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

9 August 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
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Scheduled date of filing securities report (yukashoken hokokusho)	14 August 2013	Scheduled date of dividend payments	―
Supplementary materials for financial results:	No		
Briefing session of financial results:	No		

(Rounded down to nearest million yen)

1. Consolidated Financial Results for the First Quarter FY2013 (1 April 2013 to 30 June 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	%
Q1 FY2013	69	(66.0)	(676)	―	(677)	―	(608)	―
Q1 FY2012	203	(14.7)	(613)	―	(653)	―	(653)	―

(Note) Comprehensive income: Q1 FY2013 -616 million yen (-%) Q1 FY2012 -630 million yen (-%)

	Net income per share – basic	Net income per share - diluted
	Yen	Yen
Q1 FY2013	(50.99)	―
Q1 FY2012	(55.25)	―

(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
Q1 FY2013	6,278	5,931	89.3	469.32
Q1 FY2012	6,794	6,511	89.7	511.14

(Reference) Stockholders' equity: Q1 FY2013 5,606 million yen; Q1 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	―				
FY2013 (E)		0.00	―	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)

2) Number of treasury shares at the end of the reporting period

3) Average number of outstanding shares (cumulative)

Q1 FY2013	11,946,100	FY2012	11,921,900
Q1 FY2013	—	FY2012	—
Q1 FY2013	11,936,622	Q1 FY2012	11,833,800

(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.

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1. Operating Resuts and Financial Position for Q1 FY2013

(1) Operating Results for Q1 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 first quarter of the current financial year:

Consolidated Operating Results

(millions of yen)

	Q1 FY2012	Q1 FY2013	Year-on-year changes
Net sales	203	69	(134)
Gross profit	78	30	(47)
Operating income (loss)	(613)	(676)	(62)
Ordinary income (loss)	(653)	(677)	(24)
Net income (loss)	(653)	(608)	45

(Sales and Gross profit)

Sales in the first quarter of the current financial year totalled 69 million yen (a decrease of 65.8% compared to the previous financial year). Although the royalties for Seebri® Breezhaler® (January – March 2013) were recorded, the decrease of sales is mainly due to the fact that sales of NorLevo was not recorded in the first quarter of the fiscal year.

(Operating loss)

Operating loss in the first quarter of the current financial year increased to 676 million yen, a 62 million yen difference from the previous financial year, mainly due to decrease of sales.

(Ordinary loss)

Ordinary loss in the first quarter of the current financial year increased to 677 million yen, a 24 million yen difference from the previous financial year, mainly due to decrease of sales.

(Net loss)

Net loss in the first quarter of the current financial year decreased to 608 million yen, a 45 million yen difference from the previous financial year, mainly due to recorded minority interests loss.

Breakdown of Selling, General and Administrative Expenses

(millions of yen)

	Q1 FY2012	Q1 FY2013	Year-on-year changes
Amortization of goodwill	397	397	―
Research and development expenses	106	121	14
Other expenses	188	189	1
Total selling, general and administrative expenses	692	707	15

(Selling, General and Administrative Expenses)

Selling, General and Administrative Expenses totalled 707 million yen, an increase of 2.2% 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.

The operating results by business segment are as follows.

(Domestic pharmaceutical business)

Since NorLevo® sales were not recorded in this quarter, sales of domestic pharmaceutical business segment decreased by 161 million yen compared to the previous period totalling 42 million yen, and the operating loss increased to 166 million yen (an increase of 83 million yen compared to the previous financial year).

(Overseas pharmaceutical business)

Sales in overseas pharmaceutical business segment totalled 27 million yen, as a result of received royalties on sales of Seebri® Breezhaler®. Operating loss in overseas segment increased for 65 million yen from the previous financial year, to 477 million yen.

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 commenced in March 2013.

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

The characteristic of the nano-particle technology (hereinafter known as APNT), a drug discovery platform technology that is owned by the Group's wholly-owned subsidiary Activus Pharma Co., Ltd., 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 is a problem 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, which has been very difficult to develop so far, is being considered. Collaborative research using APNT with TOA Pharmaceuticals Co., Ltd., a company that has much experience and expertise in the manufacturing and sales of pharmaceutical products, and its subsidiary Nitto Medic Co., Ltd., is currently in progress.

Collaborative research and development of new treatment drugs for posterior segment disorders is also in progress with Gifu University. Posterior segment disorders such as diabetic retinopathy and age-related macular degeneration are the main causes of visual disorders such as midlife loss of eyesight. In this collaborative research using APNT, a new ophthalmic solution that aims to improve the Quality of Life (QOL) of patients by delivering drugs effectively to the posterior segment unlike existing treatment methods is being developed.

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.

Although specific details on the progress of the collaborative development and research with the various companies are not 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 name: Seebri® Breezhaler® (EU), Seebri® Inhalation Capsules (Japan). "glycopyrronium"), a once-daily long-acting muscarinic antagonist (LAMA), was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner, Vectura.

Glycopyrronium received regulatory approval in the EU and Japan as a once-daily long-acting muscarinic antagonist (LAMA) maintenance therapy for the treatment of the symptoms of adult patients with COPD, in September 2012. In addition, a further nine approvals have been granted, including Canada and Australia. The product has since been launched in a number of countries, including Germany, UK and Japan. In the US, filing is expected in Q1 2014.

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

- Submitted for approval in the EU, Japan (Phase III in the US)-

QVA149 is an investigational inhaled, once-daily, fixed-dose combination of glycopyrronium (LAMA) and indacaterol maleate, long acting beta 2-agonist（LABA）. QVA149 is being investigated for the maintenance treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE is 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 have already completed in 2012. The studies are designed to investigate efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, shortness of breath and quality of life.

The EU and Japan marketing authorization application for QVA149 were filed in October and November 2012, respectively, and in July 2013 the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for approval of QVA149, as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The US application is expected to be submitted by the end of 2014.

(2) Financial Position

Total assets in the first quarter of the current financial year amounted to 6,278 million yen, a decrease of 516 million yen from the end of previous financial year, due to amortization of goodwill 397 million yen of Sosei R&D. As a result, the goodwill totalled 3,440 million yen.

Cash and cash equivalents as of the end of the first quarter stood at 2,273 million yen (down 264 million yen from the end of the previous financial year).The current asset to total asset ratio was 39.8%, and cash and cash equivalents to current assets ratio was 90.9%.

Total liabilities as of the end of first quarter amounted to 347 million yen, an increase of 64 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 58 million yen.

Total net assets for the first quarter were 5,931 million yen, a decrease of 580 million yen from the end of previous financial year that mainly resulted from incurred net loss of 608 million yen. Shareholders' equity ratio decreased for 0.4 points and amounted to 89.3%.

(3) 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 during this period 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)	FY2013 (as of 30 June 2013)
Assets		
Current assets		
Cash and deposits	2,537,527	2,273,290
Accounts receivable	43,572	65,904
Merchandise and finished goods	—	94,763
Other	33,632	67,811
Total current assets	2,614,733	2,501,768
Noncurrent assets		
Property, plant and equipment		
Buildings, net	2,452	2,345
Machinery, equipment and vehicles, net	32,309	29,553
Tools, furniture and fixtures, net	20,199	18,340
Total property, plant and equipment	54,961	50,238
Intangible assets		
Goodwill	3,837,905	3,440,880
Other	252,404	251,524
Total intangible assets	4,090,309	3,692,404
Investments and other assets		
Other	34,782	34,330
Total investments and other assets	34,782	34,330
Total noncurrent assets	4,180,053	3,776,973
Total assets	6,794,786	6,278,742
Liabilities		
Current liabilities		
Accounts payable – trade	161,785	220,424
Accounts payable – other	59,869	82,225
Accrued expenses	25,168	23,133
Income taxes payable	8,987	5,234
Other	27,148	16,355
Total current liabilities	282,959	347,373
Total liabilities	282,959	347,373
Net assets		
Shareholders' equity		
Capital stock	17,059,203	17,089,012
Capital surplus	18,979,943	19,009,752
Retained earnings	(31,228,973)	(31,837,640)
Total stockholders' equity	4,810,172	4,261,125
Accumulated other comprehensive income		
Foreign currency translation adjustments	1,283,642	1,345,360
Total accumulated other comprehensive income	1,283,642	1,345,360
Stock acquisition rights	236,238	213,100
Minority interests	181,773	111,783
Total net assets	6,511,827	5,931,369
Total liabilities and net assets	6,794,786	6,278,742

(2) Consolidate Statements of Income and Comprehensive Income

(thousands of yen)

	Q1 FY2012 (from 1 April 2012 to 30 June 2012)	Q1 FY2013 (from 1 April 2013 to 30 June 2013)
Net sales	203,914	69,825
Cost of sales	125,751	38,914
Gross profit	78,162	30,910
Selling, general and administrative expenses	692,124	707,512
Operating loss (-)	(613,962)	(676,601)
Non-operating income		
Interest income	48	507
Other	16	13
Total non-operating income	65	520
Non-operating expenses		
Foreign exchange losses	39,183	1,799
Total non-operating expenses	39,183	1,799
Ordinary loss (-)	(653,080)	(677,880)
Net loss before income taxes and minority interests (-)	(653,080)	(677,880)
Income taxes-current	777	776
Total income taxes	777	776
Net loss before minority interests (-)	(653,857)	(678,657)
Loss attributable to minority interests (-)	―	(69,990)
Net loss (-)	(653,857)	(608,666)
Loss attributable to minority interests (-)	―	(69,990)
Net loss before minority interests (-))	(653,857)	(678,657)
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,960)	―
Foreign currency translation adjustments	25,155	61,717
Total other comprehensive income	23,195	61,717
Comprehensive income	(630,662)	(616,939)
(Breakdown)		
Comprehensive income attributable to owners of the parent company	(630,662)	(546,949)
Comprehensive income attributable to minority interests	―	(69,990)

(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 Q1 FY2012 (1 April 2012 – 30 June 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	203,914	—	203,914
Total	203,914	—	203,914
Segment loss (-)	(83,167)	(411,534)	(494,701)

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	(494,701)
Group-wide expenses (Note)	(140,530)
Other adjustments	21,270
Operating loss on consolidated financial statements (-)	(613,962)

(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 Q1 FY2013 (1 April 2013 – 30 June 2013)

(thousands of yen)

	Domestic pharmaceuticals segment	Overseas pharmaceuticals segment	Total
Net sales			
Net sales to third parties	42,521	27,303	69,825
Total	42,521	27,303	69,825
Segment loss (-)	(166,169)	(477,225)	(643,395)

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	(643,395)
Group-wide expenses (Note)	(137,005)
Other adjustments	103,799
Operating loss on consolidated financial statements (-)	(676,601)

(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.