## FASE

### Consolidated Financial Results for the Six Months Ended June 30, 2020 (IFRS)

				August 13	, 2020
Company name:	Sosei Group Corporatior	ו		Listing: Tokyo Stock Exc	hange
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Report filing	f Quarterly Securities	Augus 2020	st 13,	Scheduled date of dividend payments:	_
Supplementary m results:	aterials for financial	Yes			
Financial results b	priefing session:	No		(Rounded milli	on yen)

## 1. Consolidated results for 6 month period ended June 30, 2020 (from January 1, 2020 to June 30, 2020)

(1) Consolidated operating results (cumulative) (Percentages are shown as year-on-year changes)

	Reve	enue	Operatin	g income	Net prof income		Net p	profit	Net p attribut owners parent c	able to of the	To compre incc	hensive
	Million	%	Million	%	Million	%	Million	%	Million	%	Million	%
	yen		yen		yen		yen		yen		yen	
6 month period ended June 30, 2020	2,516	(50.2)	(1,136)	_	(1,270)	_	(2,117)	_	(2,117)	_	(4,590)	-
6 month period ended June 30, 2019	5,056	180.4	731	_	292	_	395	_	395	_	(425)	-

	Earnings per share – basic	Earnings per share – diluted
	Yen	Yen
6 month period ended June 30, 2020	(27.45)	(27.45)
6 month period ended June 30, 2019	5.19	5.13

#### (2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of the parent company	Ratio of equity attributable to owners of the parent company to total assets
	Million yen	Million yen	Million yen	%
At June 30, 2020	51,078	40,939	40,939	80.2
At December 31, 2019	56,680	45,078	45,075	79.5

#### 2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen	Yen	Yen	Yen	Yen
FY2019	-	0.00	-	0.00	0.00
FY2020	-	0.00			
FY2020 (E)			-	0.00	0.00

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

#### 3. Business outlook and financial forecast (from January 1, 2020 to December 31, 2020)

Despite these challenging times, the Group remains committed to delivering on its mission and vision, and to serving collaboration partners and patients in our clinical trials. The Group's smaller size enabled it to quickly enact flexible business continuity plans, and therefore it has continued to make good progress across the business and remain well positioned to pursue a number of strategic opportunities. The Group is taking steps to increase partnered activity, whilst

simultaneously investing in technologies, tools and capabilities to advance an exciting pipeline of next-generation candidates that will form the basis of high value partnerships in the future.

The Group is continuing to drive a sustainable balance of resources and capital. Whilst it aims to pursue profitability, we recognize that the uncertainty caused by the COVID-19 pandemic is likely to impact on this goal. As of June 30, 2020 the Group's financial forecasts remain **unchanged** from December 31, 2019:

- Forecast cash R&D expenses in the range of JPY 4,200 to JPY 4,700 million<sup>1</sup>.
- Forecast cash G&A expenses in the range of JPY 1,800 to JPY 2,300 million<sup>2</sup>.
- The Group expects to receive upfront consideration related to new partnerships.
- The Group expects to receive milestone payments from existing drug discovery and development partnerships.
- The Group will continue to invest in technologies, tools and capabilities to advance nextgeneration candidates; while strongly managing its cost base.

The Group continues to believe it is well capitalized for the future. The Group's existing cash, cash flows from operations and existing sources of and access to financing are sufficient to cover its needs for drug discovery and early development activities, working capital, capital expenditures and debt servicing requirements, as well as to pursue business development initiatives. In addition, after the period ended June 30, 2020, the Group issued approximately JPY 5 billion of new equity and JPY 16 billion of long-term convertible bonds and intends to use the majority of the funds for a potentially transformative acquisition to pursue strategic growth.

#### \* Notes

- (1) Changes in the number of significant subsidiaries for the six month period ended June 30, 2020 (changes of specified subsidiaries affecting the scope of consolidation): 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
  - Number of shares issued at period end (including treasury shares)
  - 2) Number of treasury shares at period end
  - 3) Average number of shares in issue in period

At June 30, 2020	77,270,728 shares	At December 31, 2019	77,073,136 shares
At June 30, 2020		At December 31, 2020	213 shares
6 month period ended June 30, 2020	77,146,514 shares	6 month period ended June 30, 2019	76,358,608 shares

- \* 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 the forecasts due to various factors.
- \* The Group will disclose Supplementary materials for financial results and a presentation video on our web site, Thursday, August 13, 2020 at 17:00.

<sup>&</sup>lt;sup>1</sup> The assumed FX rate of USD:JPY 110 <sup>2</sup> The assumed FX rate of USD:JPY 110

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#### 1. Analysis of Operating Results and Financial Position

#### (1) Analysis of operating results

The Group is a science and technology-led company, specializing in drug discovery and early-stage drug development. Our mission is to make a significant contribution to improving the quality of life and health of people around the world. Our vision is to become one of Japan's global biotechnology and drug discovery champions.

During the six month period ended June 30, 2020, the Group continued to advance its drug discovery and early-stage development pipeline, as well as enhance its proprietary StaR<sup>®</sup> ("stabilized receptor") technology and Structure-based Drug Design ("SBDD") platform.

Our business model is focused across three core areas to create value; (i) supporting our existing partnerships with major global pharmaceutical companies, (ii) generating new and progressing existing collaborations in R&D with innovative technology companies and venture funds, and (iii) signing new high-value partnerships based on successful in-house drug discovery and early-stage development of new candidates.

On 25 March 2020, the Group hosted its 30<sup>th</sup> Ordinary General Meeting of Shareholders in Tokyo. At the event, the Group's Chairman, President and CEO, Mr. Shinichi Tamura, discussed the strengthened focus on the execution of the next stage of its growth strategy, which aims to leverage world-class Platform, Discovery and Early Development capabilities to advance and extend a portfolio of Partnered Programs. The Group's strategy was outlined as follows:

#### 1. Build a leading science and technology-led drug discovery business

- The acquisition of Heptares Therapeutics in 2015 with its world-leading scientific and technological capabilities, notably the StaR<sup>®</sup> G protein-coupled receptor (GPCR) technology and SBDD platform, was and remains the cornerstone of this mission.
- This technology and platform are core to the Group's drug discovery efforts and together have allowed it to establish one of the world's leading approaches to GPCR-target drug design.
- The Group will continue to leverage the significant untapped opportunity to discover drugs that target GPCRs and other membrane proteins, with a clear focus on high-value programs, including those addressing difficult to drug targets.
- 2. Generate multiple new drug candidates targeted for high-value collaborations or long-term ventures
  - The Group's science and technology-led approach has enabled it to create over 24 preclinical drug candidates in the last ten years, with seven of these having moved into human clinical trials. This high degree of productivity comes from its extremely efficient approach, which enables the Group to generate preclinical candidates 1-2 years faster than the pharmaceutical industry standard.
  - Many of these preclinical drug candidates have formed the basis of the Group's high-value collaborations, including partnerships with Pfizer, Allergan, AstraZeneca, Takeda, Genentech and more recently, AbbVie.
  - The Group will continue this drug discovery and early-stage development strategy, with an aim to execute at least 2 new high-value collaborations or long-term ventures every year.

- 3. Invest the proceeds of high-value collaborations and long-term ventures into the technologies needed to reinforce its leadership in GPCR drug discovery and SBDD
  - Technology does not stand still. The Group's goal is to become a pharma discovery partner of choice by providing a highly attractive solution to increasing innovation and productivity.
  - The Group invests its collaboration and venture proceeds to continuously refresh and enhance its technology capabilities. So far it has:
    - acquired G7 Therapeutics in Switzerland,
    - collaborated with a German-based company developing innovative DNAencoded library tools, and the University of Cambridge on Artificial Intelligence-related approaches, and
    - invested significantly in Nobel Prize winning Cryo-EM technology.
  - The Group intends to continue to acquire, or enter partnerships to secure access to, more new technologies, tools and platforms in order to remain at the cutting edge of science and technology which will expand its leadership in innovative drug discovery.

As of June 30, 2020, the Group had over 20 programs ongoing in discovery, with 13 in preclinical development, and multiple in-house and partnered programs<sup>34</sup> currently in clinical trials.

#### The Group's response to COVID-19

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March,11 2020. The Group has been carefully monitoring COVID-19 pandemic and its impact on our operations. As a business operating in the global life sciences industry, the Group has an important role to play to ensure the health and safety of all stakeholders and society. The Group's priority remains the health of its employees, community members, and investigators and patients in its clinical trials. The Group has taken several actions in response to the COVID-19 pandemic, including:

- Implemented policies and practices to ensure a safe working environment for its employees and the communities where it operates to reduce the spread of COVID-19. This includes a work from home policy for many employees, while its essential employees, primarily laboratory-based scientists, are working on an optimized rota basis and in accordance with applicable UK government health and safety protocols issued in response to the COVID-19 pandemic. The Group has also introduced weekly SARS-CoV-2 testing of its essential employees at its UK R&D facility.
- Donated supplies of personal protective equipment (PPE) to a local hospice in the United Kingdom.
- Initiated a new in-house COVID-19 R&D program to apply its unique SBDD platform and capabilities to the global research efforts to discover drugs targeting the SARS-CoV-2 coronavirus and to treat COVID-19 and infections caused by future variants of SARS-CoV-2. All findings are to be made freely available to the global research community.

On April 14, 2020, the Group announced that it would apply it Structure-based Drug Design

<sup>&</sup>lt;sup>3</sup> Includes AZD4635 combination for prostate cancer, AZD4635 for multiple solid malignancies, HTL0016878 for neurobehavioral symptoms of Alzheimer's disease, HTL0018318 for Alzheimer's disease (voluntarily suspended), PF-0781532 for T2DM/Obesity, HTL0014242 for neurological disorders, and HTL0030310 for endocrine disorders.

<sup>&</sup>lt;sup>4</sup> Phase 2 trial of HTL0018318 for DLB in Japan remains under voluntary suspension and has been withdrawn. The Group plans to resubmit a new clinical trial notification for HTL0018318 (or another novel M1 agonist) to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in the future, pending the outcome of an ongoing investigation.

Expertise in a new COVID-19 R&D program. The new R&D program is to identify novel compounds that block the activity of the SARS-CoV-2 MPro protease (Nsp5), which has been designated as an important potential target for drug development. The Mpro protease cleaves a polyprotein encoded by the viral genome into 12 non-structural proteins (Nsp4-Nsp16) some of which play crucial roles in viral replication. The Group has created a multidisciplinary team spanning structural and biophysical analysis, computational chemistry and medicinal chemistry. The team brings a wealth of experience in SBDD and cutting-edge technologies that will be applied to the precision design of new inhibitor compounds against not only the SARS-CoV-2 coronavirus but also against predicted future variants. All findings from the program will be made freely available to the global research community investigating solutions to the COVID-19 crisis. Furthermore, the Group is looking to establish collaborations with industry partners to support this program and also to contribute its unique expertise to other areas under investigation as part of the global effort by the pharmaceutical and biotechnology industries to find new treatments for COVID-19. There is no material impact to the Group's financial statements from investing in this important not-for-profit research initiative. Our aim for this project is to make a long-term contribution to the well-being of the patients around the world through industry wide collaboration.

#### Progressing our multiple partnerships with major global pharmaceutical companies

The Group continued to make good progress with its partners and has implemented measures to ensure R&D continuity and productivity under the new conditions imposed as a result of the COVID-19 situation. This is most notable with Takeda and Genentech, where our work on these respective research and development collaborations has been prioritized and continues to move forward productively.

Our other out-licensed programs are being advanced exclusively by our partners, such as with AstraZeneca, Pfizer, and AbbVie, whilst progress is ongoing, we do anticipate that some delays could emerge as a result of the global COVID-19 situation.

On 1 May 2020, the Group noted that Novartis announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended the approval in the European Union of Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate [IND/GLY/MF]) as a maintenance treatment of uncontrolled asthma in adult patients.

On 5 June 2020, the Group noted that Novartis announced that full results from the Phase IIIb ARGON study were published online in *Respiratory Medicine*. The Phase IIIb open label ARGON study showed that once-daily treatment with single inhaler, high- and medium-dose Enerzair<sup>®</sup> Breezhaler<sup>®</sup> demonstrated non-inferiority to a free combination of twice-daily, high-dose salmeterol xinafoate/fluticasone propionate (Sal/Flu) plus once-daily tiotropium (Tio), delivered in two different devices, in improving quality of life in people with uncontrolled asthma. Among secondary analyses, improvements in lung function, asthma control, health status, and reductions in moderate exacerbations were observed with high-dose once-daily IND/GLY/MF compared to high-dose Sal/Flu plus Tio.

On 25 June 2020, the Group announced that it had entered into an exclusive discovery collaboration and option to license agreement with AbbVie, a research-based global biopharmaceutical company, to discover, develop and commercialize novel medicines that modulate GPCR targets of interest to AbbVie. The collaboration will initially focus on discovery of novel small molecules targeting inflammatory and autoimmune diseases. The Group will apply its

proprietary StaR<sup>®</sup> technology and GPCR-focused SBDD capabilities and fund R&D activities through the completion of Investigational New Drug (IND)-enabling studies. AbbVie has an exclusive option to in-license the program and assume responsibility for global development and commercialization. Under the terms of the agreement, the Group is eligible to receive up to US\$32 million in upfront and near-term milestone payments, as well as potential option, development and commercial milestones of up to \$377 million, plus tiered royalties on global commercial sales. AbbVie has the option to expand the collaboration up to a total of four targets.

On 29 June 2020, the Group noted that Novartis Pharma K.K., the Japan business of strategic alliance partner Novartis, announced the world's first manufacturing and marketing approval for its Enerzair<sup>®</sup> Inhalation Capsules (medium-dose and high-dose) in Japan as a treatment of bronchial asthma (in cases requiring combination use of inhaled corticosteroid, inhaled long-acting β2-adrenergic agonist and inhaled long-acting anticholinergic agent). The achievement of this milestone results in a payment to Sosei Heptares from Novartis under the terms of the 2005 Development and Licensing agreement. Enerzair<sup>®</sup> is a long-acting beta2-agonist (LABA)/longacting muscarinic antagonist (LAMA)/inhaled corticosteroid (ICS) combination and delivers its bronchodilating and anti-inflammatory action through treatment once per day with the Breezhaler<sup>®</sup> inhaler. The two medium-dose and high-dose specifications each contain 150 µg of indacaterol acetate and 50 µg of glycopyrronium bromide, with 80 µg and 160 µg respectively of mometasone furoate. For the first time in Japan, a new digital device combining a sensor with the Breezhaler® inhaler is being made available. The sensor connects with a smartphone to record daily treatment doses and provide medication reminders. It also supports communication between patients and their physicians, contributing to the long-term management of insufficiently controlled asthma.

#### Advancing our collaborations with innovative technology and venture funds

The Group continued to make significant progress with its technology and venture partners.

On 14 January 2020, the Group announced that significant scientific progress at its spin-off companies Orexia Limited ("Orexia") and Inexia Limited ("Inexia") triggered the next tranche of funding from venture capital firm Medicxi under its €40 million commitment. The Group and Medicxi, which specializes in financing asset-centric companies, created Orexia and Inexia in 2019 to develop novel therapies based on positive modulators of the G protein-coupled receptors (GPCRs) Orexin OX1 and OX2 for neurological diseases, including narcolepsy.

On 7 May 2020, the Group announced that it had made further significant progress with its orexin program, which is being developed in conjunction with its spin-off companies Orexia and Inexia. The Group solved the structure of the agonist bound orexin OX2 receptor and identified a small molecule binding site using its unique  $StaR^{\circledast}$  technology and structure-based approach. The new improved insights into the receptor's structure will help optimize the discovery and development of novel molecules targeting neurological diseases. Orexia and Inexia are funded by Medicxi under a  $\notin$ 40 million commitment.

# Investing on our in-house discovery and early development to generate new candidates for partnering

The Group continued to make significant investments in its pipeline, as it advanced multiple discovery candidates and early development programs. The Group's two ongoing in-house Phase I clinical trials (HTL0014242 and HTL0030310) are progressing well and are now the subject of

multiple ongoing partnering discussions. We do, however, expect that some delays to the completion of these studies could emerge as a result of the global COVID-19 situation.

On 20 March 2020, the Group announced a new high-impact publication highlighting the potential of structure-based approaches to generate novel peptide-based drugs targeting GPCRs. The article entitled 'Advances in Therapeutic Peptides Targeting G Protein-coupled Receptors' (Davenport et al.) has been published by Nature Reviews Drug Discovery, a prestigious and highly influential peer-reviewed journal.

The article focuses on the new discovery strategies that leverage cutting-edge structure-based technologies, including Sosei Heptares' unique StaR<sup>®</sup> platform and cryo-EM, to generate novel and selective peptides with precisely designed activities and improved drug-like (pharmacokinetic and pharmacodynamic) properties. Such peptides include agonists, antagonists, as well as peptides designed to activate specific downstream signalling pathways (biased ligands), and dual agonists that activate two different GPCRs.

The generation of novel, precisely designed peptide leads against disease-relevant GPCRs provides multiple partnering opportunities for the Group.

#### Operational highlights after the period under review ended June 30, 2020

On 7 July 2020, the Group noted that Novartis announced that the European Commission (EC) had approved Enerzair<sup>®</sup> Breezhaler<sup>®</sup> as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of LABA/High dose of ICS who experienced one or more asthma exacerbations in the previous year. Once-daily Enerzair® Breezhaler® is the first LABA/LAMA/ICS fixed-dose combination available in the European Union (EU) for these patients. The approval also includes an optional digital companion with sensor and app that provides inhalation confirmation, medication reminders and access to objective data to better support therapeutic decisions. EC approval is based on robust efficacy and safety data from over 3,000 asthma patients in Novartis' Phase III IRIDIUM study, in which once-daily Enerzair® Breezhaler<sup>®</sup> was superior to once-daily Atectura<sup>®</sup> Breezhaler<sup>®</sup> (IND/MF) in improving the lung function of patients whose asthma is uncontrolled with LABA/ICS standard-of-care treatment. The EC decision is applicable to all 27 European Union member states as well as the UK, Iceland, Norway and Liechtenstein. The achievement of this milestone results in a payment to the Group of US\$5 million from Novartis under the terms of its 2005 Development and Licensing agreement. The Group is eligible to receive royalties from future sales of Enerzair® Breezhaler® in the EU and other markets in which it is approved.

On 10 July 2020, the Group noted that Novartis announced that full results from its Phase III IRIDIUM study were published in the prestigious peer-reviewed journal *The Lancet Respiratory Medicine*. The IRIDIUM trial met its primary endpoint with once-daily treatment with high- and medium-dose Enerzair<sup>®</sup> Breezhaler<sup>®</sup> demonstrating statistically significant improvements in lung function compared with once-daily QMF149 (IND/MF) in patients whose asthma is uncontrolled with LABA/ICS treatment. The key secondary endpoint was improvement in Asthma Control Questionnaire (ACQ-7) score for IND/GLY/MF versus IND/MF. Although both treatments delivered clinically meaningful improvements in this measure, the key secondary endpoint was not met. In secondary analyses, improvements in lung function and clinically meaningful reductions in moderate-to-severe and severe asthma exacerbation rates were observed with high-dose IND/GLY/MF compared to high-dose Sal/Flu. The overall incidence of adverse events (AE) and serious adverse events (SAE) for IND/GLY/MF and IND/MF in the IRIDIUM study were generally low

and comparable among treatment groups. Asthma exacerbation was the most reported AE and SAE. Enerzair<sup>®</sup> Breezhaler<sup>®</sup> is approved in the EU, Japan and Canada. Further regulatory reviews are currently underway in other countries.

On July 16, 2020 the Group announced that it had successfully completed an International Offering of new shares and euro-yen denominated convertible bonds due 2025 that raised a total of JPY 20.9 billion (approximately \$195 million). The Company intends to use the net proceeds of the International Offering as follows:

The majority of funds will be used to pursue strategic growth initiatives including:

- a potentially transformative acquisition to secure long-term revenue growth;
- investments in novel technologies that complement and future-proof its drug discovery platform;
- expansion of its drug candidate discovery and early development into new target classes; and
- in-licensing late-stage clinical assets to develop for the Japanese market.

Any balance of funds will be used to support organic growth initiatives, such as investments in current research activities and general corporate purposes.

As of June 30, 2020, the Group had a total of 170 employees (an increase of seven employees vs. the end of the previous fiscal year FY19).

As a result of the above activities, the Group reported the following financial results for the six month period ended June 30, 2020. Revenue of JPY 2,516 million (a decrease of JPY 2,540 million vs. the prior corresponding period), an operating loss of JPY 1,136 million (vs. an operating profit of JPY 731 million in the prior corresponding period), a net loss before income taxes of JPY 1,270 million (vs. a net profit before income taxes of JPY 292 million in the prior corresponding period), and a net loss of JPY 2,117 million (vs. a net profit of JPY 395 million in the prior corresponding period).

	6 month period ended	6 month period ended	
	June 30, 2020	June 30, 2019	Change
	¥m	¥m	
Revenue	2,516	5,056	(2,540)
Cash cost of sales	(304)	(375)	71
Cash research and development expenses	(1,500)	(1,862)	362
Cash selling, general and administrative expenses	(925)	(1,239)	314
Other cash income	32	16	16
Cash earnings	(181)	1,596	(1,777)
Non-cash costs	(955)	(865)	(90)
Operating (loss) profit	(1,136)	731	(1,867)
Net finance costs	46	(385)	431
Share of loss of associates	(180)	(54)	(126)
Net (loss) profit before income tax	(1,270)	292	(1,562)
Net (loss) profit	(2,117)	395	(2,512)

Note: Cash earnings describes operating profit before deducting depreciation, amortization, stock-based compensation expense and impairment.

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, 2020 ¥m	6 month period ended June 30, 2019 ¥m	Change
Royalty income	1,219	1,201	18
Milestone income and upfront fees	753	3,173	(2,420)
Product supply revenue	-	135	(135)
Other	544	547	(3)
	2,516	5,056	(2,540)

**Revenue** in the six month period under review totaled JPY 2,516 million (a decrease of JPY 2,540 million vs. the prior corresponding period).

**Revenue related to royalties** in the six month period under review totaled JPY 1,219 million (an increase of JPY 18 million vs. the prior corresponding period). The majority of the Group's royalty revenue relates to sales of Ultibro<sup>®</sup> Breezhaler<sup>®</sup> and Seebri<sup>®</sup> Breezhaler<sup>®</sup> by Novartis<sup>5</sup>.

In June 2020 Novartis announced that QVM149, a new inhaled LABA/LAMA/ICS therapy for the treatment of Asthma, containing the Group's out-licensed compound glycopyrronium bromide, received marketing approval in Japan and in July 2020 Novartis announced that it had received marketing approval in the EU. The Group is eligible to receive royalties on net sales of this new product.

**Revenue related to milestone income and upfront fees** in the six month period under review totaled JPY 753 million (a decrease of JPY 2,420 million vs. the prior corresponding period). Milestone revenues can vary considerably quarter on quarter and depend on the achievement of defined milestone events within a quarter. The decrease in revenue was primarily due to there being no major milestone payments from existing discovery and development partnerships in the six month period under review, whereas the Group received a US\$15m milestone payment from AstraZeneca in the prior corresponding period. The Group classifies a "major" milestone payment as any single payment greater than or equal to approximately USD 5 million.

<sup>&</sup>lt;sup>5</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 AG.

#### Operating expenses

	6 month period ended June 30, 2020 ¥m	6 month period ended June 30, 2019 ¥m	Change
Cash cost of sales	304	375	(71)
Cash research and development expenses	1,500	1,862	(362)
Cash general and administrative expenses	925	1,239	(314)
Non-cash expenses	955	865	90
Cost of sales	29	18	11
Research and development expenses	190	176	14
General and administrative expenses	736	671	65

#### Cash cost of sales

Cost of sales in the six month period under review totaled JPY 304 million yen (a decrease of JPY 71 million vs. the prior corresponding period). This is primarily related to the decrease in the costs directly associated with ORAVI® product supply. Otherwise, cost of sales comprises the fully loaded cost of those employees providing research and development services to specific customers under contracts (including other costs directly associated with these activities such as lab consumables and an allocated share of depreciation of lab equipment).

#### Cash research and development expenses

Cash research and development ("R&D") expenses in the six month period under review totaled JPY 1,500 million (a decrease of JPY 362 million vs. the prior corresponding period). The decrease in R&D spend primarily related to a reduction in project activity due to COVID-19, as well as the successful recovery of excess costs incorrectly charged by one supplier. In the period under review, 95% of R&D spend related to our UK operations.

#### Cash general and administrative expenses

Cash general and administrative ("G&A") expenses in the six month period under review totaled JPY 925 million (a decrease of JPY 314 million vs. the prior corresponding period). The decrease in G&A spend primarily related to a reduction in our UK National Insurance liability linked to share based payments as a result of the reduction in our share price over the period.

#### Non-cash expenses

Non-cash expenses primarily consist of depreciation on property, plant and equipment, amortization of intangible assets and stock-based compensation expense. Non-cash expenses in the six month period under review were JPY 955 million (an increase of JPY 90 million vs. the prior corresponding period). In total, depreciation amounted to JPY 255 million (an increase of JPY 32 million vs. the prior corresponding period). Amortization for the six month period under review totaled JPY 413 million (a decrease of JPY 58 million vs. the prior corresponding period). Stock-based compensation expense for the period was JPY 287 million (an increase of JPY 116 million vs. the prior corresponding period). The increase in stock based compensation expense reflects the issuance of new Restricted Stock Units in April 2020.

#### Operating income

Operating loss in the six month period under review totaled JPY 1,136 million (vs. an operating profit of JPY 731 million in the prior corresponding period). The main reason for the operating loss was due to the decrease in revenue (for the reasons stated above).

#### Net finance income/costs

Net finance income in the six month period under review totaled JPY 46 million (vs. a net finance costs of JPY 385 million in the prior corresponding period). The improvement was primarily due to foreign exchange related gains driven by the strength of the USD vs. GBP, as well as a reduction in interest costs due to the repayment of the Group's bank loans in December 2019.

#### Net loss

The net loss in the six month period under review totaled JPY 2,117 million (a net profit of JPY 395 million in the prior corresponding period). The main reason for the net loss was due to the decrease in revenue (for the reasons stated above).

### (2) Analysis of financial position

#### 1) Assets, liabilities and equity

#### Assets

Total assets at June 30, 2020 were JPY 51,078 million (a decrease of JPY 5,602 million vs. the end of the previous fiscal year FY19). The main reasons for the decrease were the effect of a weak GBP on the translation of GBP-denominated assets into JPY and the deconsolidation of Sosei RMF1 following the disposal in June 2020 of the Group's shareholding in Sosei CVC Limited (which controlled the fund).

#### Liabilities

Total liabilities at June 30, 2020 were JPY 10,139 million (a decrease of JPY 1,463 million vs. the end of the previous fiscal year FY19). The main decrease was in other financial liabilities which was due to the impact of the deconsolidation of Sosei RMF1.

#### Equity

Total equity at June 30, 2020 was JPY 40,939 million (a decrease of JPY 4,139 million vs. the end of the previous fiscal year FY19). This was primarily due to the net loss of JPY 2,117 million and exchange differences of translation of JPY 2,508 million.

The ratios of Cash and cash equivalents, Interest-bearing debt and Equity attributable to owners of the parent company to total assets were 30.1%, 3.2% and 80.2%, respectively.

#### 2) Cash flows

Cash and cash equivalents at June 30, 2020 decreased by JPY 13 million from the beginning of the year and amounted to JPY 15,362 million.

#### Cash flows from operating activities

Net cash provided by operating activities for the period under review totaled JPY 1,057 million. This was primarily due to income tax refunds of JPY 1,126 million.

#### Cash flows from investing activities

Net cash used in investing activities for the period under review totaled JPY 387 million. This was primarily due to a decrease in cash and cash equivalents of JPY 577 million resulting from the deconsolidation of Sosei RMF1, partially offset by sales on investment securities by Sosei RMF1 of JPY 238 million.

#### Cash flows from financing activities

Net cash used in financing activities for the period under review totaled JPY 148 million. This was primarily due to contingent consideration payments of JPY 159 million.

#### (3) Earnings forecast

#### The Group's response to COVID-19

A novel strain of coronavirus (COVID-19) was declared a global pandemic by the World Health Organization (WHO) on March,11 2020. The Group has been carefully monitoring COVID-19 pandemic and its impact on our operations. As a business operating in the global life sciences industry, the Group has an important role to play to ensure the health and safety of all stakeholders and society. The Group's priority remains the health of its employees, community members, and investigators and patients in its clinical trials. The Group has taken several actions in response to the COVID-19 pandemic, including:

- Implemented policies and practices to ensure a safe working environment for its employees and the communities where it operates to reduce the spread of COVID-19. This includes a work from home policy for many employees, while its essential employees, primarily laboratory-based scientists, continue to report to our UK R&D facility and are working on an optimized rota basis and in accordance with applicable UK government health and safety protocols issued in response to the COVID-19 pandemic. The Group has also introduced weekly SARS-CoV-2 testing of its essential employees at its UK R&D facility.
- Donated supplies of personal protective equipment (PPE) to a local hospice in the United Kingdom.
- Initiated a new in-house COVID-19 R&D program to apply its unique SBDD platform and capabilities to the global research efforts to discover drugs targeting the SARS-CoV-2 coronavirus and to treat COVID-19 and infections caused by future variants of SARS-CoV-2. All findings to be made freely available to the global research community.

#### Potential business impacts from COVID-19

The COVID-19 pandemic has created a challenging environment for people and companies across the world. The Group recognizes that the COVID-19 outbreak may have an impact on our business. While we continue to conduct drug discovery and development activities, including clinical trials, the COVID-19 pandemic has impacted, and may continue to impact, the timelines of certain of our early-stage discovery efforts and clinical trials. While the COVID-19 pandemic in the United Kingdom and Japan continues to evolve, the Group is monitoring closely for potential impacts:

- Overall business: apart from its new in-house COVID-19 R&D program, the Group is currently prioritizing revenue-generating work for its major collaboration partners. Work on in-house R&D programs, where the Group does not receive revenues from external partners, has been reduced in the short term. In-house R&D programs can be rapidly scaled up again in the future.
- Supply chain: the Group's core R&D facility in the United Kingdom has continued to operate throughout the COVID-19 pandemic. Its teams are working closely with providers across the supply chain to ensure continuity. To date the Group has not experienced any major interruptions to the supply of critical consumables for laboratory work and continue to closely monitor the situation.
- Drug discovery projects: to ensure a safe working environment for its employees, laboratory-based work is being conducted on a rota basis with some reduced capacity to enable social distancing and adherence to other government health and safety. Despite this, productivity remains strong. The Group has an extensive CRO network that is geographically diversified, and it has secured increased capacity with providers in China

and Eastern Europe. Despite this, the Group expects to see some small delays to project timelines and will continue to closely monitor the situation.

- Early development/clinical trials: patient safety is of utmost importance, and the Group is working closely with its providers and partners to advance its current clinical trials safely. The Group expects that there will be an impact to timelines for both in-house and partnered clinical programs, and that studies expected to complete in 2020 are now more likely to complete in 2021.
- Business development and new partnerships: scheduled and future partnership discussion meetings have not been impacted and are being conducted virtually.

#### Financial forecast

Despite these challenging times, the Group remains committed to delivering on its mission and vision, and to serving collaboration partners and patients in our clinical trials. The Group's smaller size enabled it to quickly enact flexible business continuity plans, and therefore it has continued to make good progress across the business and remain well positioned to pursue a number of strategic opportunities. The Group is taking steps to increase partnered activity, whilst simultaneously investing in technologies, tools and capabilities to advance an exciting pipeline of next-generation candidates that will form the basis of high value partnerships in the future.

The Group is continuing to drive a sustainable balance of resources and capital. Whilst it aims to pursue profitability, we recognize that the uncertainty caused by the COVID-19 pandemic is likely to impact on this goal. As of June 30, 2020 the Group's financial forecasts remain **unchanged** from December 31, 2019:

- Forecast cash R&D expenses in the range of JPY 4,200 to JPY 4,700 million<sup>6</sup>.
- Forecast cash G&A expenses in the range of JPY 1,800 to JPY 2,300 million<sup>7</sup>.
- The Group expects to receive upfront consideration related to new partnerships.
- The Group expects to receive milestone payments from existing drug discovery and development partnerships.
- The Group will continue to invest in technologies, tools and capabilities to advance nextgeneration candidates; while strongly managing its cost base.

The Group continues to believe it is well capitalized for the future. The Group's existing cash, cash flows from operations and existing sources of and access to financing are sufficient to cover its needs for drug discovery and early development activities, working capital, capital expenditures and debt servicing requirements, as well as to pursue business development initiatives. In addition, after the period ended June 30, 2020, the Group issued approximately JPY 5 billion of new equity and JPY 16 billion of long-term convertible bonds and intends to use the majority of the funds for a potentially transformative acquisition to pursue strategic growth.

<sup>&</sup>lt;sup>6</sup> The assumed FX rate of USD:JPY 110

The assumed FX rate of USD:JPY 110

## 2. Interim condensed consolidated financial statements and primary notes (IFRS)

1) Interim condensed consolidated statement of financial position

	June 30, 2020 (Unaudited)	December 31, 2019 (Audited)
	¥m	¥m
Assets		
Non-current assets		
Property, plant and equipment	3,604	4,120
Goodwill	13,707	14,365
Intangible assets	11,597	12,999
Investments accounted for using the equity method	3,093	3,539
Other financial assets	1,030	2,053
Other non-current assets	31	41
Total non-current assets	33,062	37,117
Current assets		
Trade receivables	2,063	1,924
Income tax receivable	103	1,765
Other current assets	488	499
Cash and cash equivalents	15,362	15,375
Total current assets	18,016	19,563
Total assets	51,078	56,680
Liabilities Non-current liabilities Deferred tax liabilities	2 051	2,008
	2,051	,
Contingent consideration in business combinations	3,106	3,203
Lease liabilities	1,500	1,704
Other financial liabilities	-	1,489
Other non-current liabilities	1,246	895
Total non-current liabilities	7,903	9,299
Current liabilities		
Trade and other payables	941	1,211
Income taxes payable	268	162
Lease liabilities	152	175
Other current liabilities	875	755
Total current liabilities	2,236	2,303
Total liabilities	10,139	11,602
Equity	27.662	27.470
Capital stock	37,662	37,479
Capital surplus	26,819	26,548
Treasury stock	(0)	(0
Retained earnings	(14,381)	(12,264
Other components of equity	(9,161)	(6,688
Equity attributable to owners of the parent	40,939	45,075
Non-controlling interests		3
Total equity	40,939	45,078
Total liabilities and equity	51,078	56,680

## 2) Interim condensed consolidated statement of comprehensive income

	Six month period ended June 30, 2020 (Unaudited) ¥m	Six month period ended June 30, 2019 (Unaudited) ¥m
Revenue	2,516	5,056
Cost of sales	(333)	(393)
Gross profit	2,183	4,663
Research and development expenses	(1,690)	(2,038)
Selling, general and administrative expenses	(1,661)	(1,910)
Other income	35	24
Other expenses	(3)	(8)
Operating (loss) profit	(1,136)	731
Finance income	369	244
Finance costs	(323)	(629)
Share of loss of associates accounted for using the equity method	(180)	(54)
Net (loss) profit before income taxes	(1,270)	292
Income tax (expense) benefit	(847)	103
Net (loss) profit for the period	(2,117)	395
Net change in fair value of equity investments designated as measured at fair value through other comprehensive income Total items that will not be reclassified subsequently to profit or loss Items that may be reclassified subsequently to profit or loss: Exchange differences on translating foreign operations Total items that may be reclassified subsequently to profit or loss <b>Total other comprehensive loss</b> <b>Total comprehensive loss for the period</b>	35 35 (2,508) (2,508) (2,473) (4,590)	(20) (20) (800) (800) (820) (425)
Net (loss) profit attributable to: Owners of the parent Non-controlling interests	(2,117) (0)	395 (0)
	(2,117)	395
Total comprehensive loss for the period attributable to: Owners of the parent Non-controlling interests	(4,590) (0) (4,590)	(425) (0)
	(0,0,0)	(425)
Earnings par share (yen)		
Earnings per share (yen) Basic (loss) earnings per share	(27.45)	5.19

## 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	Non- controlling interests ¥m	Total equity ¥m
Balance at January 1, 2020	37,479	26,548	(0)	(12,264)	(6,688)	45,075	3	45,078
Net loss for the period	-	-	-	(2,117)	-	(2,117)	(0)	(2,117)
Other comprehensive loss	-	-	-	-	(2,473)	(2,473)	-	(2,473)
Total comprehensive loss for the period	-	-	-	(2,117)	(2,473)	(4,590)	(0)	(4,590)
Issuance of new shares	183	(58)	-	-	-	125	-	125
Share-based payments	-	329	-	-	-	329	-	329
Change on loss of control of subsidiary	-	-	-	-	-	-	(3)	(3)
Total transactions with owners	183	271	-	-	-	454	(3)	451
Balance at June 30, 2020 (Unaudited)	37,662	26,819	(0)	(14,381)	(9,161)	40,939		40,939
Balance at January 1, 2019	36,854	26,042	(0)	(13,696)	(7,623)	41,577	3	41,580
Net profit (loss) for the period	-	-	-	395	-	395	(0)	395
Other comprehensive loss	-	-	-	-	(820)	(820)	-	(820)
Total comprehensive income (loss) for the period	-	-	-	395	(820)	(425)	(0)	(425)
Issuance of new shares	133	25	-	-	-	158	-	158
Share-based payments	-	171	-	_	-	171	-	171
Total transactions with owners	133	196	-	-	-	329	-	329
Balance at June 30, 2019 (Unaudited)	36,987	26,238	(0)	(13,301)	(8,443)	41,481	3	41,484

## 4) Interim condensed consolidated statement of cash flow

	Six month period ended June 30, 2020 (Unaudited) ¥m	Six month period ended June 30, 2019 (Unaudited) ¥m
Cash flows from operating activities		
(Loss) profit before income taxes	(1,270)	292
Adjustments for:		
Receipt of non-cash consideration from customer	-	(258)
Depreciation and amortization	668	705
Share-based payments	287	171
(Gain) loss on revaluation of investment securities	(244)	9
Loss on sale of investment securities	73	-
Loss (gain) on revaluation of investment in capital	75	(17)
Change in fair value of contingent consideration	136	141
Net foreign exchange loss	28	39
Interest income	(32)	(16)
Interest expenses	30	124
Share of losses of associates accounted for using the		
equity method	180	54
Increase in trade receivables	(304)	(511)
Decrease (increase) in other accounts receivables	11	(51)
Decrease in trade payables	(227)	(399)
Increase in deferred revenues	652	(555)
Other	(104)	(153)
Subtotal	(41)	130
Grants received	(+1)	34
Interest and dividends received	32	16
		(61)
Interest paid	(4)	
Income taxes refunded	1,126	2
Income taxes paid	(56)	(45)
Net cash provided by operating activities	1,057	76
Cash flows from investing activities		
Purchase of property, plant and equipment	(41)	(220)
Purchase of intangible assets	(6)	-
Payments for purchase of investment securities	-	(100)
Proceeds from sale of investment securities	238	-
Change in cash and cash equivalents due to disposal	(577)	-
Other	(1)	14
Net used in investing activities	(387)	(306)
Cash flows from financing activities		
Repayments of lease obligations	(114)	(35)
Repayments of long-term borrowings	-	(1,500)
Payment for settlement of contingent consideration	(159)	(776)
Proceeds from contributions from limited partners	-	495
Proceeds from issuance of new shares	125	158
Net cash used in financing activities	(148)	(1,658)
Effects of exchange rate changes on cash and cash		(_,_00)
equivalents	(535)	43
Net decrease in cash and cash equivalents	(13)	(1,845)
•		
Cash and cash equivalents at the beginning of the period	15,375	18,760
Cash and cash equivalents at the end of the period	15,362	16,915

#### 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

#### Issuance of New Shares and Convertible Bonds

At a board meeting held on June 30, 2020, the directors resolved to issue a New Shares and Euro-yen Denominated Convertible Bonds due 2025 through an International Offering, and the proceeds were received on July 16, 2020. A summary of the issuance is as follows:

#### a. Issuance of New Shares through an International Offering

- (1) Number of New Shares Issued: 3,301,400 shares
- (2) Issue Price (Offer Price): ¥1,595 per share
- (3) Aggregate Issue Price: ¥5,265,733,000
- (4) Amount Paid: ¥1,531.2 per share
- (5) Total Amount Paid: ¥5,055,103,680
- (6) Amount of increase in capital stock: ¥2,527,551,840
- (7) Amount of increase in capital reserves: ¥2,527,551,840
- (8) Closing Date: 16 July 2020 (London time)

(Note) The New Shares were purchased by the Underwriter at the amount paid and offered for sale at the Issue Price (Offer Price).

#### b. Issuance of Euro-yen Denominated Convertible Bonds due 2025 through an International Offering

- (1) Bonds Offered: Sosei Group Corporation Euro-yen Denominated Convertible Bonds due 2025
- (2) Aggregate Principal Amount: ¥16,000,000,000
- (3) Issue Price: 100.0% of par value (each Bond shall have a denomination of ¥10,000,000).
- (4) Offer Price: 102.5% of par value
- (5) Closing Date and Issue Date: 16 July 2020 (London time)

(6) Maturity: The Bonds will be redeemed at 100% of their principal amount on 16 July 2025. The Bonds may be redeemed prior to maturity upon, among other things, increased share prices and investor put.

- (7) Interest Rate: 0.5% per annum on the outstanding principal amount of the Bonds
- (8) Interest payment date: Payable semi-annually in arrears on 16 January and 16 July in each year.
- (9) Particulars of the Stock Acquisition Rights:
  - (i) Type and number of shares subjects to the Stock Acquisition Rights:

Type: Common stock of the Company

Number: The number of shares newly issued by the Company by the exercise of the Stock

Acquisition Rights is the number produced by dividing the total issue price of the Corporate Bonds related to the request for exercise by the conversion price described in (iii) below.

- (ii) Total number of Stock Acquisition Rights: 1,600
- (iii) Amount to be paid to exercise Stock Acquisition Rights: When exercising Stock Acquisition Rights, the bonds attached to the Stock Acquisition Rights shall be contributed, and the price of such bonds shall be the same as the par value. The conversion price shall be ¥1,834.
- (iv) Exercise period: July 30, 2020 to July 2, 2025(local time at the place where the exercise is requested). However, certain terms and conditions apply as stated in the issuance requirements.

(10) Collateral or guarantee of the bonds: The bonds do not have collateral or guarantee.

(11) Conditions for exercising Stock Acquisition Rights: The Stock Acquisition Rights may not be exercised in part.

(12) Listed exchange: Bonds with stock acquisition rights are listed on the Singapore Stock Exchange.

#### <u>C. Use of Proceeds</u>

The aggregate net proceeds of up to approximately ¥20.9 billion (US\$195 million) from the International Offerings are expected to be applied as follows:

- approximately ¥18.8 billion (US\$176 million) to be applied by the end of June 2023 towards strategic growth initiatives including: funding acquisitions, or investments in companies or technologies that complement its business; expanding drug candidate discovery and early development; and potentially in-licensing pipeline products for the Japanese market.
- approximately ¥2.1 billion (US\$20 million) to be applied by the end of June 2023 towards organic growth initiatives, including the cost of research and working capital.

Until we use the net proceeds of the International Offerings, we intend to invest the funds in short-term, interest-bearing instruments.

#### Enerzair<sup>®</sup> Breezhaler<sup>®</sup> granted marketing approval

On July 7, 2020 Novartis announced that the European Commission had approved Enerzair<sup>®</sup> Breezhaler<sup>®</sup> (QVM149; indacaterol acetate, glycopyrronium bromide and mometasone furoate) as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high-dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year. The achievement of this milestone results in a payment by Novartis to the Group of US\$5 million under the terms of its 2005 Development and Licensing agreement. The Group is eligible to receive royalties from future sales of Enerzair<sup>®</sup> Breezhaler<sup>®</sup> in the EU and other markets in which it is approved.