Consolidated Financial Results for the Second Period FY2017 (IFRS)

9 November 2017

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	9 November 2017	Scheduled date of dividend payments:	—
Supplementary materials for financial results:	Yes		
Financial results briefing session:	Yes		

(Rounded down to nearest million yen)

1. Consolidated results for the six-month ended September 30, 2017 (from April 1, 2017 to September 30, 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	%
Six-month period ended September 30, 2017	5,314	(66.5)	1,444	(88.2)	(534)	—	(498)	—	(498)	—	1,831	(51.9)
Six-month period ended September 30, 2016	15,839	523.4	12,223	—	13,245	—	10,592	—	10,716	—	3,807	—

	Earnings per share – basic	Earnings per share – diluted
	Yen	Yen
Six-month period ended September 30, 2017	(29.38)	(29.38)
Six-month period ended September 30, 2016	634.86	631.75

(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, 2017	54,893	31,094	31,090	56.6
At March 31, 2017	48,087	28,845	28,841	60.0

2. Dividends

	Dividends per share				
	End Q1	End Q2	End Q3	End Q4	Total
	Yen	Yen	Yen	Yen	Yen
FY2016	—	0.00	—	0.00	0.00
FY2017	—	0.00			
FY2017 (E)			—	0.00	0.00

3. Forecast for the FY2017 (from 1 April 1 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 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, together with increased investment in expanding our proprietary pipeline, including start up expenditure for the significant DLB opportunity in Japan, we expect Cash Earnings[1] for the full year to be around breakeven.

[1] Cash Earnings = Revenue less Cash Operating Expenditure

* Notes

(1) Changes in the number of significant subsidiaries for the six-month period ended September 30, 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 September 30, 2017	16,979,984 shares	At March 31, 2017	16,916,184 shares
2) Number of treasury shares at period end	At September 30, 2017	26 shares	At March 31, 2017	－ shares
3) Average number of shares issued for the six-month period	the six-month ended September 30, 2017	16,942,355 shares	the six-month ended September 30, 2016	16,880,446 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.

(Method of obtaining supplementary materials for financial results and contents of financial results briefing session)

The Company is scheduled to hold an online conference for analysts on November 9, 2017 (same day).
The materials and audio content of the briefing will be posted on the Company's website promptly after the conference, along with materials to be used on that day.

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1. Analysis of Operating Results and Financial Position

(1) Analysis of operating results

The Group is a global biotechnology company originating from Japan, which is 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.

In May 2017, we entered into a definitive agreement under which Sosei made an investment in and gained an exclusive option to potentially acquire MiNA Therapeutics Limited (hereafter, "MiNA"), a privately held UK biopharmaceutical company and pioneer in RNA activation therapeutics (small activating RNA, or "saRNA"). Harnessing the innate mechanism of gene activation, MiNA's technology may enable the development of new medicines that could potentially restore normal gene activation in diseases where this has been impaired and through this, potentially restore normal therapeutic protein function to patients' cells.

Under the terms of the agreement, Sosei has paid GBP 35 million for a 25.6% equity stake and an exclusive option to acquire further defined stakes and potentially 100% of MiNA for a further GBP 140 million. In addition, and should Sosei fully exercise its option, MiNA shareholders could receive up to a further GBP 240 million. This amount is contingent on the successful achievement of development and regulatory milestones and includes significant potential royalties from the successful commercialization of products emanating from MiNA's RNA activation platform.

Financial results for the six-month period ended September 30, 2017 were revenue of 5,314 million yen (a decrease of 66.5% year on year), operating income of 1,444 million yen (a decrease of 88.2%), net loss before income taxes of 534 million yen, net loss and net loss attributable to owners of the parent company of 498 million yen.

Revenue

Milestone-related revenue for the six-month period ended September 30, 2017 amounted to 3,726 million yen. This was a decrease of 10,772 million yen compared to the six-month period ended September 30, 2016 (a decrease of 74.3 %). The decrease is primarily attributable to an upfront milestone of USD 125 million received under a licensing agreement concluded with Allergan Pharmaceuticals International Limited. ("Allergan") in April 2016. Milestone-related revenue for the six-month period ended September 30, 2017 is 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.

The Phase 1 study with AZD4635 is progressing well. A maximum tolerated dose (MTD) has been established for monotherapy of AZD4635 and the dose escalation to establish the MTD in combination with AstraZeneca's checkpoint inhibitor IMFINZI™ (durvalumab) is on-going. Signal seeking Phase 1b expansion cohorts in a number of tumor types with monotherapy and/or in combination with IMFINZI™ are planned to open by the end of 2017.

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.

Allergan, under the terms of the 2016 global R&D and commercialization partnership, licensed exclusive global rights to our broad portfolio of novel subtype-selective muscarinic receptor agonists (M1, M4 and dual M1/M4 agonists) for the treatment of major neurological disorders, including Alzheimer's disease. The first healthy subject has been dosed with the first-in-class, selective muscarinic M4 receptor agonist HTL0016878 in a Phase 1 clinical study. The Phase 1 study, triggered a US$15 million milestone payment by Allergan.

Revenue related to royalties in the period under review increased by 100 million yen compared to the corresponding period in the prior year (an increase of 8.5 %), and totaled 1,276 million yen. Most of this royalty revenue is related to sales of Ultibro®

Breezhaler® and Seebri® Breezhaler® by Novartis. In December 2016, Novartis concluded a collaboration agreement with Sunovion Pharmaceuticals Inc.("Sunovion"), a wholly owned subsidiary of Dainippon Sumitomo Pharma Co., Ltd., to commercialize Utibron™ Neohaler® and Seebri™ Neohaler® in the United States. Our royalty rate is at the same rate for sales made directly by Novartis outside the United States of America and by Sunovion in the United States. Sales of Ultibro® Breezhaler® and Seebri® Breezhaler® as reported by Novartis on October 24, 2017 were USD 138 million for the period under review.

Ultibro® Breezhaler® sales(USD 101 million, +3% cc[2])*, a LAMA/LABA, were influenced by positive FLAME study results and the GOLD guidelines, which recommended LAMA/LABA as the preferred option in the majority of symptomatic patients regardless of their exacerbation risk. Ultibro® Breezhaler® 110/50 mcg (indacaterol/glycopyrronium), a first-in-class dual bronchodilator, is approved in over 90 countries, including Japan and EU countries. It is a once-daily fixed-dose combination of indacaterol (LABA) and glycopyrronium bromide (LAMA), and in the EU is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. In the US, it is marketed under the brand name Utibron™ Neohaler®.

Seebri® Breezhaler® 50 mcg (glycopyrronium) (USD 37 million, +2% cc[2]), an inhaled LAMA is approved in over 100 countries and indicated as a once daily maintenance bronchodilator treatment to relieve symptoms of patients with COPD. In the US, it is marketed under the brand name Seebri™ Neohaler®. Glycopyrronium bromide and certain use and formulation intellectual property were exclusively licensed to Novartis in April 2005 by Sosei and Vectura.

Research and development expenses

Research and development expenses for the six-month period ended September 30, 2017 increased by 564 million yen compared to the six-month period ended September 30, 2016 (an increase of 34.0%), and totaled 2,221 million yen. For the six-month period ended September 30, 2017, 94.6% 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 to support the advancement of our proprietary pipeline consisting of novel drug candidates as well as preparatory work ahead of the commencement of the Phase 2a Proof of Concept study with HTL0018318 in DLB in Japan which was announced today in a separate press release. We would expect development costs to increase substantially during the second half of the financial year, mainly attributable to start-up costs for the DLB Phase IIa, Proof of Concept Study to be conducted in Japan as well as continued advancement of our proprietary pipeline where we would expect that as from calendar year 2018, we will have, on average, on an annual basis, three new chemical entities entering into Phase 1 studies, leveraging the Group's unique GPCR StaR® structure-based drug design technology.

For the current financial year we would expect cash R&D expenditure to be in the range of between $50 million (5,600 million yen) to $55 million (6,200 million yen).

General and administrative expenses

General and administrative expenses increased by 9 million yen compared to the six-month period ended September 30, 2016, and totaled 2,078 million yen (an increase of 0.4%). 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 $20 million (2,300 million yen) to $25 million (2,800 million yen).

Operating income

Operating income totaled 1,444 million yen for the six-month period ended September 30, 2017, a decline of 10,779 million yen compared to the six-month period ended September 30, 2016. This was mainly due to the abovementioned recognition of the upfront milestone from Allergan in the prior comparative period.

Finance costs

Finance costs totaled 1,810 million yen for the six-month period ended September 30, 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

[2] CC: constant currency rates
* as reported by Novartis on October 24, 2017

liability due in the future to the former shareholders of Heptares. At 30 September 2017, the Group has to date paid $60.3 million out of the total potential amount payable of $220 million.

Net loss

The net loss for the period under review was 498 million yen, a decline of 11,090 million yen for the six-month period ended September 30, 2017 compared to the six-month period ended September 30, 2016, driven by the upfront milestone received from Allergan in 2016 as well as unfavorable movements below the operating income line including foreign exchange and contingent consideration.

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets at September 30, 2017 increased by 6,806 million yen from the end of the previous fiscal year, totaling 54,893 million yen. This was primarily due to the investment in MiNA, as well as an increase in both Intangible Assets and Goodwill as a result of movements in exchange rates.

Liabilities

Total liabilities at September 30, 2017 were 23,799 million yen, an increase of 4,558 million yen from the end of the previous fiscal year. This is mainly due to the increased interest-bearing liabilities of 4,890 million yen through bank borrowing and the estimated increase of 670 million yen of contingent consideration as discussed above. Meanwhile, repayment of 1,250 million yen of interest-bearing liabilities. The increase in debt is related to the company's acquisition of a 25.6% equity Stake in MiNA Therapeutics Limited.

Equity

Total equity at September 30, 2017 was 31,094 million yen, an increase of 2,249 million yen from the end of the previous fiscal year. This was mainly due to an increase in exchange differences on translating foreign operations of foreign affiliates in the second period under review.

2) Cash flows

Cash and cash equivalents at September 30, 2017 decreased by 1,486 million yen from the beginning of the year and amounted to 12,413 million yen.

Cash flows from operating activities

Net cash used in operating activities for the six-month period ended September 30, 2017 amounted to 88 million yen. This was primarily due to the recording of a loss before income taxes, changes in the fair value of contingent consideration and an increase in trade receivables.

Cash flows from investing activities

Net cash used in investing activities for the six-month period ended September 30, 2017 amounted to 5,077 million yen. This was primarily due to payment for the acquisition of a 25.6% share in MiNA.

Cash flows from financing activities

Net cash provided by financing activities for the six-month period ended September 30, 2017 was 3,246 million yen. This was primarily due to interest-bearing debt of 4,890 million yen related to the acquisition of the above mentioned equity stake in MiNA Therapeutics Limited, its repayment of 1,250 million yen, and contingent consideration payment of 550 million yen.

(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 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 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, together with increased investment in expanding our proprietary pipeline, including start up expenditure for the significant DLB opportunity in Japan, we expect Cash Earnings for the full year to be around breakeven.

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

1) Interim condensed consolidated statement of financial position

(JPY Million)

	At September 30, 2017	At March 31, 2017
Assets		
Non-current assets		
Property, plant and equipment	603	422
Goodwill	14,847	14,154
Intangible assets	17,800	16,970
Investments accounted for using the equity method	4,529	605
Deferred tax assets	4	4
Other financial assets	1,275	―
Other non-current assets	72	108
Total non-current assets	39,130	32,266
Current assets		
Trade and other receivables	2,381	1,382
Other current assets	969	538
Cash and cash equivalents	12,413	13,899
Total current assets	15,763	15,821
Total assets	54,893	48,087
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	3,496	3,301
Contingent consideration in business combinations	5,900	5,230
Interest-bearing debt	7,641	4,910
Other financial liabilities	604	625
Other non-current liabilities	16	175
Total non-current liabilities	17,657	14,243
Current liabilities		
Trade and other payables	2,017	1,547
Deferred income	―	4
Income taxes payables	1,065	1,378
Interest-bearing debt	2,994	1,990
Other current liabilities	66	77
Total current liabilities	6,142	4,998
Total liabilities	23,799	19,241
Equity		
Capital stock	26,133	26,004
Capital surplus	14,921	14,632
Retained earnings	(4,884)	(4,386)
Other components of equity	(5,080)	(7,409)
Equity attributable to owners of the parent	31,090	28,841
Non-controlling interests	4	4
Total equity	31,094	28,845
Total liabilities and equity	54,893	48,087

2) Interim condensed consolidated statement of comprehensive income

(JPY Million)

	Six-month period ended September 30, 2017 (April 1, 2017 – September 30,2017)	Six-month period ended September 30, 2016 (April 1, 2016 – September 30,2016)
Profit or loss		
Revenue	5,314	15,839
Cost of sales	—	—
Gross profit	5,314	15,839
Research and development expenses	(2,221)	(1,657)
Selling, general and administrative expenses	(2,078)	(2,069)
Other income	438	110
Other expenses	(9)	(0)
Operating income	1,444	12,223
Finance income	66	1,185
Finance costs	(1,810)	(162)
Share of loss of associates accounted for using the equity method	(234)	—
(Loss) profit before income taxes	(534)	13,245
Income tax benefits (expenses)	36	(2,652)
Net (loss) profit	(498)	10,592
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translating foreign operations	2,329	(6,785)
Total items that may be reclassified subsequently to profit or loss	2,329	(6,785)
Total other comprehensive income	2,329	(6,785)
Total comprehensive income	1,831	3,807
Net (loss) profit for the year attributable to:		
Owners of the parent	(498)	10,716
Non-controlling interests	(0)	(123)
	(498)	10,592
Total comprehensive income attributable to:		
Owners of the parent	1,831	3,931
Non-controlling interests	(0)	(123)
	1,831	3,807
Earnings per share (yen)		
Basic (loss) earnings per share	(29.38)	634.86
Diluted (loss) earnings per share	(29.38)	631.75

3) Interim condensed consolidated statement of changes in equity

Six-month period ended September 30, 2017 (April 1, 2017 – September 30, 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	(4,386)	(7,409)	28,841
Net loss	—	—	(498)	—	(498)
Exchange differences on translation	—	—	—	2,329	2,329
Total comprehensive (loss) income	—	—	(498)	2,329	1,831
Issuance of new shares	129	28	—	—	157
Share-based payments	—	261	—	—	261
Total transactions with owners	129	289	—	—	418
Balance at September 30, 2017	26,133	14,921	(4,884)	(5,080)	31,090

	Non-controlling interests	Total equity
Balance at April 1, 2017	4	28,845
Net loss	(0)	(498)
Exchange differences on translation	—	2,329
Total comprehensive (loss) income	(0)	1,831
Issuance of new shares	—	157
Share-based payments	—	261
Total transactions with owners	—	418
Balance at September 30, 2017	4	31,094

Six-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	—	—	10,716	—	10,716
Exchange differences on translation	—	—	—	(6,785)	(6,785)
Total comprehensive income (loss)	—	—	10,716	(6,785)	3,931
Issuance of new shares	35	5	—	—	40
Share-based payments	—	205	—	—	205
Changes in ownership interests in subsidiaries	—	1	—	—	1
Total transactions with owners	35	212	—	—	248
Balance at September 30, 2016	25,991	14,475	(3,467)	(9,677)	27,322

	Non-controlling interests	Total equity
Balance at April 1, 2016	126	23,269
Net (loss) profit	(123)	10,592
Exchange differences on translation	—	(6,785)
Total comprehensive (loss) income	(123)	3,807
Issuance of new shares	—	40
Share-based payments	—	205
Changes in ownership interests in subsidiaries	4	6
Total transactions with owners	4	252
Balance at September 30, 2016	6	27,329

4) Interim condensed consolidated statement of cash flow

(JPY Million)

-	Six-month period ended September 30, 2017 (April 1, 2017 – September 30,2017)	Six-month period ended September 30, 2016 (April 1, 2016 – September 30,2016)
Cash flows from operating activities		
(Loss) profit before income taxes	(534)	13,245
Adjustments for:		
Depreciation and amortization	484	456
Share-based payments	261	205
Grant income	(109)	(109)
Gain on loss of control of the subsidiaries	(326)	―
Net foreign exchange gain	(215)	(1,103)
Share of loss of associates accounted for using the equity method	234	―
Interest expenses	127	102
Changes in fair value of contingent consideration	1,333	59
Increase in other accounts receivables	(370)	(455)
Increase in trade receivables	(901)	(442)
Increase in trade payables	412	462
Other	(166)	96
Subtotal	230	12,518
Interest and dividends received	2	8
Interest paid	(79)	(69)
Grants received	107	97
Income tax refund	―	3
Income taxed paid	(348)	(2)
Net cash (used in) provided by operating activities	(88)	12,557
Cash flows from investing activities		
Purchase of property, plant and equipment	(203)	(110)
Payments of investment securities	(140)	―
Payments related to the capitalized development costs	(53)	(112)
Payments for acquisition of shares of associates	(3,973)	―
Proceeds from sales of investments in subsidiaries resulting in change in scope of consolidation	377	―
Purchases of other financial assets	(1,083)	―
Other	(2)	(6)
Net cash used in investing activities	(5,077)	(229)
Cash flows from financing activities		
Proceeds from long-term interest-bearing debt	4,890	―
Repayments of long-term interest-bearing debt	(1,250)	(1,000)
Payments for settlement of contingent consideration	(550)	(4,105)
Proceeds from issuance of common stock	156	40
Other	―	6
Net cash provided by (used in) financing activities	3,246	(5,058)
Effects of exchange rate changes on cash and cash equivalents	433	(1,657)
Net (decrease) increase in cash and cash equivalents	(1,486)	5,612
Cash and cash equivalents at the beginning of the year	13,899	10,068
Cash and cash equivalents at the end of the quarter	12,413	15,680

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.