

## Consolidated Financial Results for the Six Months Ended June 30, 2019 (IFRS)

August 13, 2019

Listing: Tokyo Stock Exchange Company name: Sosei Group Corporation

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

Shinichi Tamura Representative:

Representative Executive Officer, CEO

Chris Cargill

Contact person: Tel: +81-3-5210-3290 Executive Vice President, CFO

Scheduled date of Quarterly Securities Report filing August 13, 2019 Scheduled date of dividend payments:

Supplementary materials for financial results: Financial results briefing session: Yes (for institutional investors and analysts)

(Rounded million yen)

1. Consolidated results for six month period ended June 30, 2019 (from January 1, 2019 to June 30, 2019)

| (1) Consolidatea (                         | Consolidated operating results (cumulative) (Percentages are snown as year-on-year changes) |        |                    |   |            |   |  |   |               |   |         |     |
|--|---|--------|--------------------|---|------------|---|--|---|---------------|---|---------|-----|
|  | Revenue Operating income  |        | Net prof<br>income |   | Net profit |   | Net profit  Net profit  owners of the parent company |   | comprehensive |   |         |     |
|  | Million   | %      | Million            | % | Million    | % | Million  | % | Million       | % | Million | %   |
|  | yen   |        | yen                |   | yen        |   | yen  |   | yen           |   | yen     |     |
| 6 month period ended<br>June 30, 2019      | 5,056   | 180.4  | 731                | _ | 292        | _ | 395  | _ | 395           | _ | (425)   | - ] |
| 6 month period ended<br>September 30, 2018 | 1,803   | (66.1) | (3,753)            | _ | (4,142)    | _ | (3,327)  | _ | (3,327)       | _ | (3,280) | -   |

|   | Earnings per share – basic | Earnings per share – diluted |
|---|----------------------------|------------------------------|
|   | Yen                        | Yen                          |
| 6 month period ended<br>June 30, 2019     | 5.19                       | 5.13                         |
| 6month period ended<br>September 30, 2018 | (43.64)                    | (43.64)                      |

(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<br>owners of the parent company to<br>total assets |
|----------------------|--------------|--------------|---|--|
|                      | Million yen  | Million yen  | Million yen   | %  |
| At June 30, 2019     | 58,435       | 41,484       | 41,481  | 71.0   |
| At December 31, 2018 | 58,987       | 41,580       | 41,577  | 70.5   |

## 2. Dividends

|            |               | Dividends per share |        |        |       |  |  |  |
|------------|---------------|---------------------|--------|--------|-------|--|--|--|
|            | End Q1 End Q2 |                     | End Q3 | End Q4 | Total |  |  |  |
|            | Yen           | Yen                 | Yen    | Yen    | Yen   |  |  |  |
| FY2018     | 0.00          | -                   | -      | 0.00   | 0.00  |  |  |  |
| FY2019     | -             | 0.00                |        |        |       |  |  |  |
| FY2019 (E) |               |                     | -      | 0.00   | 0.00  |  |  |  |

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

The record date for the interim dividend for FY2018 is September 30, 2018 (End Q2) because the date of the start of FY2018 is April 1, 2018.

## 3. Forecast for FY2019 (from January 1, 2019 to December 31, 2019)

We have made excellent progress in strengthening our business and are well-positioned to capitalize on a number of strategic opportunities. Our highly productive GPCR-focused drug discovery platform has generated multiple new exciting candidates, and we have actively increased partnered and co-development activity, whilst simultaneously investing to advance new in-house candidates to be partnered.

The Group presents its outlook for the financial year ending December 31, 2019, targeting a more sustainable balance of resources and capital in order to prioritize the pursuit of profitability:

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

#### \* Notes

- (1) Changes in the number of significant subsidiaries for the six month period ended June 30, 2019 (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 (IFRS16)
  - 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)
  - 2) Number of treasury shares at period end
  - 3) Average number of shares in issue in period

| At June 30, 2019                      | 76,493,936 shares | At December 31, 2018                       | 76,301,936 shares |
|---------------------------------------|-------------------|--|-------------------|
| At June 30, 2019                      | 104 shares        | At December 31, 2018                       | 104 shares        |
| 6 month period ended<br>June 30, 2019 | 76,358,608 shares | 6 month period ended<br>September 30, 2018 | 76.233.998 shares |

(Note) As of July 1, 2018, the Company executed a stock split at a ratio of 4 shares per common share. "Average number of shares in issue in period" is calculated assuming that the stock split was made at the beginning of the previous consolidated fiscal year.

\* 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 Company is scheduled to hold an online conference for analysts on August 13, 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>\*</sup> Quarterly consolidated financial results reports are not subject to audit.

<sup>&</sup>lt;sup>1</sup> Management's forecast total R&D expenses for the financial year ending December 31, 2019 include (i) Cost of Sales (reallocated from Cash R&D), (ii) Cash R&D costs, and (iii) R&D facility lease costs (reallocated to interest and depreciation categories in accordance with IFRS 16).

## o Contents of Attached Materials

| 1. Analysis of Operating Results and Financial Position             | 4  |
|---|----|
| 1) Analysis of operating results                                    | 4  |
| 2) Analysis of financial position                                   | 12 |
| 3) Earnings forecast  | 13 |
| 2. Consolidated financial statements and primary notes (IFRS)       | 14 |
| 1) Interim condensed consolidated statement of financial position   | 14 |
| 2) Interim condensed consolidated statement of comprehensive income | 15 |
| 3) Interim condensed consolidated statement of changes in equity    | 16 |
| 4) Interim condensed consolidated statement of cash flow            | 17 |
| 5) Notes of interim condensed consolidated financial statements     | 18 |

## 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 six month period ended June 30, 2019 (from January 1, 2019 to June 30, 2019), the Group continued to advance its proprietary StaR® ("stabilized receptor") technology, Structure-based Drug Design ("SBDD") platform, and in-house development pipeline.

Our business model progressed across all areas; (i) existing partnerships with major global pharmaceutical companies, (ii) new and existing R&D collaborations with innovative pharmaceutical/biotechnology companies, and venture capital ("VC") funds, and (iii) in-house discovery and development of new candidates to be partnered.

As of June 30, 2019, the Group had more than 15 programs ongoing in discovery, with seven in preclinical development, and eight<sup>1,2</sup> currently in clinical trials.

In the area of partnerships with major global pharmaceutical companies, the Group reached significant milestones, with its first partnered program progressing towards Phase 2 clinical studies, as well as its strategic multi-target drug discovery collaboration nominating two new candidates to advance into clinical development.

On January 7, 2019, the Group announced it had been notified by its strategic alliance partner, AstraZeneca UK Limited ("AstraZeneca") that it had achieved 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 had established the maximum-tolerated dose of AZD4635 as a single agent and in combination with durvalumab. The study had progressed successfully to the point where the therapeutic potential of AZD4635 was being explored in multiple solid tumors. As a result, AstraZeneca moved the trial towards Phase 2, thereby triggering the milestone payment to the Group.

On March 22, 2019, the Group announced that Ultibro® Breezhaler® and Seebri®Breezhaler® had been launched in China for the treatment of chronic obstructive pulmonary disease ("COPD"). The Group, together with Vectura Group plc, exclusively licensed key intellectual property integral to the development of both products to Novartis in April 2005 and is eligible for royalties on global product sales. Both products will be promoted in China by Huizheng (Shanghai) Technology Co., Ltd., a group company of Zhejiang Hisun Pharmaceutical Co., Ltd. under license from Beijing Novartis Pharma Co., Ltd and Sandoz (China) Pharmaceutical Co., Ltd, both controlled subsidiaries of Novartis. The impact of this launch on the Group's consolidated financial results for the accounting period ending December 31, 2019 is unlikely to be material.

On March 31, 2019 and April 2, 2019, AstraZeneca presented new clinical and preclinical data on next-generation immuno-oncology candidate AZD4635 at the 2019 American Association for Cancer Research (AACR) Annual Meeting in Atlanta, USA. The data demonstrated that AZD4635

<sup>1</sup> Includes QVM149 for Asthma, AZD4635 for multiple solid malignancies, HTL0018318 for dementia with Lewy bodies (voluntarily suspended), AZD4635 for EGFRm NSCLC, HTL0016878 for neurobehavioral symptoms of Alzheimer's disease, HTL0018318 for Alzheimer's disease (voluntarily suspended), HTL0014242 for neurological disorders, and HTL0030310 for endocrine disorders.

<sup>&</sup>lt;sup>2</sup> Phase 2 trial of HTL0018318 for DLB in Japan remains under voluntary suspension. 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.

prevents adenosine-mediated immunosuppression and that early clinical activity was observed with AZD4635 monotherapy or in combination with durvalumab in patients with metastatic castration-resistant prostate cancer. The two posters presented by AstraZeneca were titled "Evidence of immune activation in the first-in-human Phase 1a dose escalation study of the adenosine 2a receptor antagonist, AZD4635, in patients with advanced solid tumors" and "The A2AR antagonist AZD4635 prevents adenosine-mediated immunosuppression of CD103+ dendritic cells," The Group made the abstracts and posters available on its corporate website on April 15, 2019, alongside a summary of AstraZeneca's key findings.

On May 14, 2019, the Group reported encouraging progress from its strategic multi-target drug discovery collaboration with Pfizer, which included the first pre-clinical development candidate nominated by Pfizer under the collaboration — a novel, oral, small molecule modulator of an undisclosed target, which triggered a US\$3 million milestone payment to the Group. The research phase of the collaboration has delivered several milestones leading to the advancement of new potential candidate programs against GPCR targets nominated by Pfizer in major disease areas. Further milestones payments are contemplated under the agreement, with potential for royalties also payable provided the criteria under the agreement are satisfied.

On May 22, 2019, Novartis presented key Phase 2 data for QVM149, a potential new inhaled combination therapy for asthma, at the 2019 annual international congress of the American Thoracic Society (ATS) in Dallas, USA. In two Phase 2 clinical studies<sup>3</sup>, QVM149 was shown to be superior to the comparators, salmeterol/fluticasone propionate (the standard-of-care treatment) and placebo, separately by demonstrating improvement in lung function in patients with asthma. In one study, QVM149 also demonstrated improvements versus placebo irrespective of administration time of morning or evening. The data from both studies also suggest that QVM149 has a favorable safety and tolerability profile.

On May 24, 2019, the Group announced it had been notified by Novartis that it had submitted a valid Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") for QVM149. The MAA filing, which was previously planned for Q4 2019, triggered a US\$2.5 million payment to the Group from Novartis. QVM149 is currently being investigated in Phase 3/3b studies (IRIDIUM<sup>4</sup> and ARGON<sup>5</sup>), which are expected to complete in Q3 2019.

On June 10, 2019, the Group announced a second new clinical candidate from its multi-target drug discovery collaboration with Pfizer had been nominated to advance into clinical development. This triggered another US\$3 million milestone payment to the Group.

<sup>&</sup>lt;sup>3</sup> Phase 2 CQVM149B2208 study (ClinicalTrials.gov Identifier: NCT03063086) Phase 2 CQVM149B2209 study (ClinicalTrials.gov Identifier: NCT03108027)

<sup>&</sup>lt;sup>4</sup> Phase 3 CQVM149B2302 study (ClinicalTrials.gov Identifier: NCT02571777)

<sup>&</sup>lt;sup>5</sup> Phase 3 CQVM149B2306 study (ClinicalTrials.gov Identifier: NCT03158311)

In the area of R&D collaborations with innovative pharmaceutical/biotechnology companies and VC funds, the Group continued to make significant progress with its partners and announced a new R&D collaboration with a VC fund relating to its orexin agonist program.

On February 4, 2019, the Group announced it had entered into a structured financing agreement with Medicxi, a VC 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 GPCRs Orexin OX1 and OX2 for neurological diseases. Medicxi will invest in both companies with an aggregate amount of up to €40 million. Under the terms of the agreement, Orexia and Inexia obtained certain related intellectual property from the Group 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 Group, 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 the Group's 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.

In the area of in-house discovery and development of new candidates to be partnered, the Group continued to make the necessary investments in its pipeline, as it advanced multiple candidates forward.

On January 31, 2019, the Group announced its wholly-owned Japanese subsidiary Sosei Co., Ltd. (the "Business") would launch ORAVI® Mucoadhesive Tablets 50mg in Japan on February 4, 2019, for the treatment of oropharyngeal candidiasis. The Business had granted an exclusive license to FUJIFILM Toyama Chemical Co., Ltd. ("FUJIFILM Toyama Chemical") for the commercialization of ORAVI® in Japan. The Business will supply ORAVI® tablets to FUJIFILM Toyama Chemical to sell into the Japanese market and is entitled to receive revenues on sales of the products to FUJIFILM Toyama Chemical and additional payments based on the achievement of sales-based milestones.

On February 20, 2019, the Group announced that the first healthy subject had been dosed with the novel small molecule HTL0030310 in a Phase 1 clinical study, marking the start of a new inhouse clinical program targeting endocrine disorders, including Cushing's disease. HTL0030310 is a potent and selective agonist of the SSTR5 (somatostatin 5) receptor and the sixth molecule designed by the Group using its GPCR SBDD platform to enter clinical development. The new clinical study with HTL0030310 is a double-blind, randomized, placebo-controlled first-in-human study in which single ascending subcutaneous doses of HTL0030310 will be administered to healthy male and female adult subjects.

The Group's other in-house discovery and development programs to be partnered continued to progress well.

As of June 30, 2019, the Group had a total of 162 employees (a decrease of seven employees vs. the end of the previous fiscal year FY18).

The Company and the Group changed its fiscal year end from March 31 to December 31 at the 28<sup>th</sup> Ordinary General Meeting of Shareholders. Comparative financial disclosures for the six month period ended June 30, 2019 therefore reference the six month period ended September 30, 2018 as the prior corresponding period.

As a result of the above activities, the Group reported the following financial results for the six month period ended June 30, 2019. Revenue of JPY 5,056 million (an increase of JPY 3,253 million vs. the prior corresponding period), an operating profit of JPY 731 million (an operating loss of JPY 3,753 million in the prior corresponding period), a net profit before income taxes of JPY 292 million (a net loss of before income taxes of JPY 4,142 million in the prior corresponding period), a net profit of JPY 395 million (a net loss of JPY 3,327 million in the prior corresponding period).

|                                     | 6 month period ended | 6 month period ended |        |
|-------------------------------------|----------------------|----------------------|--------|
|                                     | June 30, 2019        | September 30, 2018   | Change |
|                                     | ¥m                   | ¥m                   |        |
| Revenue                             | 5,056                | 1,803                | 3,253  |
| Cost of sales                       | (393)                | -                    | (393)  |
| Research and development            | (2,038)              | (4,179)              | 2,141  |
| expenses                            |                      |                      |        |
| Selling, general and administrative | (1,910)              | (1,490)              | (420)  |
| expenses                            |                      |                      |        |
| Other net income                    | 16                   | 113                  | (97)   |
| Operating profit (loss)             | 731                  | (3,753)              | 4,484  |
| Net finance costs                   | (385)                | (231)                | (154)  |
| Share of loss of associates         | (54)                 | (158)                | 104    |
| Net profit (loss) before income tax | 292                  | (4,142)              | 4,434  |
| Net profit (loss)                   | 395                  | (3,327)              | 3,722  |

Subsequent to June 30, 2019, the following events occurred:

On July 16, 2019, the Group announced that it entered into a multi-target research collaboration and license agreement with Genentech, a member of the Roche Group, to discover and develop novel medicines (new small molecules and/or biologics) that modulate GPCR targets of interest to Genentech. Under the terms of the agreement, the collaboration will combine the proprietary GPCR-focused SBDD capabilities at the Group with Genentech's discovery, development and therapeutic area expertise directed towards multiple GPCR targets nominated by Genentech. The nominated targets represent promising new therapeutic intervention points across a range of diseases. Genentech will be responsible for developing and commercializing potential new medicines for each novel target and will have exclusive global rights to these agents. The Group is eligible to receive US\$26 million in upfront and near-term payments, in addition to future milestone payments that may exceed US\$1 billion for achieving pre-specified research, development and commercialization events. The Group is also eligible to receive royalty payments on the net sales of potential future medicines resulting from the collaboration.

On July 18, 2019, the Group announced that Formosa Pharmaceuticals, Inc. ("Formosa") had received approval from the US Food and Drug Administration ("FDA") of its Investigational New Drug ("IND") application for APP13007 to commence a first-in-human ("FIH") clinical trial in the United States. APP13007 is a nanoparticle formulation of the corticosteroid clobetasol in development for the treatment of post-operative inflammation of the eye. The milestone triggered a US\$2.5 million payment to the Group from Formosa. APP13007 was originally designed and developed at Activus Pharma Inc. ("Activus"), formerly a wholly owned subsidiary of the Company. Activus was divested in August 2017 to Formosa, a wholly owned subsidiary of Formosa Laboratories, Inc., a leading manufacturer of Active Pharmaceutical Ingredients ("APIs") listed on the Taiwan Stock Exchange. The divestment was part of the Group's redirected growth strategy towards the design and development of new medicines originating from its proprietary GPCR-targeted StaR® technology and SBDD platform capabilities.

On August 5, 2019, the Group announced that it entered into a strategic multi-target partnership with Takeda Pharmaceutical Company Limited ("Takeda"), to discover, develop and commercialize novel molecules, including small molecules and biologics, that modulate GPCR targets. Under the terms of the agreement, the partnership will combine the proprietary GPCR-focused structure-based drug design capabilities at Sosei Heptares with Takeda's extensive discovery, development and therapeutic area expertise directed towards multiple GPCR targets nominated by Takeda. The nominated targets represent new therapeutic intervention points across a range of diseases. The collaboration will initially focus on high-priority gastrointestinal targets, but the agreement includes the potential expansion into other therapeutic areas. Sosei Heptares is eligible to receive up to \$26 million in upfront and near-term payments, in addition to research funding over the term of the agreement, plus future development, commercialization and net sales-based milestone payments that may exceed \$1.2 billion. Sosei Heptares is also eligible to receive tiered royalties on net sales of any licensed products by Takeda resulting from the partnership. Takeda receives exclusive global rights to develop and commercialize therapeutic agents for each novel target through specified pharmacological approaches in the collaboration.

On August 13, 2019, the Group reported a periodic update on the status of development activities with its global R&D collaboration with Allergan. The collaboration, which is focused on the development of novel muscarinic agonists in Alzheimer's disease and other neurological disorders, continues to make significant progress. Work continues on the portfolio of selective small molecule  $M_1$ ,  $M_4$  and dual  $M_1/M_4$  agonists targeting muscarinic receptors in the brain. Multiple compounds with the potential to be new candidates have been discovered and are progressing through early development. Clinical development activities with HTL0018318 (a selective M<sub>1</sub> receptor agonist) remain under voluntary suspension due to the unexpected toxicology findings identified in a nonhuman study (announced September 2018). A thorough investigation of these findings is still ongoing, and an update is now expected in late 2019. While the Group remains committed to continuing its program in Japan focused on developing new therapies for dementia with Lewy bodies ("DLB"), it has decided to withdraw the planned Phase 2 trial of HTL0018318 in DLB patients in Japan (NCT#03592862). Start-up activities for this study were underway when development of HTL0018318 was suspended in September 2018 and have been on hold ever since. The Group expects a different clinical trial approach will be required in the future and has taken this decision to minimize unnecessary expenditure with our CRO while clinical trial activities are paused. The Group plans to resubmit a new clinical trial notification for HTL0018318 (or another novel  $M_1$ agonist) to the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") in the future.

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<br>June 30, 2019<br>¥m | 6 month period ended<br>September 30, 2018<br>¥m | Change |
|--------------------------------------|---|--|--------|
| Milestone fees and lump-sum payments | 3,173                                       | 310  | 2,863  |
| Royalty income                       | 1,201                                       | 1,211  | (10)   |
| Product supply revenue               | 135   | -  | 135    |
| Other                                | 547   | 282  | 265    |
|                                      | 5,056                                       | 1,803  | 3,253  |

**Revenue** in the six month period under review totaled JPY 5,056 million (an increase of JPY 3,253 million vs. the prior corresponding period).

Revenue related to milestones in the six month period under review totaled JPY 3,173 million (an increase of JPY 2,863 million vs. the prior corresponding period). The increase in revenues related to milestones in the six month period under review was mainly due to the US\$15 million payment from AstraZeneca. It also includes milestone income from Pfizer and Novartis, as a result of progress with partnered programs, as well as upfront revenue relating to the Medicxi transaction. The prior corresponding period didn't contain any upfront payments related to new partnerships, or major milestone payments from existing discovery and development partnerships. The Group classifies a "major" milestone payment as any single payment greater than or equal to approximately USD 5 million.

**Revenue related to royalties** in the six month period under review totaled JPY 1,201 million (a decrease of JPY 10 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>6</sup>.

On July 18, 2019, our partner Novartis reported Q2 2019 sales for its Ultibro® Breezhaler® and Seebri® Breezhaler® products of USD 146 million (a decrease of USD 9 million). The breakdown of Novartis' (calendar) Q2 2019 sales by product was as follows:

- Ultibro® Breezhaler® USD 112 million (+1% compared to Q2 2018<sup>7</sup>) an inhaled LABA/LAMA, sales were broadly in line with prior year.
- Seebri® Breezhaler® USD 34 million (-9% compared to Q2 20188) an inhaled LAMA, declined due to competition in Europe.

Ultibro® Breezhaler® remains the number one LABA/LAMA across Europe. In March 2019, Ultibro® Breezhaler® and Seebri® Breezhaler® was launched by Novartis in China for the treatment of chronic obstructive pulmonary disease (COPD).

In its Q2 2019 results presentation, Novartis updated the program status of QVM149, a new inhaled LABA/LAMA/ICS therapy for the treatment of Asthma, containing the Group's out-licensed compound glycopyrronium bromide. Phase III PALLADIUM, IRIDIUM and ARGON studies of QVM149 are expected to complete in Q3 2019. The QUARTZ study was completed in Q1 2019, with publication of data planned for Q1 2020. The filing of QVM149 completed in May 2019, ahead of an expected commercial launch in 2020, from which the Group is eligible to receive further royalties on sales of this product.

<sup>&</sup>lt;sup>6</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. Utibron™ Neohaler® and Seebri™ Neohaler® were launched by Sunovion Pharmaceuticals Inc. in April 2017 and October 2017, respectively.

<sup>&</sup>lt;sup>7</sup> At constant currency rates

<sup>&</sup>lt;sup>8</sup> At constant currency rates

## Operating expenses

|                                     | 6 month period ended<br>June 30, 2019<br>¥m | 6 month period ended<br>September 30, 2018<br>¥m | Change  |
|-------------------------------------|---|--|---------|
| Cost of sales                       | 393   | -  | 393     |
| Research and development            | 2,038                                       | 4,179  | (2,141) |
| Cash expenses                       | 1,862                                       | 4,116  | (2,254) |
| Non-cash expenses                   | 176   | 63   | 113     |
| General and administrative expenses | 1,910                                       | 1,490  | 420     |
| Cash expenses                       | 1,239                                       | 896  | 343     |
| Non-cash expenses                   | 671   | 594  | 77      |

## Cost of sales

Cost of sales in the six month period under review totaled JPY 393 million yen. Cost of sales comprises (i) 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) and (ii) the costs directly associated with ORAVI® product supply.

## Research and development expenses

Cash research and development ("R&D") expenses in the six month period under review totaled JPY 1,862 million yen (a decrease of JPY 2,254 million vs. the prior corresponding period). The decrease in R&D spend primarily related to the voluntary suspension of the Phase 2a MATILDA study for DLB patients in Japan, and the result of a more focused approach to in-house drug development. In the period under review, 96 % of R&D spend related to our UK operations.

## General and administrative expenses

Cash general and administrative ("G&A") expenses in the six month period under review totaled JPY 1,239 million (an increase of JPY 343 million vs. the prior corresponding period). The increase in G&A spend primarily related to UK national insurance charges which rose due to an increase in the Company's share price. This was partially offset by a general increased prudence with regards to G&A expenditure.

#### 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 847 million (an increase of JPY 190 million vs. the prior corresponding period). In total, depreciation amounted to JPY 205 million (an increase of JPY 120 million vs. the prior corresponding period). Amortization for the six month period under review totaled JPY 471 million (an increase of JPY 28 million vs. the prior corresponding period). Stockbased compensation expense for the period was JPY 171 million (an increase of JPY 42 million vs. the prior corresponding period). During Q2 a new long-term incentive plan was approved which awards restricted stock units and performance share units to eligible employees.

## Operating profit

Operating profit in the six month period under review totaled JPY 731 million (vs. an operating loss of JPY 3,753 million in the prior corresponding period). The main reason for the operating profit was due to the increase in revenue (for the reasons stated above), and the decrease in R&D expense (for the reasons stated above) during the six month period under review vs. the prior corresponding period.

## Net finance costs

Net finance costs in the six month period under review totaled JPY 385 million (an increase of JPY 154 million vs. the prior corresponding period). The increase was primarily due to foreign exchange losses and contingent consideration charges vs. credit balances in the prior comparative period, and fair value gains arising during in the period. 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 of June 30, 2019, the Group has to date paid USD 73 million in milestones, out of the total maximum potential milestone amount payable of USD 220 million.

## Net profit

The net profit in the six month period under review totaled JPY 395 million (vs. a net loss of JPY 3,327 million in the prior corresponding period). The main reason for the net profit was due to the increase in revenue (for the reasons stated above), and the decrease in R&D expense (for the reasons stated above) during the six month period under review vs. the prior corresponding period.

## (2) Analysis of financial position

## 1) Assets, liabilities and equity

#### **Assets**

Total assets at June 30, 2019 were JPY 58,435 million (a decrease of JPY 552 million vs. the end of the previous fiscal year FY18). The main reason for this decrease was due to a decrease in cash and cash equivalents, goodwill and intangible assets (due to amortization), offset by an increase in property, plant and equipment (including the first time recognition of right to use assets of JPY 1,730 million related to the application of IFRS 16) and an increase in other financial assets.

#### Liabilities

Total liabilities at June 30, 2019 were JPY 16,951 million (a decrease of JPY 456 million vs. the end of the previous fiscal year FY18). The main reason for the decrease was due to a decrease in trade and other payables associated with lower levels of expenditure.

#### Equity

Total equity at June 30, 2019 was JPY 41,484 million (a decrease of JPY 96 million vs. the end of the previous fiscal year FY18). This was primarily due to the total comprehensive loss for the period partially offset but the issuance of new shares and share based payments

The ratio of Cash and cash equivalents, Interest-bearing debt and Equity attributable to owners of the parent company to total assets were 28.9%, 12.3% and 71.0%, respectively.

## 2) Cash flows

Cash and cash equivalents at June 30, 2019 decreased by JPY 1,845 million from the beginning of the year and amounted to JPY 16,915 million.

## Cash flows from operating activities

Net cash provided by operating activities for the period under review totaled JPY 76 million. This was predominantly due to profit before income taxes of JPY 292 million recorded for the period arising from the Group's increased revenue from milestone receipts.

## Cash flows from investing activities

Net cash used in investing activities for the period under review totaled JPY 306 million. This was primarily due to expenditure on property, plant and equipment of JPY 220 million and an additional RMF1 investment of JPY 100 million.

## Cash flows from financing activities

Net cash used in financing activities for the period under review totaled JPY 1,658 million. This was primarily due to capital repayments of long-term interest-bearing loans and lease liabilities of JPY 1,535 million plus contingent consideration payments of JPY 776 million less contributions from the limited partners in RMF1 of JPY 495 million.

## (3) Earnings forecast

We have made excellent progress in strengthening our business and are well-positioned to capitalize on a number of strategic opportunities. Our highly productive GPCR-focused drug discovery platform has generated multiple new exciting candidates, and we have actively increased partnered and co-development activities, whilst simultaneously investing to advance new in-house candidates to be partnered.

The Group presents its outlook for the financial year ending December 31, 2019, targeting a more sustainable balance of resources and capital in order to prioritize the pursuit of profitability:

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

<sup>&</sup>lt;sup>1</sup> Management's forecast total R&D expenses for the financial year ending December 31, 2019 include (i) Cash R&D costs, (ii) Cost of Sales (reallocated from Cash R&D), and (iii) R&D facility lease costs (reallocated to non-cash categories in accordance with IFRS 16).

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

## 1) Interim condensed consolidated statement of financial position

|   | June 30, 2019<br>(Unaudited) | December 31, 2018<br>(Audited) |
|---|------------------------------|--------------------------------|
|   | (Orlaudited)<br>¥m           | (Addited)<br>¥m                |
| Assets  | ****                         |                                |
| Non-current assets                                |                              |                                |
| Property, plant and equipment                     | 4,098                        | 2,715                          |
| Goodwill  | 13,942                       | 14,177                         |
| Intangible assets                                 | 13,561                       | 14,367                         |
| Investments accounted for using the equity method | 3,494                        | 3,644                          |
| Other financial assets                            | 2,045                        | 1,515                          |
| Other non-current assets                          | 314                          | 285                            |
| Total non-current assets                          | 37,454                       | 36,703                         |
| Current assets                                    |                              |                                |
| Trade and other receivables                       | 1,447                        | 987                            |
| Income tax receivable                             | 2,138                        | 2,057                          |
| Other current assets                              | 481                          | 480                            |
| Cash and cash equivalents                         | 16,915                       | 18,760                         |
| Total current assets                              | 20,981                       | 22,284                         |
| Total assets                                      | 58,435                       | 58,987                         |
| Non-current liabilities                           | 2 298                        | 2 5/12                         |
| Liabilities  Non current liabilities              |                              |                                |
| Deferred tax liabilities                          | 2,298                        | 2,542                          |
| Contingent consideration in business combinations | 3,829                        | 4,180                          |
| Interest-bearing debt                             | 4,058                        | 3,970                          |
| Other financial liabilities                       | 1,657                        | 1,179                          |
| Other non-current liabilities                     | 168                          | 87                             |
| Total non-current liabilities                     | 12,010                       | 11,958                         |
| Current liabilities                               |                              |                                |
| Trade and other payables                          | 1,469                        | 2,080                          |
| Income taxes payable                              | 158                          | 24                             |
| Interest-bearing debt                             | 3,113                        | 2,994                          |
| Other current liabilities                         | 201                          | 351                            |
| Total current liabilities                         | 4,941                        | 5,449                          |
| Total liabilities                                 | 16,951                       | 17,407                         |
| Equity  |                              |                                |
| Capital stock                                     | 36,987                       | 36,854                         |
| Capital surplus                                   | 26,238                       | 26,042                         |
| Treasury stock                                    | (0)                          | (0                             |
| Retained earnings                                 | (13,301)                     | (13,696                        |
| Other components of equity                        | (8,443)                      | (7,623                         |
| Equity attributable to owners of the parent       | 41,481                       | 41,577                         |
| Non-controlling interests                         | 3                            | 3                              |
| Total equity                                      | 41,484                       | 41,580                         |
| Total liabilities and equity                      | 58,435                       | 58,987                         |

| Interim condensed consolidated statement of con   | 6 month period ended<br>June 30, 2019<br>(Unaudited)<br>¥m | 6 month period ended<br>September 30, 2018<br>(Unaudited)<br>¥m |
|---|--|---|
|   |  |   |
| Revenue   | 5,056  | 1,80  |
| Cost of sales   | (393)  | -   |
| Gross profit  | 4,663  | 1,80  |
| Research and development expenses   | (2,038)  | (4,17   |
| Selling, general and administrative expenses  | (1,910)  | (1,49   |
| Other income  | 24   | 11  |
| Other expenses  | (8)  | (   |
| Operating profit (loss)   | 731  | (3,75   |
| Finance income  | 244  | 99  |
| Finance costs   | (629)  | (1,22   |
| Share of loss of associates accounted for using the equity  |  |   |
| method  | (54)   | (15   |
| Profit (loss) before income taxes   | 292  | (4,14   |
| Income tax benefit  | 103  | 81  |
| Net profit (loss)   | 395  | (3,32   |
| Financial assets measured at fair value through other comprehensive income Items that may be reclassified subsequently to profit or loss: | (20)   |   |
| Exchange differences on translating foreign operations  | (800)  |   |
| Total other comprehensive (loss) income   | (820)  |   |
| Total comprehensive (loss) income   | (425)  | (3,28   |
| Net profit (loss) attributable to:  |  |   |
| Owners of the parent  | 395  | (3,32   |
| Non-controlling interests   | (0)  | (   |
| Total net profit (loss)   | 395  | (3,32   |
| Total comprehensive income (loss) attributable to:  |  |   |
| Owners of the parent  | (425)  | (3,28   |
| Non-controlling interests   | (0)  | (   |
| Total comprehensive income (loss)   | (425)  | (3,28   |
| Earnings per share (yen)  |  |   |
| Basic earnings (loss) per share   | 5.19   | (43.6   |
| Diluted earnings (loss) per share   | 5.13   | (43.6   |

## 3) Interim condensed consolidated statement of changes in equity

| sy menin condensed consolidates              |               |         | ,              |          | Other      | Equity<br>attributable<br>to owners | Non-        |              |
|--|---------------|---------|----------------|----------|------------|-------------------------------------|-------------|--------------|
|  |               | Capital |                | Retained | components | of                                  | controlling |              |
|  | Capital stock | surplus | Treasury stock | earnings | of equity: | the parent                          | interests   | Total equity |
|  | ¥m            | ¥m      | ¥m             | ¥m       | ¥m         | ¥m                                  | ¥m          | ¥m           |
| Balance at January 1, 2019                   | 36,854        | 26,042  | (0)            | (13,696) | (7,623)    | 41,577                              | 3           | 41,580       |
| Net profit (loss)                            | -             | -       | -              | 395      | -          | 395                                 | (0)         | 395          |
| Other comprehensive income                   | -             | -       | -              | -        | (820)      | (820)                               | -           | (820)        |
| Total comprehensive income (loss)            | -             | -       | -              | 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       |
| Balance at April 1, 2018                     | 36,783        | 25,608  | (0)            | (7,527)  | (5,982)    | 48,882                              | 4           | 48,886       |
| Change 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)                                   | -             | -       | -              | (3,327)  | -          | (3,327)                             | (0)         | (3,327)      |
| Other comprehensive income                   | -             | -       | -              | -        | 47         | 47                                  | -           | 47           |
| Total comprehensive (loss) income            | -             | -       | -              | (3,327)  | 47         | (3,280)                             | (0)         | (3,280)      |
| Issuance of new shares                       | 68            | 12      | -              | -        | -          | 80                                  | -           | 80           |
| Share-based payments                         | -             | 129     | -              | -        | -          | 129                                 | -           | 129          |
| Total transactions with owners               | 68            | 141     | -              | -        | -          | 209                                 | -           | 209          |
| Balance at September 30, 2018<br>(Unaudited) | 36,851        | 25,749  | (0)            | (11,046) | (5,935)    | 45,619                              | 4           | 45,623       |

# 4) Interim condensed consolidated statement of cash flow

|  | 6 month period ended<br>June 30, 2019<br>(Unaudited)<br>¥m | 6 month period ended<br>September 30, 2018<br>(Unaudited)<br>¥m |
|--|--|---|
| Cash flows from operating activities                     |  |   |
| Profit (Loss) before income taxes                        | 292  | (4,142)   |
| Adjustments for:   |  |   |
| Receipt of non-cash consideration from customer          | (258)  | -   |
| Depreciation and amortization                            | 705  | 529   |
| Share-based payments                                     | 171  | 129   |
| Loss on revaluation of investment securities             | 9  | _   |
| Loss on revaluation of option to purchase shares         | -  | 1,112   |
| (Gain) on revaluation of investment in capital           | (17)   | (22)  |
| Change in fair value of contingent consideration         | 141  | (922)   |
| Net foreign exchange loss (gain)                         | 39   | (80)  |
| Interest expenses  | 124  | 112   |
| Share of loss of associates accounted for using the      |  |   |
| equity method  | 54   | 158   |
| (Increase) in trade and other receivables                | (511)  | (149)   |
| (Increase) decrease in other accounts receivables        | (51)   | 100   |
| (Decrease) in trade payables                             | (399)  | (203)   |
| Other  | (169)  | (181)   |
| Subtotal   | 130  | (3,559)   |
| Grants received  | 34   | 61  |
| Interest and dividends received                          | 16   | 8   |
| Interest paid  | (61)   | (69)  |
| Income taxes paid  | (45)   | (21)  |
| Income taxes refunded                                    | 2  | 19  |
| Net cash provided by (used in) operating activities      | 76   | (3,561)   |
| Cash flows from investing activities                     | 70   | (5,501)   |
| Purchase of property, plant and equipment                | (220)  | (1,374)   |
| Payments for purchase of investment securities           | (100)  | (550)   |
| Other  | 14   | (15)  |
|  | (306)  |   |
| Net cash (used in) investing activities                  | (300)  | (1,939)   |
| Cash flows from financing activities                     | (1 535)  | (1.500)   |
| Repayments of long-term interest-bearing debt            | (1,535)  | (1,500)   |
| Payment for settlement of contingent consideration       | (776)  | (98)  |
| Proceeds from contributions from limited partners        | 495  | - 01  |
| Proceeds from issuance of common stock                   | 158  | 81  |
| Other  | - (4. 222)   | (3)   |
| Net cash (used in) financing activities                  | (1,658)  | (1,520)   |
| Effects of exchange rate changes on cash and cash        | 43   | 66  |
| equivalents  |  |   |
| Net decrease in cash and cash equivalents                | (1,845)  | (6,954)   |
| Cash and cash equivalents at the beginning of the period | 18,760   | 28,281  |
| Cash and cash equivalents at the end of the period       | 16,915   | 21,327  |

## 5) Notes of interim condensed 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 interim condensed consolidated financial statements for the six month period ended June 30, 2019 are consistent with those applied to the consolidated financial statements for the nine month period ended December 31, 2018, except for amendments to IFRS 16 *Leases*, which became effective for the Group from January 1, 2019.

| IFRS    |        | Summary of change   |
|---------|--------|---|
| IFRS 16 | Leases | Amendment to the classification, measurement and recognition of financial instruments |

The Group transitioned to IFRS 16 in accordance with the modified retrospective approach. The prior year figures were not adjusted. The Group applied this Standard to contracts that were previously identified as leases applying IAS 17 *Leases* and IFRIC 4 *Determining whether an Arrangement contains a Lease*.

For leases that were classified as finance leases under IAS 17, the carrying amount of the right-of-use asset and the lease liability at the date of initial application of IFRS 16 were the carrying amount of the lease asset and lease liability immediately before that date measured applying IAS 17.

The Group recognizes right-of-use assets and lease liabilities at the date of initial application of IFRS 16 for leases previously classified as an operating lease under IAS 17, except short-term leases and leases for which the underlying asset is of low value. The right-of-use assets were measured at an amount equal to the lease liability adjusted by the amount of any accrued lease payments and asset retirement obligations relating to that lease. The lease liabilities were discounted at the borrowing rate as of 1 January 2019. The weighted average discount rate was 2.9%.

As part of the initial application of IFRS 16, the Group chose to apply the following practical expedients:

- 1) not to apply the new guidance to leases whose term will end within 12 months of the date of initial application. In such cases, the leases are being accounted for as short-term leases.
- 2) to exclude initial direct costs from the measurement of the right-of-use assets.

The following reconciliation to the opening balance for the lease liabilities as of January 1, 2019 is based on the operating lease obligations as of December 31, 2018:

| IFRS 16 Reconciliation   | Amount |
|--|--------|
|  | ¥m     |
| Operating lease disclosed at December 31, 2018   | 2,323  |
| IFRS 16 discounting adjustment   | (458)  |
| Other  | (48)   |
| Additional lease liabilities as a result of the initial application of IFRS 16 as of January 1, 2019 | 1,817  |

In the context of the transition to IFRS 16, right-of-use assets included in "Property, plant and equipment" of JPY 1,730 million and additional lease liabilities included in "Interest-bearing debt" of JPY 1,817 million were recognized as well as a decrease of in accrued payments within "Other non-current liabilities" of JPY 87 million as of 1 January 1, 2019.

In addition, from the commencement of the application of IFRS 16, the Group has assessed whether any new contracts include a lease. There were no new significant lease transactions in the six month period ended June 30, 2019.

The right-of-use asset is depreciated using the straight-line method over the shorter of the lease term or the useful life of the right-of-use asset. In the Interim Condensed Consolidated Balance Sheet the right-of-use asset is included in "Property, plant and equipment" and the lease liability is included in "interest-bearing debt". "Finance cost" includes interest expense on the lease liability. The interest expense represents the amount that produces a constant periodic rate of interest on the remaining balance of the lease liability. The lease liability is reduced by lease payments net of the interest expense.

For low-value asset leases and short-term leases with lease terms of 12 months or less, the Group has adopted the exemption provisions of IFRS 16 and has elected not to recognize right-of-use assets and lease liabilities. The Group recognizes lease payments for these leases as expenses over the lease term using the straight-line method.

# **5.3** Changes in accounting estimates Not applicable.

## 5.4 Operating segments

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