



## Consolidated Financial Results for the Nine Months Ended September 30, 2023 (IFRS)

November 10, 2023

Company name: Sosei Group Corporation Listing: Tokyo Stock Exchange

Security code: 4565 URL: <https://www.soseiheptares.com/>

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Representative Executive Officer, CEO

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Scheduled date of Quarterly Securities Report filing: November 10, 2023 Scheduled date of dividend payments: -

Supplementary materials for financial results: None

Financial results briefing session: None

(Rounded million yen)

1. Consolidated Results for the 9 month period ended September 30, 2023 (from January 1, 2023 to September 30, 2023)

(1) Consolidated Operating Results (cumulative)

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

	Revenue		Core operating profit		Operating income		Profit before income taxes		Net profit	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
9 month period ended September 30, 2023	5,474	(36.7)	(3,920)	-	(7,992)	-	(7,865)	-	(6,985)	-
9 month period ended September 30, 2022	8,641	140.7	1,300	-	(615)	-	(3,108)	-	(3,225)	-

	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
9 month period ended September 30, 2023	(6,985)	-	(579)	-	(85.05)	(85.05)
9 month period ended September 30, 2022	(3,225)	-	(2,308)	-	(39.46)	(39.46)

(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 September 30, 2023	149,439	57,954	57,954	38.8
At December 31, 2022	99,417	57,936	57,936	58.3

2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen	Yen	Yen	Yen	Yen
FY2022	-	0.00	-	0.00	0.00
FY2023	-	0.00	-	-	-
FY2023 (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, 2023 to December 31, 2023

A financial results forecast for the year ended December 31, 2023 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 12 of this document.

\* Notes

(1) Changes in the number of significant subsidiaries for the nine-month period ended September 30, 2023 (changes of specified subsidiaries affecting the scope of consolidation): Yes  
Newly included: 1 company (Idorsia Pharmaceuticals Japan Ltd.)

(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 September 30, 2023	82,336,777 shares	At December 31, 2022	81,923,230 shares
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2) Number of treasury shares at period end

At September 30, 2023	335 shares	At December 31, 2022	254 shares
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3) Average number of shares in issue in period

9 month period ended September 30, 2023	82,128,947 shares	9 month period ended September 30, 2022	81,738,514 shares
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\* Quarterly 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.

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## 1. Analysis of Operating Results and Financial Position

### (1) Analysis of operating results

Sosei Group Corporation ("the Group") is a science and technology-led biopharmaceutical business whose core activities are drug discovery, drug development and the sale of pharmaceutical products. Heptares Therapeutics Ltd, a wholly owned subsidiary based in UK, mainly engages in drug discovery. Idorsia Pharmaceuticals Japan Ltd. ("IPJ"), a wholly owned subsidiary based in Japan, and Idorsia Pharmaceuticals Korea Co., Ltd. ("IPK"), a wholly owned subsidiary based in South Korea, mainly engage in development and product commercialization.

In drug discovery, the Group's core scientific focus is to discover new medicines, including novel small molecules, peptides and therapeutic antibodies, targeting G Protein-Coupled Receptors ("GPCRs"). Its proprietary StaR® ("stabilized receptor") technology and structure-based drug design ("SBDD") have enabled the Group to develop small molecules, peptides and antigens for mAb discovery.

In development and commercialization, the Group owns the Japan and APAC (excluding China) territory rights to PIVLAZ® (launched in 2022) and daridorexant (filed in 2023), as well as exclusive opt-ins for the Phase 3 cenerimod and lucerastat programs. This valuable portfolio provides the opportunity for sustainable development and commercialization.

In addition, the Group has a legacy business that generates a stream of royalties on global sales of respiratory disease products Seebri® Breezhaler®, Ultibro® Breezhaler® and Enerzair® Breezhaler® of Novartis international AG ("Novartis"). These royalties provide the Group with a significant, stable source of capital to support its strategic objectives.

Following the creation of a new leadership team in 2022, management outlined a clear and evolved strategy to leverage the Group's proprietary platform, pipeline and capabilities to grow the business internationally and in Japan. This strategy is based on four key strategic pillars:

- (i) Extending and enhancing the competitive advantages of the Group's world-leading StaR®/SBDD discovery capabilities through continued internal innovation combined with external collaborations that provide access to complementary technologies.
- (ii) Diligently driving forward existing partnerships with global biopharma companies and initiating new high-value partnerships to ensure the continued flow of revenues through upfront and development milestone payments, and ultimately royalties from sales of products that reach the market.
- (iii) Transforming R&D to a program-centric operational model, entrenching target biology, and enhancing translational medicine capabilities to quickly achieve clinical proof of concept. This, in turn, is expected to enable the advancement of higher quality candidates more cost effectively, the signing of larger out-licensing deals, as well as the generation of a deeper in-house pipeline and a pathway for clinical development in Japan.
- (iv) Building out an agile, scalable and effective clinical development and commercialization business in Japan. This new strategic initiative is designed to capitalize on significant underserved opportunities that the Group sees within this large attractive market. This strategy includes in-licensing foreign de-risked approved or late-stage clinical assets, as well as expanding the pipeline with internally generated programs in the future.

**(i) Extending and enhancing the Group’s world-leading StaR®/SBDD discovery capabilities**

In terms of enhancing the Group’s world-leading StaR®/SBDD, the Group will focus on making progress with existing strategic collaborations with companies that have complementary technologies and look to collaborate with new partners. By leveraging this enhanced technology advantage in the GPCR space, the Group aims to generate and advance multiple programs into its own development pipeline while continuing to be a discovery and development partner-of-choice for leading biopharmaceutical companies.

On October 5, 2023, the Group and Verily announced the successful validation and nomination of a first GPCR target into early drug discovery for immune-mediated diseases with an initial indication focus of inflammatory bowel disease (IBD). This scientific breakthrough between the companies is the first research milestone stemming from the strategic collaboration announced in 2022 that brings together the complementary capabilities of Verily's immune profiling technology and the Group’s GPCR SBDD platform. The companies select drug targets by leveraging sophisticated computational analysis of genetic and functional genomic data and focused laboratory validation, resulting in increased confidence that identified targets have the highest relevance to human disease and significantly improved chances of clinical success.

On October 10, 2023, the Group and PharmEnable Therapeutics (“PharmEnable”) announced they have expanded their collaboration to apply their respective technologies to drive novel drug discovery for a second neurological disease target. The Group is known for its expertise in receptor protein structure determination, SBDD and translational development. PharmEnable will apply its proprietary artificial intelligence (AI)-enabled medicinal chemistry platform (chemUNIVERSE) to design highly specific drug leads for further development. Expanding their 2021 agreement, the companies will jointly conduct and share the costs of the discovery and the development program and will co-own any resulting products equally. The companies are already exploiting their complementary capabilities in an ongoing collaboration focused on an initial target receptor, where they have identified promising small molecules with a new binding mode and novel chemotype.

**(ii) Supporting our existing partnerships with major global biopharmaceutical companies to drive continued revenue flow**

In January 2023, Christopher Cargill, President and CEO of the Company, presented at the 41st Annual J.P. Morgan Healthcare Conference, and the Group had one-on-one meetings with various leading global pharmaceutical and biopharmaceutical companies at the event to strengthen existing and build new business relationships.

On January 5, 2023, the Group noted its partner Tempero Bio Inc. (“Tempero Bio”) had announced US FDA clearance of its Investigational New Drug (IND) application for TMP-301 for the treatment of alcohol and substance use disorders. TMP-301 (formerly HTL0014242) is a novel mGluR5 negative allosteric modulator (NAM) candidate discovered by the Group and licensed to Tempero Bio. Tempero Bio has initiated a Phase 1 study with TMP-301 in healthy volunteers in 2023 with support from a recently awarded USD 5.3 million grant from the US National Institute on Drug Abuse (NIDA).

On March 30, 2023, Centessa Pharmaceuticals (“Centessa”) announced, in its Full Year 2022 Financial Results and Business Update, that it had nominated ORX750, an orally administered, selective orexin receptor-2 (OX2R) agonist developed using the Group’s SBDD platform, as its product candidate with the potential to be a best-in-class therapy for narcolepsy and other sleep

disorders. Centessa also presented ORX750 increased wakefulness in NT1 model and wild type mice. ORX750 is currently in preclinical development and undergoing IND-enabling activities.

On June 27, 2023, the Group noted the decision by its partner Pfizer Inc. (“Pfizer”) to prioritize the development of clinical-stage GLP-1 receptor agonist candidate danuglipron for the treatment of diabetes and obesity and as a result has discontinued the development of lotiglipron. Both novel and orally available candidates were being advanced by Pfizer in Phase 2 clinical trials. Lotiglipron was discovered and developed by Pfizer during a multi-target research collaboration in which Pfizer had access to the Group’s proprietary StaR® technology. The Group will explore next steps with Pfizer for the future development of lotiglipron, as the Group has done previously with other partners in similar situations.

On September 12, 2023, the Group announced that its partner Neurocrine Biosciences Inc. had initiated a Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational compound NBI-1117570 in healthy adult participants. NBI-1117570 is an investigational, oral, muscarinic M1/M4 selective dual agonist that may have the potential to treat neurological and neuropsychiatric conditions and was developed utilizing the Group’s SBDD platform.

On October 31, 2023, the Group announced that it will receive a USD3.75 million milestone payment under the 2019 multi-target Research Collaboration and License Agreement with Genentech Inc. (“Genentech”), a member of the Roche Group. The discovery-based payment is related to progression of a potential first-in-class project targeting an undisclosed GPCR. Genentech will now be responsible for further development and commercialization of this potential new medicine. This milestone is the latest of an ongoing collaboration that utilizes the Group’s proprietary GPCR-focused SBDD capabilities combined with Genentech’s discovery, development and therapeutic area expertise directed towards multiple GPCR targets nominated by Genentech. Under the terms of the agreement, the Group is eligible to receive future milestone payments from Genentech, which in total may exceed USD1 billion upon achieving pre-specified research, development and commercialization events.

On November 6, 2023, the Group announced that it had been notified by Pfizer that it had entered a new oral small molecule GLP-1 receptor agonist into a Phase 1 clinical trial. PF-06954522 was discovered by Pfizer scientists during a multi-target research collaboration in which Pfizer had access to the Group’s proprietary StaR® technology. Pfizer recently detailed the entry of PF-06954522 into its Internal Medicine focused clinical pipeline as part of its Q3 2023 results on 31 October 2023.

**(iii) Transforming in-house R&D to a program-centric operating model designed to enhance productivity, value and success**

The Group is focused on strengthening its in-house R&D and has achieved its goal of advancing at least two in-house programs into clinical trials in 2023.

On July 3, 2023 the Group announced that it has dosed the first subject in a Phase 1 trial evaluating HTL0048149 (HTL’149), a first-in-class GPR52 agonist, which represents a novel mechanism of action for the treatment of schizophrenia and related neurological diseases. HTL’149 was developed to be a once-daily, orally available small molecule drug with an antipsychotic and pro-cognitive profile and to avoid the adverse effects typically associated with existing antipsychotic drugs. HTL’149 achieves this profile through selectively targeting the orphan GPR52 receptor in the

brain to address positive symptoms (e.g. psychosis, delusions, hallucinations), negative symptoms (e.g. social withdrawal) and cognitive impairment (e.g. attention, working memory and executive function) associated with schizophrenia. Through this novel mechanism of action, HTL'149 aims to address the significant proportion of schizophrenia patients who do not respond to or suffer side effects leading to compliance issues from using existing antipsychotics. Furthermore, current antipsychotic drugs do not effectively treat the negative or cognitive symptoms of disease. The Phase 1 trial is a two-part, randomized, double-blind, placebo-controlled, single- and multiple-ascending dose study to assess the safety, pharmacokinetics, and pharmacodynamics of oral HTL'149 in healthy volunteers aged 18-55 years. The trial is being conducted in the UK and is expected to read-out initial data in 12-18 months from initiation.

On August 10, 2023, the Group announced that the first patient had been dosed in a Phase 1/2a clinical trial evaluating its orally available small molecule cancer immunotherapy drug HTL0039732 for advanced solid tumors under an agreement with Cancer Research UK. HTL0039732 works by blocking signalling through a specific type of prostaglandin receptor, the prostaglandin E2 (PGE2)-type prostanoid receptor 4 (EP4). In cancer, PGE2 acts in the tumor microenvironment to trigger cancer cells to evade the immune system. Targeting EP4 to block the effects of PGE2 increases the ability of the immune system to detect and control cancer cells and makes HTL0039732 a potential candidate to treat patients with cancers that generally do not respond well to current immunotherapies, such as microsatellite stable colorectal, gastroesophageal, head and neck, and castrate-resistant prostate cancer. Cancer Research UK's Centre for Drug Development (CDD) is sponsoring, designing and conducting the Phase 1/2a trial with three main objectives: to define the toxicity, tolerability and pharmacokinetics of HTL0039732, to identify the recommended dose for Phase 2 studies, and to assess its antitumor activity as a monotherapy and in combination with the PD-L1 inhibitor atezolizumab. Phase 2a of the trial will expand the optimal combination dose in up to four cohorts in specified cancer indications. The Group holds a license to the results generated under the trial to continue the clinical development and commercialization of HTL0039732.

#### **(iv) Building out a leading sales platform in Japan**

On April 1, 2023, the Group appointed Christopher Cargill, President and CEO, to the position of Representative Director and President of Sosei Co. Ltd., effective the same date. This appointment has enabled Mr. Cargill to directly manage the subsidiary's business and to focus on strengthening the Japan business to achieve its strategic goals.

A key element of this strategy was to build an agile, scalable and effective clinical development and commercialization business capability that would enable the Company to deliver life-changing medicines to patients in Japan and capitalize on the significant underserved opportunities that it sees within this large attractive market.

On July 20, 2023, the Group acquired Idorsia Limited's pharmaceuticals business in Japan and APAC (ex-China)<sup>1</sup>, accelerating its transformation into a fully integrated biopharmaceutical Group. This included the acquisition of 100% of IPJ and IPK (the "Transaction").

The acquisition of IPJ and IPK addresses this objective to build out a leading sales platform in Japan and was the conclusion of a rigorous global search by the Group team. The cash-flow positive Transaction, which is fully funded by existing cash and a new long-term, low-rate corporate loan,

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<sup>1</sup> APAC (ex-China) territory rights includes Japan, South Korea, Australia, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam

provides the Group with multiple strategic benefits by:

- Accelerating the Company's mission by adding experienced clinical development capability and profitable commercial operations in Japan, with a lean model for sales and marketing, and the ability to scale and create further value.
- Securing and expanding the Company's future pipeline with two major products PIVLAZ® and daridorexant; exclusive opt-ins for cenerimod and lucerastat; and selected rights to up to five additional clinical-stage programs from Idorsia's global pipeline.
- Bringing a highly skilled team with a proven track record of excellence and delivery, led by Dr. Satoshi Tanaka, who has directed several New Drug Application (Japan) and Ministry of Food and Drug Safety (South Korea) approvals and successful commercial launches over the past two decades.
- Leveraging Japan's quality clinical environment to target underserved, specialty disease areas; and providing a platform to expand across broader APAC regions and extend product launches.

The Transaction also brings together complementary capabilities to develop and commercialize novel medicines across Japan and APAC (ex-China) from three sources of innovation: (i) The Group's wholly owned discovery and early development pipeline, (ii) selected clinical candidates from Idorsia's pipeline, and (iii) in-licensing of Japan/APAC (ex-China) rights to clinical product candidates from third parties.

In addition, the Company will continue to seek partners for novel candidates or programs discovered by the Group for development and commercialization outside of Japan/APAC territories where significant unmet needs exist as well as the requirements for substantial expertise and resources.

On October 31, 2023, the Group announced that IPJ has submitted a New Drug Application ("NDA") to the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") for the approval of daridorexant (ACT541468), a dual orexin receptor antagonist which has been co-developed with Mochida Pharmaceutical Co., Ltd. ("Mochida"), for the treatment of adult patients with insomnia. In relation to the filing of this NDA, the Group will receive JPY 1.5 billion.

The NDA is supported by positive results of a randomized, double-blind, placebo-controlled Phase 3 study in Japan to investigate the efficacy and safety of daridorexant. Daridorexant was approved in the US and Europe in January and April 2022, respectively, and is marketed by Idorsia in these and other approved territories as QUVIVIQ™. In December 2019, Mochida and Idorsia Pharmaceuticals Ltd. entered into an exclusive license agreement for the co-development and co-marketing of daridorexant for insomnia and related disorders in Japan. Under the agreement, Mochida and IPJ have jointly developed daridorexant.

#### **(v) Other developments in the nine month period ended September 30, 2023**

On March 15, 2023, the Company changed the stock market on which its shares are listed from the Growth Market segment to the Prime Market segment, after it received approval from the Tokyo Stock Exchange (TSE).

The Company expects the move to the Prime Market will help it to achieve its vision by providing enhanced support and access to the long-term capital through greater exposure to institutional investment funds, both domestic and international. This will result from a deepening and



broadening of its shareholder base to reflect the global nature of the business. On April 27, 2023, The Company's shares were included in the Tokyo Stock Price Index (TOPIX), an important stock market index for the TSE in Japan.

As of September 30, 2023, the Group had a total of 348 employees (an increase of 146 employees vs. the end of the prior year). This increase is primarily due to the acquisition of IPJ and IPK, and their inclusion in the scope of the consolidation for the nine month period ended September 30, 2023.

As a result of the above activities, the Group reported the following financial results for the nine month period ended September 30, 2023. The results of IPJ and IPK from the date of acquisition (July 20, 2023) have been included in the following financial results.

Revenue of JPY 5,474 million (a decrease of JPY 3,167 million vs. the prior corresponding period), an operating loss of JPY 7,992 million (vs. an operating loss of JPY 615 million in the prior corresponding period), a loss before income taxes of JPY 7,865 million (vs. a loss before income taxes of JPY 3,108 million in the prior corresponding period), and a net loss of JPY 6,985 million (vs. a net loss of JPY 3,225 million in the prior corresponding period).

	9 month period ended September 30, 2023	9 month period ended September 30, 2022	Change
	¥m	¥m	
<b>Revenue</b>	<b>5,474</b>	<b>8,641</b>	(3,167)
Cost of sales	(1,352)	(740)	(612)
Research and development expenses	(7,013)	(5,623)	(1,390)
Selling, general and administrative expenses	(6,012)	(3,170)	(2,842)
<b>Operating expenses</b>	<b>(14,377)</b>	<b>(9,533)</b>	<b>(4,844)</b>
Net other income	911	277	634
<b>Operating loss</b>	<b>(7,992)</b>	<b>(615)</b>	<b>(7,377)</b>
Net finance income	127	110	17
Share of loss of associate accounted for using the equity method	-	(767)	767
Impairment loss on investments accounted for using the equity method	-	(1,836)	1,836
<b>Loss before income taxes</b>	<b>(7,865)</b>	<b>(3,108)</b>	<b>(4,757)</b>
Income tax benefit (loss)	880	(117)	997
<b>Net loss</b>	<b>(6,985)</b>	<b>(3,225)</b>	<b>(3,760)</b>

**Alternative performance measure**

**Core operating profit / loss** (Note 1)

<b>Operating loss</b> (as stated above)	<b>(7,992)</b>	<b>(615)</b>	<b>(7,377)</b>
<i>Adjustments:</i>			
Depreciation	621	421	200
Amortization	875	579	296
Share-based payments (Note 2)	568	382	186
Restructuring (Note 2)	53	533	(480)
M&A related costs	1,272	-	1,272
Cost of sales adjustment (Note 3)	683	-	683
<b>Core operating (loss) profit</b>	<b>(3,920)</b>	<b>1,300</b>	<b>(5,220)</b>

**Average exchange rate during period**

USD:JPY	138.09	127.94	10.15
GBP:JPY	171.91	160.51	11.40

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 the impact of an accounting adjustment for inventory acquired in a business combination in the nine month period ended September 30, 2023.

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

	9 month period ended September 30, 2023 ¥m	9 month period ended September 30, 2022 ¥m	Change
Pharmaceutical product sales	2,408	80	2,328
Upfront fees and milestone income	974	5,947	(4,973)
Deferred revenue releases	908	623	285
Milestone revenue recognized at milestone event	66	4,151	(4,085)
Upfront fee revenue recognized at deal inception	-	1,173	(1,173)
Royalty income	1,877	1,918	(41)
Other revenue	215	696	(481)
Total	5,474	8,641	(3,167)

**Revenue** in the nine month period under review totaled JPY 5,474 million (a decrease of JPY 3,167 million vs. the prior corresponding period).

**Pharmaceutical product sales** in the nine month period under review totaled JPY 2,408 million (an increase of JPY 2,328 million vs. the prior corresponding period). This was primarily due to the inclusion of IPJ in the scope of consolidation in July, which resulted in the addition of PIVLAZ<sup>®</sup> sales.

**Revenue related to upfront fees and milestone income** in the nine month period under review totaled JPY 974 million (a decrease of JPY 4,973 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 some contracts, income relating to research and development services is included within upfront fee revenue or milestone revenue, and recorded initially as deferred revenue. Such income is transferred from deferred revenue to revenue as a result of the performance of research and development activity in the period under review. The decrease in upfront fees and milestone income in the nine-month period under review was primarily due to signing no new partnership agreements and the occurrence of one milestone event in the current period vs. one upfront fee and three milestone events in the prior corresponding period.

**Revenue related to royalties** in the nine month period under review totaled JPY 1,877 million (a decrease of JPY 41 million vs. the prior corresponding period). The Group's royalty revenue relates to sales of Ultibro<sup>®</sup> Breezhaler<sup>®</sup>, Seebri<sup>®</sup> Breezhaler<sup>®</sup> and Enerzair<sup>®</sup> Breezhaler<sup>®</sup> by Novartis<sup>2</sup>.

## Operating expenses

### Cost of sales

Cost of sales in the nine month period under review totaled JPY 1,352 million (an increase of JPY 612 million vs. the prior corresponding period). Cost of sales excluding the effect of including IPJ/IPK in the scope of consolidation in the nine month period under review totaled JPY 350 million (a decrease of JPY 390 million vs. the prior corresponding period). This was due to a decrease in cost of sales, the internal costs of delivering research and development services to customers, as a result of lower revenues from contract research and development contracts. JPY 1,002 million

<sup>2</sup> Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura. Seebri<sup>®</sup>, Ultibro<sup>®</sup>, Enerzair<sup>®</sup> and Breezhaler<sup>®</sup> are registered trademarks of Novartis.

has been recoded for the cost of sales of PIVLAZ® due to the inclusion of IPJ in the scope of consolidation.

#### *Research and development expenses*

Research and development (“R&D”) expenses in the nine month period under review totaled JPY 7,013 million (an increase of JPY 1,390 million vs. the prior corresponding period). R&D expenses excluding the effect of including IPJ/IPK in the scope of consolidation in the nine month period under review totaled JPY 6,655 million (an increase of JPY 1,032 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 358 million has been included for R&D expenses relating to IPJ/IPK. In the period under review, 94% of R&D spend related to our UK operations.

#### *Selling, general and administrative expenses*

Selling, general and administrative (“G&A”) expenses in the nine month period under review totaled JPY 6,012 million (an increase of JPY 2,842 million vs. the prior corresponding period). G&A expenses excluding the effect of including IPJ/IPK in the scope of consolidation in the nine month period under review totaled JPY 4,595 million (an increase of JPY 1,425 million vs. the prior corresponding period). This was primarily due to the inclusion of non-recurring M&A related costs of JPY 1,272 million. JPY 1,417 million has been included for G&A expenses relating to IPJ/IPK, including an amortization charge on Idorsia related intangible assets.

#### *Net other income*

Net other income in the nine month period under review totaled JPY 911 million (an increase of JPY 634 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 nine month period under review totaled JPY 7,992 million (vs. an operating loss of JPY 615 million in the prior corresponding period). This increase reflects the combined effect of all of the movements explained above.

#### *Net finance income*

Net finance income in the nine month period under review totaled JPY 127 million (an increase of JPY 17 million vs. the prior corresponding period). This was primarily due to an increase in interest income as a result of higher UK interest rates, while foreign exchange losses increased as a result of foreign exchange effects.

#### *Share of loss of associate accounted for using the equity method*

The Group ceased to equity account for MiNA (Holdings) Limited (“MiNA”) from October 2022, accordingly, there was no share of profit / loss of associates accounted for using the equity method in the nine month period under review.

#### *Impairment loss on investments accounted for using the equity method*

Impairment loss on investments accounted for using the equity method for the nine month period ended 30 September 2022 was due to a decrease in the estimated value of MiNA, which was an associate accounted for under the equity method.

### ***Loss before income taxes***

Loss before income taxes in the nine month period under review totaled JPY 7,865 million (vs. a loss before income taxes of JPY 3,108 million in the prior corresponding period). This increase reflects the combined effect of all of the movements explained above.

### ***Income tax benefit***

Income tax benefit in the nine month period under review totaled JPY 880 million (vs. an income tax loss of JPY 117 million in the prior corresponding period). The tax benefit 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 nine month period under review totaled JPY 6,985 million (vs. a net loss of JPY 3,225 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 loss in the nine month period under review totaled JPY 3,920 million (vs. a core operating profit of JPY 1,300 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 621 million (an increase of JPY 200 million vs. the prior corresponding period, including JPY 160 million impact from inclusion of IPJ/IPK in the scope of consolidation).
- Amortization totaled JPY 875 million (an increase of JPY 296 million vs. the prior corresponding period, including JPY 243 million impact from inclusion of IPJ/IPK in the scope of consolidation).
- Share-based payments totaled JPY 568 million (an increase of JPY 186 million vs. the prior corresponding period).
- Restructuring costs totaled JPY 53 million (a decrease of JPY 480 million vs. the prior corresponding period). These costs related to a management restructuring program at a subsidiary company (including JPY 26 million of accelerated share-based payment expenses vs. JPY 158 million in the prior corresponding period).
- M&A related costs, including professional advisory fees, totaled JPY 1,272 million (including acquisition-related costs relating to the transaction with Idorsia totaled JPY 1,147, there were no M&A related costs in the prior corresponding period).
- Cost of sales adjustment totaling JPY 683 million. This relates to an accounting adjustment for inventory acquired in a business combination which feeds through to cost of sales, and which will cease when all the opening inventory has been sold (there was no cost of sales adjustment in the prior corresponding period).

## **(2) Analysis of financial position**

### **1) Assets, liabilities and equity**

#### *Assets*

Total assets as at September 30, 2023 were JPY 149,439 million (an increase of JPY 50,022 million vs. December 31, 2022, the end of the prior financial year). This was primarily due to an increase in intangible assets of JPY 44,109 million resulting from the inclusion of IPJ/IPK in the scope of consolidation.

#### *Liabilities*

Total liabilities as at September 30, 2023 were JPY 91,485 million (an increase of JPY 50,004 million vs. December 31, 2022, the end of the prior financial year). This was primarily due to the borrowing of JPY 40,000 million to finance the acquisition of IPJ/IPK shares and related assets.

#### *Equity*

Total equity as at September 30, 2023 was JPY 57,954 million (a decrease of JPY 18 million vs. December 31, 2022, the end of the prior financial year). This was primarily due to an increase in other components of equity of JPY 6,406 million mainly relating to an increase in exchange gains on translation, partially offset by the net loss of JPY 6,985 million.

The ratios of Cash and cash equivalents, Interest-bearing debt and Equity attributable to owners of the parent company to total assets were 28.4%, 49.1% and 38.8%, respectively.

### **2) Cash flows**

Cash and cash equivalents as at September 30, 2023 decreased by JPY 24,171 million from the beginning of the year and amounted to JPY 42,386 million. The main drivers of each cash flow in the nine month period ended September 30, 2023 were as follows:

#### *Cash flows from operating activities*

Net cash used in investing activities during the period under review totaled JPY 4,446 million. This was primarily due to the acquisition of IPJ/IPK shares and related assets.

#### *Cash flows from investing activities*

Net cash used in investing activities during the period under review totaled JPY 62,941 million. This was primarily due to the acquisition of IPJ/IPK shares, etc. in connection with business combination.

#### *Cash flows from financing activities*

Net cash provided by financing activities in the period under review totaled JPY 39,596 million. This was primarily due to long-term borrowings to finance the acquisition of IPJ/IPK and related assets.

#### *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 3,620 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 with existing partners. These payments are dependent on multiple factors, including negotiations with (potential) partners, R&D policies of partners and clinical trial results of development candidates, and these factors are difficult for the Group to control. Therefore, a Group financial results forecast for 2023 has not been provided because it is difficult to forecast revenue.

Based on its extremely productive drug discovery platform (StaR<sup>®</sup>/SBDD), the Group aims to further improve efficiency and add value to drug discovery by introducing an agile development model and enhancing translational medicine capabilities and will continue to make sufficient R&D investments in 2023 to achieve this goal. We will continue to target a balance between capital and investments in the pursuit of growth in corporate value.

Cost estimates for our business and anticipated developments / initiatives in 2023 are as follows:

- Forecast R&D expenses in the range of JPY 10,000 to JPY 12,000 million<sup>3</sup> (increased due to acquisition of Idorsia business).
- Forecast G&A expenses in the range of JPY 9,000 to JPY 11,000 million<sup>3</sup> (increased due to acquisition of Idorsia business).
- We are in discussions with several new potential business partners and may 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 at existing partners.
- We continue to expand our drug candidate discovery into novel drug targets to enhance our pipeline.
- We planned to start clinical trials of multiple development candidates for which we have rights. This has been achieved.

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<sup>3</sup> The assumed USD:JPY FX rate in 2023 is 143 and GBP:JPY FX rate is 166.

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

### 1) Interim Condensed Consolidated Balance Sheet

	September 30, 2023 (Unaudited) ¥m	December 31, 2022 (Audited) ¥m
<b>Assets</b>		
<b>Non-current assets</b>		
Property, plant and equipment	8,092	3,791
Goodwill	24,888	15,306
Intangible assets	53,070	8,577
Deferred tax assets	1,945	-
Other financial assets	3,071	1,737
Other non-current assets	68	64
<b>Total non-current assets</b>	<b>91,134</b>	<b>29,475</b>
<b>Current assets</b>		
Trade and other receivables	3,888	2,462
Inventories	3,996	32
Income taxes receivable	2,332	58
Other financial assets	329	-
Other current assets	5,374	833
Cash and cash equivalents	42,386	66,557
<b>Total current assets</b>	<b>58,305</b>	<b>69,942</b>
<b>Total assets</b>	<b>149,439</b>	<b>99,417</b>
<b>Liabilities and Equity</b>		
<b>Liabilities</b>		
<b>Non-current liabilities</b>		
Deferred tax liabilities	2,033	2,922
Corporate bonds	28,393	27,981
Borrowings	34,107	-
Lease liabilities	4,199	1,577
Provisions	465	118
Other non-current liabilities	4,715	4,791
<b>Total non-current liabilities</b>	<b>73,912</b>	<b>37,389</b>
<b>Current liabilities</b>		
Trade and other payables	3,846	1,628
Income taxes payable	297	260
Current portion of long-term borrowings	5,798	-
Lease liabilities	811	176
Other financial liabilities	-	36
Other current liabilities	6,821	1,992
<b>Total current liabilities</b>	<b>17,573</b>	<b>4,092</b>
<b>Total liabilities</b>	<b>91,485</b>	<b>41,481</b>
<b>Equity</b>		
Capital stock	41,780	41,335
Capital surplus	29,677	29,525
Treasury stock	(1)	(1)
Retained earnings	(15,896)	(8,911)
Other components of equity	2,394	(4,012)
Equity attributable to owners of the parent	57,954	57,936
<b>Total equity</b>	<b>57,954</b>	<b>57,936</b>
<b>Total liabilities and equity</b>	<b>149,439</b>	<b>99,417</b>



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

	Nine month period ended September 30, 2023 (Unaudited) ¥m	Nine month period ended September 30, 2022 (Unaudited) ¥m
<b>Revenue</b>	<b>5,474</b>	8,641
Cost of sales	(1,352)	(740)
<b>Gross profit</b>	<b>4,122</b>	7,901
Research & development expenses	(7,013)	(5,623)
Selling, general & administrative expenses	(6,012)	(3,170)
Other income	944	278
Other expenses	(33)	(1)
<b>Operating loss</b>	<b>(7,992)</b>	(615)
Finance income	992	635
Finance costs	(865)	(525)
Share of loss of associates accounted for using the equity method	-	(767)
Impairment loss on investments accounted for using the equity method	-	(1,836)
<b>Loss before income taxes</b>	<b>(7,865)</b>	(3,108)
Income tax benefit (loss)	880	(117)
<b>Net loss</b>	<b>(6,985)</b>	(3,225)
<b>Other comprehensive income:</b>		
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	462	(383)
Total items that will not be reclassified subsequently to profit or loss	462	(383)
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	5,944	1,300
Total items that may be reclassified subsequently to profit or loss	5,944	1,300
<b>Total other comprehensive income</b>	<b>6,406</b>	917
<b>Total comprehensive income</b>	<b>(579)</b>	(2,308)
<b>Net loss for the period attributable to:</b>		
Owners of the parent	(6,985)	(3,225)
	<b>(6,985)</b>	<b>(3,225)</b>
<b>Total comprehensive income for the period attributable to:</b>		
Owners of the parent	(579)	(2,308)
	<b>(579)</b>	<b>(2,308)</b>
<b>Earnings per share (yen)</b>		
Basic loss per share	(85.05)	(39.46)
Diluted loss per share	(85.05)	(39.46)

### 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
<b>Balance at January 1, 2023</b>	<b>41,335</b>	<b>29,525</b>	<b>(1)</b>	<b>(8,911)</b>	<b>(4,012)</b>	<b>57,936</b>	<b>57,936</b>
Net loss	-	-	-	(6,985)	-	(6,985)	(6,985)
Other comprehensive income	-	-	-	-	6,406	6,406	6,406
Total comprehensive income	-	-	-	(6,985)	6,406	(579)	(579)
Issuance of new shares	445	(445)	-	-	-	-	-
Share-based payments	-	597	-	-	-	597	597
Acquisition of treasury stock	-	-	(0)	-	-	(0)	(0)
Total transactions with owners	445	152	(0)	-	-	597	597
<b>Balance at September 30, 2023 (Unaudited)</b>	<b>41,780</b>	<b>29,677</b>	<b>(1)</b>	<b>(15,896)</b>	<b>2,394</b>	<b>57,954</b>	<b>57,954</b>
<b>Balance at January 1, 2022</b>	<b>41,036</b>	<b>29,100</b>	<b>(0)</b>	<b>(9,768)</b>	<b>(2,900)</b>	<b>57,468</b>	<b>57,468</b>
Net loss	-	-	-	(3,225)	-	(3,225)	(3,225)
Other comprehensive income	-	-	-	-	917	917	917
Total comprehensive income	-	-	-	(3,225)	917	(2,308)	(2,308)
Issuance of new shares	299	(299)	-	-	-	0	0
Share-based payments	-	542	-	-	-	542	542
Acquisition of treasury stock	-	-	(1)	-	-	(1)	(1)
Total transactions with owners	299	243	(1)	-	-	541	541
<b>Balance at September 30, 2022 (Unaudited)</b>	<b>41,335</b>	<b>29,343</b>	<b>(1)</b>	<b>(12,993)</b>	<b>(1,983)</b>	<b>55,701</b>	<b>55,701</b>

#### 4) Interim Condensed Consolidated Statement of Cash Flows

	Nine month period ended September 30, 2023 (Unaudited) ¥m	Nine month period ended September 30, 2022 (Unaudited) ¥m
<b>Cash flows from operating activities</b>		
Loss before income taxes	(7,865)	(3,108)
Adjustments for:		
Depreciation and amortization	1,496	1,000
Share-based payments	594	540
Loss on investments in securities	38	15
Change in fair value of contingent consideration	(109)	(78)
Net foreign exchange loss (gain)	104	(51)
Interest income	(883)	(96)
Interest expenses	592	509
Share of loss of associate accounted for using the equity method	-	767
Impairment loss on investments accounted for using the equity method	-	1,836
Decrease in trade and other receivables	2,449	969
Increase in trade payables	568	72
(Decrease) increase in deferred revenue	(908)	3,560
Other	276	(829)
Subtotal	<b>(3,648)</b>	5,106
Grants received	14	32
Interest received	721	96
Interest paid	(158)	(121)
Income tax refunded	0	0
Income taxes paid	(1,375)	(260)
<b>Net cash (used in) provided by operating activities</b>	<b>(4,446)</b>	4,853
<b>Cash flows from investing activities</b>		
Purchase of property, plant and equipment	(494)	(201)
Purchase of intangible assets	(19)	-
Payments for acquisition of business	(62,428)	-
Proceeds from contingent consideration receivable	-	137
Other	0	-
<b>Net cash used in investing activities</b>	<b>(62,941)</b>	(64)
<b>Cash flows from financing activities</b>		
Proceeds from long-term borrowings	39,900	-
Payment of lease liabilities	(292)	(153)
Payment for settlement of contingent consideration	-	(4,680)
Other	(12)	(1)
<b>Net cash provided by (used in) financing activities</b>	<b>39,596</b>	(4,834)
Effects of exchange rate changes on cash and cash equivalents	3,620	1,133
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(24,171)</b>	1,088
Cash and cash equivalents at the beginning of the period	66,557	60,087
<b>Cash and cash equivalents at the end of the period</b>	<b>42,386</b>	61,175

## 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.