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

12 February 2014

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 February 2014	Scheduled date of dividend payments	—
Supplementary materials for financial results:	—		
Briefing session of financial results:	—		

(Rounded down to nearest million yen)

1. Consolidated Financial Results for the Third Quarter FY2013 (1 April 2013 to 31 December 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	%
Q3 FY2013	1,851	(0.5)	(479)	—	(553)	—	(403)	—
Q3 FY2012	1,861	123.1	(331)	—	(305)	—	(200)	—

(Note) Comprehensive income: Q3 FY2013 - 193 Million yen (-%) Q3 FY2012 -168 Million yen (-%)

	Net income per share – basic	Net income per share - diluted
	Yen	Yen
Q3 FY2013	(33.76)	—
Q3 FY2012	(16.93)	—

(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	Shareholders' equity per share
	Million yen	Million yen	%	Yen
Q3 FY2013	6,554	6,371	93.7	513.20
FY2012	6,794	6,511	89.7	511.14

(Reference) Stockholders' equity: Q3 FY2013 6,142 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 Q2	End Q3	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	2,100	7.2	(1,150)	—	(1,180)	—	(1,000)	—	(83.67)

(Note) Please see "(5) Consolidated Financial Forecast for FY2013" on page 7 for more information.

* 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 revised accounting standards: None
2) Changes due to revised 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)	Q3 FY2013	11,968,100	FY2012	11,921,900
2) Number of treasury shares at the end of the reporting period	Q3 FY2013	—	FY2012	—
3) Average number of outstanding shares (cumulative)	Q3 FY2013	11,951,542	Q3 FY2012	11,848,964

(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 Results and Financial Position for Q3 FY2013

(1) Operating Results for Q3 FY2013

The Group pursues 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 licensees and the sales from its pharmaceutical products.

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

Consolidated Operating Results

(Million yen)

	Q3 FY2012	Q3 FY2013	Year-on-year changes
Net sales	1,861	1,851	(10)
Gross profit	1,575	1,666	91
Operating income (loss)	(331)	(479)	(148)
Ordinary income (loss)	(305)	(553)	(248)
Net income (loss)	(200)	(403)	(202)

(Sales and Gross profit)

Sales in the third quarter of the current financial year totalled 1,851 million yen, as a result of received milestone payments triggered by regulatory approvals of Ultibro®* in Europe in Japan, and royalties from the sales of Seebri®*.

(Operating loss)

Operating loss in the third quarter of the current financial year was 479 million yen. A decrease of 148 million yen, compared to the third quarter in the previous financial year, was primarily due to the increase of selling, general and administrative expenses. For more details on selling, general and administrative expenses please see the below table “Breakdown of Selling, General and Administrative Expenses”.

(Ordinary loss)

Ordinary loss in the third quarter of the current financial year increased to 553 million yen, a 248 million yen difference from the previous financial year, primarily due to the exchange rate loss.

(Net loss)

Net loss in the third quarter of the current financial year increased to 403 million yen primarily due to the exchange rate loss.

Breakdown of Selling, General and Administrative Expenses

(Million yen)

	Q3 FY2012	Q3 FY2013	Year-on-year changes
Amortization of goodwill	1,191	1,191	—
Research and development expenses	258	375	117
Other expenses	458	580	122
Total selling, general and administrative expenses	1,907	2,146	239

* *Ultibro® Breezhaler® (EU) / Ultibro® Inhalation Capsules (Japan) and Seebri® Breezhaler® 50 mcg (EU) / Seebri® Inhalation Capsules 50 mcg (Japan) are the registered trademarks of Novartis AG.*

(Selling, General and Administrative Expenses)

Selling, general and administrative expenses totalled 2,146 million yen, an increase of 12.5% 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 134 million yen in this quarter. This was mainly due to the evaluation of accounts receivable and cash deposits of the foreign subsidiary based on the exchange rate at the end of the third quarter.

(Subsidy income)

Subsidy income of 10 million yen was recorded in this quarter, due to received grant for development of pharmaceutical products based on APNT technology.

(R&D subsidy)

R&D subsidy of 47 million yen was recorded in this quarter for the expenses incurred for the Japan marketing authorization transfer for NorLevo® to ASKA Pharmaceuticals.

The operating results by business segment are as follows:

(Domestic pharmaceutical business)

Sales of domestic pharmaceutical business segment totalled 429 million yen. Although a milestone payment triggered by marketing authorization transfer to ASKA Pharmaceutical was recorded, a decrease compared to the previous period was primarily due to the decrease of NorLevo® sales in Japan.

Operating loss in domestic segment totalled 269 million yen.

(Overseas pharmaceutical business)

Sales in overseas pharmaceutical business segment totalled 1,421 million yen. An increase of 25 million yen compared to the same period in the previous year is mainly due to a difference in exchange rate of milestones received in a foreign currency and received royalties.

Operating loss in overseas segment totalled 87 million yen.

(2) Research and development activities

Research and development activities in the third quarter were focused on undergoing Phase III clinical trial of SO-1105, as well as the research and development based on nano-technology (APNT). As a result, R&D expenses amounted to 375 million yen (a 45.4% increase on a year-to year basis). In addition, Novartis' first- in- class once daily dual bronchodilator QVA149 was granted approval in Europe and Japan, and was launched in November 2013. NVA237 and QVA149 have been developed by Novartis International AG ("Novartis"), thus R&D costs for the two 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.
In addition, on 4 February 2014 Sosei signed a distribution and commercialization agreement for SO-1105 in Japan
with FUJIFILM Pharma.

■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") is 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. Investigation is underway into exploitation of this feature through application of the technology to injections, ophthalmic solutions and inhalations with poorly soluble compounds. The technology was chosen by the New Energy and Industrial Technology Development Organization (NEDO) as one of the sponsored projects under its Innovation Commercialization Venture Support Project 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 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 the 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 an 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 underway.

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

■**NVA237** *COPD : Launched in the EU and Japan, Phase III in the US*
Asthma : Phase III
NVA237 (glycopyrronium bromide; brand names: Seebri® Breezhaler® (EU), Seebri® Inhalation Capsules 50mcg (Japan); "Seebri") 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 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 has been launched in Germany, Japan and other major markets.
In its FY2013 results announcement Novartis disclosed that the US filing for NVA237 is now expected in Q4 2014. It also announced that a Phase III clinical trial program targeted toward a future expansion of indication of Seebri for uncontrolled asthma has been initiated.

■**QVA149** *COPD : Approved in the EU and Japan, Phase III ongoing in the US*

QVA149 (glycopyrronium bromide/indacaterol maleate; brand names: Ultibro® Breezhaler® (EU), Ultibro®

Inhalation Capsules (Japan); "Ultibro")) is an inhaled, fixed-dose combination of the LAMA, glycopyrronium bromide (NVA237) and the LABA, indacaterol maleate. Ultibro was investigated for the maintenance treatment of COPD in the Phase III IGNITE clinical trial program.

Once-daily Ultibro was first approved in the EU and Japan in September 2013 as a maintenance bronchodilator treatment for COPD, and has also been approved in Canada. Ultibro has been launched in Germany, the Netherlands, Denmark, Ireland and Japan. By combining the efficacy benefits and safety profiles of both LAMA and LABA, Ultibro is expected to set a new standard of care in COPD.

The US filing for QVA149 is expected in Q4 2014.

(4) Financial Position

Although received milestone payments from Novartis caused cash and cash equivalents to increase by 755 million yen, total assets decreased by 240 million yen to 6,554 million yen as a result of the recorded amortization of goodwill 1,191 million yen. Subsequently, the goodwill totalled 2,646 million yen.

Cash and cash equivalents as of the end of the third quarter amounted to 3,293 million yen (an increase of 755 million yen from the end of the previous financial year). The current asset to total asset ratio was 54.6%, and cash and cash equivalents to current assets ratio was 92.0%.

Total liabilities as of the end of third quarter amounted to 182 million yen, a decrease of 100 million yen from the end of previous financial year, mainly due to a 115 million yen decrease of accounts payable relating to the purchase of NorLevo® inventory.

Total net assets for the third quarter were 6,371 million yen, a decrease of 140 million yen from the end of previous financial year that mainly resulted from a recorded net loss of 403 million yen. Shareholders' equity ratio increased by 4.0 points to 93.7%.

(5) Consolidated Financial Forecast for FY2013

Due to unanticipated change of the filing schedule for NVA237 in the US to Q4 2014, the milestone payment initially expected to be received in Q4 FY2013 could not be recorded in this fiscal year. Subsequently, this has necessitated revision to the Company's previous forecasts.

Revised forecast for net sales now includes the sales of NorLevo®, milestone payments for Ultibro®, and the royalties from the sales of Seebri®. 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 Development Organization (NEDO) as one of the sponsored projects under its Innovation Commercialization Venture Support Project. The income from that grant is expected to be booked as non-operating income. As a result, the revised forecast is as shown in the below table.

	Net Sales	Operating Income	Ordinary Income	Net Income	Net income per share-basic
	Million yen	Million yen	Million yen	Million yen	Yen
Previous forecast (A)	2,850	(400)	(300)	(300)	(25.16)
Revised forecast (B)	2,100	(1,150)	(1,180)	(1,000)	(83.67)
Increase/Decrease (B-A)	(750)	(750)	(880)	(700)	—
Increase/Decrease (%)	(26.3)	—	—	—	—
FY2013 actual	1,958	(953)	(788)	(646)	(54.54)

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 Q1 FY2013 and has been included into the scope of the Group's financial statements.

3. Consolidated Financial Statements

(1) Consolidated Balance Sheets

(Thousand yen)

	FY2012 (as of 31 March 2013)	Q3 FY2013 (as of 31 December 2013)
Assets		
Current assets		
Cash and deposits	2,537,527	3,293,134
Accounts receivable	43,572	157,500
Other	33,632	129,180
Total current assets	2,614,733	3,579,815
Noncurrent assets		
Property, plant and equipment		
Buildings, net	2,452	2,129
Machinery, equipment and vehicles, net	32,309	24,489
Tools, furniture and fixtures, net	20,199	16,709
Total property, plant and equipment	54,961	43,328
Intangible assets		
Goodwill	3,837,905	2,646,831
Other	252,404	249,764
Total intangible assets	4,090,309	2,896,595
Investments and other assets		
Other	34,782	34,316
Total investments and other assets	34,782	34,316
Total noncurrent assets	4,180,053	2,974,240
Total assets	6,794,786	6,554,055
Liabilities		
Current liabilities		
Accounts payable – trade	161,785	46,656
Accounts payable – other	59,869	79,077
Accrued expenses	25,168	31,259
Income taxes payable	8,987	3,895
Other	27,148	21,573
Total current liabilities	282,959	182,461
Total liabilities	282,959	182,461
Net assets		
Shareholders' equity		
Capital stock	17,059,203	17,103,615
Capital surplus	18,979,943	19,024,355
Retained earnings	(31,228,973)	(31,632,453)
Total stockholders' equity	4,810,172	4,495,517
Accumulated other comprehensive income		
Foreign currency translation adjustments	1,283,642	1,646,553
Total accumulated other comprehensive income	1,283,642	1,646,553
Stock acquisition rights	236,238	200,578
Minority interests	181,773	28,944
Total net assets	6,511,827	6,371,593
Total liabilities and net assets	6,794,786	6,554,055

(2) Consolidate Statements of Income and Comprehensive Income

(Thousand yen)

	Q3 FY2012 (from 1 April 2012 to 31 December 2012)	Q3 FY2013 (from 1 April 2013 to 31 December 2013)
Net sales	1,861,499	1,851,476
Cost of sales	285,707	184,557
Gross profit	1,575,792	1,666,918
Selling, general and administrative expenses	1,907,351	2,146,641
Operating loss (-)	(331,559)	(479,723)
Non-operating income		
Interest income	436	2,051
Gain on sales of marketable securities	4,596	―
Foreign exchange gains	3,577	―
Subsidy income	17,733	10,307
R&D subsidy	―	47,619
Other	44	157
Total non-operating income	26,387	60,135
Non-operating expenses		
Foreign exchange losses	―	134,389
Total non-operating expenses	―	134,389
Ordinary loss (-)	(305,171)	(553,977)
Extraordinary income		
Gain on reversal of stock acquisition rights	31,175	―
Total extraordinary income	31,175	―
Net loss before income taxes and minority interests (-)	(273,995)	(553,977)
Income taxes-current	2,332	2,331
Total income taxes	2,332	2,331
Net loss before minority interests (-)	(276,328)	(556,308)
Loss attributable to minority interests (-)	(75,695)	(152,829)
Net loss (-)	(200,633)	(403,479)
Loss attributable to minority interests (-)	(75,695)	(152,829)
Net loss before minority interests (-)	(276,328)	(556,308)
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,419)	―
Foreign currency translation adjustments	109,206	362,910
Total other comprehensive income	107,787	362,910
Comprehensive income	(168,541)	(193,398)
(Breakdown)		
Comprehensive income attributable to owners of the parent company	(92,846)	(40,568)
Comprehensive income attributable to minority interests	(75,695)	(152,829)

(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 Q3 FY2012 (1 April 2012 – 31 December 2012)

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

(Thousand yen)

	Domestic pharmaceuticals segment	Overseas pharmaceuticals segment	Total
Net sales			
Net sales to third parties	465,682	1,395,816	1,861,499
Total	465,682	1,395,816	1,861,499
Segment profit (loss)	(240,328)	199,025	(41,303)

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

(Thousand yen)

Profits	Amount
Sum of profits of reportable segments	(41,303)
Group-wide expenses (Note)	(354,065)
Other adjustments	63,810
Operating loss on consolidated financial statements	(331,559)

(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 Q3 FY2013 (1 April 2013 – 31 December 2013)

(Thousand yen)

	Domestic pharmaceuticals segment	Overseas pharmaceuticals segment	Total
Net sales			
Net sales to third parties	429,703	1,421,772	1,851,476
Total	429,703	1,421,772	1,851,476
Segment profit (loss)	(269,532)	(87,162)	(356,694)

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

(Thousand yen)

Profits	Amount
Sum of profits of reportable segments	(356,694)
Group-wide expenses (Note)	(436,707)
Other adjustments	313,678
Operating loss on consolidated financial statements (-)	(479,723)

(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.

(Material Subsequent Events)

A Distribution Agreement with FUJIFILM Pharma

Sosei Group's consolidated subsidiary, Sosei Co., Ltd., ("Sosei K.K.") signed a distribution agreement for commercialization of SO-1105 in Japan with FUJIFILM Pharma Co., Ltd ("FUJIFILM Pharma") on 4 February 2014.

Under the terms of the agreement with FUJIFILM Pharma, Sosei K.K. will be responsible for registration, manufacturing and supply, and FUJIFILM Pharma for marketing and distribution of SO-1105. Based on this agreement, Sosei K.K. is entitled to receive a total of 900 million yen for key initial payment and achieved development and regulatory milestones, as well as margin on the sales of SO-1105 to FUJIFILM Pharma. Additional payments may also be received upon achievement of sales-based milestones.

The distribution agreement with FUJIFILM Pharma, which has expertise in infectious diseases, is expected to help Sosei expand the reach of SO-1105 to more oropharyngeal candidiasis patients.