



Consolidated Financial Results for the Nine Month Period Ended September 30, 2021 (IFRS)

November 11, 2021

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 Financial results briefing session: No

(Rounded million yen)

1. Consolidated Results for the 9 month period ended September 30, 2021 (from January 1, 2021 to September 30, 2021)

(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, 2021	3,590	(19.2)	(4,225)	—	(4,152)	—	(1,825)	—	(1,825)	—	2,094	—
9 month period ended September 30, 2020	4,443	(42.8)	(1,217)	—	(1,478)	—	(1,642)	—	(1,642)	—	(3,319)	—

	Earnings per share – basic		Earnings per share – diluted	
	Yen		Yen	
9 month period ended September 30, 2021	(22.50)		(22.50)	
9 month period ended September 30, 2020	(21.03)		(21.03)	

(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, 2021	88,956		53,773		53,773		60.4	
At December 31, 2020	76,465		52,381		52,381		68.5	

2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen				
FY2020	-	0.00	-	0.00	0.00
FY2021	-	0.00	-	-	-
FY2021 (E)	-	-	-	0.00	0.00

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

3. Forecast for the year from January 1, 2021 to December 31, 2021

We continue to focus on expanding our drug discovery business and remain well positioned to capitalize on growth opportunities. Our SBDD platform and highly productive drug discovery engine has generated multiple new exciting drug candidates, and we will continue to take steps to increase partnered and co-investment activity to ensure all programs are rapidly advanced in a

capital efficient manner. At the same time, we will invest in new technologies, tools and capabilities to maintain our competitive edge and bring forward an exciting pipeline of next-generation programs in areas of high unmet medical need.

The Group expects 2021 to be a year of increased investment in R&D and in strategic growth initiatives, including taking steps to secure an acquisition of a revenue-generating business to support our medium-term plan for corporate expansion. The Group is making increased R&D investments this year in the preclinical and clinical advancement of its portfolio of lead muscarinic agonist compounds for schizophrenia and other neurological disorders, following their reversion to in-house programs from AbbVie in January 2021. The Group's current intention is to partner the portfolio of muscarinic agonist programs in the near term, which if successful, will have the impact of shifting the clinical trial costs and risks associated with these neurology programs to a well-capitalized global partner. The Group expects any partner to be able to accelerate late-stage development of these programs and support the Group's vision to bring these novel medicines to patients sooner. Furthermore, the Group is in advanced discussions with a leading global charitable foundation to secure grant funding to advance the SARS-CoV-2 Mpro inhibitor program – targeting rapid development of a single agent without the need for co-dosing with other anti-viral therapies.

In line with recent years, our strategy remains the same, and in our underlying drug discovery business we will continue to target a sustainable balance of resources and capital in the pursuit of growth in corporate value:

- Forecast cash R&D expenses in the underlying drug discovery business in the range of JPY 5,000 to JPY 5,750 million¹ (increased from previously guided range of JPY 4,000 to 5,000).
 - The change to the guided range reflects increased investment in high-value in-house programs and the acceleration of development associated with the regained muscarinic agonist programs.
- Forecast cash G&A expenses in the underlying drug discovery business in the range of JPY 1,800 to JPY 2,300 million² (unchanged).
- We expect to receive upfront payments related to new partnerships.
- We expect to receive milestone payments from existing drug discovery and development partnerships.
- We will continue to invest in technologies, tools and capabilities that complement and future-proof our drug discovery platform, as well as advance next-generation candidates; all while strongly managing our cost base.
- We will continue to explore a potentially transformative acquisition to secure long-term revenue growth.
- We will expand our drug candidate discovery and early development capabilities into new target classes.
- We will continue to explore late-stage clinical assets to in-license and develop for the Japanese market.

The Group has a strong cash runway into 2024 to fund its drug discovery and early-stage development activities.

¹ The assumed FX rate of USD:JPY 106

² The assumed FX rate of USD:JPY 106

* Notes

(1) Changes in the number of significant subsidiaries for the nine-month period ended September 30, 2021 (changes of specified subsidiaries affecting the scope of consolidation): None

(2) Changes in accounting policies, changes in accounting estimates

1) Changes in accounting policies required by IFRS: None

2) Changes due to changes in accounting policies other than those of item 1: None

3) Changes in accounting estimates: None

(3) Number of common shares issued

1) Number of shares issued at period end (including treasury shares)

At September 30, 2021	81,518,316 shares	At December 31, 2020	80,596,128 shares
At September 30, 2021	213 shares	At December 31, 2020	213 shares
9 month period ended September 30, 2021	81,075,836 shares	9 month period ended September 30, 2020	78,116,362 shares

2) Number of treasury shares at period end

3) Average number of shares in issue in period

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

* *Explanation regarding the appropriate use of forecasts of business results and other points to be noted*

Note concerning forward-looking statements: The financial forecast is based on judgements and estimates that have been prepared on the basis of information available as of the time of disclosure of this material. The actual business results may differ materially from the forecasts due to various factors.

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1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

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

During the nine months ended September 30, 2021, the Group continued to advance its drug discovery and early-stage development pipeline, as well as enhance its proprietary StaR® (“stabilized receptor”) and aligned technologies, and Structure-based Drug Design (“SBDD”) platform.

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

As of September 30, 2021, the Group had over 20 programs in total ongoing in discovery, with multiple in-house and partnered programs currently in preclinical/clinical trials^{3,4}.

Due to the Group's renewed focus on small molecules and therapeutic antibodies, peptide discovery programs, which include HTL0030310 (an SS1R agonist), GLP-1 antagonist and Dual GLP-2/GLP-1 agonist, have been set aside for academic or industrial partnerships and will not be progressed any further by the Group in-house on a fully funded basis.

Supporting new and existing partnerships with major global pharmaceutical companies

The Group continued to make good progress with its partners and retained COVID-19 safety measures to ensure R&D continuity and productivity, regardless of the relaxing of Government guidelines in the U.K. in July 2021. All research and development activity continues to move forward productively.

Pfizer partnership

On May 19, 2021, the Group announced it had been notified by Pfizer that the first subject in a clinical trial had been dosed with PF-07258669, a new drug candidate nominated from the multi-target drug discovery collaboration between the two companies. Achievement of this milestone triggered a payment of US\$5 million to Sosei Heptares. PF-07258669 was nominated for advancement by Pfizer in December 2019 generating a US\$3 million milestone payment at that time. Pfizer nominated three distinct clinical candidates from the collaboration with the Group during 2019, all of which are now progressing in Phase 1 clinical trials. These candidates have also now been disclosed by Pfizer as:

- PF-07081532 (an oral GLP1 receptor agonist for Type 2 Diabetes Mellitus and Obesity)
- PF-07054894 (a CCR6 antagonist targeting Inflammatory Bowel Disease) and

³ Includes Imaradenant (AZD4635) for multiple solid malignancies, HTL0016878 for neurological diseases, HTL0018318 for neurological diseases (voluntarily suspended), HTL009936 for neurological diseases, PF-07081532 for T2DM/Obesity, PF-07054894 for Inflammatory Bowel Disease, PF-07258669 for Anorexia, BHV3100 for neurological diseases, TMP301 for neurological disorders, and HTL0030310 for endocrine disorders.

⁴ Phase 2 trial of HTL0018318 for DLB in Japan remains under voluntary suspension and has been withdrawn. The Group may resubmit a new clinical trial notification for HTL0018318 (or another novel M1 agonist) to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in the future, pending the outcome of an ongoing analysis and studies into toxicology findings.

- PF-07258669 (an MC4 receptor antagonist for Anorexia)

Biohaven partnership

On June 23, 2021, the Group announced that the first healthy subject had been dosed with HTL0022562 in a Phase 1 clinical study. HTL0022562 (also known as BHV3100) is a novel, small molecule calcitonin gene-related peptide (CGRP) receptor antagonist discovered by the Group and the lead compound in a portfolio of CGRP antagonists licensed to Biohaven in December 2020 for development as new therapies for CGRP-mediated disorders. The trial is a Phase 1, randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, and pharmacokinetics of a single ascending dose and multiple ascending doses of subcutaneous HTL0022562 in healthy adult subjects. The trial aims to enroll 88 subjects at a single center in the UK and is expected to complete in 2022.

The Group advanced HTL0022562 successfully through a preclinical development program demonstrating its promising and differentiated properties for further investigation in human trials. Under the global collaboration and license agreement with Biohaven, the Group will conduct the Phase 1 clinical trial itself, receiving a milestone payment for its initiation, and is also eligible for development costs for conducting the trial. Biohaven will lead all future studies and development activities and the Group will be eligible for further milestone payments and royalties. HTL0022562 is the tenth drug candidate overall generated from the Group's SBDD platform to enter clinical development.

Advancing R&D through co-investments with innovative technology and venture funds

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

PharmEnable

On January 12, 2021, the Group and PharmEnable, a UK drug discovery company, announced they had entered a collaboration to apply their respective technologies to drive novel drug discovery against a challenging G protein-coupled receptor ("GPCR") target associated with neurological diseases. The collaboration will combine the Group's world-leading GPCR-focused SBDD platform, which has fully structurally enabled the GPCR target, providing detailed structural insights and an assessment of tractability, with PharmEnable's proprietary advanced artificial intelligence (AI)-enabled and medicinal chemistry technologies (ChemUniverse and ChemSeek) to identify novel, highly specific drug leads for further development. PharmEnable's approach identifies three-dimensional (3D) drug candidate hits with improved specificity compared with traditional screening methods and allows the company to take on particularly challenging biological targets, such as "peptidergic" GPCRs, which have proved difficult to drug using existing approaches. The natural agonist ligand of a peptidergic GPCR is a large, complex peptide and is often very difficult to block with a small molecule, particularly one that has properties suitable for development as a therapeutic agent for neurological disease. Under the agreement, the companies will jointly conduct and share the costs of the discovery and development program and will co-own any resulting products.

Metrion Biosciences

On February 1, 2021, the Group and Metrion Biosciences, a specialist UK-based ion channel CRO and drug discovery company, announced they had entered into a strategic technology collaboration where for the first time the Group will apply its world-leading SBDD expertise and platform to ion channels. The collaboration aims to demonstrate the potential of the Group's SBDD technologies to address disease-associated ion channels and work towards establishing a

leadership position in this area, in a similar way that it has done for GPCRs. As a first step, the Group and Metrion will combine their respective capabilities in a drug discovery program to identify novel, highly specific drug leads for further development against a single ion channel associated with neurological diseases. Metrion will contribute intellectual property, know-how and use of screening models for the nominated ion channel target. The Group will have exclusive, full global rights to all molecules identified and directed to the targets for development.

Orexia Therapeutics / Centessa Pharmaceuticals

On February 16, 2021, the Group noted the announcement from Centessa Pharmaceuticals (“Centessa”) about its launch as a novel asset-centric pharmaceutical company designed and built to advance a portfolio of highly validated programs. In conjunction with its launch, Centessa completed the merger of 10 private biotech companies (“Centessa Subsidiaries”) that would each continue to develop its assets with oversight from the Centessa management team. Centessa was founded by specialist life science venture capital firm Medicxi and raised \$250 million in an oversubscribed Series A financing from a group of blue-chip investors. Centessa’s asset-centric R&D model applied at scale has assembled best-in-class or first-in-class assets, each of which is led by specialized teams committed to accelerate development and reshape the traditional drug development process. With its unique operational framework, Centessa aims to reduce some of the key R&D inefficiencies that classical pharmaceutical companies face because of structural constraints. Each Centessa Subsidiary team is asset-focused, in that it prosecutes a single program or biological pathway, with leadership provided by subject matter experts who are given a high degree of autonomy to advance each program. With a singular focus on advancing exceptional science, combined with proprietary capabilities, including structure-based drug discovery and design, the subsidiary teams enable Centessa to potentially develop and deliver impactful medicines to patients. Orexia Therapeutics (“Orexia”), a new entity comprising Orexia Limited and Inexia Limited, which were created in February 2019 by the Group and Medicxi, was merged into Centessa. Orexia is developing oral and intranasal orexin receptor agonists using structure-based drug design approaches. These agonists target the treatment of narcolepsy type 1, where they have the potential to directly address the underlying pathology of orexin neuron loss, as well as other neurological disorders characterized by excessive daytime sleepiness. The Group continues to provide research services to Orexia and its equity holding in Orexia was converted into a proportional shareholding in Centessa.

On April 21, 2021, Centessa management filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission (“SEC”) for a proposed initial public offering (“IPO”) of the American Depositary Shares (“ADSs”) of Centessa Pharmaceuticals plc. On June 4, 2021 Centessa Pharmaceuticals plc. successfully completed its IPO achieving a market capitalization of US\$1.7 billion and raising US\$379.5 million, and its ADSs started trading on the Nasdaq Global Market under the symbol “CNTA.” As at September 30, 2021, the Group owned 929,353 shares of Centessa Pharmaceuticals plc, representing approximately 1% of its issued share capital.

InveniAI®

On July 6, 2021 the Group and InveniAI® LLC (“InveniAI,”), a global leader in pioneering the application of artificial intelligence (AI) and machine learning (ML) to transform innovation across drug discovery and development, announced the initiation of a new R&D collaboration. The objective of the collaboration is to identify new therapeutic product concepts for immune diseases where an AI and ML based approach can be applied to generate compelling evidence for the role of GPCRs in relevant immunomodulatory pathways; the goal being to use these targets as a basis for SBDD to generate novel compounds that could improve responses to existing immunotherapies. The collaboration will combine InveniAI's AI-powered platform for target discovery with the

Group's world-leading GPCR SBDD and early development capabilities generate and advance transformative therapeutics across disease indications that remain with high unmet medical needs.

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

The Group continued to make significant investments in its pipeline, as it advanced multiple discovery candidates and early development programs.

On January 5, 2021, the Group announced it regained the worldwide rights to its muscarinic agonist programs including all assets in development under the program, together with all associated intellectual property licensed by the Group to Allergan, and all clinical and preclinical data generated under the partnership. The program was licensed to Allergan in April 2016, and Allergan was acquired by AbbVie in May 2020. This decision to return worldwide rights was based on business decisions regarding AbbVie's pipeline strategy and not on any efficacy, safety or other data related to the collaboration programs. The Group has since conducted a full internal review and determined a strategy to re-partner the program in 2021.

Activities related to former wholly-owned subsidiaries

The Group received a milestone related to a program previously created by Activus Pharma Inc. ("Activus"). On March 11, 2021, the Group announced that Formosa Pharmaceuticals, Inc. ("Formosa") had dosed the first patient in a 370-patient randomized Phase 3 clinical trial of APP13007 in the United States (ClinicalTrials.gov Identifier: NCT04739709). APP13007 is a nanoparticle formulation of a steroid in development for the treatment of inflammation and pain after cataract surgery. 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 Sosei Heptares' redirected growth strategy towards the design and development of new medicines originating from its proprietary GPCR-targeted StaR[®] technology and structure-based drug design platform capabilities.

Activities related to financing

On July 27, 2021, the Group issued euro-yen denominated convertible bonds due 2026 in the principal amount of JPY 30 billion in an international offering. The new funds were used to repurchase the Group's existing convertible bonds due 2025, and will be used to accelerate the Group's strategic growth initiatives, including acquisitions and investments, and to lower funding costs, extend the maturity profile of its debt, and further strengthen the Group's financial base.

On July 28, 2021, the Group repurchased JPY 15.75 billion in principal amount of its existing convertible bonds due 2025 (which had an aggregate principal amount of JPY 16 billion). The remaining convertible bonds, totaling JPY 0.25 billion in principal amount, were converted by their holders into stock in September 2021.

As of September 30, 2021, the Group had a total of 196 employees (an increase of 6 employees vs. the end of the previous financial year, 2020).

As a result of the above activities, the Group reported the following financial results for the nine month period ended September 30, 2021. Revenue of JPY 3,590 million (a decrease of JPY 853 million vs. the prior corresponding period), an operating loss of JPY 4,225 million (vs. an operating loss of JPY 1,217 million in the prior corresponding period), a net loss before taxes of JPY 4,152 million (vs. a net loss before income taxes of JPY 1,478 million in the prior corresponding period), and a net loss of JPY 1,825 million (vs. a net loss of JPY 1,642 million in the prior corresponding period).

	9 month period ended September 30, 2021	9 month period ended September 30, 2020	Change
	¥m	¥m	¥m
Revenue	3,590	4,443	(853)
Cash cost of sales	(523)	(421)	(102)
Cash research and development expenses	(4,010)	(2,411)	(1,599)
Cash selling, general and administrative expenses	(1,832)	(1,339)	(493)
Net other cash income	117	42	75
Cash earnings	(2,658)	314	(2,972)
Non-cash costs	(1,567)	(1,531)	(36)
Operating loss	(4,225)	(1,217)	(3,008)
Net finance (costs) income	(249)	43	(292)
Share of gain (loss) of associates	116	(304)	420
Gain on reversal of impairment loss for investments accounted for using the equity method	206	-	206
Loss before income taxes	(4,152)	(1,478)	(2,674)
Net Loss for the period	(1,825)	(1,642)	(183)
YTD average exchange rate			
USD: JPY	108.86	107.57	1.29
GBP: JPY	150.88	136.69	14.19

Notes:

1. Cash earnings describes operating profit/(loss) before deducting depreciation, amortization, stock-based compensation expenses and impairment losses.

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, 2021	9 month period ended September 30, 2020	Change
	¥m	¥m	¥m
Milestone income and upfront fees	1,366	1,962	(596)
Royalty income	1,704	1,762	(58)
Product supply revenue	(45)	-	(45)
Other	565	719	(154)
	3,590	4,443	(853)

Revenue in the nine month period under review totaled JPY 3,590 million (a decrease of JPY 853 million vs. the prior corresponding period).

Revenue related to milestone income and upfront fees in the nine month period under review totaled JPY 1,366 million (a decrease of JPY 596 million vs. the prior corresponding period). Milestone income and upfront fees can vary considerably quarter on quarter and depend on the achievement of defined milestone events and the commencement of new partnership agreements within a quarter. The decrease in revenues related to milestones and upfront fees in the nine month period under review was due to the achievement of five milestone events in the current period generating JPY 882 million of revenue vs. one upfront fee and five milestone events in the prior corresponding period generating JPY 1,664 million of revenue. In addition, license revenue of JPY500m was reversed in the nine month period under review as a result of a payment relating to changes in pharmaceutical product distribution arrangements. However, JPY450 million of revenue relating to the changes in these arrangements will be recorded in the fourth quarter. These reductions are partially offset by an increase of JPY 686 million in the amount released from deferred revenue in the nine month period under review vs. the prior corresponding period.

Revenue related to royalties in the nine month period under review totaled JPY 1,704 million (a decrease of JPY 58 million vs. the prior corresponding period). The Group's royalty revenue relates to sales of Ultibro[®] Breezhaler[®], Seebri[®] Breezhaler[®] and Enerzair[®] Breezhaler[®] by Novartis⁵.

Operating expenses

	9 month period ended September 30, 2021	9 month period ended September 30, 2020	Change
	¥m	¥m	¥m
Cash cost of sales	523	421	102
Cash research and development expenses	4,010	2,411	1,599
Cash general and administrative expenses	1,832	1,339	493
Non-cash expenses:	1,567	1,531	36
Cost of sales	115	110	5
Research and development expenses	322	285	37
General and administrative expenses	1,056	1,136	(80)
Other expenses	74	-	74

Cash cost of sales

Cash cost of sales in the nine month period under review totaled JPY 523 million (an increase of JPY 102 million vs. the prior corresponding period). Cash cost of sales comprises the fully loaded cost of those employees providing research and development services to specific customers under contracts (including other costs directly associated with these activities such as lab consumables).

⁵ Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura. Seebri[®], Ultibro[®], Enerzair[®] and Breezhaler[®] are registered trademarks of Novartis AG.

Cash research and development expenses

Cash research and development (“R&D”) expenses in the nine month period under review totaled JPY 4,010 million (an increase of JPY 1,599 million vs. the prior corresponding period). The increase in R&D spend reflects higher activity levels on in-house programs, participation in new co-development collaborations and the impact of a stronger GBP vs. JPY. In particular, the Group made increased R&D investments in the year to date in the preclinical and clinical advancement of its portfolio of lead muscarinic agonist compounds for schizophrenia and other neurological disorders, following their reversion to in-house programs from AbbVie in January 2021. The Group’s current intention is to partner the portfolio of muscarinic agonist programs in the near term, which if successful, will have the impact of shifting the clinical trial costs and risks associated with these CNS programs to a well-capitalized global partner. The Group expects any partner to be able to accelerate late-stage development of these programs and support the Group’s vision to bring these novel medicines to patients sooner. In addition, costs in the prior corresponding period were lower than normal due to the slowdown in expenditure that followed the declaration of the COVID-19 global pandemic in March 2020. Furthermore, the prior corresponding period also included a one off credit relating to the successful resolution of disputed costs charged by one supplier. The increase in R&D spend in 2021 was anticipated and management’s latest forecast of total R&D cash expenses for the full year is in the range of JPY 5,000 to JPY 5,750 million⁶ (increased from previously guided range of JPY 4,000 to 5,000). The change to the guided range reflects increased investment in high-value in-house programs including the acceleration of development associated with the regained muscarinic agonist programs. In the period under review 98% of R&D spend related to our UK operations.

Cash general and administrative expenses

Cash general and administrative (“G&A”) expenses in the nine month period under review totaled JPY 1,832 million (an increase of JPY 493 million vs. the prior corresponding period). The increase in G&A spend is primarily due to an increase in personnel related expenses and professional advisory fees as the Group continued to evaluate strategic growth opportunities. In addition, personnel related expenses in the prior corresponding period were lower than normal as a result of a reduction in the UK share based payment related National Insurance liability which was driven by share price movements in that particular period. Despite the relative increase in G&A spend vs. the prior corresponding period, the current period spend is in-line with our budgeted plans, and therefore our full year forecast cash G&A expenses remain unchanged, in the range of JPY 1,800 to 2,300 million.

Non-cash expenses

Non-cash expenses primarily consist of depreciation on property, plant and equipment, amortization of intangible assets, stock-based compensation expenses and impairment losses. Non-cash expenses in the nine month period under review were JPY 1,567 million (an increase of JPY 36 million vs. the prior corresponding period). In total, depreciation amounted to JPY 410 million (a decrease of JPY 38 million vs. the prior corresponding period). Amortization for the nine month period under review totaled JPY 551 million (a decrease of JPY 76 million vs. the prior corresponding period). Stock-based compensation expense for the period was JPY 532 million (an increase of JPY 76 million vs. the prior corresponding period). Impairment loss in the nine month period was JPY 74 million. This was due to an intangible asset impairment charge associated with a reduction in Oravi® sales and profitability forecasts.

⁶ The assumed FX rate of USD:JPY 106

Operating loss

Operating loss in the nine month period under review totaled JPY 4,225 million (vs. an operating loss of JPY 1,217 million in the prior corresponding period). The main reason for the increase in the operating loss is the reduction in revenue and increase in operating expenses.

Net finance costs

Net finance costs in the nine month period under review totaled JPY 249 million (an increase of JPY 292 million vs. the prior corresponding period). This increase is primarily due recording an accounting cost relating to the repurchase and cancellation of the Euro-yen denominated convertible bonds due 2025.

Share of gain (loss) of associates accounted for using the equity method

Share of gain (loss) of associates accounted for using the equity method in the period under review totaled JPY 116 million (an increase of JPY 420 million vs. the prior corresponding period). This was due to MiNA (Holdings) Limited, an affiliated company of the Group, recording a net profit for the nine month period under review vs. a net loss in the prior corresponding period.

Gain on reversal of impairment loss for investments accounted for using the equity method

Gain on reversal of impairment loss for investments accounted for using the equity method in the nine month period under review totaled JPY 206 million. This was due to an increase in the fair value of shares in JITSUBO, an affiliated company of the Group, which was divested in April 2021.

Income tax benefit (expense)

Income tax benefit in the nine month period under review totaled JPY2,327 million (vs. an Income tax expense of JPY 164 million in the prior corresponding period). This tax benefit has arisen from multiplying the net loss before income tax by the estimated effective tax rate for the fiscal year ending December 31, 2021. Due to the nature of the group's operations, which are concentrated on research & development activities in UK, income tax benefit/expense may fluctuate in each quarter due to the effects of UK R&D tax expenditure super deductions at 230% and changes in forecasted results for the full fiscal year. Accordingly, the amounts accrued for income tax benefit/expense for the nine month period under review may differ materially from the full year income tax benefit/expense.

Net loss for the period

Net loss for the nine month period under review totaled JPY 1,825 million (a net loss of JPY 1,642 million in the prior corresponding period). The main reason for the increase in net loss is the increase in the operating loss partially offset by the tax benefit.

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets as at September 30, 2021 were JPY 88,956 million (an increase of JPY 12,491 million vs. the end of the previous financial year, 2020). The primary reason for the increase was the net cash inflow from the issuance and repurchase of convertible bonds. In addition, there were gains in the fair value of listed securities and the values of GBP-denominated assets were boosted on translation into JPY by the effect of a strong GBP.

Liabilities

Total liabilities as at September 30, 2021 were JPY 35,183 million (an increase of JPY 11,099 million vs. the end of the previous financial year, 2020). This was primarily due to the issuance of new convertible bonds totaling JPY 27,212 million (with a face value of JPY 30,000 million) net of the repurchase and conversion of existing convertible bonds totaling JPY 14,937 million (with a face value of JPY 16,000 million).

Equity

Total equity as at September 30, 2021 was JPY 53,773 million (an increase of JPY 1,392 million vs. the end of the previous financial year, 2020). This was primarily due to total comprehensive income exceeding the impact on equity of share and convertible bond related transactions during the period.

The ratios of Cash and cash equivalents, Interest-bearing debt and Equity attributable to owners of the parent company to total assets were 56.0%, 32.7% and 60.4%, respectively.

2) Cash flows

Cash and cash equivalents as at September 30, 2021 increased by JPY 9,833 million from the beginning of the year and amounted to JPY 49,841 million.

Cash flows from operating activities

Net cash used in operating activities during the period under review totaled JPY 2,888 million. This was primarily due to operating expenses exceeding revenues.

Cash flows from investing activities

Net cash provided by investing activities during the period under review totaled JPY 379 million. This was primarily due to (i) the receipt of contingent consideration income totaling JPY 273 million, and (ii) the sale of the Group's investment in an associated undertaking for JPY 206 million.

Cash flows from financing activities

Net cash provided by financing activities for the period under review totaled JPY 11,191 million. This was primarily due to the issuance of new convertible bonds raising JPY 29,877 million less outflows relating to the repurchase and cancellation of existing convertible bonds totaling JPY 18,958 million.

Effects of exchange rate changes on cash and cash equivalents

Effects of exchange rate changes on cash and cash equivalents for the period under review totaled JPY 1,151 million. This increase in cash and cash equivalents was primarily due to a stronger GBP vs. JPY.

(3) Earnings Forecast

We continue to focus on expanding our drug discovery business and remain well positioned to capitalize on growth opportunities. Our SBDD platform and highly productive drug discovery engine has generated multiple new exciting drug candidates, and we will continue to take steps to increase partnered and co-investment activity to ensure all programs are rapidly advanced in a capital efficient manner. At the same time, we will invest in new technologies, tools and capabilities to maintain our competitive edge and bring forward an exciting pipeline of next-generation programs in areas of high unmet medical need.

The Group expects 2021 to be a year of increased investment in R&D and in strategic growth initiatives, including seeking an acquisition of a revenue-generating business to support our medium-term plan for corporate expansion. The Group is making increased R&D investments this year in the preclinical and clinical advancement of its portfolio of lead muscarinic agonist compounds for schizophrenia and other neurological disorders, following their reversion to in-house programs from AbbVie in January 2021. The Group's current intention is to partner the portfolio of muscarinic agonist programs in the near term, which if successful, will have the impact of shifting the clinical trial costs and risks associated with these neurology programs to a well-capitalized global partner. The Group expects any partner to be able to accelerate late-stage development of these programs and support the Group's vision to bring these novel medicines to patients sooner. Furthermore, the Group is in advanced discussions with a leading global charitable foundation to secure grant funding to advance the SARS-CoV-2 Mpro inhibitor program – targeting rapid development of a single agent without the need for co-dosing with other anti-viral therapies.

In line with recent years, our strategy remains the same, and in our underlying drug discovery business we will continue to target a sustainable balance of resources and capital in the pursuit of growth in corporate value:

- Forecast cash R&D expenses in the underlying drug discovery business in the range of JPY 5,000 to JPY 5,750 million⁷ (increased from previously guided range of JPY 4,000 to 5,000).
 - The change to the guided range reflects increased investment in high-value in-house programs and the acceleration of development associated with the regained muscarinic agonist programs.
- Forecast cash G&A expenses in the underlying drug discovery business in the range of JPY 1,800 to JPY 2,300 million⁸ (unchanged).
- We expect to receive upfront payments related to new partnerships.
- We expect to receive milestone payments from existing drug discovery and development partnerships.
- We will continue to invest in technologies, tools and capabilities that complement and future-proof our drug discovery platform, as well as advance next-generation candidates; all while strongly managing our cost base.
- We will continue to explore a potentially transformative acquisition to secure long-term revenue growth.
- We will expand our drug candidate discovery and early development capabilities into new target classes.
- We will continue to explore late-stage clinical assets to in-license and develop for the Japanese market.

The Group has a strong cash runway into 2024 to fund its drug discovery and early-stage development activities.

⁷ The assumed FX rate of USD:JPY 106

⁸ The assumed FX rate of USD:JPY 106

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

1) Interim Condensed Consolidated Balance Sheet

	September 30, 2021 (Unaudited) ¥m	December 31, 2020 (Audited) ¥m
Assets		
Non-current assets		
Property, plant and equipment	3,752	3,824
Goodwill	14,785	14,134
Intangible assets	12,050	11,802
Investments accounted for using the equity method	3,433	3,087
Other financial assets	3,107	1,593
Other non-current assets	13	7
Total non-current assets	37,140	34,447
Current assets		
Trade and other receivables	1,046	939
Income taxes receivable	261	420
Other financial assets	84	-
Other current assets	584	651
Cash and cash equivalents	49,841	40,008
Total current assets	51,816	42,018
Total assets	88,956	76,465
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	1,411	2,457
Contingent consideration in business combinations	507	1,107
Corporate bonds	27,307	14,789
Lease liabilities	1,630	1,664
Other non-current liabilities	550	1,082
Total non-current liabilities	31,405	21,099
Current liabilities		
Trade and other payables	1,299	1,508
Contingent consideration in business combinations	437	-
Income taxes payable	124	29
Lease liabilities	190	170
Other current liabilities	1,728	1,278
Total current liabilities	3,778	2,985
Total liabilities	35,183	24,084
Equity		
Capital stock	41,036	40,220
Capital surplus	28,934	30,452
Treasury stock	(0)	(0)
Retained earnings	(12,610)	(10,785)
Other components of equity	(3,587)	(7,506)
Equity attributable to owners of the parent company	53,773	52,381
Total equity	53,773	52,381
Total liabilities and equity	88,956	76,465

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

	Nine month period ended September 30, 2021 (Unaudited) ¥m	Nine month period ended September 30, 2020 (Unaudited) ¥m
Revenue	3,590	4,443
Cost of sales	(638)	(531)
Gross profit	2,952	3,912
Research & development expenses	(4,332)	(2,696)
Selling, general & administrative expenses	(2,888)	(2,475)
Other income	118	45
Other expenses	(75)	(3)
Operating loss	(4,225)	(1,217)
Finance income	478	538
Finance costs	(727)	(495)
Share of gain (loss) of associates accounted for using the equity method	116	(304)
Gain on reversal of impairment loss for investments accounted for using the equity method	206	-
Loss before income taxes	(4,152)	(1,478)
Income tax benefit (expense)	2,327	(164)
Net loss for the period	(1,825)	(1,642)
Other comprehensive income:		
Items that will not be reclassified subsequently to profit or loss:		
Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	1,234	28
Total items that will not be reclassified subsequently to profit or loss	1,234	28
Items that may be reclassified subsequently to profit or loss:		
Exchange differences on translating foreign operations	2,685	(1,705)
Total items that may be reclassified subsequently to profit or loss	2,685	(1,705)
Total other comprehensive income (loss)	3,919	(1,677)
Total comprehensive income (loss) for the period	2,094	(3,319)
Net loss for the period attributable to:		
Owners of the parent company	(1,825)	(1,642)
Non-controlling interests	-	(0)
	(1,825)	(1,642)
Total comprehensive income (loss) for the period attributable to:		
Owners of the parent company	2,094	(3,319)
Non-controlling interests	-	(0)
	2,094	(3,319)
Earnings per share (yen)		
Basic loss per share	(22.50)	(21.03)
Diluted loss per share	(22.50)	(21.03)

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 company ¥m	Non- controlling interests ¥m	Total equity ¥m
Balance at January 1, 2021	40,220	30,452	(0)	(10,785)	(7,506)	52,381	-	52,381
Net loss	-	-	-	(1,825)	-	(1,825)	-	(1,825)
Other comprehensive income	-	-	-	-	3,919	3,919	-	3,919
Total comprehensive (loss) income for the period	-	-	-	(1,825)	3,919	2,094	-	2,094
Issuance of new shares	689	(88)	-	-	-	601	-	601
Share-based payments	-	532	-	-	-	532	-	532
Issuance of convertible bonds	-	1,809	-	-	-	1,809	-	1,809
Repurchase and cancellation of convertible bonds	-	(3,877)	-	-	-	(3,877)	-	(3,877)
Conversion of convertible bonds	127	106	-	-	-	233	-	233
Total transactions with owners	816	(1,518)	-	-	-	(702)	-	(702)
Balance at September 30, 2021 (Unaudited)	41,036	28,934	(0)	(12,610)	(3,587)	53,773	-	53,773
Balance at January 1, 2020	37,479	26,548	(0)	(12,264)	(6,688)	45,075	3	45,078
Net Loss	-	-	-	(1,642)	-	(1,642)	(0)	(1,642)
Other comprehensive loss	-	-	-	-	(1,677)	(1,677)	-	(1,677)
Total comprehensive loss for the period	-	-	-	(1,642)	(1,677)	(3,319)	(0)	(3,319)
Issuance of new shares	2,732	2,402	-	-	-	5,134	-	5,134
Share-based payments	-	499	-	-	-	499	-	499
Issuance of convertible bonds	-	841	-	-	-	841	-	841
Change on loss of control of subsidiary	-	-	-	-	-	-	(3)	(3)
Total transactions with owners	2,732	3,742	-	-	-	6,474	(3)	6,471
Balance at September 30, 2020 (Unaudited)	40,211	30,290	(0)	(13,906)	(8,365)	48,230	-	48,230

4) Interim Condensed Consolidated Statement of Cash Flows

	Nine month period ended September 30, 2021 (Unaudited) ¥m	Nine month period ended September 30, 2020 (Unaudited) ¥m
Cash flows from operating activities		
Loss before income taxes	(4,152)	(1,478)
Adjustments for:		
Depreciation and amortization	961	1,008
Share-based payments	532	456
Impairment loss	74	-
Gain on investments in securities	(3)	(291)
Loss on sale of investments in securities	-	73
Loss on investment in capital	-	75
Change in fair value of contingent consideration	(348)	(49)
Net foreign exchange (gain) loss	(131)	23
Interest income	(3)	(33)
Interest expenses	349	114
Share of (gain) loss of associates accounted for using the equity method	(116)	304
Gain on reversal of impairment loss for investments accounted for using the equity method	(206)	-
Decrease in trade and other receivables	244	601
Decrease in trade payables	(65)	(319)
(Decrease) increase in deferred revenues	(163)	532
Other	(62)	19
Subtotal	(3,089)	1,035
Grants received	-	2
Interest and dividends received	3	33
Interest paid	(130)	(7)
Income tax refunded	382	1,336
Income taxes paid	(54)	(167)
Net cash (used in) provided by operating activities	(2,888)	2,232
Cash flows from investing activities		
Purchase of property, plant and equipment	(97)	(54)
Purchase of intangible assets	(3)	(10)
Change in cash and cash equivalents on disposal of subsidiaries	-	(577)
Proceeds from sale of investment in associate	206	-
Proceeds from sales on investment securities	-	238
Distribution by limited partnership	-	295
Proceeds from contingent consideration receivable	273	-
Other	-	(1)
Net cash provided by (used in) investing activities	379	(109)
Cash flows from financing activities		
Repayments of lease liabilities	(138)	(168)
Proceeds from issuance of corporate bonds	29,877	15,902
Payments for repurchase and cancellation of corporate bonds	(18,958)	-
Payment for settlement of contingent consideration	(191)	(190)
Proceeds from issuance of common stock	601	5,134
Net cash provided by financing activities	11,191	20,678
Effects of exchange rate changes on cash and cash equivalents	1,151	(376)
Net increase in cash and cash equivalents	9,833	22,425
Cash and cash equivalents at the beginning of the period	40,008	15,375
Cash and cash equivalents at the end of the period	49,841	37,800

5) Notes of Interim Condensed Consolidated Financial Statements

5.1 *Notes related to going concern assumptions*

Not applicable.

5.2 *Change in accounting policy*

Not applicable.

5.3 *Changes in accounting estimates*

Not applicable.

5.4 *Operating segments*

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

5.5 *Significant subsequent events*

Not applicable.