Consolidated Financial Results for the First Quarter FY2017 (IFRS)

10 August 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		
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Scheduled date of security report filing: 10 August 2017 — Scheduled date of dividend payments: ―
Supplementary materials for financial results: ―
Financial results briefing session: ―

(Rounded down to nearest million yen)

1. Consolidated results for the three-month ended June 30, 2017 (from April 1, 2017 to June 30, 2017)

(1) Consolidated operating results (cumulative) (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	%
Three-month period ended June 30, 2017	2,784	(81.5)	731	(94.4)	349	(97.4)	339	(96.9)	339	(97.0)	1,481	(74.9)
Three-month period ended June 30, 2016	15,082	―	12,955	―	13,515	―	11,097	―	11,150	―	5,912	331.0

	Net income per share – basic	Net income per share – diluted
	Yen	Yen
Three-month period ended June 30, 2017	20.09	20.03
Three-month period ended June 30, 2016	661.09	657.72

(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	%
Three-month period ended June 30, 2017	53,854	30,421	30,417	56.5
FY2016	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	―		―		
FY2017 (E)		0.00	―	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 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 as we advance our proprietary pipeline and scale up our discovery capability. We also intend to expand our capacity and capability in both our translational medicine and clinical development functions to support our proprietary pipeline as it advances towards the clinic.

Because of the increasingly diverse and global nature of our business, the Group has significant exposure to currency fluctuations relative to our reporting currency. Financial agreements in our industry are usually written in USD and all of our current revenue generating contracts are in this currency. Additionally, with the location of our main R&D activities in the UK, our cost base is very heavily sterling weighted. Whilst we endeavour to cover foreign currency transactions, our financial statements, as reported, are exposed to movements in the value of the pound and USD, which may affect our reported financial results.

In summary, given that we are unlikely to repeat the revenue seen last year, and with increased investment in expanding and extending our capabilities and as our proprietary pipeline advances, whilst, we are aiming for profitability for the current financial year, this is not something we can guarantee due to the uncertain nature of the timing of the receipt of milestone payments, the need to continue to invest in the maturation of our proprietary pipeline as well as the impact that movements in foreign exchange may have on our financial results.

* 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: 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 financial year end (including treasury shares)	the three-month ended June 30, 2017	16,925,384 shares	FY2016	16,916,184 shares
2) Number of treasury shares at financial year end	the three-month ended June 30, 2017	− shares	FY2016	− shares
3) Average number of shares issued during financial year	the three-month ended June 30, 2017	16,919,703 shares	the three-month ended June 30, 2016	16,866,325 shares

* Quarterly consolidated financial results reports are not subject to quarterly 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 originating from Japan, which is currently 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, and development of pharmaceutical candidates extending through to the self commercialization of our own medicines.

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

MiNA's lead development candidate is MTL-CEBPA, which is a small activating RNA (saRNA) that targets and activates a 'master' gene regulator of liver function, known as CEBPA (CCAAT/enhancer binding protein alpha), and which until now has been regarded as 'undruggable'. The levels of CEBPA are decreased in patients with liver diseases. By restoring CEBPA expression to normal levels, MTL-CEBPA has been shown to slow or reverse liver disease and improve liver function in a range of pre-clinical studies including models of liver cancer, liver cirrhosis, nonalcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

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 consolidated fiscal year under review were revenue of 2,784 million yen (a decrease of 81.5% year on year), operating income of 731 million yen, net income before income taxes of 349 million yen, net income of 339 million yen, and net income attributable to owners of the parent company of 339 million yen.

The Group recorded the following consolidated financial results for the first three-month period ended June 30, 2017.

Revenue

Milestone-related revenue in the quarter under review amounted to 2,016 million yen. This was a decrease of 12,444 million yen compared to the corresponding quarter in the prior year (a decrease of 86.1%). 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 in the first quarter of the current year is attributable to milestones from AstraZeneca UK Limited ("AstraZeneca") and Teva Pharmaceutical Industries Ltd ("Teva").

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 (HTL1071) 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 August 2015, we entered into an agreement with Astra Zeneca to develop novel immuno-oncology treatments for a range of cancers. Under the agreement, AstraZeneca gained exclusive global rights to develop, manufacture and commercialize the adenosine A_{2A} receptor antagonist, AZD4635 (HTL1071), a small molecule immuno-oncology candidate, and potential additional A_{2A} receptor-blocking compounds across a range of cancers, including in combination with its existing portfolio of immunotherapies. Subject to successful completion of development and commercialization milestones, we are also eligible to receive more than USD500 million, as well as up to double-digit tiered royalties on net sales.

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. We entered into a licensing and drug-discovery agreement in November 2015 under which

Teva received exclusive global rights to develop, manufacture and commercialize novel, small molecule calcitonin gene-related peptide (CGRP) antagonists discovered by our wholly owned subsidiary, Heptares for the treatment of migraine. Under the terms of the agreement, we will receive research funding, and are eligible to receive additional research, development and commercialization milestone payments of up to USD400 million. In addition, we are eligible to receive royalties on net sales of products resulting from the alliance.

Revenue related to royalties in the quarter under review increased by 23 million yen compared to the corresponding quarter in the prior year (an increase of 4.2%), and totaled 586 million yen. Most of this royalty revenue is related to the 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, 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 July 18, 2017 were USD 135 million for the quarter under review.

Research and development expenses

Research and development expenses for the quarter under review increased by 170 million yen compared to the corresponding period in the prior year (increase of 18.3%), and totaled 1,100 million yen. For the period under review, 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 (‘Wave2’). We intend to progress up to 3 molecules into full pre-clinical development and at least one molecule into Phase Ⅰ in the next 12-18 months. Cash costs for the period increased by 18.3% with headcount related costs contributing to 40% of that increase, and third party Research and Development expenses for Wave 2 contributing the majority of the remainder. We would expect development costs to increase substantially during the remainder of the year.

The quarter under review saw the continuation of activities designed to scale up our discovery capability and expand our clinical development capacity. This investment has the aim to enable the identification of up to three new drug candidates per annum, utilizing Heptares’ unique StaR® structure-based drug design technology. Additionally, as we look to advance our own proprietary portfolio (‘Wave 2’), we have strengthened our clinical development and translational medicine capabilities so that we are able to progress our proprietary development drug candidates into Human clinical trials.

General and administrative expenses

General and administrative expenses declined by 227 million yen compared to the first quarter of the previous fiscal year, to 1,024 million yen (down 18.1%). This was mainly due to advisory expenses in connection with the collaboration with Allergan incurred in the first quarter of the previous fiscal year, as well as to a smaller degree bonus payments made to executives and other employees, also related to the successful signing of the Allergan collaboration agreement in the previous fiscal year.

Operating income

First quarter operating income totaled 731 million yen, a decline of 12,223 million yen from the first quarter of the previous year. This was mainly due to the abovementioned recognition of the upfront milestone from Allergan in the prior comparative period, an increase in R&D investment, which has been offset to some degree by lower G&A expenses.

Finance costs

First quarter finance costs totaled 282 million yen. This was mainly attributable to foreign exchange losses in connection with appreciation in the British pound impacting fair value adjustments of foreign-currency denominated assets in our UK operations.

Net income

First quarter net income was 339 million yen, a decline of 10,757 million yen compared to the first quarter of the previous year.

(2) Analysis of financial position

1) Assets, liabilities and equity

Assets

Total assets at the end of the first quarter were 53,854 million yen, an increase of 5,766 million yen over the end of the previous fiscal year. This was primarily due to the investment in MiNA Therapeutics, as well as an increase in both Intangible Assets and Goodwill as a result of movements in exchange rates.

Liabilities

Total liabilities at the end of the first quarter were 23,432 million yen, an increase of 4,190 million yen over the end of the previous fiscal year. This was primarily due to a net increase in interest-bearing debt of 4,890 million yen. 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 the end of the first quarter was 30,421 million yen, an increase of 1,576 million yen over 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 first quarter under review.

2) Cash flows

Cash and cash equivalents at the end of the first quarter amounted to 12,983 million yen, a decrease of 916 million yen from the end of the previous fiscal year.

Cash flows from operating activities

Net cash used in operating activities for the first quarter amounted to 207 million yen. This was primarily due to an increase in trade receivables.

Cash flows from investing activities

Net cash used in investing activities for the first quarter was 5,168 million yen. This was primarily due to the investment in MiNA Therapeutics Limited.

Cash flows from financing activities

Net cash provided by financing activities for the first quarter was 4,399 million yen. This was primarily due to an 4,890 million yen increase in Interest Bearing Debt related to the acquisition of the above mentioned equity stake in MiNA Therapeutics Limited, offset by a repayment of 500 million yen.

(3) Earnings forecast

The Group's current revenues are increasingly dependent on milestone payments received from existing collaboration agreements with our partners and accordingly there can be wide variances in the amount of revenues we may receive in each financial year. A clear priority is to build a proprietary pipeline of novel first in class or best in class molecules. Our current proprietary pipeline consists of discovery stage candidates which will require time to progress until a material value inflection point, such as that seen in the Allergan collaboration is reached.

As such, whilst we are aiming for profitability for the current financial year, this is not something we can guarantee due to the uncertain nature of the timing of the receipt of milestone payments, the need to continue to invest in the maturation of our proprietary pipeline and the unpredictability of movements in foreign exchange markets.

2. Consolidated financial statements and primary notes (IFRS)

1) Consolidated statement of financial position

(JPY Million)

	Three-month ended June 30, 2017	Fiscal year ended June 30, 2017
Assets		
Non-current assets		
Property, plant and equipment	515	422
Goodwill	14,518	14,154
Intangible assets	17,446	16,970
Investments accounted for by the equity method	4,494	605
Deferred tax assets	4	4
Other financial assets	1,093	—
Other non-current assets	107	108
Total non-current assets	38,182	32,266
Current assets		
Trade and other receivables	1,914	1,382
Other current assets	773	538
Cash and cash equivalents	12,983	13,899
Total current assets	15,672	15,821
Total assets	53,854	48,087
Liabilities and Equity		
Liabilities		
Non-current liabilities		
Deferred tax liabilities	3,425	3,301
Contingent consideration related to corporate acquisition	4,783	5,230
Interest-bearing liabilities	8,331	4,910
Other financial liabilities	614	625
Other non-current liabilities	243	175
Total non-current liabilities	17,398	14,243
Current liabilities		
Trade and other payables	1,924	1,547
Deferred income	11	4
Income tax payables	1,050	1,378
Interest-bearing liabilities	2,986	1,990
Other current liabilities	59	77
Total current liabilities	6,033	4,998
Total liabilities	23,432	19,241
Equity		
Capital stock	26,013	26,004
Capital surplus	14,719	14,632
Retained earnings	(4,046)	(4,386)
Other components of equity	(6,268)	(7,409)
Equity attributable to owners of the parent company	30,417	28,841
Non-controlling interests	4	4
Total equity	30,421	28,845
Total liabilities and equity	53,854	48,087

2) Consolidated statement of comprehensive income

(JPY Million)

	Three-month ended June 30, 2017 (April 1, 2017 – June 30,2017)	Three-month ended June 30, 2016 (April 1, 2016 – June 30,2016)
Revenue	2,784	15,082
Cost of sales	—	—
Gross profit (loss)	2,784	15,082
Research and development expenses	1,100	930
Selling, general and administrative expenses	1,024	1,252
Other income	73	55
Other expenses	—	0
Operating income (loss)	731	12,955
Finance income	20	761
Finance costs	282	202
Share of profit (loss) of associates accounted for using equity method	119	—
Income (loss) before income taxes for quarter	349	13,515
Income tax expenses	9	2,417
Net income (loss) for quarter	339	11,097
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translating foreign operations	1,141	(5,185)
Total items that may be reclassified subsequently to profit or loss	1,141	(5,185)
Total other comprehensive income	1,141	(5,185)
Comprehensive income for quarter	1,481	5,912
Net income (loss) for the year attributable to:		
Owners of the parent company	339	11,150
Non-controlling interests	(0)	(52)
Net income (loss) for quarter	339	11,097
Comprehensive income for quarter attributable to:		
Owners of the parent company	1,481	5,965
Non-controlling interests	(0)	(52)
Comprehensive income for quarter	1,481	5,912
Net income per share (yen)		
Basic net income (loss)	20.09	661.09
Diluted net income (loss)	20.03	657.72

3) Consolidated statement of changes in equity

Three-month ended June 30, 2017 (April 1, 2017 – June 30, 2017)

	Capital stock	Capital surplus	Retained earnings	Other components of equity Foreign currency translation adjustments on overseas operations	Equity attributable to owners of the parent company
Balance as of 1 April 2017	26,004	14,632	(4,386)	(7,409)	28,841
Net income (loss) for quarter	–	–	339	–	339
Foreign currency translation adjustments	–	–	–	1,141	1,141
Comprehensive income for quarter	–	–	339	1,141	1,481
Issuance of new shares	8	1	–	–	9
Stock based compensation expense	–	85	–	–	85
Total business transactions with owners	8	87	–	–	95
Balance as of 30 June 2017	26,013	14,719	(4,046)	(6,268)	30,417

	Non-controlling interests	Total equity
Balance as of 1 April 2017	4	28,845
Net income (loss) for quarter	(0)	339
Foreign currency translation adjustments	–	1,141
Comprehensive income for quarter	(0)	1,481
Issuance of new shares	–	9
Stock based compensation expense	–	85
Total business transactions with owners	–	95
Balance as of 30 June 2017	4	30,421

Three-month ended June 30, 2016 (April 1, 2016 – June 30, 2016)

	Capital stock	Capital surplus	Retained earnings (Restatement)	Other components of equity Foreign currency translation adjustments on overseas operations (Restatement)	Equity attributable to owners of the parent company (Restatement)
Balance as of 1 April 2016	25,955	14,263	(14,184)	(2,891)	23,142
Net income (loss) for quarter	–	–	11,150	–	11,150
Foreign currency translation adjustments	–	–	–	(5,185)	(5,185)
Comprehensive income for quarter	–	–	11,150	(5,185)	5,965
Issuance of new shares	30	4	–	–	34
Stock based compensation expense	–	103	–	–	103
Total business transactions with owners	30	108	–	–	138
Balance as of 30 June 2016	25,986	14,371	(3,034)	(8,076)	29,246

	Non-controlling interests	Total equity (Restatement)
Balance as of 1 April 2016	126	23,269
Net income (loss) for quarter	(52)	11,097
Foreign currency translation adjustments	–	(5,185)
Comprehensive income for quarter	(52)	5,912
Issuance of new shares	–	34
Stock based compensation expense	–	103
Total business transactions with owners	–	138
Balance as of 30 June 2016	73	29,320

4) Consolidated statement of cash flow

(JPY Million)

-	Three-month ended June 30, 2017 (April 1, 2017 – June 30,2017)	Three-month ended June 30, 2016 (April 1, 2016 – June 30,2016)
Cash flows from operating activities		
Net income before income taxes (loss)	349	13,515
Depreciation and amortization	230	234
Stock-based compensation expense	85	94
Subsidy income	(72)	(55)
Foreign exchange losses (gains)	199	557
Share of (profit) loss of associates accounted for using equity method	119	―
Interest expense	56	35
Fluctuation in fair value in connection with contingent consideration	21	149
Decrease (increase) in accounts receivable	(183)	(363)
Decrease (increase) in accounts receivable – trade	(537)	(1,299)
Decrease (increase) in accounts payable – trade	(188)	443
Other	31	404
Subtotal	113	13,716
Interest and dividends received	0	0
Payments of interest	(35)	(18)
Proceeds from subsidy	62	55
Income tax paid	(348)	(2)
Cash flows from operating activities	(207)	13,751
Cash flows from investing activities		
Purchases of property, plant and equipment	(80)	(56)
Capitalized development costs	(29)	(65)
Payments for purchase of shares of affiliated companies	(3,973)	―
Payment for other financial assets	(1,083)	―
Other	(1)	(6)
Net cash used in investing activities	(5,168)	(128)
Cash flows from financing activities		
Net increase (decrease) from short-term interest-bearing debt	(500)	(500)
Proceeds from borrowing long-term interest-bearing debt	4,890	―
Settlement of contingent consideration	―	(77)
Proceeds from issuance of common stock	9	34
Net cash from financing activities	4,399	(542)
Effect of exchange rate changes on cash and cash equivalents	59	(2,499)
Increase (decrease) in cash and cash equivalents	(916)	10,580
Cash and cash equivalents at the beginning of year	13,899	10,068
Cash and cash equivalents at the end of year	12,983	20,649

5) Notes related to going concern assumptions

Not applicable.

6) Change in accounting policy

Applicable accounting criterion From the First Quarter FY2017

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 consolidated statement of financial position due to these changes in accounting policy

7) Changes in accounting estimates

Not applicable.