



## Consolidated Financial Results for the FY2018 (IFRS)

February 12, 2019

Listing: Tokyo Stock Exchange

Company name: Sosei Group Corporation  
 Security code: 4565 URL: <https://www.soseiheptares.com/>  
 Representative: Shinichi Tamura  
 Representative Executive Officer, CEO  
 Contact person: Chris Cargill  
 Executive Vice President, CFO  
 Scheduled date of annual general meeting: March 27, 2019  
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 Scheduled date of dividend payments: -  
 Supplementary materials for financial results: Yes  
 Financial results briefing session: Yes (for institutional investors and analysts)

Tel: +81-3-5210-3290

(Rounded million yen)

### 1. Consolidated results for 9 months ended December 31, 2018

#### (1) Consolidated operating results

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

	Revenue		Operating income		Net profit before income taxes		Net profit		Net profit attributable to owners of the parent company		Total comprehensive income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
9 months ended December 31, 2018	2,872	—	(5,734)	—	(7,243)	—	(5,978)	—	(5,977)	—	(7,619)	—
12 months ended March 31, 2018	6,955	(63.2)	(2,291)	—	(3,702)	—	(2,654)	—	(2,654)	—	(1,227)	—

	Earnings per share - basic	Earnings per share - diluted	Ratio of net income to equity attributable to owners of the parent company	Ratio of net income before income taxes to total assets	Ratio of operating income to revenue
	Yen	Yen	%	%	%
9 months ended December 31, 2018	(78.40)	(78.40)	(13.2)	(11.3)	(199.6)
12 months ended March 31, 2018	(37.55)	(37.55)	(6.9)	(6.3)	(32.9)

(Note) Investment loss under equity method: 488 million yen for 9 months ended December 31, 2018; and 276 million yen for 12 months ended March 31, 2018

(Note) The Company and the Group changed the end of their fiscal year from March 31 to December 31. The % changes have not been omitted because FY2018 was for a nine month period whereas FY2017 was for a twelve month period.

(Note) Effective July 1, 2018, the Company executed a stock split at a ratio of 4 shares per common share. Earnings per share has been calculated as if the stock split had occurred at the beginning of the previous consolidated fiscal year.

#### (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	Equity per share - attributable to owners of the parents
	Million yen	Million yen	Million yen	%	Yen
At December 31, 2018	58,987	41,580	41,577	70.5	544.89
At March 31, 2018	69,486	48,886	48,882	70.3	641.31

(Note) Effective July 1, 2018, the Company executed a stock split at a ratio of 4 shares per common share. Earnings per share has been calculated as if the stock split had occurred at the beginning of the previous consolidated fiscal year.

#### (3) Consolidated cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of the year
	Million yen	Million yen	Million yen	Million yen
9 months ended December 31, 2018	(3,995)	(2,808)	(2,268)	18,760
12 months ended March 31, 2018	(2,167)	(6,148)	22,641	28,281

### 2. Dividends

	Dividends per share					Total amount of dividends	Dividend payout ratio (consolidated)	Ratio of dividend to equity attributable to owners of the parent company (consolidated)
	End Q1	End Q2	End Q3	End Q4	Total			
FY2017	—	0.00	—	0.00	0.00	—	—	—
FY2018	0.00	—	—	0.00	0.00	—	—	—
FY2018 (E)	—	0.00	—	0.00	0.00	—	—	—

(Note) The record date for the interim dividend for the FY2018 is June 30, 2018 (End Q1).

### 3. Forecast for the twelve month period from January 1, 2019 to December 31, 2019

We have made excellent progress in strengthening our wider business and are well positioned to capitalize on a number of strategic opportunities. Our highly productive platform has generated multiple new exciting candidates, and we are now taking steps to increase partnered and co-development activity, whilst simultaneously investing to advance our exciting pipeline of emerging in-house assets.

The Group expects an improved outlook for the financial year ending December 31, 2019, as we target a more sustainable balance of resources and capital in order to prioritize the pursuit of profitability:

- Forecast cash R&D expenses in the range of JPY 4,320 to JPY 4,860 million<sup>1</sup>
- Forecast cash G&A expenses in the range of JPY 1,620 to JPY 2,160 million<sup>2</sup>
- We expect to receive upfront payments related to new partnerships.
- We expect to receive major milestone payments<sup>3</sup> from existing discovery and development partnerships.
- We will continue to take a more focused approach to in-house pipeline investment and will look to strongly manage our cost base.
- The Group has a strong cash runway into 2020 to fund its drug development activities and is proactively seeking to extend the cash runway into 2021.

#### \* Notes

(1) Changes in the number of significant subsidiaries for the nine month ended December 31, 2018 (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: Yes

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 December 31, 2018	76,301,936	shares	At March 31, 2018	76,219,936	shares
2) Number of treasury shares at period end	At December 31, 2018	104	shares	At March 31, 2018	104	shares
3) Average number of shares issued for the period	9 months ended December 31, 2018	76,256,495	shares	12 months ended March 31, 2018	70,687,212	shares

(Note) As of July 1, 2018, the Company has executed a stock split at a ratio of 4 shares per common share. "Number of shares issued at period end", "Number of treasury shares at period end" and "Average number of shares in issue in period" are calculated assuming that the stock split had been made at the beginning of the previous consolidated fiscal year.

\* The Tanshin, including the consolidated financial statements presented within it, is not subject to audit.

\* Explanation regarding the appropriate use of forecast and other points to be noted

(Note concerning forward-looking statements)

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

The Company is scheduled to hold an online conference for analysts on February 12, 2019 (same day).

The materials for the briefing session and the content will be posted on the Company's website promptly after the conference, along with materials to be used on that day.

<sup>1</sup> The assumed FX rate of USD:JPY 108

<sup>2</sup> The assumed FX rate of USD:JPY 108

<sup>3</sup> The Group classifies "major" milestone payments as any single payment greater than or equal to USD 5 million.

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# 1. Analysis of Operating Results and Financial Position

## (1) Analysis of operating results

The Group is a clinical-stage biotechnology company. Our vision is to become one of Japan's global biotechnology champions by discovering and developing highly innovative medicines targeting G Protein-Coupled Receptors ("GPCRs").

During the nine month period ended December 31, 2018 (from April 1, 2018 to December 31, 2018), the Group continued to advance its proprietary StaR® ("stabilized receptor") technology, Structure-based Drug Design ("SBDD") platform, and in-house development pipeline.

We continued to make excellent progress in strengthening our wider business and are well-positioned to capitalize on a number of strategic opportunities.

Our balanced business model progressed across all areas; (i) partnerships with major global pharmaceutical companies, (ii) collaborations in R&D with innovative biotechnology companies, and (iii) in-house proprietary drug development.

As of December 31, 2018, the Group had 15 programs ongoing in discovery, with 4 in preclinical development, and 7<sup>4</sup> currently in clinical trials.

**In the area of partnerships with major global pharmaceutical companies**, our next-generation cancer immunotherapy candidate, AZD4635 continued to progress through patient-based clinical studies.

On April 18, 2018, the Group together with its partner AstraZeneca UK Limited ("AstraZeneca") announced new data demonstrating that AZD4635 induces anti-tumor immunity alone and in combination with anti-PD-L1 immunotherapies in preclinical models. AZD4635 is a potent and selective, orally available, small molecule adenosine A2a receptor antagonist. AZD4635 was discovered by the Group's wholly-owned subsidiary Heptares Therapeutics ("Heptares"), and AstraZeneca licensed exclusive global rights to the molecule in 2015. The clinical potential of AZD4635 is being thoroughly investigated by AstraZeneca and the following studies are ongoing:

- Phase Ib study assessing safety, tolerability, pharmacokinetics and biological activity in patients with solid malignancies (NCT#02740985); and
- Phase Ib/II study assessing safety, tolerability and anti-tumor activity of novel combination therapies in patients with advanced epidermal growth factor receptor ("EGFRm") mutated non-small cell lung cancer ("NSCLC") (NCT#03381274).

On September 18, 2018, the Group together with Allergan, its license partner for HTL0018318, announced that it had decided to voluntarily suspend clinical development activities with HTL0018318 pending the investigation of an unexpected toxicology finding in an animal study involving non-human primates. The voluntary suspension is not based on any human findings. Patient safety is of the utmost importance to the Group and Allergan. Scientists from both the Group and Allergan are investigating these findings which remain of unknown cause. The investigations will delay the start of planned Phase II study in patients with Alzheimer's Disease (AD) by at least six months, however we expect it could be longer.

**In the area of collaborations in R&D with innovative biotechnology companies**, the Group's programs also continued to advance efficiently.

On May 24, 2018, the Group provided an update on its collaboration with PeptiDream. The collaboration, which began in 2017, aims to discover, develop and commercialize novel peptide therapeutics targeting Protease activated receptor 2 ("PAR2"), a GPCR with an important role in inflammatory disease. The combination of the Group's proprietary StaR® technology, providing a purified and stable receptor, and PeptiDream's proprietary Peptide Discovery Platform System ("PDPS") has allowed for rapid identification of high affinity and selective peptide antagonists against PAR2. The peptides are undergoing further characterization and optimization, with the intention of advancing the most promising leads towards clinical development. As per the terms of the agreement, the Group and PeptiDream jointly conduct and share the costs of the discovery and development program and will co-own any resulting products.

<sup>4</sup> Includes AZD4635 for multiple solid malignancies, AZD4635 for EGFRm NSCLC, HTL0016878 for neurobehavioral symptoms of Alzheimer's disease, HTL0018318 for Alzheimer's disease (voluntarily suspended), HTL0018318 for dementia with Lewy bodies (voluntarily suspended), QVM149 for Asthma, and HTL0014242 for neurological disorders.

On November 7, 2018, the Group announced that it had entered a new collaboration agreement with Germany-based DyNAbind GmbH designed to extend its leadership in GPCR medicine design and accelerate new drug discovery. The collaboration agreement aims to pioneer the application of next-generation DNA-based technologies against StaR® proteins to rapidly generate and optimize selective and potent small molecule drug candidates for multiple GPCR drug targets, including historically hard-to-drug targets.

**In the area of in-house proprietary drug development**, the Group continued to make the necessary investments in our pipeline as we advanced multiple candidates towards clinical studies.

On June 18, 2018, the Group received all necessary approvals to begin its Phase IIa MATILDA study assessing the safety, tolerability, and efficacy of novel muscarinic M1 receptor agonist HTL0018318 in patients with Dementia with Lewy-bodies (DLB). However, patient recruitment was stopped due to the aforementioned voluntary suspension of clinical development activities with HTL0018318.

On September 25, 2018, the Group announced that it received approval in Japan for ORAVI® Mucoadhesive Tablets 50mg. ORAVI® is a novel formulation of the Japanese pharmacopeia miconazole (antifungal agent), the once-daily treatment mucoadhesive tablet to treat oropharyngeal candidiasis (“OPC”) in patients. ORAVI® applies Lauriad™ proprietary technology for extended delivery of high concentrations of miconazole directly to the infected site in the mouth. The Group has granted an exclusive license to FUJIFILM Group for the commercialization of ORAVI® in Japan. The Group received a milestone payment of JPY 200 million (approximately USD 2 million equivalent) from FUJIFILM Pharma Co., Ltd upon approval and is entitled to receive consideration for the supply of product, plus additional payments based on the achievement of sales-based milestones, from FUJIFILM Toyama Chemical Co., Ltd.

On December 13, 2018, the Group announced that the first healthy subject had been dosed with a novel small molecule HTL0014242 in a Phase I clinical study, marking the start of a new in-house clinical program targeting neurological disorders. HTL0014242 is a potent, orally available, selective Metabotropic Glutamate Receptor 5 (mGlu5) negative allosteric modulator1 (NAM), precision-designed by the Company using its GPCR SBDD platform. The new clinical study with HTL0014242 is a first-in-human double-blind, randomized, oral single ascending dose study in healthy male and female adult subjects. This study is being conducted in the UK and will assess safety, tolerability and pharmacokinetics of HTL0014242 in up to 48 subjects. Preliminary results are expected in the second half of 2019.

The Group’s other in-house proprietary drug development programs continued to progress well.

**In the area of strategic investments**, the Group continued to monitor its investment in RNA Therapeutics pioneer, MiNA Therapeutics (“MiNA”).

On September 19, 2018, the Group announced that its strategic minority investment company, MiNA, provided an update from its ongoing Phase I study of small activating RNA (“saRNA”) candidate MTL-CEBPA in advanced liver cancer patients. It was reported that there had been observations of tumor responses in three patients when administered approved liver cancer therapies subsequent to treatment with MTL-CEBPA. These observations were anecdotal, and not part of the OUTREACH study data. The observations are very interesting and may support the potential of MTL-CEBPA to enhance the benefit of other oncology drugs to modulate the tumor immune microenvironment. As a result of the observations, MiNA has committed to investigating these findings in further clinical development.

On October 18, 2018, the Group announced that it did not exercise its exclusive option to acquire further equity in MiNA (Holdings) Limited, the parent company of the MiNA group. The Group’s decision was based on: (1) an evaluation of the investment opportunity including a rigorous analysis of interim data from MiNA’s Phase I/IIa OUTREACH study of MTL-CEBPA as a single agent in advanced liver cancer patients; and (2) the prioritization of resources directed towards other opportunities across our partnered and in-house GPCR-targeted drug candidate portfolio, which we believe have more value creation potential. MiNA’s decision to evaluate MTL-CEBPA in combination with sorafenib represents the most promising clinical strategy and the Group remains a supportive shareholder with a significant shareholding.

On December 20, 2018, the Group noted that MiNA announced enrolment of the first patients treated with MTL-CEBPA in combination with sorafenib in OUTREACH, the multi-center Phase 1b clinical trial in patients with advanced liver cancer. The study is designed to assess the safety, tolerability and clinical activity of MTL-CEBPA in combination with sorafenib. OUTREACH

is currently being conducted at multiple clinical trials sites in the United Kingdom, Singapore and Taiwan.

**With regard to the executive management team**, the Group announced that Mr. Chris Cargill was appointed to Executive Vice President and Chief Financial Officer on November 1, 2018.

On December 12, 2018, the Group announced that it was decided by mutual consent that Mr. Peter Bains would step down as President and CEO of the Company on 31 December 2018. Mr. Bains also resigned as a Director of the Company simultaneously. Mr. Shinichi Tamura, Executive Chairman, founder and former CEO of Sosei, was re-appointed as Chairman, President & CEO effective as of 1 January 2019. The re-appointment of Mr. Tamura as CEO provides a seamless transition that enabled the Company to intensify its focus on developing innovative, new medicines whilst generating greater value for shareholders. The Group will continue to make prudent investment in R&D and promote its leading scientific platform, portfolio and business globally. The Group's strategic decisions will place its Japanese and global investors top-of-mind, to maximize shareholder value.

**With regard to operational matters**, the Group decided in November 2018 to close its research facility in Zurich, Switzerland. The decision was made to simplify the R&D structure and improve the allocation of capital. The Zurich research facility's core technology assets, CHESS and SaBRE, will be repatriated to the U.K. during the first half of 2019 and will be housed at the Group's purpose-built, state-of-the-art facility at Granta Park, Cambridge, U.K.

As of December 31, 2018, the Group had a total of 171 employees (an increase of 19 employees vs. March 31 2018).

Comparison of the financial results for the current nine month fiscal period with that of the previously reported twelve-month fiscal period is affected by the change of accounting reference date. To assist in understanding the current financial period's performance, supplementary unaudited summary proforma information is additionally presented. The proforma information compares the nine month period ended December 31, 2018 to the nine month period ended December 31, 2017 ('prior corresponding period').

The Group reported the following financial results for nine month period ended December 31, 2018. Revenue of JPY 2,872 million (a decrease of JPY 3,405 million vs. the prior corresponding period), an operating loss of JPY 5,734 million (an increase of JPY 5,640 million vs. the prior corresponding period), a net loss before income taxes of JPY 7,243 million (an increase of JPY 5,344 million vs. the prior corresponding period) and a net loss of JPY 5,978 million (an increase of JPY 4,265 million vs. the prior corresponding period).

	Reported		Proforma	
	9 months ended December 31, 2018 ¥m	Year ended March 31, 2018 ¥m	9 months ended December 31, 2018 ¥m	9 months ended December 31, 2017 ¥m
<b>Revenue</b>	<b>2,872</b>	6,955	<b>2,872</b>	6,277
Cost of sales	(335)	-	(335)	-
Research and development expenses	(5,384)	(4,935)	(5,384)	(3,456)
Selling, general and administrative expenses	(2,704)	(4,482)	(2,704)	(3,213)
Other net expenses	(183)	171	(183)	298
<b>Operating (loss)</b>	<b>(5,734)</b>	(2,291)	<b>(5,734)</b>	(94)
Net finance costs	(955)	(1,135)	(955)	(1,610)
Share of loss of associates	(488)	(276)	(488)	(195)
Impairment loss on associates	(66)	-	(66)	-
<b>Net loss before income tax</b>	<b>(7,243)</b>	(3,702)	<b>(7,243)</b>	(1,899)
<b>Net loss</b>	<b>(5,978)</b>	(2,654)	<b>(5,978)</b>	(1,713)

Subsequent to December 31, 2018, the following events occurred:

- On January 7, 2019, the Group announced it had been notified by AstraZeneca that it had reached a clinical development milestone with its partnered next generation immuno-oncology candidate AZD4635, triggering a US\$15 million payment from AstraZeneca. The clinical study to date has established the maximum-tolerated dose of AZD4635 as a single agent and in combination with durvalumab. The study has progressed successfully to the point where the therapeutic potential of AZD4635 is being explored in multiple solid tumors. As a result, AstraZeneca is moving the trial towards Phase 2, thereby triggering the milestone payment to the Group. Headline data from the Phase 1 study is planned to be presented at a scientific congress in 2019. The Group expects to receive the \$15 million payment by the end of March 2019.
- On January 31, 2019, the Group announced it will launch ORAVI® in Japan on 4 February 2019. The effect of the launch on the Group's outlook for the accounting period ending December 2019 is not expected to be material.
- On February 4, 2019, the Group announced it had entered into a structured financing agreement with Medicxi, a venture fund dedicated to financing asset-centric companies, to form two independent companies, Orexia Ltd ("Orexia") and Inexia Ltd ("Inexia"), that aim to develop novel therapies based on positive modulators of the G protein-coupled receptors Orexin OX1 and OX2 for neurological diseases. Medicxi will be investing in both companies with an aggregate amount of up to €40 million. Under the terms of the agreement, Orexia and Inexia will obtain some of our certain intellectual property and have the rights to exploit a series of Orexin OX1 and OX2 positive modulators and products derived therefrom, including dual OX1/OX2 agonists, designed and developed by the Company, as well as access to proprietary know-how and development capabilities. Orexia will focus on the development of oral therapies, while Inexia will focus on the development of candidates for intranasal delivery using the Optinose Exhalation Delivery System. The Group will retain an equity holding in both companies and will receive R&D payments as well as further payments on the achievement of pre-defined development milestones. The funding, which is committed by Medicxi, will enable the further development and optimization of lead candidates for oral or intranasal administration into clinical development and through to proof-of-concept, utilizing Sosei Heptares' platform, discovery and clinical development expertise including extensive experience of neurological disorders. Specific target indications will be determined as the programs advance, and will include narcolepsy, a rare sleep disorder.

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

	Proforma		
	9 months ended December 31, 2018 ¥m	9 months ended December 31, 2017 ¥m	Change
Royalty income	2,104	2,053	51
Milestone fees and lump-sum payments	340	3,783	(3,443)
Other	428	441	(13)
	<b>2,872</b>	<b>6,277</b>	<b>(3,405)</b>

**Revenue related to royalties** in the nine month period under review totaled JPY 2,104 million (an increase of JPY 51 million vs. the prior corresponding period). The majority of the Group's royalty revenue relates to sales of Ultibro® Breezhaler® and Seebri® Breezhaler® by Novartis<sup>5</sup>.

On January 30, 2019, our partner Novartis reported total calendar Q4 2018 sales for its Ultibro® Breezhaler® and Seebri® Breezhaler® products of USD 159 million (a decrease of USD 3 million). The breakdown of Novartis' calendar Q4 2018 sales by product was as follows:

- Ultibro® Breezhaler® USD 122 million (+5% compared to calendar Q4 2017<sup>6</sup>) an inhaled LABA/LAMA, showed continued growth, driven by positive FLAME and CLAIM study results as well as the GOLD Strategy 2018 Report and further supported by the published SUNSET study results.
- Seebri® Breezhaler® USD 37 million (-9% compared to calendar Q4 2017<sup>7</sup>) an inhaled LAMA, declined due to competition in Europe and a focus of resources on Ultibro® Breezhaler®.

Total sales of Ultibro® Breezhaler® and Seebri® Breezhaler® in the current 9 month reporting period were USD 458 million (+5% on the prior corresponding period).

Ultibro® Breezhaler® remains the number one LABA/LAMA across Europe. Furthermore, in its (calendar) Q4 2018 results presentation, Novartis confirmed its commitment to respiratory products that contain the Group's out-licensed compound glycopyrronium bromide. Novartis confirmed that the status has not changed from Q3 2018 and enrolment of the Phase III IRIDIUM, PALLADIUM and QUARTZ studies of QVM149 for asthma have been completed. The filing of QVM149 is planned for H2 2019, ahead of an expected commercial launch in 2020, and the Group is eligible to receive further royalties on sales of this product.

**Revenue related to milestones** in the nine month period under review totaled JPY 340 million (a decrease of JPY 3,443 million vs. the prior corresponding period). The prior corresponding period contained major milestone payments from Allergan (USD 15 million), AstraZeneca (USD 12 million) and Teva Pharmaceutical Industries Ltd ("Teva") (USD 5 million). Therefore, the main reason for the decline in milestone revenues was the absence of any upfront payments related to new partnerships, and the absence of any major milestone payments from existing discovery and development partnerships. This was previously disclosed in the Group's forecasts at the FY2017 full year results on May 10, 2018. The Group classifies a "major" milestone payment as any single payment greater than or equal to approximately USD 5 million.

#### Cost of sales

Cost of sales represents the fully loaded cost of those employees providing research and development services to specific customers under contracts. It also includes other costs directly associated with these activities such as lab consumables and an allocated share of depreciation of lab equipment.

<sup>5</sup> Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura. In the US, these products are available at different doses or regimens under the names Utibron™ Neohaler® and Seebri™ Neohaler® and Sunovion Pharmaceuticals Inc. has assumed as of December 21, 2016 US commercialization rights for them. Seebri™ Neohaler® was launched in October 2017 by Sunovion Pharmaceuticals Inc.

<sup>6</sup> At constant currency rates

<sup>7</sup> At constant currency rates



*Research and development expenses and General and administrative expenses*

	Proforma		
	<b>9 months ended December 31, 2018</b>	9 months ended December 31, 2017	Change
	¥m	¥m	
Research and development	<b>5,384</b>	3,456	1,928
Cash expenses	<b>5,187</b>	3,370	1,817
Non-cash expenses	<b>197</b>	86	111
General and administrative expenses	<b>2,704</b>	3,213	(509)
Cash expenses	<b>1,611</b>	2,099	(488)
Non-cash expenses	<b>1,093</b>	1,114	(21)

*Research and development cash expenses*

Cash research and development (“R&D”) expenses in the nine month period under review totaled JPY 5,187 million yen (an increase of JPY 1,817 million vs. the prior corresponding period). This was primarily due to increased preparatory spend related to our Phase IIa MATILDA study for DLB in Japan (which entered voluntary hold on 18 September 2018), together with continued investment in our in-house drug development programs, platform and translational science capabilities. In the period under review, 97% of R&D spend related to our UK operations. The Group’s guidance for cash R&D expenditure improved as a result of a more focused approach to in-house pipeline investment, and decreased R&D spend (primarily related to the voluntary suspension of the Phase IIa MATILDA study for DLB patients in Japan).

*General and administrative cash expenses*

Cash general and administrative (“G&A”) expenses in the nine month period under review totaled JPY 1,611 million (a decrease of JPY 488 million vs. the prior corresponding period). This was primarily due to a reduction in National Insurance charges in the U.K. (related to Stock-Based Compensation), as well as tight management of costs.

*Non-cash expenses*

Non-cash expenses consist of depreciation on property, plant and equipment, amortization of intangible assets, and stock-based compensation expenses. Non-cash expenses in the nine month period under review were JPY 1,290 million (an increase of JPY 90 million vs. the prior corresponding period). In total, depreciation expense for the nine month period under review totaled JPY 205 million (an increase of JPY 107 million vs. the prior corresponding period). Amortization amounted to JPY 665 million (a decrease of JPY 1 million vs. the prior corresponding period). The stock-based compensation expense for the period was JPY 420 million (a decrease of JPY 16 million vs. the prior corresponding period).

*Other net expenses*

Other net expenses totaled JPY 183 million, a decrease of JPY 481 million vs. the prior corresponding period. The current period cost comprises a charge for impairment partially offset by grant income. The impairment charge relates to intangible assets recognized at the time of the acquisition of Heptares. One program that had an identified value at the time of the acquisition was discontinued during the period. In the prior corresponding period other income included proceeds received from the disposal of Actavis Pharma of JPY 326 million.

*Operating loss*

Operating loss in the nine month period under review totaled JPY 5,734 million (an increase of JPY 5,640 million vs. the prior corresponding period). The main reason for the increase in operating loss is the decrease in revenue (for the reasons stated above) and the increase in R&D expense (for the reasons stated above) during the nine month period under review.

#### *Net Finance costs*

Net finance costs in the nine month period under review totaled JPY 955 million (a decrease of JPY 655 million vs. the prior corresponding period). Finance costs include interest expense, foreign exchange gains / losses and fair value movements in financial assets and liabilities. In the current reporting period they included a JPY 1,121 million write-down related to the lapsing of our exclusive option to increase our investment in MiNA. The main reasons for the decrease compared to the prior corresponding period are the inclusion of a contingent consideration credit and foreign exchange (as a result of more stable JPY, USD, and GBP rates) in the nine month period under review. As a reminder to our valued Shareholders, the contingent consideration charge relates to additional purchase consideration to be paid to the former shareholders of Heptares Therapeutics Limited. The contingent consideration charge represents the re-measurement of the estimated liability due in the future to the former shareholders of Heptares Therapeutics Limited. As at 31 December 2018, the Group has to date paid USD 66 million in milestones, out of the total maximum potential milestone amount payable of USD 220 million.

#### *Net loss*

The net loss in the nine month period under review totaled JPY 5,978 million (an increase of JPY 4,265 million vs. the prior corresponding period). The main reason for the increase in net loss is the decrease in revenue (for the reasons stated above), and the increase in R&D expense (for the reasons stated above) during the nine month period under review.

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

### 1) Assets, liabilities and equity

#### *Assets*

Total assets at December 31, 2018 were JPY 58,987 million (a decrease of JPY 10,499 million vs. the end of the previous fiscal year). The main reason for the decrease is a reduction of JPY 9,521 million in cash and cash equivalents associated with operating activity expenditure and debt repayments.

#### *Liabilities*

Total liabilities at December 31, 2018 were JPY 17,407 million (a decrease of JPY 3,193 million vs. the end of the previous fiscal year). The main reasons for the decrease are a reduction of JPY 2,209 million in interest-bearing liabilities, a decrease in the fair value of the contingent consideration liability of JPY 454 million, and a decrease in deferred tax liabilities of JPY 535 million.

#### *Equity*

Total equity at December 31, 2018 was JPY 41,580 million (a decrease of JPY 7,306 million vs. the end of the previous fiscal year). This decrease is primarily due to the net loss for the period (JPY 5,978 million) and the impact of exchange differences arising on translation of foreign operations (JPY 1,641 million). The ratio of equity attributable to owners of the parent company to total assets was 70.5%, an increase of 0.2% vs. the end of the previous fiscal year.

### (3) Analysis of cash flows

Cash and cash equivalents at December 31, 2018 decreased by JPY 9,521 million from the beginning of the year and amounted to JPY 18,760 million.

#### *Cash flows from operating activities*

Net cash used in operating activities for the period under review totaled JPY 3,995 million. This is predominantly due to loss before income taxes recorded for the period arising from the Group's increased investment in R&D.

#### *Cash flows from investing activities*

Net cash used in investing activities for the period under review totaled JPY 2,808 million. This is primarily due to the acquisition of fixed assets totaling JPY 1,807 million related to investment in our new R&D facility at Granta Park, Cambridge, United Kingdom, and investments totaling JPY 650 million made by Sosei RMF1 Limited Partnership for Investment, which is the Group's wholly-owned subsidiary.

#### *Cash flows from financing activities*

Net cash used in financing activities for the period under review totaled JPY 2,268 million. This was primarily due to repayments of long-term interest-bearing debt of JPY 2,255 million.

### (4) Earnings forecast for the twelve month period from January 1, 2019 to December 31, 2019

We have made excellent progress in strengthening our wider business and are well-positioned to capitalize on a number of strategic opportunities. Our highly productive platform has generated multiple new exciting candidates, and we are now taking steps to increase partnered and co-development activity, whilst simultaneously investing to advance our exciting pipeline of emerging in-house assets.

The Group expects an improved outlook for the financial year ending December 31, 2019, as we target a more sustainable balance of resources and capital in order to prioritize the pursuit of profitability:

- Forecast cash R&D expenses in the range of JPY 4,320 to JPY 4,860 million<sup>8</sup>
- Forecast cash G&A expenses in the range of JPY 1,620 to JPY 2,160 million<sup>9</sup>
- We expect to receive upfront payments related to new partnerships.
- We expect to receive major milestone payments from existing discovery and development partnerships.
- We will continue to take a more focused approach to in-house pipeline investment and will look to strongly manage our cost base.
- The Group has a strong cash runway into 2020 to fund its drug development activities and is proactively seeking to extend the cash runway into 2021.

## 2. Basic policy on selection of accounting standards

The Group has applied International Financial Reporting Standards since the year ended March 2014.

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<sup>8</sup> The assumed FX rate of USD:JPY 108

<sup>9</sup> The assumed FX rate of USD:JPY 108

### 3. Consolidated financial statements and primary notes (IFRS)

#### 1) Consolidated statement of financial position

	December 31, 2018 ¥m	March 31, 2018 ¥m
<b>Assets</b>		
<b>Non-current assets</b>		
Property, plant and equipment	2,715	1,156
Goodwill	14,177	14,685
Intangible assets	14,367	16,670
Investments accounted for using the equity method	3,644	4,424
Deferred tax assets	-	6
Other financial assets	1,515	1,619
Other non-current assets	285	10
<b>Total non-current assets</b>	<b>36,703</b>	<b>38,570</b>
<b>Current assets</b>		
Trade and other receivables	987	753
Income tax receivable	2,057	1,057
Other current assets	480	825
Cash and cash equivalents	18,760	28,281
<b>Total current assets</b>	<b>22,284</b>	<b>30,916</b>
<b>Total assets</b>	<b>58,987</b>	<b>69,486</b>
<b>Liabilities and Equity</b>		
<b>Liabilities</b>		
<b>Non-current liabilities</b>		
Deferred tax liabilities	2,542	3,077
Contingent consideration in business combinations	4,180	4,634
Interest-bearing debt	3,970	6,178
Other financial liabilities	1,179	1,073
Other non-current liabilities	87	43
<b>Total non-current liabilities</b>	<b>11,958</b>	<b>15,005</b>
<b>Current liabilities</b>		
Trade and other payables	2,080	2,411
Income taxes payable	24	39
Interest-bearing debt	2,994	2,995
Other current liabilities	351	150
<b>Total current liabilities</b>	<b>5,449</b>	<b>5,595</b>
<b>Total liabilities</b>	<b>17,407</b>	<b>20,600</b>
<b>Equity</b>		
Capital stock	36,854	36,783
Capital surplus	26,042	25,608
Treasury stock	(0)	(0)
Retained earnings	(13,696)	(7,527)
Other components of equity	(7,623)	(5,982)
Equity attributable to owners of the parent	41,577	48,882
Non-controlling interests	3	4
<b>Total equity</b>	<b>41,580</b>	<b>48,886</b>
<b>Total liabilities and equity</b>	<b>58,987</b>	<b>69,486</b>

## 2) Consolidated statement of comprehensive income

	9 months ended December 31, 2018 ¥m	12 months ended March 31, 2018 ¥m
<b>Revenue</b>	<b>2,872</b>	6,955
Cost of sales	<b>(335)</b>	-
<b>Gross profit</b>	<b>2,537</b>	6,955
Research and development expenses	<b>(5,384)</b>	(4,935)
Selling, general and administrative expenses	<b>(2,704)</b>	(4,482)
Other income	<b>140</b>	565
Other expenses	<b>(323)</b>	(394)
<b>Operating (loss)</b>	<b>(5,734)</b>	(2,291)
Finance income	<b>434</b>	104
Finance costs	<b>(1,389)</b>	(1,239)
Share of loss of associates accounted for using the equity method	<b>(488)</b>	(276)
Impairment loss on investments accounted for using the equity method	<b>(66)</b>	-
<b>Loss before income taxes</b>	<b>(7,243)</b>	(3,702)
Income tax benefit	<b>1,265</b>	1,048
<b>Net loss</b>	<b>(5,978)</b>	(2,654)
<b>Other comprehensive income:</b>		
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	<b>(1,641)</b>	1,427
Total items that may be reclassified subsequently to profit or loss	<b>(1,641)</b>	1,427
<b>Total other comprehensive income</b>	<b>(1,641)</b>	1,427
<b>Total comprehensive (loss) income for the year</b>	<b>(7,619)</b>	(1,227)
<b>Net loss attributable to:</b>		
Owners of the parent	<b>(5,977)</b>	(2,654)
Non-controlling interests	<b>(1)</b>	(0)
	<b>(5,978)</b>	(2,654)
<b>Total comprehensive (loss) income for the year attributable to:</b>		
Owners of the parent	<b>(7,618)</b>	(1,227)
Non-controlling interests	<b>(1)</b>	(0)
	<b>(7,619)</b>	(1,227)
<b>Earnings per share (yen)</b>		
Basic loss per share	<b>(78.40)</b>	(37.55)
Diluted loss per share	<b>(78.40)</b>	(37.55)

### 3) Consolidated statement of changes in equity

	Capital stock ¥m	Capital surplus ¥m	Treasury stock ¥m	Retained earnings ¥m	Other components of equity: Exchange differences on translating foreign operations ¥m	Equity attributable to owners of the parent ¥m	Non- controlling interests ¥m	Total equity ¥m
<b>Balance at April 1, 2017</b>	26,004	14,632	-	(4,873)	(7,409)	28,354	4	28,359
Net loss	-	-	-	(2,654)	-	(2,654)	(0)	(2,654)
Exchange differences on translation	-	-	-	-	1,427	1,427	-	1,427
Total comprehensive (loss) income for the year	-	-	-	(2,654)	1,427	(1,227)	(0)	(1,227)
Issuance of new shares	10,779	10,389	-	-	-	21,168	-	21,168
Share-based payments	-	587	-	-	-	587	-	587
Purchase of treasury stock	-	-	(0)	-	-	(0)	-	(0)
Total transactions with owners	10,779	10,976	(0)	-	-	21,755	-	21,755
<b>Balance at March 31, 2018</b>	<b>36,783</b>	<b>25,608</b>	<b>(0)</b>	<b>(7,527)</b>	<b>(5,982)</b>	<b>48,882</b>	<b>4</b>	<b>48,886</b>
Changes in accounting policies	-	-	-	(192)	-	(192)	-	(192)
Balance after restatement	36,783	25,608	(0)	(7,719)	(5,982)	48,690	4	48,694
Net loss	-	-	-	(5,977)	-	(5,977)	(1)	(5,978)
Exchange differences on translation	-	-	-	-	(1,641)	(1,641)	-	(1,641)
Total comprehensive (loss) for the year	-	-	-	(5,977)	(1,641)	(7,618)	(1)	(7,619)
Issuance of new shares	71	13	-	-	-	84	-	84
Share-based payments	-	421	-	-	-	421	-	421
Total transactions with owners	71	434	-	-	-	505	-	505
<b>Balance at December 31, 2018</b>	<b>36,854</b>	<b>26,042</b>	<b>(0)</b>	<b>(13,696)</b>	<b>(7,623)</b>	<b>41,577</b>	<b>3</b>	<b>41,580</b>

#### 4) Consolidated statement of cash flow

	9 months ended December 31, 2018 ¥m	12 months ended March 31, 2018 ¥m
<b>Cash flows from operating activities</b>		
Loss before income taxes	(7,243)	(3,702)
Adjustments for:		
Depreciation and amortization	879	1,028
Share-based payments	421	597
Grant income	(128)	(235)
Gain on loss of control of subsidiaries	-	(326)
Loss on investment in capital	105	-
Gain on investment in securities	(187)	-
Loss on lapse of option to purchase shares	1,121	-
Net foreign exchange (gain) loss	(47)	123
Share of loss of associates accounted for using the equity method	488	276
Impairment loss on investments accounted for using equity method	66	-
Impairment loss	319	390
Interest expenses	162	259
Change in fair value of contingent consideration	(216)	655
(Increase) decrease in other accounts receivables	224	(149)
Decrease in trade and other receivables	(243)	640
Increase in trade and other payables	210	723
Other	7	(252)
Subtotal	(4,062)	27
Interest and dividends received	16	12
Interest paid	(99)	(162)
Grants received	154	186
Income taxes paid	(23)	(2,230)
Income tax refund	19	-
<b>Net cash (used in) operating activities</b>	<b>(3,995)</b>	<b>(2,167)</b>
<b>Cash flows from investing activities</b>		
Purchase of property, plant and equipment	(1,807)	(880)
Purchase of intangible assets	(352)	-
Payments related to capitalized development costs	-	(88)
Payments for purchase of shares of associates	-	(3,973)
Payments for purchase of investment securities	(650)	(490)
Proceeds from sales of investments in subsidiaries resulting in change in scope of consolidation	-	378
Purchases of other financial assets	-	(1,084)
Other	1	(11)
<b>Net cash (used in) investing activities</b>	<b>(2,808)</b>	<b>(6,148)</b>
<b>Cash flows from financing activities</b>		
Proceeds from long-term interest-bearing debt	-	4,890
Repayments of long-term interest-bearing debt	(2,255)	(2,750)
Payment for settlement of contingent consideration	(97)	(1,156)
Proceeds from issuance of common stock	84	21,167
Proceeds from contributions from limited partners	-	495
Other	-	(5)
<b>Net cash (used in) provided by financing activities</b>	<b>(2,268)</b>	<b>22,641</b>
Effects of exchange rate changes on cash and cash equivalents	(450)	56
<b>Net decrease in cash and cash equivalents</b>	<b>(9,521)</b>	<b>14,382</b>
Cash and cash equivalents at the beginning of the period	28,281	13,899
<b>Cash and cash equivalents at the end of the period</b>	<b>18,760</b>	<b>28,281</b>

## 5) Notes to the consolidated financial statements

### 5.1 Notes related to going concern assumptions

Not applicable.

### 5.2 Change in accounting policy

The significant accounting policies applied to the Group's Consolidated financial statements for the nine month period ended 31 December 2018 are consistent with those applied to the consolidated financial statements for the twelve month period ended March 31, 2018, except for amendments to IFRS 9 *Financial Instruments* and the implementation of IFRS 15 *Revenue from Contracts with Customers*, which became effective for the Group from 1 April 2018.

IFRS		Summary of change
IFRS 9	Financial Instruments	Amendment to the classification, measurement and recognition of financial instruments
IFRS 15	Revenue from Contracts with Customers	Introduces a new revenue recognition framework based on the satisfaction of performance obligations together with new disclosure requirements. The new standard requires companies to follow a 5-step approach to revenue recognition: <ul style="list-style-type: none"><li>· Identify the contract</li><li>· Identify performance obligations in the contract</li><li>· Determine the transaction price</li><li>· Allocate the transaction price to the performance obligations in the contract</li><li>· Recognize revenue when (or as) the entity satisfies a performance obligation</li></ul>

Each of the Group's material research and licensing agreements have been analyzed to identify the consideration receivable (the transaction price) and the underlying promises to supply goods or services (performance obligations). Such obligations can include the grant of the license, the provision of research and development services and the supply of product. The transaction price arising under each contract has been matched to performance obligations and revenue has been recognized at a point in time or over time in line with the satisfaction of the performance obligations.

In adopting IFRS 15 the Group has applied the modified retrospective approach causing a cumulative adjustment to decrease equity by JPY 192 million, a corresponding decrease in deferred revenue of JPY 468 million (included in trade and other payables), a decrease in intangible assets of JPY 923 million and a decrease in deferred tax liabilities of JPY 263 million. Some of the revenue that had been recorded as deferred revenue in accordance with IAS 18 in the prior year has been released to the income statement in the current reporting period. Revenue relating to the grant of a license by the Group has been recognised at a point in time and revenue relating to the provision of research and development services has been recognised over time in line with the delivery of those services. Intangible assets arising from an in-license transaction and related capitalized development costs, which had been accounted in accordance with IAS 38, required amendment upon the adoption of IFRS 15. These costs were adjusted retrospectively by amortizing the balances over their useful economic lives starting from the point of their commercialization. As a consequence of measuring and reporting revenue relating to the provision of research and development services the cost of providing these services has been separately reported under Cost of Sales.

In accordance with the requirements of the Standard, where the modified retrospective approach is adopted, prior year results are not restated. No adjustments were required to be made to prior year results upon adopting the amendments to IFRS 9. The adoption of IFRS9 and IFRS15 has not had a material impact on the results for the period ended December 31, 2018.

### 5.3 Changes in fiscal year end

The Company and the Group changed their fiscal year end from March 31 to December 31 after the 28th ordinary general meeting of shareholders. The 29th term is therefore a nine month period from April 1, 2018 to December 31, 2018. Comparative disclosures are for the twelve month period ended 31 March 2018 which is the most recent period for which audited accounts exist.



## 5.4 Operating segments

### Overview of reportable segments

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

### Information regarding products and services

The breakdown of revenue is as follows

	<b>9 months ended December 31, 2018</b>	12 months ended March 31, 2018
	¥m	¥m
Royalty income	<b>2,104</b>	2,561
Milestone fees and lump-sum payments:	<b>340</b>	3,840
Allocated to research and development services	218	-
Allocated to the grant of licenses	122	3,840
Other:	<b>428</b>	554
Allocated to research and development services	428	554
	<b>2,872</b>	6,955

### Geographical information

The following table provides the Group's revenue from external customers by location and information about its non-current assets by location.

#### Revenues from external customers

Country	<b>9 months ended December 31, 2018</b>	12 months ended March 31, 2018
	¥m	¥m
Japan	<b>594</b>	267
Switzerland	<b>2,035</b>	2,459
Ireland	<b>177</b>	1,917
USA	<b>66</b>	160
UK	-	1,415
Israel	-	716
Other	-	21
	<b>2,872</b>	6,955

#### Non-current assets

	<b>At December 31, 2018</b>	At March 31, 2018
	¥m	¥m
Japan	<b>2,482</b>	2,460
UK	<b>32,628</b>	34,516
Other	<b>1,593</b>	1,588
	<b>36,703</b>	38,564

Non-current assets do not include deferred tax assets.

### Information about major customers

Name of customer	<b>9 months ended December 31, 2018</b>	12 months ended March 31, 2018
	¥m	¥m
Novartis International AG	<b>2,035</b>	2,459
Daiichi Sankyo Company, Limited	<b>294</b>	164
FUJIFILM Pharma Co., Ltd.	<b>232</b>	-
Allergan Pharmaceuticals International Limited	<b>177</b>	1,917
AstraZeneca UK Limited	-	1,415
Teva Pharmaceutical Industries Limited	-	716

## 5.5 Earnings per share

If the stock split on July 1, 2018 had occurred at the beginning of the previous fiscal year, the basic loss per share and the diluted loss per share for the nine month ended December 31, 2018 and for the twelve-month ended March 31, 2018 would have been as follows:

### Basic earnings per share

The following table shows basic loss per share and explains the basis for the calculation.

	9 months ended December 31, 2018	12 months ended March 31, 2018
Net (loss) attributable to owners of the parent (¥m)	(5,977)	(2,654)
Weighted-average number of common shares outstanding (Shares)	76,256,495	70,687,212
Basic (loss) per share (¥)	(78.40)	(37.55)

### Diluted earnings per share

The following table shows diluted loss per share and the basis for the calculation.

	9 months ended December 31, 2018	12 months ended March 31, 2018
Net (loss)	(5,977)	(2,654)
Adjustment to net profit used in the calculation of diluted earnings per share (¥m)	-	-
Net (loss) used in the calculation of diluted earnings per share (¥m)	(5,977)	(2,654)
Weighted-average number of common shares outstanding (Shares)	76,256,495	70,687,212
Increases in number of common shares used in the calculation of diluted earnings per share (Shares):		
Increases in number of common shares due to the exercise of stock options (Shares)	-	-
Weighted-average number of common shares outstanding used in the calculation of diluted earnings per share (Shares)	76,256,495	70,687,212
Diluted (loss) per share (¥)	(78.40)	(37.55)

In the nine month period ended December 31, 2018 and in the twelve month period ended March 31, 2018, there is no dilutive effect from potential common shares as partial conversion of stock options reduced the loss per share.

## 5.6 Subsequent events

### *Milestone income*

On January 7, 2019, the Group announced it had been notified by AstraZeneca that it had reached a clinical development milestone with its partnered next generation immuno-oncology candidate AZD4635, triggering a US\$15 million payment from AstraZeneca. The clinical study to date has established the maximum-tolerated dose of AZD4635 as a single agent and in combination with durvalumab. The study has progressed successfully to the point where the therapeutic potential of AZD4635 is being explored in multiple solid tumors. As a result, AstraZeneca is moving the trial towards Phase 2, thereby triggering the milestone payment to the Group. Headline data from the Phase 1 study is planned to be presented at a scientific congress in 2019.

### *Bank Loan Covenant*

On February 1, 2019 the Company received notification from the banks participating in the Company's syndicated loans that they would not require repayment of the loans following a breach of the loan covenants caused by two consecutive periods of loss. Details of the loan balances are as follows:

<b>Opening date</b>	<b>Opening balance ¥m</b>	<b>Loan balance at December 31, 2018 ¥m</b>
September 28, 2015	10,000	3,500
May 18, 2017	5,000	3,500
	15,000	7,000

The total period end loan balance is covered by the Group's cash balances by more than two and a half times. The Company is required to comply with the following loan covenants:

- i) The amount of net assets in the consolidated statements of financial position at December 31 and June 30 of each year must be maintained at no less than 75% of the amount at the respective corresponding date of the previous fiscal year.
- ii) The borrower must not record an operating loss or net loss in the consolidated statements of profit or loss and other comprehensive income for two consecutive fiscal years.