Consolidated Financial Report for the Second Quarter FY2013 (fiscal year ending 31 March 2014) (Japanese GAAP) (Consolidated)

11 November 2013

Company name:	Sosei Group Corporation		Listing: TSE
Securities code:	4565		URL: http://www.sosei.com/
Representative:	Shinichi Tamura, Board Director Representative Executive Officer, CEO		
Contact person:	Hidetoshi Torami Executive Vice President, CFO		Tel: +81-3-5210-3290
Scheduled date of filing securities report (yukashoken hokokusho)	13 November 2013	Scheduled date of dividend payments	―
Supplementary materials for financial results:		Yes	
Briefing session of financial results:		Yes	

(Rounded down to nearest million yen)

1. Consolidated Financial Results for the Second Quarter FY2013 (1 April 2013 to 30 September 2013)

(1) Consolidated operating results

(Percentage figures show year-on-year change.)

	Net sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Q2 FY2013	1,583	30.0	(18)	―	(133)	―	(39)	―
Q2 FY2012	1,218	51.4	(215)	―	(267)	―	(179)	―

(Note) Comprehensive income: Q2 FY2013 25 million yen (-%) Q2 FY2012 -239 million yen (-%)

	Net income per share – basic	Net income per share - diluted
	Yen	Yen
Q2 FY2013	(3.30)	―
Q2 FY2012	(15.14)	―

(Note) On 1 April 2013, the Company made a 100-for-1 stock split for its common shares. The number of common shares issued for the prior financial years was calculated assuming the stock split had taken place as at the beginning of the relevant financial year.

(2) Consolidated financial position

	Total assets	Total net assets	Shareholders' equity ratio	Sharehoders' equity per share
	Million yen	Million yen	%	Yen
Q2 FY2013	6,921	6,583	90.9	526.06
FY2012	6,794	6,511	89.7	511.14

(Reference) Stockholders' equity: Q2 FY2013 6,291 million yen; FY2012 6,093 million yen

(Note) On 1 April 2013, the Company made a 100-for-1 stock split for its common shares. The number of common shares issued for the prior financial years was calculated assuming the stock split had taken place as at the beginning of the relevant financial year.

2. Dividends

	Annual dividends per share				
	End Q1	End 2Q	End 3Q	Year end	Total
	Yen	Yen	Yen	Yen	Yen
FY2012	―	0.00	―	0.00	0.00
FY2013	―	0.00			
FY2013 (E)			―	0.00	0.00

3. Forecast for FY2013, financial year ending 31 March 2014 (from 1 April 2013 to 31 March 2014)

(Percent indications show percent changes from corresponding figures for the previous period.))

	Net sales		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	2,850	45.6	(400)	—	(300)	—	(300)	—	(25.16)

(Note) Revision to the latest financial forecasts: No

* 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, and restatements

1) Changes due to changes in accounting standards: None
2) Changes due to changes in accounting policies except 1): None
3) Changes in accounting estimates: None
4) Restatements: None

(3) Number of common shares issued

1) Number of shares issued at the end of the reporting period (including treasury shares)	Q2 FY2013	11,959,100	FY2012	11,921,900
2) Number of treasury shares at the end of the reporting period	Q2 FY2013	—	FY2012	—
3) Average number of outstanding shares (cumulative)	Q2 FY2013	11,945,649	Q2 FY2012	11,836,248

(Note) On 1 April 2013, the Company made a 100-for-1 stock split for its common shares. The number of common shares issued for the prior financial years was calculated assuming the stock split had taken place as at the beginning of the relevant financial year.

* Implementation status of financial audit

At the time of disclosure of this quarterly financial report, the audit procedures of the financial statements pursuant to the Financial Instruments and Exchange Law are yet to be completed.

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

Materials and information provided in this financial report may contain “forward-looking statements” based on management’s current expectations or forecasts. Such statements are subject to risks and uncertainties that could cause the Group's actual results to differ materially from the forecasted results. The Group assumes no obligation to update any such forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

○ Contents of Attached Materials

1. Operating Resuts and Financial Position for Q2 FY2013

(1) Operating Results for Q2 FY2013

The Group pursuit pharmaceutical research and development mainly through its subsidiaries based in Japan and the UK. The main source of its revenue comes from the development milestones and royalties from the licences and the sales from its pharmaceutical products.

The Group recorded the following consolidated financial results for the second quarter of the current financial year:

Consolidated Operating Results

(millions of yen)

	Q2 FY2012	Q2 FY2013	Year-on-year changes
Net sales	1,218	1,583	364
Gross profit	1,069	1,410	340
Operating income (loss)	(215)	(18)	197
Ordinary income (loss)	(267)	(133)	133
Net income (loss)	(179)	(39)	139

(Sales and Gross profit)

Sales in the second quarter of the current financial year totalled 1,583 million yen (an increase of 29.9% compared to the previous financial year). The increase of sales is due to the recorded milestones and royalties, and the favourable exchange rate.

(Operating loss)

Operating loss in the second quarter of the current financial year decreased to 18 million yen, a 197 million yen difference from the previous financial year, primarily due to the increase of sales. For more details on Selling, General and Administrative Expenses please see below “Breakdown of SG&A Expenses”.

(Ordinary loss)

Ordinary loss in the second quarter of the current financial year decreased to 133 million yen, a 133 million yen difference from the previous financial year, primarily due to the increase of sales.

(Net loss)

Net loss in the second quarter of the current financial year decreased to 39 million yen, a 139 million yen difference from the previous financial year, primarily due to an increase of sales.

Breakdown of Selling, General and Administrative Expenses

(millions of yen)

	Q2 FY2012	Q2 FY2013	Year-on-year changes
Amortization of goodwill	794	794	―
Research and development expenses	180	225	45
Other expenses	311	409	98
Total selling, general and administrative expenses	1,285	1,429	143

(Selling, General and Administrative Expenses)

Selling, General and Administrative Expenses totalled 1,429 million yen, an increase of 11.2% from the previous financial year that was mainly due to the increase in R&D expenses related to the ongoing SO-1105 Phase III clinical trial, and the new business projects related start-up expenses.

(Foreign Exchange Loss)

Foreign exchange loss amounted to 116 million yen in this quarter. This was mainly due to the evaluation of accounts collectible from the foreign subsidiary based on the exchange rate at the end of the quarter (end of September 2013).

The operating results by business segment are as follows:

(Domestic pharmaceutical business)

Sales of domestic pharmaceutical business segment increased by 35 million yen compared to the previous period, totalling 265 million yen, primarily due to the increase of NorLevo® sales in Japan and Australia. Operating loss increased to 232 million yen (an increase of 29 million yen compared to the previous financial year), mainly due to increase of R&D expenses incurred for the Phase III clinical trial of SO-1105.

(Overseas pharmaceutical business)

Sales in overseas pharmaceutical business segment totalled 1,317 million yen, an increase of 329 million yen, mainly as a result of received milesotens and royalties and favourable exchange rate. Operating profit in overseas segment increased for 110 million yen from the previous financial year, to 314 million yen.

(2) Cash Flow

	Q2 FY2012	Q3 FY2013	Year-on-year change
Cash flows from operating activities	(415)	(476)	(60)
Cash flows used in investment activities	(10)	(7)	2
Cash flows from financing activities	27	45	18

Cash flows used for operating activities in the second quarter amounted to 476 million yen, as a result of recorded net loss before income taxes and minority interests 133 million yen, depreciation and amortization 794 million yen, and an increase of accounts receivable 1,169 million yen from the same period of the previous year.

The cash flows used for investing activities was 7 million yen, mainly spent on property, plant and equipment.

The cash from financing activities in the second quarter amounted to 45 million yen and is mainly due to the issuance of shares.

(3) Reaserch and development activities

Reaserch and development activities in the second quarter were focused on undergoing Phase III clinical trial of SO-1105, as well as the research and development of nano-technology (APNT). As a result, R&D expenses amounted to 225 million yen (25.2% increase on a year-to year basis). In addition, first- in- class once daily dual bronchodilator QVA149 was granted approval in Europe and Japan. NVA237 and QVA149 have been developed by Novarits International AG (“Novartis”), thus R&D costs for these products have not been incurred.

The progress of the main products under development for the domestic pharmaceutical business is as follows.

■SO-1105 (Indication: oropharyngeal candidiasis)

- Phase III clinical trial 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 which is caused by infection due to mainly a form of 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 BioAlliance Pharma from France and is now approved for marketing in 24 European countries, the US and Korea since obtaining the first approval in October 2006 in France. The Group believes that this product can also contribute to patient compliance in Japan and thus had obtained the exclusive development and marketing rights of SO-1105 in Japan from BioAlliance in May 2011. The Phase III clinical trial designed to evaluate the efficacy and safety of this developmental product is ongoing.

■APNT (Activus Pure Nano-particle Technology): Nano-particle technology

Since the acquisition of Activus Pharma in August 2010., the research and development activities have been focused on development of nano-particle technology ("APNT") to ensure the constant improvement and eventual practical application. In July 2013 patent for the basic technology was granted in Japan. The effort to secure patents in other areas will continue as well, together with the efforts to constantly keep adding value to the existing technology. The characteristic of the nano-particle technology ("APNT"), lies in its ability to pulverize poorly soluble compounds to nano-sized crystal particles ranging from 50 to 200nm levels and keep compounds virtually free from contamination, which could not be achieved with existing technology at an extremely low level. Making use of this feature, the application of this technology on injections, ophthalmic solutions and inhalations with poorly soluble compounds is being investigated. The technology was chosen by the New Energy and Industrial Technology Organization (NEDO) as one of the sponsored projects under its innovation commercialization and venture support program from April 2011 – February 2013, and for the second time from April 2013 – February 2014. In addition, collaborative research based on APNT with TOA Pharmaceuticals Co., Ltd., a company that has an extensive experience and expertise in the manufacturing and sales of pharmaceutical products, and its subsidiary Nitto Medic Co., Ltd., is ongoing with all parties having their intention focused on delivering needed drugs to the patients as quickly as possible.

Research and development of new treatment drugs for posterior eye disorders is also in progress. Posterior eye disorders such as diabetic retinopathy and age-related macular degeneration are the main causes of visual disorders such as midlife loss of eyesight. We are hoping to improve the patient adherence and compliance by developing an eye drop that would, unlike existing technologies, effectively deliver drug to the posterior eye segment.

At the same time and to ensure the early practical application of APNT, Activus is focusing on the development of the ophthalmic solution for anterior eye diseases, such as infectious cornea inflammation caused by bacteria and viruses, infectious conjunctivitis, etc.

Although specific details on the progress of development and research cannot be disclosed due to patent strategy reasons, development of products in the field of ophthalmologic drugs where the technological features of APNT can be best exploited are in progress.

The progress of the main products under development for the overseas pharmaceutical business is as follows.

■NVA237 (Glycopyrronium bromide. Indication: Chronic obstructive pulmonary disease (COPD))

- Launched in the EU and Japan (Phase III in the US)-

NVA237 (glycopyrronium bromide; brand names: Seebri® Breezhaler® (EU), Seebri® Inhalation Capsules 50mcg (Japan)) is an inhaled long-acting muscarinic antagonist (LAMA) that was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. Once-daily Seebri® Breezhaler® was first approved in the EU and Japan in September 2012 as a maintenance bronchodilator treatment for COPD, and has been approved in over 50 countries including Canada and Australia. Seebri® Breezhaler® has been launched in Germany, the UK, Japan and other major markets.

The US filing is expected in the first half of 2014.

■QVA149 (Indication: Chronic obstructive pulmonary disease (COPD))

- Approvedin the EU and Japan (Phase III in the US)-

QVA149 (glycopyrronium bromide/indacaterol maleate; brand names: Ultibro® Breezhaler® (EU), Ultibro® Inhalation Capsules (Japan)) is an inhaled, fixed-dose combination of the LAMA, glycopyrronium bromide (NVA237) and the LABA, indacaterol maleate. Ultibro® Breezhaler® was investigated for the treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE was one of the largest international clinical trial programs in COPD comprising 11 studies in total (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON,RADIATE, LANTERN, FLAME) with more than 10,000 patients across 52 countries. The first eight studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK, BLAZE, ARISE, BEACON) completed in 2012. The studies were designed to investigate efficacy (lung function, exercise endurance, exacerbations, shortness of breath and quality of life), safety and tolerability of patients treated with Ultibro.

In September 2013 Novartis was granted approval for once-daily Ultibro® Breezhaler® in the EU and Japan, as a maintenance bronchodilator treatment for COPD. By combining the benefits of both LAMA and LABA, Ultibro® Breezhaler® is expected to set a new standard of care in COPD.

(4) Financial Position

Total assets in the second quarter of the current financial year increased for 126 million yen to 6,921 million yen, as a results of recorded amortization of goodwill 794 million yen and an increase of 1,212 million yen in accounts receivable after the milestones from Novartis were recorded. As a result, the goodwill totalled 3,043 million yen.

Cash and cash equivalents as of the end of the second quarter stood at 2,226 million yen (decrease of 311 million yen from the end of the previous financial year). The current asset to total asset ratio was 51.2%, and cash and cash equivalents to current assets ratio was 62.8%.

Total liabilities as of the end of second quarter amounted to 338 million yen, an increase of 55 million yen from the end of previous financial year, mainly due to increase in recorded accounts payable that related to the purchase of NorLevo® stocks of 50 million yen.

Total net assets for the second quarter were 6,583 million yen, an increase of 71 million yen from the end of previous financial year that mainly resulted from increased in capital stock and capital surplus after the issuance of new shares. Shareholders' equity ratio increased for 1.2 points and amounted to 90.9%.

(5) Consolidated Financial Forecast for the Year Ending 31 March 2014

Net sales are forecasted to come from the sales of NorLevo®, milestone income of glycopyrronium and QVA149, and the royalties from the sales of Seebri® Breezhaler®. In addition, the project "Development of Nanotechnology-based Innovative Ophthalmic Solutions" by Activus Pharma Co., Ltd. has been chosen by the New Energy and Industrial Technology Organization (NEDO) as one of the sponsored projects under its innovation commercialization and venture support program. The income from that grant is expected to be booked as non-operating income. As a result, the results for the full year is forecasted at net sales of 2,850 million yen, an operating loss of 400 million yen, an ordinary loss of 300 million yen and a net loss of 300 million yen.

2. Explanatory Notes in Financial Results Summary

(1) Changes Related to Significant Subsidiaries

Not applicable

Although not applicable to Changes Related to Significant Subsidiaries, a new subsidiary, Sosei Corporate Venture Capital, was established in the previous quarter and has been included into the scope of the Group's financial statements.

3. Consolidated Financial Statements

(1) Consolidated Balance Sheets

(thousands of yen)

	FY2012 (as of 31 March 2013)	Q2 FY2013 (as of 30 September 2013)
Assets		
Current assets		
Cash and deposits	2,537,527	2,226,308
Accounts receivable	43,572	1,256,063
Other	33,632	64,535
Total current assets	2,614,733	3,546,907
Noncurrent assets		
Property, plant and equipment		
Buildings, net	2,452	2,237
Machinery, equipment and vehicles, net	32,309	26,796
Tools, furniture and fixtures, net	20,199	16,478
Total property, plant and equipment	54,961	45,512
Intangible assets		
Goodwill	3,837,905	3,043,855
Other	252,404	259,644
Total intangible assets	4,090,309	3,294,500
Investments and other assets		
Other	34,782	34,316
Total investments and other assets	34,782	34,316
Total noncurrent assets	4,180,053	3,374,328
Total assets	6,794,786	6,921,236
Liabilities		
Current liabilities		
Accounts payable – trade	161,785	212,267
Accounts payable – other	59,869	80,632
Accrued expenses	25,168	21,270
Income taxes payable	8,987	7,721
Other	27,148	16,233
Total current liabilities	282,959	338,124
Total liabilities	282,959	338,124
Net assets		
Shareholders' equity		
Capital stock	17,059,203	17,097,322
Capital surplus	18,979,943	19,018,062
Retained earnings	(31,228,973)	(31,268,377)
Total stockholders' equity	4,810,172	4,847,008
Accumulated other comprehensive income		
Foreign currency translation adjustments	1,283,642	1,444,242
Total accumulated other comprehensive income	1,283,642	1,444,242
Stock acquisition rights	236,238	205,918
Minority interests	181,773	85,941
Total net assets	6,511,827	6,583,111
Total liabilities and net assets	6,794,786	6,921,236

(2) Consolidate Statements of Income and Comprehensive Income

(thousands of yen)

	Q2 FY2012 (from 1 April 2012 to 30 September 2012)	Q2 FY2013 (from 1 April 2013 to 30 September 2013)
Net sales	1,218,360	1,583,005
Cost of sales	148,550	172,319
Gross profit	1,069,809	1,410,685
Selling, general and administrative expenses	1,285,612	1,429,222
Operating loss (-)	(215,802)	(18,537)
Non-operating income		
Interest income	385	1,433
Subsidy income	2,979	―
Other	44	62
Total non-operating income	3,408	1,495
Non-operating expenses		
Foreign exchange losses	54,657	116,638
Total non-operating expenses	54,657	116,638
Ordinary loss (-)	(267,051)	(133,681)
Extraordinary income		
Gain on reversal of stock acquisition rights	14,057	―
Total extraordinary income	14,057	―
Net loss before income taxes and minority interests (-)	(252,994)	(133,681)
Income taxes-current	1,555	1,554
Total income taxes	1,555	1,554
Net loss before minority interests (-)	(254,549)	(135,235)
Loss attributable to minority interests (-)	(75,396)	(95,831)
Net loss (-)	(179,153)	(39,403)
Loss attributable to minority interests (-)	(75,396)	(95,831)
Net loss before minority interests (-))	(254,549)	(135,235)
Other comprehensive income		
Valuation difference on available-for-sale securities	(3,661)	―
Foreign currency translation adjustments	19,078	160,599
Total other comprehensive income	15,417	160,599
Comprehensive income	(239,131)	25,364
(Breakdown)		
Comprehensive income attributable to owners of the parent company	(163,735)	121,196
Comprehensive income attributable to minority interests	(75,396)	(95,831)

(4) Consolidated Statements of Cash Flows

(thousands of yen)

	Q2 FY2012 (from 1 April 2012 to 30 September 2012)	Q2 FY2013 (from 1 April 2013 to 30 September 2013)
Cash flows from operating activities		
Net loss before income taxes and minority interests (-)	(252,994)	(133,681)
Depreciation	12,538	11,713
Amortization of goodwill	794,049	794,049
Share-based compensation expenses	14,618	—
Gain on reversal of stock acquisition rights	(14,057)	—
Foreign exchange losses (gains)	33,695	(9,174)
Decrease (increase) in receivables – trade	(963,644)	(1,169,191)
Decrease (increase) in advance payments	17,715	(25,153)
Increase (decrease) in payables – trade	49,693	50,482
Increase (decrease) in accrued expenses	(114,402)	(4,832)
Other	(16,092)	(10,785)
Subtotal	(438,881)	(475,003)
Interests and dividends received	385	1,433
Proceeds from subsidy	25,692	—
Income taxes paid	(3,110)	(3,109)
Net cash provided by operating activities	(415,913)	(476,679)
Cash flows from investing activities		
Purchase of property, plant and equipment	(10,359)	(7,766)
Other	0	—
Net cash provided by investing activities	(10,358)	(7,766)
Cash flows from financing activities		
Proceeds from issuance of common stock	27,579	45,919
Net cash provided by financing activities	27,579	45,919
Effect of exchange rate changes on cash and cash equivalents	(26,250)	127,306
Increase (decrease) in cash and cash equivalents	(424,943)	(311,219)
Cash and cash equivalents at beginning of financial year	1,497,653	2,537,527
Cash and cash equivalents at end of financial year	1,072,709	2,226,308

(3) Notes to consolidated financial statements

(Notes Related to Going Concern Assumptions)

Not applicable

(Notes Regarding Significant Changes in the Amount of Shareholders' Equity)

Not applicable

(Segment Information)

I) Reportable segments for Q2 FY2012 (1 April 2012 – 30 September 2012)

1. Net sales, profits or losses, assets, liabilities and other items by reportable segment

(thousands of yen)

	Domestic pharmaceuticals segment	Overseas pharmaceuticals segment	Total
Net sales			
Net sales to third parties	229,815	988,544	1,218,360
Total	229,815	988,544	1,218,360
Segment profit (loss)	(203,090)	204,024	934

2. Differences between reportable segment information and consolidated financial statements (items concerning difference adjustment)

(thousands of yen)

Profits	Amount
Sum of profits of reportable segments	934
Group-wide expenses (Note)	(259,277)
Other adjustments	42,540
Operating loss on consolidated financial statements (-)	(215,802)

(Note) Group-wide expenses are those incurred by the holding company that does not generate earnings on its own.

3. Information concerning loss on impairment of non-current assets by reporting segment

No material information to report.

II) Reportable segments for Q2 FY2013 (1 April 2013 – 30 June 2013)

(thousands of yen)

	Domestic pharmaceuticals segment	Overseas pharmaceuticals segment	Total
Net sales			
Net sales to third parties	265,271	1,317,734	1,583,005
Total	265,271	1,317,734	1,583,005
Segment profit (loss)	(232,515)	314,295	81,780

2. Differences between reportable segment information and consolidated financial statements (items concerning difference adjustment)

(thousands of yen)

Profits	Amount
Sum of profits of reportable segments	81,780
Group-wide expenses (Note)	(308,771)
Other adjustments	208,454
Operating loss on consolidated financial statements (-)	(18,537)

(Note) Group-wide expenses are those incurred by the holding company that does not generate earnings on its own.

3. Information concerning loss on impairment of non-current assets by reporting segment

No material information to report.