Consolidated Financial Results for the Fiscal Year ended 31 March 2016 (IFRS)

13 May 2016

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

Date of general shareholders' meeting:	24 June 2016	Scheduled date of dividend payments:	-
Scheduled date of security report filing:	27 June 2016		
Supplementary materials for financial results:	Yes		
Financial results briefing session:	Yes (for institutional investors and analysts)		

(Rounded down to nearest million yen)

1. Consolidated results for the FY2015 (from 1 April 2015 to 31 March 2016)

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

	Revenue		Operating income		Net income before income taxes		Net income		Net income attributable to owners of the parent company		Total comprehensive income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2015	8,151	122.0	1,075	3.1	(3,297)	-	(1,547)	-	(1,432)	-	(4,400)	-
FY2014	3,671	77.4	1,043	38.0	1,301	76.4	510	(66.6)	516	(66.2)	210	(87.5)

	Net income per share – basic	Net income per share – diluted	Ratio of net income to equity attributable to owners of the parent company	Ratio of net income before income taxes to total assets	Ratio of operating income to revenue
	Yen	Yen	%	%	%
FY2015	(93.60)	(93.60)	(7.6)	(6.9)	13.2
FY2014	37.51	37.14	7.1	5.4	28.4

Note: Investment income under equity method: - million yen for FY2015; and - million yen for FY2014

Note: The consolidated financial statement for FY2014 has been retroactively adjusted due to provisional accounting treatment of the corporate acquisition in February 2015.

(2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of the parent company	Ratio of equity attributable to owners of the parent company to total assets	Equity per share attributable to owners of the parent company
	Million yen	Million yen	Million yen	%	Yen
FY2015	47,354	23,269	23,142	48.9	1,373.03
FY2014	47,833	14,842	14,600	30.5	1,060.00

(3) Consolidated cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at the end of year
	Million yen	Million yen	Million yen	Million yen
FY2015	4,471	(337)	863	10,068
FY2014	92	(22,018)	19,864	5,573

2. Dividends

	Dividends per share					Total amount of dividends	Dividend payout ratio (consolidated)	Ratio of dividend to equity attributable to owners of the parent company (consolidated)
	End Q1	End Q2	End Q3	Year end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
FY2014	—	0.00	—	10.00	10.00	137	24.2	0.9
FY2015	—	0.00	—	0.00	0.00	—	—	—
FY2016 (E)	—	0.00	—	0.00	0.00		—	

Note: Breakdown of FY2014 year-end dividends: commemorative dividend of JPY 10.00

3. Forecast for the FY2016 (from 1 April 2016 to 31 March 2017)

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

	Revenue		Operating income		Net income before income taxes		Net income attributable to owners of the parent company		Ratio of net income to equity attributable to owners of the parent company
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2016	27,925	242.6	17,096	-	14,901	-	13,064	-	775.07

* Notes

(1) Changes in the number of significant subsidiaries during the financial year (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 financial year end (including treasury shares)	FY2015	16,855,284 shares	FY2014	13,774,000 shares
2) Number of treasury shares at financial year end	FY2015	－ shares	FY2014	－ shares
3) Average number of shares issued during financial year	FY2015	15,302,675 shares	FY2014	13,760,098 shares

* Implementation status of financial audit

The audit procedures of the financial statements pursuant to the Financial Instruments and Exchange Law have not been completed.

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

1. The financial forecast is based on judgments and estimates that have been prepared on the basis of information available as at the time of disclosure of this material and assumptions about uncertain factors that could affect the forecasts of business results made as at the time of disclosure of this material. The actual business results may differ materially from the forecasts due to various factors in the future. For forecast premises and usage notes for earnings forecasts, please refer to “1. Analysis of Operating Results and Financial Position (1) Analysis of Operating Results (Earnings forecast for the FY2016).”

2. The Group will hold a web conference for analysts on 13 May 2016 (Friday). Following the event, we will publish a recording and materials used on the day on our website.

○ Contents of Attached Materials

1．Analysis of Operating Results and Financial Position

(1) Analysis of operating results

(Current term operating results)

The Group aims to become a global biotechnology company anchored in Japan with a focus on global research and development and licensing activities. In FY2015, the Group's UK subsidiary Heptares Therapeutics Ltd. ("Heptares") was very successful, signing collaborative pipeline deals with big pharma companies AstraZeneca UK Limited ("AstraZeneca") and Teva Pharmaceutical Industries Ltd. ("Teva"), as well as a strategic collaboration with Pfizer Inc. ("Pfizer") to develop new drugs.

Moreover, as sales of COPD therapies Seebri® (NVA237) and Ultibro® (QVA149) progressed well this fiscal year, royalty income exceeded that of the previous year and the Group recorded milestone revenue of 22.5 million dollars in connection with the regulatory approval of both therapies in the US, the world's largest pharmaceutical marketplace.

* *Ultibro® Breezhaler® (EU) / Ultibro® Inhalation Capsules (Japan) and Seebri® Breezhaler® 50mcg (EU) /Seebri® Inhalation Capsules 50 mcg (Japan) are the registered trademarks of Novartis.*

Consolidated operating results for the fiscal year under review are shown in the below chart.

Consolidated operating results

(JPY Millions)

	FY2014	FY2015	Change
Revenue	3,671	8,151	4,480
Gross profit	3,602	8,147	4,544
Operating income	1,043	1,075	32
Net income (loss)	510	(1,547)	(2,057)

(Note) The consolidated financial statement for FY2014 has been retroactively adjusted due to provisional accounting treatment of the corporate acquisition in February 2015.

(Revenue and gross profit)

Revenue for this financial year totaled 8,151 million yen, an increase of 4,480 million yen compared to the previous financial year. This was mainly due to milestones and increased royalty revenue from Seebri® (NVA237) and Ultibro® (QVA149), and receipt of upfront payments for out-licensing of Heptares pipeline.

(Operating income)

Operating income in this financial year totaled 1,075 million yen, an increase of 32 million yen compared to the previous year. This is due to increase in revenue and gross profit as described above, and increased R&D expenses and SG&A expenses in accordance with the revenue increase.

(Net income)

Net loss totaled 1,547 million yen, a net income decrease of 2,057 million yen compared to the previous year. This is mainly because while operating income increased and income tax expense was negative, there was a write-down due to changed fair value of the contingent consideration of the corporate acquisition, and interest expense on debt was generated.

Breakdown of research and development; selling, general and administrative expenses

(JPY Million)

	FY2014	FY2015	Change
Research and development expenses	557	3,916	3,359
Selling, general and administrative expenses	2,011	3,293	1,281
Personnel expenses	425	1,222	796
Outsourcing expenses	1,051	697	(353)
Other	534	1,373	838

(Note) The consolidated financial statement for FY2014 has been retroactively adjusted due to provisional accounting treatment of the corporate acquisition in February 2015.

(Research and development expenses; selling, general and administrative expenses)

R&D expenses during the current financial year increased 3,359 million yen from the previous financial year, and totaled 3,916 million yen. Also, SG&A expenses increased 1,281 million yen from the previous financial year, and totaled 3,293 million yen. This was mainly due to incurring increased expenditure for expanding Heptares' pipeline.

(Financial expenses)

This fiscal year, 4,377 million yen of financial expenses were recorded. This is mainly due to a write-down of 3,816 million yen from changed fair value of the contingent consideration of the corporate acquisition, and 438 million yen interest expense on debt.

(Matters related to corporate income tax expense)

This fiscal year income tax expense was negative 1,750 million yen due to recording Heptares' deferred tax assets.

The Group is composed of subsidiary units classified in domestic and overseas pharmaceutical business segments. Information by business segment is as follows.

(Domestic pharmaceutical business)

Revenue in the domestic pharmaceutical business segment amounted to 197 million yen. This is mainly due to increased royalties from NorLevo compared to the previous financial year. Operating income fell by 192 million yen, and the operating loss totaled 537 million yen.

Progress with the main products under development for the domestic pharmaceutical business is as follows.

<u>In-licensing</u>

■SO-1105 *Oropharyngeal Candidiasis: Phase III ongoing*

SO-1105 is an antifungal agent, administered as a muco-adhesive buccal tablet for the treatment of oropharyngeal candidiasis in immunocompromised patients. Oropharyngeal candidiasis is an inflammatory mucous membrane disease afflicting the oral cavity and pharynx. It is caused by infection due mainly to a fungus known as *Candida albicans*, and it is commonly found in patients suffering from chronic diseases such as diabetes and immunocompromised patients such as those suffering from HIV infection. This drug was originally developed by Onxeo (ex-BioAlliance Pharma of France), and it has been approved for marketing in 24 European countries, the U.S., and Korea since first obtaining approval in October 2006 in France. The Group believes that this product can also contribute to patient compliance in Japan and thus obtained the exclusive development and marketing rights for SO-1105 in Japan from Onxeo in May 2011.

Presently, Phase III clinical trials for efficacy and safety of this product are in progress.

The Group has already signed an exclusive domestic commercialization agreement with FUJIFILM Pharma Co., Ltd.

<u>Research and development based on platform technologies</u>

■Molecular Hiving™: A new method of liquid-phase peptide synthesis

Molecular Hiving™ is a new liquid-phase peptide synthesis technology. Conventional peptide synthesis technologies include

SPPS (solid-phase peptide synthesis) and liquid-phase peptide synthesis (LPPS) but in general, SPPS is expensive and produces a low volume; meanwhile LPPS is widely used for mass production but is unable of synthesizing long-chain peptides. Molecular Hiving™ is an innovative technology with advantages of both SPPS and LPPS, and can enable high-volume, low-cost synthesis. Unlike SPPS, Molecular Hiving™ enables monitoring of the peptide synthesis process, which leads to production of peptides of higher quality compared to those produced by conventional methods.

Pre-clinical trials are underway for two generic development candidates with Molecular Hiving™ applications: JIT-2001 (cardiovascular diseases) and JIT-1007 (orphan diseases).

■Peptune™: novel peptide modification technology

Peptune™ is a peptide modification new element technology; it improves effectiveness and safety by modifying the steric of the peptide, and is useful for improving the stability of drugs. Moreover, using this technology enables peptides and small molecule drugs to be synthesized, so it is expected that peptides with new features will be produced.

In addition, Peptune is expected to enable enhancement of the effectiveness and safety of lead peptides furnished by Heptares' technology.

■APNT (Activus Pure Nanoparticle Technology): *Nanoparticle technology*

APNT is technology differentiable from existing technology in that it enables pulverizing poorly soluble compounds to nano-sized crystal particles ranging from the 50-nm level to the 200-nm level while minimizing contamination. Making use of this feature, APNT demonstrates advantages in applications related to injections, ophthalmic solutions, and inhalations with poorly soluble compounds, which have been very difficult or impossible to achieve to date.

Pre-clinical trials are underway for two development candidates with APNT applications: APP13002 (infectious eye diseases) and APP13007 (inflammatory eye diseases).

(Overseas pharmaceutical business)

The revenue of the overseas pharmaceutical business segment totaled 7,954 million yen, an increase of 4,465 million yen compared to the previous year. The difference from the previous financial year was attributable to the milestones and increased royalties from Seebri® (NVA237) and Ultibro® (QVA149), and upfront payments from out-licensing Heptares' pipeline. In addition, operating income totaled 1,665 million yen, down 699 million yen compared to the previous year.

Progress made in the overseas pharmaceutical business is set out below.

Pipeline and Products

■ QVA149 COPD: Launched by Novartis in the EU, Japan, etc.

QVA149 (indacaterol maleate/glycopyrronium bromide); brand names: Ultibro® Breezhaler® (EU), Ultibro® Inhalation Capsules (Japan); "Ultibro") is a once-daily inhaled, fixed-dose combination of the LAMA (glycopyrronium bromide) and the LABA (indacaterol maleate), indicated as a maintenance bronchodilator treatment to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD). Ultibro is a once-daily LABA/LAMA approved as first-in-class in over 80 countries including EU, Japan, Canada, Mexico and Australia and launched in over 40 countries including Germany, Japan and Canada.

In the US, QVA149 was approved in October 2015 as a twice-daily inhaled, fixed-dose combination of indacaterol 27.5 mcg and glycopyrrolate 15.6 mcg, for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema, and under the brand name Utibron™ Neohaler®.

■ NVA237 COPD: Launched by Novartis in the EU, Japan, etc

NVA237 (glycopyrronium bromide; brand names: Seebri® Breezhaler® (EU), Seebri® Inhalation Capsules 50mcg (Japan); "Seebri"), is a LAMA indicated as a maintenance bronchodilator treatment to relieve symptoms in patients with COPD that was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. Seebri has been approved in over 90 countries across Europe, Japan, Canada, Latin America, Asia, Australia and the Middle East.

In the US, NVA237 was approved in October 2015 as a twice-daily inhaled monotherapy for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema, under the brand name Seebri™ Neohaler® (glycopyrrolate 15.6 mcg).

Under the terms of agreement with Novartis, the approval of both products in the US had triggered a milestone payment to Sosei

of USD 22.5 million. In addition, Sosei is entitled to receive royalties on global net sales of both products. Royalties are recognized following the quarter in which the products are sold. On 27 January 2016, Novartis announced that sales of Ultibro and Seebri for 2015 (January – December 2015) were USD 260 million and USD 150 million respectively.

<For reference>
Sales of Ultibro® and Seebri®, announced at Novartis' Q1 2016 results briefing (January – March 2016) on 21 April 2016.

	January to March		Change vs previous year (%)
	2016	2015	
	USD million	USD million	
Ultibro® Breezhaler®	78	52	50
Seebri® Breezhaler®	35	37	(5)

** Seebri®, Ultibro®, Breezhaler® and Neohaler® are registered trademarks of Novartis AG.*
Seebri™ and Utibron™ are trademarks of Novartis AG.

■ QVM149 Asthma

In December 2015 Novartis announced the first Phase III trial of QVM149, a new inhaled triple therapy for asthma.

QVM149 is a fixed dose, once daily combination of the LAMA glycopyrronium bromide, the LABA indacaterol, and the inhaled corticosteroid (ICS) mometasone fuorate.

Enrolment of the first patients into the trial programme has triggered the receipt of a milestone payment to Sosei of USD 3.75 million under the terms of the Licence Agreement. First regulatory filings of QVM149 are planned for 2018.

Drug discovery through platform technology

■ StaR® (Stabilised Receptor) technology: Drug discovery platform technology

Heptares StaR® technology is the first in the world that is able to produce GPCRs with improved thermostability (StaR® proteins). GPCRs (G protein-coupled receptors) are proteins found embedded in the cell membrane. They act as a bridge between the interior and exterior environment of the cell. As such, they can transfer information in the form of biochemical signals, and play a role in many physiological and biological processes, including taste, vision, smell, autonomic nervous system function, behaviour, immunity etc. GPCRs are, therefore, the most important target molecules in medicine. However, when removed from the cell membrane, the molecular structure grows unstable and unclear, thus it has been difficult to perform structure-based discovery research. StaR® technology advances structural analysis of GPCRs and enables powerful and highly selective drug discovery based on molecular structure design that, to date, has been very difficult or impossible to do with confidence.

Heptares has a broad and well-stocked pipeline targeting neurological, immuno-oncology, metabolic and rare disease areas. In research and development, Heptares is advancing multiple pipeline products. The company is also actively engaged in partnerships harnessing its platform technology, and licensing of its in-house pipeline.

Progress in this consolidated cumulative period is as follows:

- **Initiation of therapeutic antibody program with MorphoSys**

In July last year, Heptares exercised an option to initiate a therapeutic antibody program arising from the alliance it entered with German company MorphoSys AG in February 2013. This means that the Heptares pipeline, hitherto focused on low-molecular-weight compounds, is expected to expand to include antibodies. Moreover, through these alliances, Heptares will continue to explore the possibility of wide-ranging applications of StaR® technology to antibody therapeutics, not just low-molecular-weight compounds.

- **Adenosine A2A receptor antagonist with AstraZeneca**

In terms of licensing its own pipeline, in August last year, Heptares entered into a licensing agreement with the global pharmaceutical company AstraZeneca to develop immuno-oncology treatments for cancer. AstraZeneca acquired exclusive

global rights to develop, manufacture and commercialise the adenosine A2A receptor antagonist, HTL-1071, a small molecule immuno-oncology candidate, and potential additional A2A receptor-blocking compounds. AstraZeneca is exploring HTL-1071 and additional compounds across a range of cancers, including in combination with its existing portfolio of immunotherapies. The companies will also collaborate to discover further A2A receptor-blocking compounds for development in cancer immunotherapy. Under the terms of the agreement, Heptares has received an upfront payment of $10 million and is eligible to receive additional, significant near term milestone payments based on agreed pre-clinical and/or clinical events. Subject to successful completion of development and commercialisation milestones, Heptares is also eligible to receive more than $500 million, as well as up to double-digit tiered royalties on net sales.

- **Grant to develop Orexin-1 receptor antagonists**

In September last year, Heptares was awarded a research and development grant of 5.5 million dollars from the National Institute on Drug Abuse (NIDA), one of the US National Institutes of Health, for its Orexin-1 receptor antagonist research project. The company will use the grant over the next three years for part of the operating costs of the project to adapt selective antagonists of the Orexin-1 receptor to treat cocaine abuse and addiction.

- **Agreement to Discover and Develop Novel Small Molecule CGRP Antagonists for Treatment of Migraine with Teva**

In November 2015, Heptares and Teva Pharmaceutical Industries Ltd entered into a licensing and drug-discovery agreement under which Teva received exclusive global rights to develop, manufacture and commercialize novel, small molecule calcitonin gene-related peptide (CGRP) antagonists discovered by Heptares for the treatment of migraine.

Under the terms of the agreement, Heptares has received an upfront payment of $10 million and research funding, and is eligible to receive additional research, development and commercialization milestone payments of up to $400 million. In addition, Heptares will be eligible to receive royalties on net sales of products resulting from the alliance.

- **Strategic Drug Discovery Collaboration with Pfizer**

In November 2015, Heptares entered into a strategic drug discovery collaboration with Pfizer Inc. to research and develop potential new medicines directed at up to 10 GPCR targets across multiple therapeutic areas. Heptares will use its proprietary GPCR structure-guided platform to help deliver StaR® proteins, high-resolution crystal structures and other technologies to support the discovery of potential novel agents directed to the GPCR targets selected by Pfizer. Pfizer will be responsible for developing and commercializing any potential therapeutic agents (small molecules or biologics derived from StaR antigens) for each target and will have exclusive global rights to any potential resulting agents. Heptares is eligible to receive potential research, development, regulatory and commercial milestone payments of up to USD 189 million per target. In addition, Heptares is eligible to receive potential tiered royalties on the net sales of any products that are commercialized by Pfizer.

In addition, Sosei and Pfizer Seiyaku KK (“Pfizer KK”) have entered into an equity agreement under which Sosei allocates 471,284 Sosei common stock to Pfizer KK.

(Significant subsequent events)

- **Agreement with Allergan to develop and commercialize novel therapeutic drugs for Alzheimer’s and other neurological diseases**

In April 2016, Heptares and Allergan entered an agreement to develop and commercialize novel subtype-selective muscarinic receptor agonists for the treatment of major neurological diseases including Alzheimer’s disease. Allergan will receive exclusive rights to develop and commercialize Heptares’ broad clinical and preclinical portfolio of M1, M4 and dual M1/M4 agonists, including HTL9936 and HTL18318, selective M1 agonists currently in Phase 1 clinical development. Heptares will receive USD 125 million upfront and is eligible for milestone payments of up to approximately USD 665 million associated with the successful Phase 1, 2 and 3 clinical development and launch of the first three licensed compounds for multiple indications and up to approximately USD 2.5 billion associated with achieving certain annual sales thresholds during the several years following launch. In addition, Heptares is eligible to receive up to double-digit tiered royalties on net sales of all products resulting from the partnership. Allergan is also committing up to USD50 million to a research and development program to be conducted jointly by Allergan and Heptares aimed at advancing multiple candidates through Phase 2 clinical studies. Allergan will be responsible for the development of licensed compounds upon initiation of Phase 2b studies and for subsequent manufacturing and commercialization of the products.

(Earnings forecast for the FY2016)

Revenue is forecasted to come from milestones from out-licensing Heptares’ pipeline, royalties from Seebri® and Ultibro®, and milestone revenue from the US approval of NVA237 and QVA149. As a result, our earnings forecast for the full term are 27,925 million yen for revenue, 17,096 million yen for operating income, 14,901 million yen for net income before taxes, and 13,064

million yen for net income attributable to the owners of the parent company.

(2) Analysis of financial position

The financial position as of the end of the current financial year was as follows.

Financial position

(JPY millions)

	FY2014	FY2015	Change
Total assets	47,833	47,354	(479)
Cash flows from operating activities	92	4,471	4,378
Cash flows from investing activities	(22,018)	(337)	21,680
Cash flows from financing activities	19,864	863	(19,000)

(Note) The consolidated financial statement for FY2014 has been retroactively adjusted due to provisional accounting treatment of the corporate acquisition in February 2015.

(Assets)

Assets totaled 47,354 million yen at the end of the financial year, a decrease of 479 million yen from the previous year. This is mainly because, while cash and cash equivalents increased compared to the previous fiscal year, trade and other receivables decreased and valuation of goodwill and intangible assets decreased due to fluctuations in exchange rates.

(Matters related to contingent consideration due to corporate consolidation)

In accordance with the amount Heptares, a subsidiary consolidated in February 2015, is expected to receive in milestone and royalty income, the Group recognized the contingent consideration of the estimated value of additional payment for share acquisition of 9,994 million yen as a non-current liability. This has been calculated taking into consideration the current value of the contingent consideration related to the maximum USD 220 million for the Heptares share acquisition announced in February 2015.

(Cash flows from operating activities)

Although net loss before taxes was 3,297 million yen, due to increase of fair value connected with the contingent consideration, and decrease in operating receivables and other factors, cash flows from operating activities increased by 4,378 million yen compared to last year, and totaled 4,471 million yen.

(Cash flows from investing activities)

Cash outflow as 337 million yen from investing activities this fiscal year due to acquisition of tangible fixed assets and spending related to R&D.

(Cash flows from financing activities)

Cash inflow from financing activities totaled 863 million yen. While funds borrowed from Mizuho Bank were repaid, there was inflow from issuing common stock.

(3) Basic policy on distribution of profits and dividends for current and next financial years

The pharmaceutical development conducted by the Group requires large amounts of up-front investment over long development periods. However, the Group believes that the active replenishment of its pipeline (developmental products) is important to realize preservation of stable revenue and project growth. The Group has acquired stable revenue through Seebri® and Ultibro®. It is in a position to comprehensively determine the balance between strategic investments for future operating results, financial position and business growth, and profit distribution for shareholders.

2. Status of the Corporate Group

The Group is composed of the Group and six consolidated subsidiaries, and its principal business is research and development, and selling of pharmaceutical products. Business segments are categorized primarily on the basis of geographical location (namely, domestic pharmaceutical business and overseas pharmaceutical business).

Business segment	Company name	Nature of business
Company-wide business activities	Sosei Group Corporation	Planning of management strategy for entire Group and undertaking administrative duties on behalf of its subsidiaries
Domestic pharmaceutical business	Sosei Co., Ltd.	Pharmaceutical R&D and sales
	Activus Pharma Co., Ltd.	Development of pharmaceuticals based on the nanoparticle technology
	Sosei CVC Ltd.	Management of regenerative medicine fund
	Jitsubo Ltd.	Development of peptide drugs, licensing peptide manufacturing technology, peptide drug discovery research
Overseas pharmaceutical business	Sosei R&D Ltd.	Overseas development and commercialization through licensing, overseas business development etc.
	Heptares Therapeutics Ltd.	Producing structural analysis and early lead compounds of GPCRs, seeking drug candidates using proprietary StaR® technology etc.

3. Management Policy

(1) Basic corporate management policy

As a biopharmaceutical company, the Group is actively focusing on continuing enhancement of its product pipeline, by utilizing the global network established through the technology transfer that preceded its bio business and its unique development strategy. Through the early provision of vital pharmaceutical products to the world, the Group aims to develop ever further as a global biopharmaceutical company that transcends national and regional boundaries, supporting people's health and helping them to live happy and rewarding lives.

(2) Target management indicators

The Group aims to achieve sustainable growth by actively undertaking R&D of pharmaceutical products and securing earnings by bringing the products it develops directly to the market or by licensing them out. The Group conducts its business activities with the goal of expediting R&D in ways that improve the pipeline still further, thereby being quick to bring to market, sell, or out-license a large number of developed products.

(3) Mid- to long-term management strategy

The development of pharmaceutical products is a sphere characterized by fierce competition between numerous domestic and overseas companies, research institutions, and other entities, including major international corporations. Development requires massive investment and long lead times, and the likelihood of success is not high. Given this, and given the Group's relatively small scale in terms of factors such as human resources, finance, and plant and equipment, we adhere to the following strategy for developing pharmaceutical products.

1) Positioning

By using the network and experience it has gained through its activities involving technology transfers throughout its history, the Group evaluates the situation in the pharmaceutical industry in Japan from a global perspective and introduces pharmaceutical products from Europe and North America into the Japanese market, at the same time seizing even greater business opportunities overseas on the basis of seeds it has an access to both in Japan and internationally.

The Group also pursues the development of its unique business model as a biopharmaceutical company that has the capacity to mitigate risk in its pharmaceutical development. In addition, while adhering firmly to our founding vision of aiming to become "a global biopharmaceutical company anchored in Japan," we are quick to address changes in the environment and adopt the most appropriate strategies on a case-by-case basis.

2) Pipeline strategy

The distinguishing characteristic of the Group's pipeline strategy is the building of a balanced portfolio in which risks are controlled by combining developmental products with different risks, lead times, and costs.

3) Collaboration in R&D

We aim to incorporate state-of-the-art technologies by building wide-ranging collaborative relationships at each stage of research and development, thereby avoiding increases in fixed costs. The Group builds its R&D structure by combining its own R&D personnel with the aforesaid collaborative relationships.

4) Securing of earnings

The Group aims to secure earnings by employing the following three models, doing so through the previously mentioned pipeline strategy that gives emphasis on the risk control and building of wide-ranging collaborative relationships.

(a) Model entailing securing earnings by identifying products already launched in overseas markets or in late-stage development, and developing them in-house primarily for the domestic market until they start generating revenue.
(b) Model based on securing earnings from milestone and royalty income from out-licensed products. This entails the Group targeting the global market by developing products up to a stage at which their marketability is enhanced, following which they are out-licensed to other pharmaceutical companies.
(c) Model based on securing earnings through future development, filing/approval, and commercialization milestones and royalties from products related to our R&D pipeline via joint research and development agreements based on our platform technology.

For each developmental product the Group takes into consideration factors such as the financial condition, R&D structure, and competitive advantage of the product in order to plan whether to select model (a), (b), or (c) and thereby secure a stable and timely earnings stream.

(4) Issues to be addressed

1) Realization of growth through early development of innovative drugs

The patents for the COPD therapies—the pillar of the Group's revenue—will expire in 2026. Therefore, in order to maintain growth and stable revenue in the future, it is important to continue making upfront investment in promoting late-stage development of innovative, large-scale products that fill unmet medical needs. The pipelines of Jitsubo and Heptares, acquired last financial year, contain possible first-in-class products with innovative mechanisms of action. In order to ensure early results through the expansion of these pipelines, we will continue working to use management resources efficiently and conduct licensing activities.

2) Diversification and stabilization of funding

Corporate value can be enhanced by seeking out and introducing products that are promising candidates for development and then expediting their development to later stages, but this increases R&D costs. We will continue to consider the possibility of diversifying and stabilizing funding according to needs in order to strengthen the foundations of our business, including through investment in research and development.

3) Creation of shareholder value

The group believes that investing proactively in promising R&D candidates, and making strategic investment in corporate acquisitions to strengthen the foundation of management, will increase corporate value and lead to creation of shareholder value. In the future, the Group intends to proceed with investigating investments, timing, and methods while taking the financial situation into account. Furthermore, the Group currently considers it important to prioritize internal reserves for upfront investments, and will endeavor to deliver a return to shareholders while taking into account the income position.

4) Strengthening corporate governance

Through the corporate acquisitions conducted last financial year, domestic and foreign subsidiaries each increased by one company, and the Group has evolved into a more global corporate entity. Therefore, the Group recognizes the creation of a more advanced and efficient governance system as one of the management issues. We are working to improve corporate governance to increase integrity and transparency without impairing management efficiency, and gain deeper trust from stakeholders.

4. Basic policy for the selection of accounting standards

The Group has applied International Financial Reporting Standards since the year ended March 2014 in order to enable easier comparison of financial information in capital markets.

5. Consolidated Financial Statements (IFRS)

(1) Consolidated statement of financial position

(JPY millions)

	Cumulative FY2015 (31 March 2016)	Cumulative FY2014 (31 March 2015)
Assets		
Non-current assets		
Property, plant and equipment	270	266
Goodwill	15,426	16,428
Intangible assets	19,313	21,712
Deferred tax assets	1,658	364
Other non-current assets	49	43
Total non-current assets	36,718	38,814
Current assets		
Trade and other receivables	97	2,481
Accrued corporate income tax	-	579
Other current assets	469	385
Cash and cash equivalents	10,068	5,573
Total current assets	10,635	9,019
Total assets	47,354	47,833
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred income	21	29
Deferred tax liabilities	3,688	4,455
Contingent consideration related to corporate acquisition	9,994	7,024
Interest-bearing liabilities	6,847	-
Other non-current liabilities	74	13
Total non-current liabilities	20,626	11,522
Current liabilities		
Trade and other payables	1,335	1,358
Deferred income	20	135
Income tax payables	70	34
Interest-bearing liabilities	1,990	19,877
Other current liabilities	42	63
Total current liabilities	3,458	21,468
Total liabilities	24,084	32,991
Equity		
Capital stock	25,955	19,478
Capital surplus	14,263	7,774
Retained earnings	(14,184)	(12,614)
Other components of equity	(2,891)	(38)
Equity attributable to owners of the parent company	23,142	14,600
Non-controlling interests	126	241
Total equity	23,269	14,842
Total liabilities and equity	47,354	47,833

(2) Consolidated statement of comprehensive income

(JPY millions)

	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)
Revenue	8,151	3,671
Cost of sales	4	68
Gross profit	8,147	3,602
Research and development expenses	3,916	557
Selling, general and administrative expenses	3,293	2,011
Other income	149	12
Other expenses	11	2
Operating income	1,075	1,043
Finance income	4	405
Finance costs	4,377	147
Net income before income taxes	(3,297)	1,301
Income tax expenses	(1,750)	791
Net income	(1,547)	510
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translating foreign operations	(2,853)	(299)
Total items that may be reclassified subsequently to profit or loss	(2,853)	(299)
Total other comprehensive income	(2,853)	(299)
Comprehensive income	(4,400)	210
Net income for the year attributable to:		
Owners of the parent company	(1,432)	516
Non-controlling interests	(114)	(5)
Net income	(1,547)	510
Comprehensive income for the year attributable to:		
Owners of the parent company	(4,285)	216
Non-controlling interests	(114)	(5)
Comprehensive income	(4,400)	210
Net income per share (yen)		
Basic	(93.60)	37.51
Diluted	(93.60)	37.14

(3) Consolidated statement of changes in equity

(JPY millions)

	Capital	Capital surplus			Retained earnings
		Capital reserve	Other capital surplus	Capital surplus total	
Balance as of 1 April 2014	19,453	21,573	(26,934)	261	14,354
Net income	-	-	516	-	516
Foreign currency translation adjustments	-	-	-	(299)	(299)
Total comprehensive income for the year	-	-	516	(299)	216
Issuance of new shares	24	4	-	-	29
Deficit compensation	-	(13,803)	13,803	-	-
Variation due to corporate acquisition	-	-	(0)	-	(0)
Total business transactions with owners	24	(13,799)	13,803	-	29
Balance as of 31 March 2015	19,478	7,774	(12,614)	(38)	14,600
Net income	-	-	(1,432)	-	(1,432)
Foreign currency translation adjustments	-	-	-	(2,853)	(2,853)
Total comprehensive income for the year	-	-	(1,432)	(2,853)	(4,285)
Surplus dividend	-	-	(137)	-	(137)
Issuance of new shares	6,477	6,350	-	-	12,828
Stock-based compensation expense	-	137	-	-	137
Total business transactions with owners	6,477	6,488	(137)	-	12,828
Balance as of 31 March 2016	25,955	14,263	(14,184)	(2,891)	23,142

	Non-controlling interests	Total equity
Balance as of 1 April 2014	-	14,354
Net income	(5)	510
Foreign currency translation adjustments	-	(299)
Total comprehensive income	(5)	210
Issuance of new shares	-	29
Deficit compensation	-	-
Variation due to corporate acquisition	247	247
Total business transactions with owners	247	276
Balance as of 31 March 2015	241	14,842
Net income	(114)	(1,547)
Foreign currency translation adjustments	-	(2,853)
Total comprehensive income	(114)	(4,400)
Dividends from surplus	-	(137)
Issuance of new shares	-	12,828
Stock-based compensation expense	-	137
Total business transactions with owners	-	12,828
Balance as of 31 March 2016	126	23,269

(4) Consolidated statement of cash flow

(JPY millions)

	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)
Cash flows from operating activities		
Net income before income taxes	(3,297)	1,301
Stock-based compensation expense	137	-
Depreciation and amortization	926	98
Subsidy income	(145)	(11)
Interest expense	438	60
Foreign exchange losses (gains)	219	90
Changes in fair value related to the contingent consideration	3,816	86
Decrease (increase) in accounts receivable	(102)	46
Decrease (increase) in accounts receivable – trade	2,414	(2,360)
Increase (decrease) in accounts payable – trade	162	900
Other	(307)	(139)
Subtotal	4,261	72
Interest and dividends received	4	9
Payments of interest	(311)	(0)
Proceeds from subsidy	77	33
Income tax refunded	493	-
Income tax paid	(53)	(22)
Cash flows from operating activities	4,471	92
Cash flows from investing activities		
Purchases of property, plant and equipment	(130)	(88)
Capitalized development costs	(199)	(250)
Payments for acquisition of control over subsidiaries	-	(21,676)
Other	(7)	(1)
Net cash used in investing activities	(337)	(22,018)
Cash flows from financing activities		
Net increase from short-term interest-bearing debt	(21,000)	19,850
Proceeds from borrowing long-term interest-bearing debt	9,800	-
Repayment of long-term interest-bearing debt	-	(15)
Settlement of contingent consideration	(686)	-
Proceeds from issuance of common stock	12,884	29
Dividend payments	(135)	-
Net cash from financing activities	863	19,864
Effect of exchange rate changes on cash and cash equivalents	(501)	419
Increase (decrease) in cash and cash equivalents	4,495	(1,641)
Cash and cash equivalents at the beginning of year	5,573	7,214
Cash and cash equivalents at the end of year	10,068	5,573

(5) Notes on Consolidated Financial Statements

(Notes related to going concern assumptions)

Not applicable.

(Change in accounting policy)

The significant accounting policies the Group will apply to consolidated financial statements are identical to the accounting policies applied to consolidated financial statements in the previous financial year.

(Segment information)

(1) Overview of reportable segments

The Group's reportable segments are components of business activities for which discrete financial information is available, and such information is regularly reviewed by the Group's board of directors in order to make decisions about the allocation of the resources and assess performance. The Group has adopted the holding company structure, and the holding company is responsible for management and administration of the entire Group. The Group has two reportable segments (namely, domestic pharmaceutical business and overseas pharmaceutical business), based on the legal entities that are the current profit management units. The domestic pharmaceutical business segment mainly imports products from overseas for sale both in Japan and overseas. The overseas pharmaceutical business segment mainly introduces and develops pharmaceuticals for out-licensing.

The following table shows major products in the major segments, with reportable segments established as described above.

Reportable segments	Company name	Main products
Domestic pharmaceutical business	・Sosei Co., Ltd. ・Activus Pharma Co., Ltd. ・Jitsubo Ltd.	・SO-1105 ・APP13002 ・APP13007 ・JIT-2001 ・JIT-1007
Overseas pharmaceutical business	・Sosei R&D Ltd. ・Heptares Therapeutics Ltd.	・Seebri® ・Ultibro® ・Muscarinic M_1, M_4, and dual M_1 / M_4 receptor agonists ・CGRP antagonists ・Adenosine A_{2A} antagonist

(2) Revenue, profit and loss and other financial information of reportable segments

Revenue, profit and loss and other financial information for each reportable segment are as shown below. The accounting policies the Group will apply to each segment are identical to the accounting policies applied to consolidated financial statements in the previous financial year.

FY2014 (1 April 2014 to 31 March 2015)

(JPY millions)

	Reportable segments			Adjustments	Consolidated
	Domestic pharmaceuticals	Overseas pharmaceuticals	Total		
Revenue from third parties	181	3,489	3,671	—	3,671
Revenue between segments	—	—	—	—	—
Total	181	3,489	3,671	—	3,671
Operating income or loss	(344)	2,364	2,019	(976)	1,043
Finance income/costs (net)					257
Net income before income taxes					1,301
Other items					
Depreciation and amortization	21	72	93	5	98

The adjustment amount relates to the holding company, which does not belong to any reportable segment.

FY2015 (1 April 2015 to 31 March 2016)

(JPY millions)

	Reportable segments			Adjustments	Consolidated
	Domestic pharmaceuticals	Overseas pharmaceuticals	Total		
Revenue from third parties	197	7,954	8,151	—	8,151
Revenue between segments	0	—	0	(0)	—
Total	197	7,954	8,152	(0)	8,151
Operating income or loss	(537)	1,665	1,128	(52)	1075
Finance income/costs (net)					(4,373)
Net income before income taxes					(3,297)
Other items					
Depreciation and amortization	36	886	923	2	926

The adjustment amount relates to the holding company, which does not belong to any reportable segment.

(3) Information regarding products and services

Information regarding the revenue for each product/service is not separately presented because the same is presented in the reporting segments above.

(4) Geographical information

The following table provides geographical information relating to external revenue and non-current assets.

External revenue

(JPY millions)

	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)
Japan	197	106
Switzerland	5,096	3,466
UK	1,319	11
Israel	1,267	―
Other	271	86
Total	8,151	3,671

Revenue is classified by country or region based on the locations of customers.

Non-current assets

(JPY millions)

	FY2015 (31 March 2016)	FY2014 (31 March 2015)
Japan	1,960	1,736
United Kingdom	33,099	36,713
Total	35,059	38,450

Non-current assets do not include financial products and deferred tax assets.

(5) Information on major customers

Revenues

(JPY thousand)

Name of customer	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)	Relevant segment
Novartis Pharma AG	5,096	3,466	Overseas pharmaceutical business
AstraZeneca	1,319	11	Overseas pharmaceutical business
Teva	1,267	―	Overseas pharmaceutical business

(Earnings per share)

(1) Basic net income per share

The following table shows basic net income per share and basis for calculation thereof.

	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)
Net income for the year attributable to owners of the parent company [JPY millions]	(1,432)	510
Weighted average number of common shares outstanding (shares)	15,302,675	13,760,098
Basic net income per share [JPY]	(93.60)	37.51

(2) Diluted net income per share

The following table shows diluted net income per share and basis for calculation thereof.

This financial year, there is no dilutive effect from latent shares as part conversion of stock options reduced net loss per share.

	FY2015 (1 April 2015 - 31 March 2016)	FY2014 (1 April 2014 - 31 March 2015)
Net income for the year attributable to owners of the parent company [JPY millions]	(1,432)	516
Adjusted net income used in the calculation of diluted net income per share [JPY millions]	—	—
Net income used in the calculation of diluted net income per share [JPY millions]	(1,432)	516
Weighted average number of common shares outstanding [shares]	15,302,675	13,760,098
Increases in number of common shares used in the calculation of diluted net income per share [shares]		
Increases due to the exercise of stock options [shares]	-	138,040
Weighted average number of common shares outstanding used in the calculation of diluted net income per share [shares]	15,302,675	13,898,138
Diluted net income per share [JPY]	(93.60)	37.14

(Significant subsequent events)

On 7 April 2016, the Group's subsidiary Heptares and global big pharma Allergan plc's wholly owned subsidiary Allergan Pharmaceuticals International Limited entered an agreement to develop and commercialize novel subtype-selective muscarinic receptor agonists for the treatment of major neurological diseases including Alzheimer's disease.

Under the terms of the agreement, Heptares will receive USD 125 million (around 14,086 million yen) upfront and is eligible for milestone payments of up to approximately USD 665 million (around 74,938 million yen) ~~million~~ associated with the successful Phase 1, 2 and 3 clinical development and launch of the first three licensed compounds for multiple indications and up to approximately USD 2.5 billion (around 281,725 million yen) associated with achieving certain annual sales thresholds during the several years following launch. In addition, Heptares is eligible to receive up to double-digit tiered royalties on net sales of all products resulting from the partnership. Allergan is also committing up to USD50 million (around 5,634 million yen) ~~million~~ to a research and development program to be conducted jointly by Allergan and Heptares aimed at advancing multiple candidates through Phase 2 clinical studies. Allergan will be responsible for the development of licensed compounds upon initiation of Phase 2b studies and for subsequent manufacturing and commercialization of the products.

(Other notes)

(Corporate merger)

1) Heptares Therapeutics Ltc.

a) Impact of retroactive adjustment

The acquisition consideration for Heptares, which was acquired in February 2015, was allocated to acquired assets and assumed liabilities based on fair value on the day the Group acquired control. Allocation of acquisition consideration was completed in the fourth quarter of the fiscal year 2015. Consequently, the fair value of assets and liabilities on the date of the Heptares acquisition has been adjusted. This adjustment is applied retroactively to the date of the acquisition.

The impact on the consolidated balance sheet of the previous fiscal year is 20,493 million yen of intangible fixed assets, -16,394 million yen of goodwill, and deferred tax liabilities of 4,085 million yen.

The impact on the consolidated income statement for the previous fiscal year is -65 million yen of income before income taxes, -65 million yen of net income, and -52 million yen attributable to owners of the Group.