront payment of EUR 25 million from Boehringer Ingelheim in the first quarter of 2024 and is eligible for an option exercise payment of EUR 60 million and further development, regulatory and commercialization milestone payments totaling up to EUR 670 million plus tiered royalties on future Boehringer Ingelheim product sales.

Boehringer Ingelheim has the exclusive option to license the Group's portfolio of GPR52 agonists following the completion of the Group's ongoing Phase 1 and subsequent Phase 1b trial and further Phase 2 enabling activities with NXE0048149, a first-in-class GPR52 agonist. The Group will retain control and act as sponsor of these trials until option exercise, estimated in 2025. The licensed portfolio includes NXE0048149 as well as multiple differentiated back-up compounds.

On April 16, 2024, the Group announced that it had been notified by its partner Neurocrine Biosciences ("Neurocrine") that NBI-1117568, an oral selective muscarinic M4 receptor agonist being advanced in Phase 2 clinical trials by Neurocrine for the treatment of schizophrenia and other neuropsychiatric disorders, had successfully completed a long-term preclinical toxicity program that meets US Food & Drug Administration ("FDA") requirements to allow for safe, chronic (i.e. long-term) dosing in future clinical trials. The achievement of this important safety development milestone triggered a USD 15 million payment to the Group from Neurocrine.

NBI-1117568 is the most advanced candidate from a broad portfolio of novel clinical and preclinical subtype-selective muscarinic M4, M1 and dual M1/M4 receptor agonists discovered by the Group and advancing under the 2021 global collaboration with Neurocrine for the treatment of major neurological disorders. These candidates have potential to address a range of neurological and neuropsychiatric conditions and include:

- NBI-1117568 (an M4 selective agonist) in Phase 2 trials with top-line data expected in Q3 2024
- NBI-1117570 (an M1/M4 selective dual agonist) in Phase 1
- NBI-1117569 (an M4-preferring agonist) in Phase 1
- NBI-1117567 (an M1-preferring agonist) in Phase 1

On May 9, 2024, Neurocrine announced that it had initiated its Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational compound NBI-1117567 in healthy adult participants. NBI-1117567 is an investigational, oral, muscarinic M1 preferring (M1/M4) selective agonist discovered by the Group that may have the potential to treat symptoms of cognition in patients with neurological and neuropsychiatric conditions.

On May 30, 2024, the Group announced that it would receive USD 4.6 million in milestone payments from Centessa Pharmaceuticals pursuant to a license agreement which utilized the Group's technology in the design of Centessa's novel orexin receptor 2 (OX2R) agonist, ORX750. The milestones were achieved upon approval of the ORX750 Investigational New Drug application and progression of ORX750 into a Phase 1 clinical trial. ORX750 is an investigational, orally

administered, highly potent and selective OX2R agonist designed to directly target the underlying pathophysiology of orexin neuron loss in narcolepsy type 1 (NT1), with potential applicability to narcolepsy type 2 (NT2), idiopathic hypersomnia, and other sleep-wake disorders with normal orexin levels.

On June 27, 2024, the Group announced that it had reached an important R&D milestone under its multi-target discovery collaboration with AbbVie targeting neurological diseases, resulting in a payment of USD 10 million to the Group. The Group and AbbVie entered into this multi-target collaboration in 2022 to leverage the Group's NxWave™ platform to discover, develop and commercialize new medicines targeting novel GPCR targets associated with neurological disease. Under the terms of the agreement, the Group is eligible to receive up to US$40 million in near-term research milestones, as well as further potential option, development and commercial milestones totalling up to US$1.2 billion, plus tiered royalties on global sales.

In-house programs

On March 21, 2024, the Group announced it had dosed the first subject in a Phase 1 trial evaluating its novel EP4 receptor agonist, NXE0033744 (NXE'744) for the treatment of Inflammatory Bowel Disease ("IBD"), a therapeutic area where there remains significant unmet need for millions of people worldwide.

NXE'744 is a potent, selective and gut-restricted prostaglandin EP4 receptor agonist that has been uniquely designed to bring clinical benefit by accelerating the healing of damaged epithelial mucosa and suppressing exaggerated gut inflammation, with minimal systemic exposure to avoid adverse events. This approach is widely recognized to promote deeper remission and offer better long-term clinical outcomes. NXE'744 aims to address the significant unmet need of people with IBD that do not achieve satisfactory disease control. Current treatments for IBD typically achieve remission rates of less than 25%, and the safety profile of these drugs mean that they require careful monitoring.

The Phase 1 trial is a first-in-human randomized, double-blind study to assess the safety, pharmacokinetics and effects on pharmacodynamic biomarkers of single and multiple ascending doses of NXE'744 in adult healthy volunteers and people with Crohn's disease to generate proof of mechanism. The trial will be conducted in the UK and initial data read-outs are anticipated from 2025.

Also on March 21, 2024, the Group announced it had regained full ownership from GSK of NXE0027477 (formerly GSK4381406), a clinic-ready, highly selective, first-in-class, oral GPR35 agonist in development as a potential new treatment for IBD. GPR35 is an important orphan GPCR with an established genetic association to IBD.

NXE0027477 was designed by the Group using its NxWave™ platform and licensed to GSK in 2020. Since then, NXE0027477 has been advanced through a joint development program, generating promising mechanistic, preclinical efficacy and safety data suggesting that it may have the potential to improve intestinal barrier function and reduce visceral pain in gastrointestinal indications such as ulcerative colitis and irritable bowel syndrome. The UK Medicines and Healthcare products Regulatory Agency ("MHRA") gave approval in mid-2023 for NXE0027477 to be investigated in first-in-human studies.

Following a change in GSK's pipeline priorities, the Group regained full ownership of the NXE0027477 program including associated intellectual property licensed by the Group to GSK, and preclinical data generated under the partnership for no upfront payment. The Group expects to determine the optimal strategy for further clinical development of the program, which could include in-house development and re-partnering.

(iii) Leveraging Cutting-Edge Science and Technology

The Group's capabilities and leadership in unlocking GPCRs to rational SBDD approaches are recognized across the industry and have enabled the generation of 30+ novel drug candidates and programs, which are currently being advanced by global biopharma partners and internally.

This powerful, world-leading platform provides the Group with unprecedented access to new targets and candidates to continuously feed its rich pipeline. the Group is focused on reinforcing and extending this leadership through continual internal innovation, including the broad application of AI and machine learning technologies alongside collaboration with global technology leaders from industry and academia. Current technology partners include Verily, Kallyope, PeptiDrream, PharmEnable and PrecisionLife.

On May 30, 2024, the Group and PrecisionLife, an AI-driven precision medicine company, announced the expansion of their strategic R&D partnership into auto-immune disorders with the potential to identify new drug targets for the treatment of complex, chronic conditions. This is the latest in a series of collaborative agreements between the Group and PrecisionLife, which began in 2022. The partnership aims to establish new drug targets and subsequently potential precision targeted therapies for auto-immune disorders, each linked to subgroups of patients by PrecisionLife's mechanism-based patient stratification biomarkers.

PrecisionLife finds combinations of biological features that together are associated with disease risk and/or protective effects. These combinations, along with mechanistic biomarkers and causal biology insights to identify which patients will respond to treatment, may empower the Group to more accurately position known and novel targets for the right responder populations in each target product profile.

Activities related to former wholly-owned subsidiaries

The Group received a milestone related to a program previously created by Activus Pharma Inc. ("Activus"), formerly a wholly owned subsidiary of the Company.

On March 6, 2024, the Group announced that Formosa Pharmaceuticals, Inc. ("Formosa") had received approval from the US FDA for clobetasol propionate ophthalmic suspension 0.05% (APP13007), for the treatment of post-operative inflammation and pain following ocular surgery. As a result, the Group received a USD 2.5 million payment from Formosa in April 2024. APP13007 was originally designed and developed at Activus, which was divested in August 2017 to Formosa, a wholly owned subsidiary of Formosa Laboratories, Inc., a leading manufacturer of Active Pharmaceutical Ingredients ("APIs") listed on the Taiwan Stock Exchange. Activus developed APP13007 using its proprietary Activus Pure Nanoparticle Technology to create a novel nanoparticle formulation of steroid for treating postoperative inflammation of the eye. Since the divestment, Formosa progressed the development of APP13007 to FDA approval.

Other developments in the period under review (six month period ended June 30, 2024)

On April 1, 2024, the Company changed its company name to Nxera Pharma Co., Ltd., having received approval at the 34th Ordinary General Meeting of Shareholders held on March 27, 2024. The new name expresses the Company's vision to lead the next era of medicine- from Japan, for Japan, and by extension, to the world – and its mission to accelerate the development of life-changing medicines, by investing in science and technology. The Company's subsidiaries, formerly Heptares Therapeutics and Idorsia Pharmaceuticals Japan and Korea, have all been renamed under the Nxera Pharma brand to Nxera Pharma UK Limited, Nxera Pharma Japan Co., Ltd. ("NPJ") and Nxera Pharma Korea Co., Ltd., respectively.

Employees

As of June 30, 2024, the Group had a total of 360 employees (an increase of 10 employees vs. the end of the prior year).

Financial Results

As a result of the above activities, the Group reported the following financial results for the six month period ended June 30, 2024.

- Revenue of JPY 12,720 million (an increase of JPY 10,574 million vs. the prior corresponding period)
- IFRS operating loss of JPY 3,654 million (vs. an operating loss of JPY 4,168 million in the prior corresponding period)
- Core operating profit (alternative performance measure) of JPY 1,176 million (vs. a core operating loss of JPY 2,720 million in the prior corresponding period)
- Loss before income taxes of JPY 3,158 million (vs. a loss before income taxes of JPY 3,760 million in the prior corresponding period)
- Net loss of JPY 4,703 million (vs. a net loss of JPY 2,060 million in the prior corresponding period)

	6 month period ended June 30, 2024 ¥m	6 month period ended June 30, 2023 ¥m	Change
Revenue	**12,720**	2,146	10,574
Cost of sales	**(3,492)**	(225)	(3,267)
Research and development expenses	**(5,487)**	(4,039)	(1,448)
Selling, general and administrative expenses	**(8,022)**	(2,571)	(5,451)
Operating expenses	**(17,001)**	(6,835)	(10,166)
Net other income	**627**	521	106
Operating loss	**(3,654)**	(4,168)	514
Net finance income	**496**	408	88
Loss before income taxes	**(3,158)**	(3,760)	602
Income tax (expense) benefit	**(1,545)**	1,700	(3,245)
Net loss	**(4,703)**	(2,060)	(2,643)
Alternative performance measure			
Core operating profit / loss (Note 1)			
Operating loss (as stated above)	**(3,654)**	(4,168)	514
Adjustments:			
Depreciation	**804**	294	510
Amortization	**1,183**	407	776
Share-based payments (Note 2)	**633**	328	305
Restructuring (Note 2)	**28**	53	(25)
Cost of sales adjustment (Note 3)	**1,619**	-	1,619
Integration costs (Note 4)	**563**	-	563
M&A related costs	**-**	366	(366)
Core operating profit (loss)	**1,176**	(2,720)	3,896
Average exchange rate during period			
USD:JPY	**152.12**	134.82	17.30
GBP:JPY	**192.42**	166.29	26.13

Notes 1. Core operating profit/loss is defined as IFRS Operating profit/loss + material non-cash costs + material non-recurring costs and highlights the underlying recurring cash generating capability of the business.

2. Accelerated share-based payment expenses are included in Restructuring.
3. Cost of sales includes a non-cash accounting adjustment to the cost of inventory sold in the period which was originally acquired as part of the Idorsia transaction in July 2023.
4. Incremental one-off integration costs including IT system integration and corporate rebranding.

The Group operates as a single business segment and, therefore, segmental information has been omitted. Further explanation of the Group's financial performance is detailed below.

Revenue

	6 month period ended June 30, 2024 ¥m	6 month period ended June 30, 2023 ¥m	Change
Pharmaceutical product sales	**5,393**	64	5,329
Upfront fees and milestone income	**6,264**	667	5,597
Milestone revenue recognized at milestone event	3,438	-	3,438
Deferred revenue releases	1.434	667	767
Upfront fee revenue recognized at deal inception	1,392	-	1,392
Royalty income	**1,031**	1,252	(221)
Other revenue	**32**	163	(131)
Total	**12,720**	2,146	10,574

Revenue in the six month period under review totaled JPY 12,720 million (an increase of JPY 10,574 million vs. the prior corresponding period).

Pharmaceutical product sales in the six month period under review totaled JPY 5,393 million (an increase of JPY 5,329 million vs. the prior corresponding period). This was primarily due to the addition of NPJ in the scope of consolidation from July 2023, which resulted in the inclusion of PIVLAZ® sales in the period under review.

Revenue related to upfront fees and milestone income in the six month period under review totaled JPY 6,264 million (an increase of JPY 5,597 million vs. the prior corresponding period). Upfront fees and milestone income comprises upfront fee revenue, milestone revenue and deferred revenue releases. Upfront fees and milestone income can vary considerably year on year and depend on the commencement of new partnership agreements and the achievement of defined milestone events within that year.

In respect of some of the Group's partnership agreements, income relating to the provision of research and development services to customers is included within upfront fees or development milestone fees receivable by the Group, and recorded initially as deferred revenue in the balance sheet. Such income is transferred from deferred revenue in the balance sheet to revenue in the income statement as a result of the performance of research and development activity in the period under review. The increase in upfront fees and milestone income in the six month period under review was primarily due to signing one new partnership agreement and the occurrence of four milestone events in the current period vs. no upfront fees or milestone events in the prior corresponding period.

Revenue related to royalties in the six month period under review totaled JPY 1,031 million (a decrease of JPY 221 million vs. the prior corresponding period). The Group's royalty revenue relates to sales of Ultibro® Breezhaler®, Seebri® Breezhaler® and Enerzair® Breezhaler® by Novartis[1].

[1] Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Nxera and Vectura. Seebri®, Ultibro®, Enerzair® and Breezhaler® are registered trademarks of Novartis.

Operating expenses

Cost of sales

Cost of sales in the six month period under review totaled JPY 3,492 million (an increase of JPY 3,267 million vs. the prior corresponding period). Cost of sales excluding the effect of including NPJ/NPK in the scope of consolidation in the six month period under review totaled JPY 1,136 million (an increase of JPY 911 million vs. the prior corresponding period). The remaining cost primarily comprises external costs, internal staff costs, lab depreciation and consumables costs incurred in the performance of R&D activities that have generated revenue in the period. The increase is primarily due to the inclusion of costs associated with the clinical stage collaboration with Boehringer Ingelheim which commenced in March 2024. JPY 2,356 million has been recorded for the cost of sales of PIVLAZ® due to the inclusion of NPJ in the scope of consolidation.

Research and development expenses

Research and development ("R&D") expenses in the six month period under review totaled JPY 5,487 million (an increase of JPY 1,448 million vs. the prior corresponding period). R&D expenses excluding the effect of including NPJ/NPK in the scope of consolidation in the six month period under review totaled JPY 4,674 million (an increase of JPY 635 million vs. the prior corresponding period). This increase primarily reflects an increased investment in discovery activities, but also reflects the impact of the weaker Yen. JPY 813 million has been included for R&D expenses relating to NPJ/NPK. In the period under review, 85% of R&D spend related to the Group's UK operations.

Selling, general and administrative expenses

Selling, general and administrative ("G&A") expenses in the six month period under review totaled JPY 8,022 million (an increase of JPY 5,451 million vs. the prior corresponding period). G&A expenses excluding the effect of including NPJ/NPK in the scope of consolidation in the six month period under review totaled JPY 3,282 million (an increase of JPY 711 million vs. the prior corresponding period). This increase was primarily due to incremental spend on personnel and professional fees to strengthen organizational capabilities, including supply chain management, as well as the cost of integrating IT systems and unifying the Group under the Nxera Pharma brand. JPY 4,740 million has been included for G&A expenses relating to the NPJ/NPK businesses, including an amortization charge on Idorsia related intangible assets.

Net other income

Net other income in the six month period under review totaled JPY 627 million (an increase of JPY 106 million vs. the prior corresponding period). This was primarily due to a higher R&D expenditure-related UK tax credit.

Operating loss

Operating loss in the six month period under review totaled JPY 3,654 million (vs. an operating loss of JPY 4,168 million in the prior corresponding period). This decrease reflects the combined effect of all of the movements explained above.

Net finance income

Net finance income in the six month period under review totaled JPY 496 million (an increase of JPY 88 million vs. the prior corresponding period). This was primarily due to an increase in interest income as a result of higher UK interest rates.

Loss before income taxes

Loss before income taxes in the six month period under review totaled JPY 3,158 million (vs. a loss before income taxes of JPY 3,760 million in the prior corresponding period). This decrease reflects the combined effect of all of the movements explained above.

Income tax expense
Income tax expense in the six month period under review totaled JPY 1,545 million (vs. an income tax benefit of JPY 1,700 million in the prior corresponding period). The tax expense reflects the application of the estimated full year effective tax to the year-to-date results for each taxable entity.

Net loss
Net loss in the six month period under review totaled JPY 4,703 million (vs. a net loss of JPY 2,060 million in the prior corresponding period). This increase reflects the combined effect of all of the movements explained above.

Alternative performance measure: Core operating profit / loss
Core operating profit / loss is an alternative performance measure which adjusts for material non-cash costs and one-off costs in order to provide insights into the recurring cash generating capability of the core business.

Core operating profit in the six month period under review totaled JPY 1,176 million (vs. a core operating loss of JPY 2,720 million in the prior corresponding period). In calculating core operating loss, the following adjustments to the IFRS operating loss have been made:

- Depreciation totaled JPY 804 million (an increase of JPY 510 million vs. the prior corresponding period, including a JPY 405 million impact from inclusion of NPJ/NPK in the scope of consolidation).
- Amortization totaled JPY 1,183 million (an increase of JPY 776 million vs. the prior corresponding period, including a JPY 713 million impact from inclusion of NPJ/NPK in the scope of consolidation).
- Share-based payments totaled JPY 633 million (an increase of JPY 305 million vs. the prior corresponding period).
- Restructuring costs totaled JPY 28 million (a decrease of JPY 25 million vs. the prior corresponding period). These costs related to a management restructuring program at a subsidiary company and reorganization (there were no accelerated share-based payment expenses charged in the current period vs. JPY 26 million in the prior corresponding period).
- Cost of sales adjustment totaled JPY 1,619 million. This relates to an accounting adjustment for inventory acquired in the Idorsia transaction in 2023 which feeds through to cost of sales when inventory is sold, and which will cease when all the opening inventory has been used up (there was no cost of sales adjustment in the prior corresponding period).
- Integration costs totaled JPY 563 million. These costs represent one-off incremental integration costs, including IT system integration costs and the cost of the rebranding the Group under the Nxera Pharma name (there were no integration costs in the prior corresponding period).
- M&A related costs, including professional advisory fees were not incurred in the six month period under review (JPY 366 million in the prior corresponding period).

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets as at June 30, 2024 were JPY 156,484 million (a decrease of JPY 714 million vs. December 31, 2023, the end of the prior financial year). This reduction was primarily due to the payment of liabilities (including bank borrowings) which utilized cash, but the impact was partially offset by the effect of foreign exchange rate movements on asset values.

Liabilities

Total liabilities as at June 30, 2024 were JPY 87,504 million (a decrease of JPY 2,884 million vs. December 31, 2023, the end of the prior financial year). This reduction was primarily due to the repayment of bank borrowings.

Equity

Total equity as at June 30, 2024 was JPY 68,980 million (an increase of JPY 2,170 million vs. December 31, 2023, the end of the prior financial year). This was primarily due to an increase in other components of equity of JPY 6,242 million mainly relating to an increase in exchange gains on translation, partially offset by the net loss of JPY 4,703 million.

The ratios of Cash and cash equivalents, Interest-bearing debt and Equity attributable to owners of the parent company to total assets were 32.6%, 45.4% and 44.1%, respectively.

2) Cash flows

Cash and cash equivalents as at June 30, 2024 increased by JPY 1,919 million from the beginning of the year and amounted to JPY 50,984 million. The main drivers of each cash flow in the six month period ended June 30, 2024 were as follows:

Cash flows from operating activities

Net cash generated through operating activities during the period under review totaled JPY 1,511 million. This was primarily due to cash revenues exceeding cash operating costs.

Cash flows from investing activities

Net cash generated through investing activities during the period under review totaled JPY 434 million. This was primarily due to the receipt of contingent consideration following the achievement of a development milestone by Formosa.

Cash flows from financing activities

Net cash used in financing activities in the period under review totaled JPY 3,498 million. This was primarily due to the repayment of long-term bank borrowings.

Effects of exchange rate changes on cash and cash equivalents

Effects of exchange rate changes on cash and cash equivalents during the period under review totaled JPY 3,472 million. This positive impact was primarily due to a stronger GBP vs. JPY and a stronger USD vs JPY.

(3) Future outlook

A substantial portion of the Group's revenue is derived from upfront payments from new partnerships and milestone payments as a result of the progress of R&D projects with existing partners. These payments are dependent on multiple factors, including negotiations with potential new and existing partners, R&D policies of partners and clinical trial results of development candidates, and many of these factors are outside of the Group's control. Therefore, a consolidated financial results forecast has not been provided due to the difficulty in forecasting revenue, a significant proportion of which is one-time in nature.

The Group aims to further improve efficiency and add value to its drug discovery capabilities and pipeline, and will continue to make the necessary R&D investments in 2024 to achieve these goals. Management will continue to target a balance between available capital and investment in the pursuit of growth in corporate and shareholder value.

Going forward, the Group expects to generate increasing revenues from its commercial activities in Japan and the APAC regions. We provide the following guidance on PIVLAZ® product sales as well as key cost estimates for our overall business:

- Forecast PIVLAZ® Sales (NHI basis) of JPY 16,000 million or more[2] (unchanged).
- Forecast R&D expenses in the range of JPY 12,000 to JPY 14,000 million[3] (unchanged).
- Forecast SG&A expenses in the range of JPY 18,000 to JPY 20,000 million[3] (unchanged).

Anticipated developments / initiatives for 2024 are as follows:

- We expect the approval of daridorexant in Japan.
- We expect to receive upfront payments relating to one or more new partnerships.
- We expect to receive milestone payments as a result of the progress of R&D projects at existing partners.
- We expect to start clinical trials of multiple development candidates for which we have rights.
- We will seek out late-stage clinical candidates to in-license and develop for the Japanese and APAC markets.
- We will continue to expand and enhance our novel drug pipeline through our drug discovery efforts.

[2] Product sales in the Income Statement are stated at net sales price.

[3] The assumed USD:JPY FX rate in 2024 is 140 and GBP:JPY FX rate is 172. Please note that the cost estimates are for existing operations, and if the estimates change significantly as a result of strategic developments, such as the in-licensing of development candidates or the acquisition of new businesses, we will make an announcement.

2. Interim Condensed Consolidated Financial Statements and Primary Notes (IFRS)

1) Interim Condensed Consolidated Balance Sheet

	June 30, 2024 (Unaudited) ¥m	December 31, 2023 (Audited) ¥m
Assets		
Non-current assets		
Property, plant and equipment	**7,932**	7,900
Goodwill	**26,110**	24,623
Intangible assets	**52,246**	52,291
Deferred tax assets	**2,874**	3,964
Other financial assets	**3,657**	3,266
Other non-current assets	**21**	42
Total non-current assets	**92,840**	92,086
Current assets		
Trade and other receivables	**6,603**	5,064
Inventories	**2,314**	2,903
Income taxes receivable	**2,084**	2,099
Other financial assets	**-**	316
Other current assets	**1,659**	5,665
Cash and cash equivalents	**50,984**	49,065
Total current assets	**63,644**	65,112
Total assets	**156,484**	157,198
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	**1,963**	1,490
Corporate bonds	**30,694**	30,551
Bank borrowings	**29,777**	32,664
Lease liabilities	**3,944**	3,985
Provisions	**507**	484
Other non-current liabilities	**5,116**	4,029
Total non-current liabilities	**72,001**	73,203
Current liabilities		
Trade and other payables	**3,909**	4,244
Income taxes payable	**262**	378
Corporate bonds	**—**	143
Current portion of long-term bank borrowings	**5,798**	5,798
Lease liabilities	**861**	832
Other financial liabilities	**5**	-
Other current liabilities	**4,668**	5,790
Total current liabilities	**15,503**	17,185
Total liabilities	**87,504**	90,388
Equity		
Capital stock	**47,172**	46,807
Capital surplus	**34,315**	34,048
Treasury stock	**(2)**	(1)
Retained earnings	**(20,807)**	(16,104)
Other components of equity	**8,302**	2,060
Equity attributable to owners of the parent	**68,980**	66,810
Total equity	**68,980**	66,810
Total liabilities and equity	**156,484**	157,198

2) Interim Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Income

	Six month period ended June 30, 2024 (Unaudited) ¥m	Six month period ended June 30, 2023 (Unaudited) ¥m
Revenue	**12,720**	2,146
Cost of sales	**(3,492)**	(225)
Gross profit	**9,228**	1,921
Research and development expenses	**(5,487)**	(4,039)
Selling, general and administrative expenses	**(8,022)**	(2,571)
Other income	**630**	552
Other expenses	**(3)**	(31)
Operating loss	**(3,654)**	(4,168)
Finance income	**880**	784
Finance costs	**(384)**	(376)
Loss before income taxes	**(3,158)**	(3,760)
Income tax (expense) benefit	**(1,545)**	1,700
Net loss	**(4,703)**	(2,060)
Other comprehensive income:		
Items that will not be reclassified subsequently to profit or loss:		
Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	**250**	377
Total items that will not be reclassified subsequently to profit or loss	**250**	377
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	**5,992**	6,052
Total items that may be reclassified subsequently to profit or loss	**5,992**	6,052
Total other comprehensive income	**6,242**	6,429
Total comprehensive income	**1,539**	4,369
Net loss for the period attributable to:		
Owners of the parent	**(4,703)**	(2,060)
	(4,703)	(2,060)
Total comprehensive income for the period attributable to:		
Owners of the parent	**1,539**	4,369
	1,539	4,369
Earnings per share (yen)		
Basic loss per share	**(52.51)**	(25.13)
Diluted loss per share	**(52.51)**	(25.13)

3) Interim Condensed Consolidated Statement of Changes in Equity

	Capital stock ¥m	Capital surplus ¥m	Treasury stock ¥m	Retained earnings ¥m	Other components of equity ¥m	**Equity attributable to owners of the parent ¥m**	**Total equity ¥m**
Balance at January 1, 2024	46,807	34,048	(1)	(16,104)	2,060	66,810	66,810
Net loss	-	-	-	(4,703)	-	(4,703)	(4,703)
Other comprehensive income	-	-	-	-	6,242	6,242	6,242
Total comprehensive income	-	-	-	(4,703)	6,242	1,539	1,539
Issuance of new shares	365	(365)	-	-	-	-	-
Share-based payments	-	633	-	-	-	633	633
Purchase of treasury stock	-	-	(1)	-	-	(1)	(1)
Early redemption of corporate bonds	-	(1)	-	-	-	(1)	(1)
Total transactions with owners	365	267	(1)	-	-	631	631
Balance at June 30, 2024 (Unaudited)	47,172	34,315	(2)	(20,807)	8,302	68,980	68,980
Balance at January 1, 2023	41,335	29,525	(1)	(8,911)	(4,012)	57,936	57,936
Net loss	-	-	-	(2,060)	-	(2,060)	(2,060)
Other comprehensive income	-	-	-	-	6,429	6,429	6,429
Total comprehensive income	-	-	-	(2,060)	6,429	4,369	4,369
Issuance of new shares	445	(445)	-	-	-	-	-
Share-based payments	-	357	-	-	-	357	357
Purchase of treasury stock	-	-	(0)	-	-	(0)	(0)
Total transactions with owners	445	(88)	(0)	-	-	357	357
Balance at June 30, 2023 (Unaudited)	41,780	29,437	(1)	(10,971)	2,417	62,662	62,662

4) Interim Condensed Consolidated Statement of Cash Flows

	Six month period ended June 30, 2024 (Unaudited) ¥m	Six month period ended June 30, 2023 (Unaudited) ¥m
Cash flows from operating activities		
Loss before income taxes	**(3,158)**	(3,760)
Adjustments for:		
Depreciation and amortization	**1,987**	701
Share-based payments	**633**	354
Change in fair value of contingent consideration	**(38)**	(101)
Net foreign exchange gain	**(134)**	(134)
Interest income	**(726)**	(534)
Interest expenses	**370**	357
(Increase) decrease in trade payables	**(415)**	1,728
Decrease in inventories	**589**	32
Decrease in trade payables	**(497)**	(194)
Increase (decrease) in deferred revenue	**2,343**	(667)
Other	**194**	22
Subtotal	**1,148**	(2,196)
Grants received	**-**	13
Interest received	**651**	449
Interest paid	**(199)**	(83)
Income taxes paid	**(246)**	(1,163)
Income tax refunded	**157**	0
Net cash provided by (used in) operating activities	**1,511**	(2,980)
Cash flows from investing activities		
Purchase of property, plant and equipment	**(102)**	(200)
Purchase of intangible assets	**(3)**	(12)
Investment in loan note	**-**	(1,540)
Proceeds from contingent consideration receivable	**379**	-
Other	**160**	-
Net cash provided by (used in) investing activities	**434**	(1,752)
Cash flows from financing activities		
Repayments of long-term bank borrowings	**(2,900)**	-
Repayment of lease liabilities	**(447)**	(107)
Payments for early redemption of corporate bonds	**(150)**	-
Other	**(1)**	(0)
Net cash used in financing activities	**(3,498)**	(107)
Effects of exchange rate changes on cash and cash equivalents	**3,472**	3,880
Net increase (decrease) in cash and cash equivalents	**1,919**	(959)
Cash and cash equivalents at the beginning of the period	**49,065**	66,557
Cash and cash equivalents at the end of the period	**50,984**	65,598

5) Notes of Interim Condensed Consolidated Financial Statements

5.1 Notes related to going concern assumptions

Not applicable.

5.2 Change in accounting policy

Not applicable.

5.3 Changes in accounting estimates

Not applicable.

5.4 Operating segments

The Group operates a single business segment being the pharmaceutical business.

. *5.5 Significant subsequent events*

Not applicable.