Consolidated Financial Results for the Nine months Ended September 30, 2019 (IFRS)

November 12, 2019

Company name:	Sosei Group Corporation		Listing: Tokyo Stock Exchange
Security code:	4565	URL:	https://www.soseiheptares.com/
Representative:	Shinichi Tamura Representative Executive Officer, CEO		
Contact person:	Christopher Cargill Executive Vice President, CFO		Tel: +81-3-5210-3290

Scheduled date of Quarterly Securities Report filing	November 12, 2019	Scheduled date of dividend payments:	—
Supplementary materials for financial results:	No		
Financial results briefing session:	No		

(Rounded million yen)

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

(1) Consolidated operating results (cumulative) (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 month period ended September 30, 2019	7,770	170.5	1,094	—	1,142	—	1,461	—	1,461	—	(102)	—
9 month period ended December 31, 2018	2,872	(53.9)	(5,734)	—	(7,243)	—	(5,978)	—	(5,977)	—	(7,619)	—

	Earnings per share – basic	Earnings per share – diluted
	Yen	Yen
9 month period ended September 30, 2019	19.11	18.91
9 month period ended December 31, 2018	(78.40)	(78.40)

(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
	Million yen	Million yen	Million yen	%
At September 30, 2019	59,322	42,424	42,421	71.5
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 June 30, 2018 (End Q1) 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 activity, whilst simultaneously

investing to advance new in-house discovery 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[1] 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 2021 to fund its activities and is proactively seeking to extend the cash runway into late 2022.

*** Notes**

(1) Changes in the number of significant subsidiaries for the nine month period ended September 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)	At September 30, 2019	76,993,536 shares	At December 31, 2018	76,301,936 shares
2) Number of treasury shares at period end	At September 30, 2019	213 shares	At December 31, 2018	104 shares
3) Average number of shares in issue in period	9 month period ended September 30, 2019	76,485,742 shares	9 month period ended December 31, 2018	76,256,495 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.

* Quarterly consolidated financial results reports are not subject to audit.

* The Group changed the end of the fiscal year from March 31 to December 31 at the 28th ordinary general meeting of shareholders and it will continue to have a December fiscal year end. The 29th term is a nine month irregular term

** 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.

---

[1] The assumed FX rate of USD:JPY 108

[2] 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).

○ Contents of Attached Materials

1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

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

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

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

As of September 30, 2019, the Group had more than 15 programs ongoing in discovery, with seven in preclinical development, and seven[1][2] currently in clinical trials.

In the area of partnerships with major global pharmaceutical companies, the Group reached significant milestones, with its first partnered program entering Phase 2 clinical studies with AstraZeneca UK Limited ("AstraZeneca"), as well as its strategic multi-target drug discovery collaboration with Pfizer Inc. ("Pfizer") nominating two new candidates to advance into preclinical development. Furthermore, in the third quarter the Group entered into two new strategic partnerships with Genentech Inc. ("Genentech") and Takeda Pharmaceutical Company Limited ("Takeda") respectively.

On January 7, 2019, the Group announced it had been notified by its strategic alliance partner, 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 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 supplies 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 March 22, 2019, the Group announced that Ultibro® Breezhaler® and Seebri®Breezhaler® had

[1] Includes QVM149 for Asthma, AZD4635 for multiple solid malignancies, HTL0018318 for dementia with Lewy bodies (voluntarily suspended and withdrawn), 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.

[2] Phase 2 trial of HTL0018318 for DLB in Japan remains under voluntary suspension and has been withdrawn. The Group plans to resubmit a new clinical trial notification for HTL0018318 (or another novel M1 agonist) to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in the future.

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 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[3], 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 triggered a US$2.5 million payment to the Group from Novartis. QVM149 was investigated in Phase 3/3b studies (IRIDIUM[4] and ARGON[5]), which have completed in Q3 2019. Please see the paragraph on Subsequent Events for comments on the trial results.

[3] Phase 2 CQVM149B2208 study (ClinicalTrials.gov Identifier: NCT03063086)
Phase 2 CQVM149B2209 study (ClinicalTrials.gov Identifier: NCT03108027)
[4] Phase 3 CQVM149B2302 study (ClinicalTrials.gov Identifier: NCT02571777)
[5] Phase 3 CQVM149B2306 study (ClinicalTrials.gov Identifier: NCT03158311)

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 preclinical development. This triggered a US$3 million milestone payment to the Group.

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 the form of an upfront payment, and expects early progress payments over the next two to three years). In addition to this, the Group is also eligible to receive 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 August 5, 2019, the Group announced that it had entered into a strategic multi-target partnership with 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 the Group 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. the Group is eligible to receive up to $26 million (in the form of an upfront payment, and expects early progress payments over the next two to three years). In addition to this, the Group is also eligible to receive 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_1 receptor agonist) remain under voluntary suspension due to the unexpected toxicology findings identified in a non-human 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 on clinical trial activities. 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.

In the area of collaborations with innovative technology companies and venture funds, the Group continued to make significant progress with its partners and announced a new R&D collaboration with a venture 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 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 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 early development of new candidates to be partnered, the Group continued to make the necessary investments in its pipeline, as it advanced multiple discovery candidates through and into early development.

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 in-house 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 early development programs continued to progress well.

In the area of activities related to former wholly-owned subsidiaries, the Group received a milestone related to a program previously created by Activus Pharma Inc. ("Activus").

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, 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.

As of September 30, 2019, the Group had a total of 173 employees (an increase of four 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 28th Ordinary General Meeting of Shareholders. Comparative financial disclosures for the nine month period ended September 30, 2019 therefore reference the nine month period ended December 31, 2018 as the prior corresponding period.

As a result of the above activities, the Group reported the following financial results for the nine month period ended September 30, 2019. Revenue of JPY 7,770 million (an increase of JPY 4,898 million vs. the prior corresponding period), an operating profit of JPY 1,094 million (an operating loss of JPY 5,734 million in the prior corresponding period), a net profit before income taxes of JPY 1,142 million (a net loss before income taxes of JPY 7,243 million in the prior corresponding period), a net profit of JPY 1,461 million (a net loss of JPY 5,978 million in the prior corresponding period).

	9 month period ended September 30, 2019 ¥m	9 month period ended December 31, 2018 ¥m	Change
Revenue	**7,770**	2,872	4,898
Cost of sales	**(605)**	(335)	(270)
Research and development expenses	**(3,152)**	(5,384)	2,232
Selling, general and administrative expenses	**(2,649)**	(2,704)	55
Other net income (expenses)	**(270)**	(183)	(87)
Operating profit (loss)	**1,094**	(5,734)	6,828
Net finance income (costs)	**166**	(955)	1,121
Share of loss of associates	**(118)**	(488)	370
Impairment loss on associates	**-**	(66)	66
Net profit (loss) before income tax	**1,142**	(7,243)	8,385
Net profit (loss)	**1,461**	(5,978)	7,439

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

Revenue

	9 month period ended September 30, 2019 ¥m	9 month period ended December 31, 2018 ¥m	Change
Milestone fees and upfront fees	**5,092**	340	4,752
Royalty income	**1,718**	2,104	(386)
Product supply revenue	**203**	-	203
Other	**757**	428	329
	7,770	2,872	4,898

Revenue in the nine month period under review totaled JPY 7,770 million (an increase of JPY4,898 million vs. the prior corresponding period).

Revenue related to milestones and upfront fees in the nine month period under review totaled JPY 5,092 million (an increase of JPY 4,752 million vs. the prior corresponding period). The increase was due to the occurrence of milestone events in the nine month period under review plus the commencement of new collaborations with Medicxi, Genentech and Takeda. Milestone income included a US$15m receipt from AstraZeneca and receipts from Pfizer, Novartis and FUJIFILM. 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 nine month period under review totaled JPY 1,718 million (a decrease of JPY 386 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[6].

On October 22, 2019, our partner Novartis reported Q3 2019 sales for its Ultibro® Breezhaler® and Seebri® Breezhaler® products of USD 125 million (a decrease of USD 19 million). The breakdown of Novartis' (calendar) Q3 2019 sales by product was as follows:

- Ultibro® Breezhaler® USD 97 million (-8% compared to Q3 2018[7]) an inhaled LABA/LAMA, sales declined mainly due to enhanced competition in Japan and Europe.
- Seebri® Breezhaler® USD 28 million (-16% compared to Q3 2018[8]) an inhaled LAMA, declined mainly 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 Q3 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. QVM149 was investigated in Phase 3/3b Studies, IRIDIUM and ARGON, which have completed in Q3 2019. QVM149 was submitted for registration in Europe in May 2019 and in Japan in Q3 2019. The Group is eligible to receive further royalties on net sales of this product once commercialized.

[6] 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.

[7] At constant currency rates

[8] At constant currency rates

Operating expenses

	9 month period ended September 30, 2019 ¥m	9 month period ended December 31, 2018 ¥m	Change
Cost of sales	**605**	335	270
Research and development	**3,152**	5,384	(2,232)
Cash expenses	**2,887**	5,187	(2,300)
Non-cash expenses	**265**	197	68
General and administrative expenses	**2,649**	2,704	(55)
Cash expenses	**1,632**	1,611	21
Non-cash expenses	**1,017**	1,093	(76)

Cost of sales

Cost of sales in the nine month period under review totaled JPY 605 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 which launched in February 2019.

Research and development expenses

Cash research and development ("R&D") expenses in the nine month period under review totaled JPY 2,887 million yen (a decrease of JPY 2,300 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 discovery. 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 nine month period under review totaled JPY 1,632 million (an increase of JPY 21 million vs. the prior corresponding period). The increase in G&A spend primarily related to UK national insurance charges which rose due to the increase in the Company's share price. This was largely 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 nine month period under review were JPY 1,282 million (a decrease of JPY 8 million vs. the prior corresponding period). In total, depreciation amounted to JPY 307 million (an increase of JPY 102 million vs. the prior corresponding period due to the Group's investment in its state-of-the-art R&D facility in the UK which opened in August 2018 plus the impact of a change in accounting for lease property costs). Amortization for the nine month period under review totaled JPY 693 million (an increase of JPY 29 million vs. the prior corresponding period). Stock-based compensation expense for the period was JPY 282 million (a decrease of JPY 139 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 nine month period under review totaled JPY 1,094 million (vs. an operating loss of JPY 5,734 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 nine month period under review vs. the prior corresponding period.

Net finance income (costs)
Net finance income in the nine month period under review totaled JPY 166 million (an increase of JPY 1,121 million vs. a loss in the prior corresponding period). The increase was primarily due to a loss of JPY 1,121 million recorded for the nine month period ended December 31, 2018 arising from the Group's decision not to exercise its option to acquire more shares in its associate, MiNA (Holdings) Limited.

Net profit
The net profit in the nine month period under review totaled JPY 1,461 million (vs. a net loss of JPY 5,978 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), the decrease in R&D expense (for the reasons stated above) and decrease in net finance costs (for the reasons stated above) during the nine month period under review vs. the prior corresponding period.

Subsequent Events
Subsequent to September 30, 2019, the following events occurred:

On October 1, 2019, Novartis announced positive results from its Phase III IRIDIUM trial. The results showed that the investigational, once-daily, inhaled combination QVM149 (indacaterol acetate, glycopyrronium bromide and mometasone furoate or IND/GLY/MF) achieved a superior improvement in lung function than QMF149 (indacaterol acetate and mometasone furoate or IND/MF) in asthma patients who were uncontrolled on treatment with a long-acting beta agonist/inhaled corticosteroid (LABA /ICS). Detailed results from the IRIDIUM trial will be presented at upcoming medical congresses. As stated above, on 24 May 2019 the regulatory submission for QVM149 was accepted for review by the European Medicines Agency. QVM149 was also investigated in the Phase IIIb ARGON study, which compared it with a combination of salmeterol/fluticasone and tiotropium. Results from the completed ARGON study will be announced after the data is analyzed. Under the agreement, the Group is entitled to certain development and sales-based milestones, and royalties on net sales upon successful commercialization of QVM149. On September 30 and October 1, 2019, further clinical data from the broader development program of Novartis with QVM149 were presented at the European Respiratory Society (ERS) International Congress 2019.

On October 9, 2019, the Group announced that it had been notified by its partner Genentech, a member of the Roche Group, of its desire to nominate a new GPCR disease target, which triggered a US$3 million payment to the Group. This US$3 million payment formed part of the US$26 million figure noted by the Group in its announcement on the signing of the collaboration and license agreement.

On October 22, 2019, Novartis included a statement within its Q3 financial results confirming that the regulatory submission for QVM149 has been submitted to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA").

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets at September 30, 2019 were JPY 59,322 million (an increase of JPY 335 million vs. the end of the previous fiscal year FY18). The main reason for this increase was due to an increase in cash and cash equivalents (arising from new collaborations and milestone receipts) and 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), offset by reductions in intangible assets (due to amortization and impairment) and income tax receivables (due to the receipt of tax credits).

Liabilities

Total liabilities at September 30, 2019 were JPY 16,898 million (a decrease of JPY 509 million vs. the end of the previous fiscal year FY18). The main reason for the decrease was due to a decrease in contingent consideration in business combinations, a decrease in deferred tax liabilities (which unwind in line with amortization), a decrease in debt (due to scheduled repayments) and a decrease in trade creditors (due to lower levels of expenditure) partial offset by an increase in other liabilities (due to the inclusion of deferred revenue relating to new collaborations).

Equity

Total equity at September 30, 2019 was JPY 42,424 million (an increase of JPY 844 million vs. the end of the previous fiscal year FY18). The main reason for the increase was due to 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 34.9%, 10.8% and 71.5%, respectively.

2) Cash flows

Cash and cash equivalents at September 30, 2019 increased by JPY 1,969 million from the beginning of the year and amounted to JPY 20,729 million.

Cash flows from operating activities

Net cash provided by operating activities for the period under review totaled JPY 4,232 million. This was predominantly due to profit before income taxes of JPY 1,142 million recorded for the period arising from the Group's increased revenue from milestone receipts and upfront fees relating to new collaborations.

Cash flows from investing activities

Net cash used in investing activities for the period under review totaled JPY 215 million. This was primarily due to an additional RMF1 investment of JPY 250 million and expenditure on property, plant and equipment of JPY 244 million less contingent consideration receipts of JPY 269 million.

Cash flows from financing activities

Net cash used in financing activities for the period under review totaled JPY 2,074 million. This was primarily due to capital repayments of long-term interest-bearing loans and lease liabilities of JPY 2,302 million plus contingent consideration payments of JPY 931 million less proceeds from the issuance of common stock of JPY 664 million and 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 activities, whilst simultaneously investing to advance new in-house discovery 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[1] (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 2021 to fund its activities and is proactively seeking to extend the cash runway into late 2022.

---

[1] The assumed FX rate of USD:JPY 108

[2] 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 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

	September 30, 2019 (Unaudited) ¥m	December 31, 2018 (Audited) ¥m
Assets		
Non-current assets		
Property, plant and equipment	**3,914**	2,715
Goodwill	**13,706**	14,177
Intangible assets	**12,703**	14,367
Investments accounted for using the equity method	**3,333**	3,644
Other financial assets	**1,941**	1,515
Other non-current assets	**295**	285
Total non-current assets	**35,892**	36,703
Current assets		
Trade and other receivables	**1,049**	987
Income tax receivable	**1,292**	2,057
Other current assets	**360**	480
Cash and cash equivalents	**20,729**	18,760
Total current assets	**23,430**	22,284
Total assets	**59,322**	58,987
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	**2,025**	2,542
Contingent consideration in business combinations	**3,501**	4,180
Interest-bearing debt	**3,246**	3,970
Other financial liabilities	**1,588**	1,179
Other non-current liabilities	**941**	87
Total non-current liabilities	**11,301**	11,958
Current liabilities		
Trade and other payables	**1,165**	2,080
Income taxes payable	**156**	24
Interest-bearing debt	**3,134**	2,994
Other current liabilities	**1,031**	351
Provisions	**111**	-
Total current liabilities	**5,597**	5,449
Total liabilities	**16,898**	17,407
Equity		
Capital stock	**37,410**	36,854
Capital surplus	**26,432**	26,042
Treasury stock	**(0)**	(0)
Retained earnings	**(12,235)**	(13,696)
Other components of equity	**(9,186)**	(7,623)
Equity attributable to owners of the parent	**42,421**	41,577
Non-controlling interests	**3**	3
Total equity	**42,424**	41,580
Total liabilities and equity	**59,322**	58,987

2) Interim condensed consolidated statement of comprehensive income

	9 month period ended September 30, 2019 (Unaudited) ¥m	9 month period ended December 31, 2018 (Audited) ¥m
Revenue	**7,770**	2,872
Cost of sales	**(605)**	(335)
Gross profit	**7,165**	2,537
Research and development expenses	**(3,152)**	(5,384)
Selling, general and administrative expenses	**(2,649)**	(2,704)
Other income	**36**	140
Other expenses	**(306)**	(323)
Operating profit (loss)	**1,094**	(5,734)
Finance income	**437**	434
Finance costs	**(271)**	(1,389)
Share of loss of associates accounted for using the equity method	**(118)**	(488)
Impairment loss on investments accounted for using the equity method	**-**	(66)
Profit (loss) before income taxes	**1,142**	(7,243)
Income tax benefit	**319**	1,265
Net profit (loss)	**1,461**	(5,978)
Other comprehensive income:		
Items that may not be reclassified subsequently to profit or loss:		
Financial assets measured at fair value through other comprehensive income	**(22)**	-
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	**(1,541)**	(1,641)
Total other comprehensive (loss)	**(1,563)**	(1,641)
Total comprehensive (loss)	**(102)**	(7,619)
Net profit (loss) attributable to:		
Owners of the parent	**1,461**	(5,977)
Non-controlling interests	**(0)**	(1)
Total net profit (loss)	**1,461**	(5,978)
Total comprehensive (loss) attributable to:		
Owners of the parent	**(102)**	(7,618)
Non-controlling interests	**(0)**	(1)
Total comprehensive (loss)	**(102)**	(7,619)
Earnings (loss) per share (yen)		
Basic earnings (loss) per share	**19.11**	(78.40)
Diluted earnings (loss) per share	**18.91**	(78.40)

3) Interim condensed consolidated statement of changes in equity

	Capital stock ¥m	Capital surplus ¥m	Treasury stock ¥m	Retained earnings ¥m	Other components of equity: ¥m	**Equity attributable to owners of the parent ¥m**	Non-controlling interests ¥m	**Total equity ¥m**
Balance at January 1, 2019	**36,854**	**26,042**	**(0)**	**(13,696)**	**(7,623)**	**41,577**	**3**	**41,580**
Net profit (loss)	-	-	-	1,461	-	**1,461**	(0)	**1,461**
Other comprehensive loss	-	-	-	-	(1,563)	**(1,563)**	-	**(1,563)**
Total comprehensive income (loss)	-	-	-	1,461	(1,563)	**(102)**	(0)	**(102)**
Issuance of new shares	556	108	-	-	-	**664**	-	**664**
Purchase of treasury stock	-	-	(0)	-	-	**(0)**	-	**(0)**
Share-based payments	-	282	-	-	-	**282**	-	**282**
Total transactions with owners	556	390	(0)	-	-	**946**	-	**946**
Balance at September 30, 2019 (Unaudited)	**37,410**	**26,432**	**(0)**	**(12,235)**	**(9,186)**	**42,421**	**3**	**42,424**
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	-	-	-	(5,977)	-	(5,977)	(1)	(5,978)
Other comprehensive loss	-	-	-	-	(1,641)	(1,641)	-	(1,641)
Total comprehensive loss	-	-	-	(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
Balance at December 31, 2018 (Audited)	36,854	26,042	(0)	(13,696)	(7,623)	41,577	3	41,580

4) Interim condensed consolidated statement of cash flow

	9 month period ended September 30, 2019 (Unaudited) ¥m	9 month period ended December 31, 2018 (Audited) ¥m
Cash flows from operating activities		
Profit (loss) before income taxes	**1,142**	(7,243)
Adjustments for:		
Receipt of non-cash consideration from customer	**(251)**	-
Depreciation and amortization	**1,049**	879
Share-based payments	**282**	421
Impairment loss	**298**	319
Loss (gain) on revaluation of investment securities	**72**	(187)
Loss on lapse of option to purchase shares	**-**	1,121
(Gain) loss on revaluation of investment in capital	**(86)**	105
Change in fair value of contingent consideration	**(275)**	(216)
Net foreign exchange gain	**(97)**	(47)
Interest expenses	**174**	162
Share of loss of associates accounted for using the equity method	**118**	488
Impairment loss on investments accounted for using equity method	**-**	66
Increase in trade and other receivables	**(119)**	(243)
(Increase) decrease in other accounts receivables	**(18)**	224
Increase in trade payables	**761**	210
Increase in provisions	**111**	
Other	**275**	(121)
Subtotal	**3,436**	(4,062)
Grants received	**44**	154
Interest and dividends received	**40**	16
Interest paid	**(83)**	(99)
Income taxes paid	**(90)**	(23)
Income taxes refunded	**885**	19
Net cash provided by (used in) operating activities	**4,232**	(3,995)
Cash flows from investing activities		
Purchase of property, plant and equipment	**(244)**	(1,807)
Purchase of intangible assets	**(11)**	(352)
Payments for purchase of investment securities	**(250)**	(650)
Proceeds from contingent consideration receivable	**269**	-
Other	**21**	1
Net cash (used in) investing activities	**(215)**	(2,808)
Cash flows from financing activities		
Repayments of long-term interest-bearing debt	**(2,302)**	(2,255)
Payment for settlement of contingent consideration	**(931)**	(97)
Proceeds from contributions from limited partners	**495**	-
Proceeds from issuance of common stock	**664**	84
Net cash (used in) financing activities	**(2,074)**	(2,268)
Effects of exchange rate changes on cash and cash equivalents	**26**	(450)
Net decrease in cash and cash equivalents	**1,969**	(9,521)
Cash and cash equivalents at the beginning of the period	**18,760**	28,281
Cash and cash equivalents at the end of the period	**20,729**	18,760

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 nine month period ended September 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 nine month period ended September 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.