



8 August 2012

**Summary of Consolidated Financial Results  
for the Q1 ended 30 June 2012  
(abridged English version)**

Sosei Group Corporation ("Sosei"; TSE Mothers Index: 4565) today reported financial results for the Q1 ended 30 June 2012.

Net sales during the quarter totalled ¥203M (¥238M in the same period last year). Income in this period was primarily based on the sales of NorLevo<sup>®</sup> (emergency contraceptive) in Japan and Australia. 14.7% decrease in sales compared to the same period last year is due to the difference in received milestones. The launch of NorLevo<sup>®</sup> triggered the milestone in the same period last year, whereas no milestone payment was received in this quarter.

Selling, General and Administrative (SG&A) expenses were ¥692M (¥663M in the comparative period last year). Within SG&A expenses, R&D expenses increased to ¥106M (from ¥53M in the same period last year) as development costs for SO-1105 were incurred in this period. Other SG&A costs were ¥188M (¥212M in the same period) and amortization of goodwill was ¥397M (same as the amount in the comparative period last year).

As a result, operating loss was ¥613M (¥526M in the same period last year), while net loss was ¥653M (¥531M in the same period of the prior year).

The Group had ¥1,204M of cash, cash equivalents and short-term investments as of 30 June 2012, compared to ¥1,497M as of 31 March 2012.

## Highlights of the first quarter:

### **NVA237 and QVA149 for chronic obstructive pulmonary disease (COPD)**

NVA237 is a dry powder formulation for inhalation of glycopyrronium bromide, a long-acting muscarinic antagonist (LAMA) with a rapid onset of activity. NVA237 was licensed to Novartis in April 2005 by Sosei and our co-development partner, Vectura Group.

At present, NVA237 is under regulatory review in the EU, where it was submitted for approval in September 2011 under the brand name Seebri<sup>®</sup> Breezhaler<sup>®</sup>. In June 2012, Novartis received positive CHMP opinion on NVA237 with recommendation for granting of marketing authorisation.

In Japan, Novartis submitted NVA237 for approval in November 2011, and signed a co-promotion agreement with Eisai Co. Ltd in the same month.

In the US, Novartis expects to file the product for approval at the beginning of 2014.

QVA149, a fixed-dose combination of NVA237 and indacaterol maleate (Onbrez<sup>®</sup> Breezhaler<sup>®</sup>) remains on track for submission in ex-US countries starting in the fourth quarter of 2012. In April 2012 Novartis announced topline data from the first four Phase III studies, SHINE, BRIGHT, ENLIGHTEN and ILLUMINATE. The results from these studies, demonstrate the potential of QVA149 in the treatment of COPD. The four studies are key components of the IGNITE program, which is one of the largest international patient registration programs in COPD, comprising 10 studies in total, and including more than 5,700 patients across 42 countries. These studies are designed to investigate efficacy, safety and tolerability, lung function, exercise endurance, exacerbations, dyspnoea and quality of life.

- SHINE demonstrated the superiority of QVA149 compared to indacaterol or NVA237 alone. The study also showed QVA149's superiority compared to placebo and open-label tiotropium.
- BRIGHT demonstrated that patients taking QVA149 experienced significantly better exercise endurance than those taking placebo, while
- ENLIGHTEN showed that QVA149 was well tolerated, with a safety and tolerability profile similar to placebo.

- The ILLUMINATE study demonstrated superior lung function of once-daily QVA149 compared to twice-daily Seretide<sup>®</sup>.

In the US, Novartis expects to file the product for approval at the end of 2014.

To date, Sosei has received \$35M from Novartis and, under the terms of the licence, could receive up to an additional \$152.5M for achievement of regulatory and commercialisation targets for both NVA237 and QVA149. In addition, royalties will be received on product sales in the event of successful product launches.

### **SO-1105 for oropharyngeal candidiasis (OPC)**

Sosei Group's wholly owned Japanese subsidiary, Sosei Co., Ltd. acquired development and commercialisation rights to Loramyc<sup>®</sup> (development code: SO-1105) in Japan from BioAlliance Pharma in May 2011. Loramyc<sup>®</sup> is an antifungal agent, administered as a muco-adhesive buccal tablet for the treatment of oropharyngeal candidiasis in immunocompromised patients. Loramyc<sup>®</sup> has been registered in 26 European countries, in South Korea, and the United States. Phase I clinical study designed to evaluate the pharmacokinetics and safety of SO-1105 in healthy Japanese adults was successfully completed in July 2012.

<b>Sosei Group Corporation</b>		
<b>Consolidated Financial Results (Unaudited)</b> ( Yen Millions)		
	Q1 ended 30 June	
	2012	2011
Net sales	203	238
Cost of sales	125	101
Gross Profit	78	137
Selling, General and Administration Research & Development (R&D)	106	53
Amortisation of goodwill	397	397
Other SGA	<u>188</u>	<u>212</u>
Total Selling, General and Administration	692	663
Operating profit/(loss)	(613)	(526)
Non-operating income/(expenses)	(39)	(4)
Income/(loss) before taxes	(653)	(530)
Income tax (charge)/credit	<u>(0)</u>	<u>(0)</u>
Net income/(loss)	(653)	(531)
Average number of shares outstanding	118,338	118,338

**Consolidated Balance Sheet Data (Unaudited)**  
( Yen Millions)

	FY2012 Q1 ended 30 June	FY2011 ended 31 March
Cash, cash equivalents and short-term investments	1,204	1,497
Goodwill	5,028	5,426
Total assets	6,834	7,390
Total liabilities	351	288
Total stockholders equity (excluding impact of foreign exchange gains & losses and Stock Acquisition Rights)	4,660	5,314

**Forecast for the Fiscal Year Ending 31 March 2013**

The financial forecast for the year ending 31 March 2013 remains unchanged from that announced on 15 May 2012.