Consolidated Financial Results for the Third Period FY2017 (IFRS)

14 February 2018

Company name:	Sosei Group Corporation		Listing: Tokyo Stock Exchange
Security code:	4565	URL: http://www.sosei.com/	
Representative:	Peter Bains Representative Executive Officer, CEO		
Contact person:	Harumi Banse Corporate Communication, Manager		Tel: +81-3-5210-3290

Scheduled date of security report filing	14 February 2018	Scheduled date of dividend payments:	–
Supplementary materials for financial results:	No		
Financial results briefing session:	No		

(Rounded down to nearest million yen)

1. Consolidated results for the nine-month ended December 31, 2017 (from April 1, 2017 to December 31, 2017)

(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	%
Nine-month period ended December 31, 2017	6,277	(63.3)	(94)	–	(1,899)	–	(1,713)	–	(1,713)	–	692	88.9
Nine-month period ended December 31, 2016	17,118	121.1	12,633	346.6	13,281	522.4	10,048	380.6	10,206	370.9	6,241	186.4

	Earnings per share – basic	Earnings per share – diluted
	Yen	Yen
Nine-month period ended December 31, 2017	(99.49)	(99.49)
Nine-month period ended December 31, 2016	604.44	602.12

(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 December 31, 2017	73,949	50,653	50,649	68.5
At March 31, 2017	48,087	28,359	28,354	59.0

2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen	Yen	Yen	Yen	Yen
FY2016	–	–	–	–	–
FY2017	–	–	–		
FY2017 (E)				–	–

3. Forecast for the FY2017 (from 1 April 2017 to 31 March 2018)

The Group's current revenues are increasingly dependent on milestone payments received from our collaboration agreements. With these programs, the development strategies and schedules are determined by our partners and, accordingly, it is difficult for us to forecast if and when milestones will be earned and there can also be wide differences in revenues between financial years. The Allergan agreement that was signed in April 2016 was exceptional in terms of the size of the upfront milestone that we received and as a result we anticipate a significant decline in revenues in the current financial year.

In the short to medium term, we expect to see an increase in R&D investment, consistent with our strategy to leverage our StaR® technology to generate a proprietary pipeline of high value drug candidates (we are targeting six wholly-owned compounds to enter into Phase 1 studies over the next two years). We will strategically evolve our business model to include a greater emphasis on developing and commercializing or co-promoting our own products in selected indications (e.g. rare/orphan and specialty) and markets (U.S., U.K., Japan). In the short term, we will continue to earn development based milestones from our existing partnerships, as well as from a growing royalty stream from our legacy respiratory disease products. Over the medium to long term, our risk-balanced capital allocation framework is expected to deliver a combination of sales revenues from our own commercialized and/or co-promoted products, plus royalties and upfront, development and sales milestones from our partnered programs.

Given that FY2016 included the substantial $125m upfront payment from Allergan, we will not repeat the revenue seen last year. Furthermore, we are continuing to increase investment in expanding our wholly-owned pipeline, including start-up expenditure for HTL0018318 for DLB in Japan. Since our half year results in November 2017, the revenue outlook for FY2017 has slightly changed, owing to a delay in the timing of a forecast minor milestone receipt. In addition, we also expect a modest increase in cash operating expenditure. As such, we now expect cash earnings (revenue less cash operating expenditure) for the full year to be in the range of breakeven to a $(7) million loss.

* Notes
(1) Changes in the number of significant subsidiaries for the nine-month period ended December 31, 2017 (changes of specified subsidiaries affecting the scope of consolidation): None

(2) Changes in accounting policies, changes in accounting estimates
1) Changes in accounting policies required by IFRS: Yes
2) Changes due to changes in accounting policies other than those of item 1: None
3) Changes in accounting estimates: None

(3) Number of common shares issued

1) Number of shares issued at period end (including treasury shares)	At December 31, 2017	19,054,984 shares	At March 31, 2017	16,916,184 shares
2) Number of treasury shares at period end	At December 31, 2017	26 shares	At March 31, 2017	− shares
3) Average number of shares issued for the nine-month period	the nine-month ended December 31, 2017	17,219,144 shares	the nine-month ended December 31, 2016	16,886,384 shares

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

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

○ Contents of Attached Materials

1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

The Group is a global biotechnology company focused on pharmaceutical research and development. Over the middle-to-long term, we aim to become a fully integrated biotechnology company incorporating all aspects of a commercial stage biotechnology company from discovery, design and development of drug candidates extending through to the commercialization of our own medicines.

Financial results for the nine-month period ended December 31, 2017 were revenue of 6,277 million yen (a decrease of 63.3 % year on year), operating loss of 94 million yen, net loss before income taxes of 1,899 million yen, net loss and net loss attributable to owners of the parent company of 1,713 million yen.

<u>Revenue</u>

Revenue related to royalties in the period under review increased by 273 million yen compared to the corresponding period in the prior year (an increase of 15.3 %), and totaled 2,053 million yen. The majority of the Company's royalty revenue is related to sales of Ultibro® Breezhaler® and Seebri® Breezhaler® by Novartis. On January 24, 2018, Novartis reported quarterly total sales for Ultibro® Breezhaler® and Seebri® Breezhaler® of USD 162 million for its Q4 three-month period ended 31 December 2017. Specifically, with regard to sales of Ultibro® Breezhaler® and Seebri® Breezhaler®, Novartis reported the following:

- Ultibro® Breezhaler® (USD 120 million, +26% cc), a LABA/LAMA, grew driven by positive FLAME study results and the GOLD recommendations, which recommended LABA/LAMA as the preferred option in the majority of symptomatic patients regardless of their exacerbation risk. This is further reinforced by the recently published FLASH Clinical Trial supporting direct switch from ICS/LABA to Ultibro® Breezhaler®. Ultibro® Breezhaler®, a first-in-class dual bronchodilator, is approved in over 100 countries, including Japan, EU countries and China (approved in December 2017). It is a once-daily fixed-dose combination of indacaterol and glycopyrronium bromide, and in the EU is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.
- Seebri® Breezhaler® (USD 42 million, +4% cc), an inhaled LAMA is approved in over 100 countries and indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with COPD. Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura.
- In the US, these products are available at different doses or regimens under the names Utibron™ Neohaler® and Seebri™ Neohaler® and Sunovion Pharmaceuticals Inc. has assumed as of December 21, 2016 US commercialization rights for them. Seebri™ Neohaler® was launched in October 2017 by Sunovion Pharmaceuticals Inc.

Milestone-related revenue for the nine-month period ended December 31, 2017 amounted to 3,783 million yen. This was a decrease of 11,291 million yen compared to the nine-month period ended December 31, 2016 (a decrease of 74.9 %). The decrease is primarily attributable to an upfront milestone of USD 125 million received from Allergan Pharmaceuticals International Limited. ("Allergan") in April 2016. Milestone-related revenue for the nine-month period ended December 31, 2017 is predominantly attributable to milestones from AstraZeneca UK Limited ("AstraZeneca"), Teva Pharmaceutical Industries Ltd ("Teva") and Allergan.

- In April 2017, we received a USD 12 million milestone payment from our partner AstraZeneca due to the successful completion of a preclinical study that demonstrated a clear effect of AZD4635 in reversing adenosine-mediated T-cell suppression and enhancing anti-tumor immunity. Blockade of A_{2A} signaling with AZD4635 was found to reduce tumor growth when used alone and in combination with anti-PD-L1 checkpoint inhibitors.
- In May 2017, we received a USD 5 million milestone payment from our partner Teva due to the nomination of a preclinical candidate, a calcitonin gene-related peptide (CGRP) antagonist, for advancement into further preclinical studies as an investigational treatment for migraine.
- In September 2017, we received a USD 15 million milestone payment from our partner Allergan on the successful dosing of the first healthy subject with the first-in-class, selective muscarinic M4 receptor agonist HTL0016878 in a Phase 1 clinical study.
- No other major disclosable milestones were received during the third quarter FY2017 (1 October 2017 to 31 December 2017).

<u>Research and development expenses</u>

Research and development expenses for the nine-month period ended December 31, 2017 increased by 1,128 million yen compared to the nine-month period ended December 31, 2016 (an increase of 48.4%), and totaled 3,456 million yen. For the nine-month period ended December 31, 2017, 97% of research and development spend was related to our UK operations. The majority of the increase was the expansion and extension of our development and translational medicine capabilities supporting the advancement of our proprietary pipeline consisting of novel drug candidates as well as preparatory work ahead of the commencement of the Phase 2 Proof of Concept study with HTL0018318 in dementia with Lewy bodies (DLB) in Japan.

For the current financial year we would expect cash R&D expenditure to be in the range of between $45 million (5,000 million yen) to $50 million (5,600 million yen).

General and administrative expenses

General and administrative expenses increased by 460 million yen compared to the nine-month period ended December 31, 2016, and totalled 3,213 million yen (an increase of 16.7%). Increases were seen predominantly in non-cash costs including an increase in the amortization of intangibles driven by the G7 Therapeutics acquisition in November 2016 as well as an increase in stock based compensation as we look to ensure our remuneration system is competitive in the global market place.

For the current financial year we would expect cash G&A to be in the range of $25 million (2,800 million yen) to $27.5 million (3,100 million yen).

Operating loss

Operating loss totaled 94 million yen for the nine-month period ended December 31, 2017, a decline of 12,727 million yen to the nine-month period ended December 31, 2016.

Finance costs

Finance costs totaled 1,700 million yen for the nine-month period ended December 31, 2017. This was mainly attributable to foreign exchange losses due to the appreciation in the British pound impacting fair value adjustments to foreign-currency denominated assets in our UK operations as well as the Contingent Consideration Charge related to additional purchase consideration to be paid to the former shareholders of Heptares. The "Contingent Consideration" charge represents the re-measurement of the estimated liability due in the future to the former shareholders of Heptares. At December 31, 2017, the Group has to date, paid $65.5 million, out of the total potential amount payable of $220 million.

Net loss

The net loss for the period under review was 1,713 million yen, a decline of 11,761 million yen for the nine-month period ended December 31, 2017 compared to the nine-month period ended December 31, 2016.

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets at December 31, 2017 increased by 25,862 million yen from the end of the previous fiscal year, totaling 73,949 million yen. The main reason for this increase was an increase of 18,238 million yen in cash and cash equivalents due to the issuance of common stock, arising from the successful Global Equity Offering conducted in November 2017.

Liabilities

Total liabilities at December 31, 2017 were 23,296 million yen, an increase of 3,568 million yen from the end of the previous fiscal year. This is mainly due to increased interest-bearing liabilities of 4,890 million yen through bank borrowing related to the company's acquisition of a 25.6% equity Stake in MiNA Therapeutics Limited, offset by repayment of 2,000 million yen.

Equity

Total equity at December 31, 2017 was 50,653 million yen, an increase of 22,294 million yen from the end of the previous fiscal year. This was primarily due to an increase of 10,778 million yen in capital stock and 10,389 million yen in capital surplus as a result of the issuance of common stock, arising from the successful Global Equity Offering completed in November 2017.

2) Cash flows

Cash and cash equivalents at December 31, 2017 increased by 18,238 million yen from the beginning of the year and amounted to 32,137 million yen.

Cash flows from operating activities

Net cash used in operating activities for the nine-month period ended December 31, 2017 amounted to 115 million yen. This was predominantly due to the operating loss recorded for the period as well as tax payments, offset to some degree by changes in the fair value measurement of contingent consideration as well as a decrease in net current assets.

Cash flows from investing activities

Net cash used in investing activities for the nine-month period ended December 31, 2017 amounted to 5,704 million yen. This was primarily due to the acquisition of a 25.6% stake in MiNA Therapeutics (plus an exclusive option to acquire up to 100% at pre-determined economics).

Cash flows from financing activities

Net cash provided by financing activities for the nine-month period ended December 31, 2017 was 23,647 million yen. This was primarily due to Proceeds from Issuance of Common Stock of 21,307 million yen, from the successful Global Equity Offering completed in November 2017.

(3) Earnings forecast

The Group's current revenues are increasingly dependent on milestone payments received from our collaboration agreements. With these programs, the development strategies and schedules are determined by our partner companies and, accordingly, it is difficult for us to forecast if and when milestones will be earned and there can be wide differences in revenues between financial years. The Allergan agreement that was signed in April 2016 was exceptional in terms of the size of the upfront milestone that we received and as a result we anticipate a significant decline in revenues in the current financial year.

In the short to medium term, we expect to see an increase in R&D investment, consistent with our strategy to leverage our StaR® technology to generate a proprietary pipeline of high value drug candidates. We will strategically evolve our business model to include a greater emphasis on developing and commercializing or co-promoting our own products in selected indications (e.g. rare/orphan and specialty) and markets (U.S., U.K., Japan). In the short term, we will continue to earn development based milestones from our existing partnerships, as well as from a growing royalty stream from our legacy respiratory disease products. Over the medium to long term, our risk-balanced capital allocation framework is expected to deliver a combination of sales revenues from our own commercialized and/or co-promoted products, plus royalties and upfront, development and sales milestones from our partnered programs.

Given that FY2016 included the substantial $125m upfront payment from Allergan, we will not repeat the revenue seen last year. Furthermore, we are continuing to increase investment in expanding our wholly-owned pipeline, including start-up expenditure for HTL0018318 for DLB in Japan. Since our interim half year results in November 2017, the revenue outlook for FY2017 has slightly changed, owing to a delay in the timing of a forecast minor milestone receipt. In addition, we also expect a modest increase in cash operating expenditure. As such, we now expect cash earnings (revenue less cash operating expenditure) for the full year to be in the range of breakeven to a $(7) million loss.

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

1) Interim condensed consolidated statement of financial position

(JPY Million)

	At December 31, 2017	At March 31, 2017
Assets		
Non-current assets		
Property, plant and equipment	804	422
Goodwill	14,886	14,154
Intangible assets	17,420	16,970
Investments accounted for using the equity method	4,592	605
Deferred tax assets	338	4
Other financial assets	1,690	–
Other non-current assets	13	108
Total non-current assets	39,743	32,266
Current assets		
Trade and other receivables	1,047	1,382
Other current assets	1,022	538
Cash and cash equivalents	32,137	13,899
Total current assets	34,206	15,821
Total assets	73,949	48,087
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	3,550	3,175
Contingent consideration in business combinations	5,142	5,230
Interest-bearing debt	6,910	4,910
Other financial liabilities	1,088	625
Other non-current liabilities	31	175
Total non-current liabilities	16,721	14,116
Current liabilities		
Trade and other payables	2,741	1,547
Deferred income	–	4
Income taxes payables	758	1,991
Interest-bearing debt	2,994	1,990
Other current liabilities	82	77
Total current liabilities	6,575	5,611
Total liabilities	23,296	19,728
Equity		
Capital stock	36,782	26,004
Capital surplus	25,457	14,632
Retained earnings	(6,586)	(4,873)
Other components of equity	(5,004)	(7,409)
Equity attributable to owners of the parent	50,649	28,354
Non-controlling interests	4	4
Total equity	50,653	28,359
Total liabilities and equity	73,949	48,087

2) Interim condensed consolidated statement of comprehensive income

(JPY Million)

	Nine-month period ended December 31, 2017 (April 1, 2017 – December 31,2017)	Nine-month period ended December 31, 2016 (April 1, 2016 – December 31,2016)
Profit or loss		
Revenue	6,277	17,118
Cost of sales	-	—
Gross profit	6,277	17,118
Research and development expenses	(3,456)	(2,328)
Selling, general and administrative expenses	(3,213)	(2,753)
Other income	501	597
Other expenses	(203)	(0)
Operating income	(94)	12,633
Finance income	90	1,721
Finance costs	(1,700)	(1,013)
Share of loss of associates accounted for using the equity method	(195)	(60)
(Loss) profit before income taxes	(1,899)	13,281
Income tax benefits (expenses)	186	(3,232)
Net (loss) profit	(1,713)	10,048
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translating foreign operations	2,405	(3,806)
Total items that may be reclassified subsequently to profit or loss	2,405	(3,806)
Total other comprehensive income	2,405	(3,806)
Total comprehensive income	692	6,241
Net (loss) profit for the year attributable to:		
Owners of the parent	(1,713)	10,206
Non-controlling interests	(0)	(158)
	(1,713)	10,048
Total comprehensive income attributable to:		
Owners of the parent	692	6,399
Non-controlling interests	(0)	(158)
	692	6,241
Earnings per share (yen)		
Basic (loss) earnings per share	(99.49)	604.44
Diluted (loss) earnings per share	(99.49)	602.12

3) Interim condensed consolidated statement of changes in equity

Nine-month period ended December 31, 2017 (April 1, 2017 – December 31, 2017)

	Capital stock	Capital surplus	Retained earnings	Other components of equity	Equity attributable to owners of the parent
				Exchange differences on translating foreign operations	
Balance at April 1, 2017	26,004	14,632	(4,873)	(7,409)	28,354
Net loss	—	—	(1,713)	—	(1,713)
Exchange differences on translation	—	—	—	2,405	2,405
Total comprehensive (loss) income	—	—	(1,713)	2,405	692
Issuance of new shares	10,778	10,389	—	—	21,167
Share-based payments	—	436	—	—	436
Total transactions with owners	10,778	10,825	—	—	21,603
Balance at September 30, 2017	36,782	25,457	(6,586)	(5,004)	50,649

	Non-controlling interests	Total equity
Balance at April 1, 2017	4	28,359
Net loss	(0)	(1,713)
Exchange differences on translation	—	2,405
Total comprehensive (loss) income	(0)	692
Issuance of new shares	—	21,167
Share-based payments	—	436
Total transactions with owners	—	21,603
Balance at September 30, 2017	4	50,653

Nine-month period ended September 30, 2016 (April 1, 2016 – September 30, 2016)

	Capital stock	Capital surplus	Retained earnings	Other components of equity	Equity attributable to owners of the parent
				Exchange differences on translating foreign operations	
Balance at April 1, 2016	25,955	14,263	(14,184)	(2,891)	23,142
Net profit	—	—	10,206	—	10,206
Exchange differences on translation	—	—	—	(3,806)	3,806
Total comprehensive income (loss)	—	—	10,206	(3,806)	6,399
Issuance of new shares	46	6	—	—	52
Share-based payments	—	276	—	—	276
Changes in ownership interests in subsidiaries	—	1	—	—	1
Changes in the scope of consolidation	—	(11)	—	—	(11)
Total transactions with owners	46	272	—	—	319
Balance at September 30, 2016	26,002	14,535	(3,977)	(6,698)	29,862

	Non-controlling interests	Total equity
Balance at April 1, 2016	126	23,269
Net (loss) profit	(158)	10,048
Exchange differences on translation	—	(3,806)
Total comprehensive (loss) income	(158)	6,241
Issuance of new shares	—	52
Share-based payments	—	276
Changes in ownership interests in subsidiaries	4	6
Changes in the scope of consolidation	32	20
Total transactions with owners	36	355
Balance at September 30, 2016	4	29,867

4) Interim condensed consolidated statement of cash flow

(Millions of yen)

	Nine-month period ended December 31, 2017 (Unaudited)	Nine-month period ended December 31, 2016 (Unaudited)
Cash flows from operating activities		
(Loss) profit before income taxes	(1,899)	13,281
Adjustments for:		
Depreciation and amortization	754	677
Share-based payments	436	276
Grant income	(171)	(158)
Gain on sales of investments in subsidiaries	(326)	—
Net foreign exchange loss (gain)	131	(1,545)
Gain on loss of control of the subsidiary	-	(417)
Share of loss of associates accounted for using the equity method	195	60
Impairment loss	194	-
Interest expenses	196	149
Changes in fair value of contingent consideration	1,164	864
Decrease (Increase) in other accounts receivables	(291)	(529)
Decrease (Increase) in trade and other receivables	387	(705)
Increase in trade payables	748	209
Other	(356)	(78)
Subtotal	1,162	12,083
Interest and dividends received	2	9
Interest paid	(123)	(100)
Grants received	108	131
Income tax refund	–	12
Income taxes paid	(1,264)	(4)
Net cash (used in) provided by operating activities	(115)	12,132
Cash flows from investing activities		
Purchase of property, plant and equipment	(456)	(161)
Payments of investment securities	(490)	–
Payments related to the capitalized development costs	(70)	(152)
Payments for acquisition of consolidated subsidiaries	–	(1,188)
Payments for acquisition of shares of associates	(3,973)	(500)
Proceeds from sales of investments in subsidiaries resulting in change in scope of consolidation	377	–
Purchases of other financial assets	(1,083)	–
Other	(9)	(28)
Net cash used in investing activities	(5,704)	(2,031)

	Nine-month period ended December 31, 2017 (Unaudited)	Nine-month period ended December 31, 2016 (Unaudited)
Cash flows from financing activities		
Proceeds from long-term interest-bearing debt	4,890	–
Repayments of long-term interest-bearing debt	(2,000)	(1,500)
Payment for settlement of contingent consideration	(1,045)	(4,105)
Proceeds from issuance of common stock	21,307	52
Proceeds from contributions from limited partners	495	660
Other	–	6
Net cash provided by (used in) financing activities	23,647	(4,886)
Effects of exchange rate changes on cash and cash equivalents	410	157
Net (decrease) increase in cash and cash equivalents	18,238	5,372
Cash and cash equivalents at the beginning of the year	13,899	10,068
Cash and cash equivalents at the end of the quarter	32,137	15,441

5) Notes related to going concern assumptions

Not applicable.

6) Change in accounting policy

Applicable accounting criterion from this fiscal year

IFRS		Summary of New/Revision
IAS 7	Statement of Cash Flows	Adds disclosure related to changes in liabilities occurring from financial activities
IAS 12	Income Taxes	Clarifies requirements related to recognition of deferred tax assets connected with unrealized losses

No material impact on summary of interim condensed consolidated statement of financial position due to these changes in accounting policy

7) Changes in accounting estimates

Not applicable.