14 November 2011

Summary of Consolidated Financial Results for the First Half Year ended 30 September 2011 (abridged English version)

Sosei Group Corporation (4565, Tokyo Stock Exchange, Mothers Index) today reported financial results for the first half ended 30 September 2011.

The net sales for the first half year totalled ¥804M (¥709M in the same period a year ago). The income in this period is primarily based on milestone revenue from Novartis triggered by NVA237 filing for marketing authorisation with the European Medicines Agency (EMA), and sales of NorLevo® (emergency contraceptive) in Japan and Australia.

Cost of Goods Sold (COGS) increased to ¥194M from ¥49M in the previous year due to the increase in sales of NorLevo® in Japan.

Selling, General and Administration (SGA) expenses were ¥1,295M (¥1,201M, in the previous year). Within SGA, R&D expenses were ¥100M (¥122M in the comparative period last year). Other SGA costs increased by 40.7% to ¥401M due to additional overhead costs. Amortisation of goodwill relating to the 2005 acquisition amounted to ¥794M, which is equivalent to the previous year on a pro-rated basis. Consequently, the operating loss increased to ¥685M from ¥541M, and the net loss increased to ¥755M from ¥616M in the comparative period last year.

The Group had ¥1,189M of cash and ¥531M of accounts receivables as of 30 September 2011, compared to ¥1,751M of cash on 31 March 2011.

Progress of product development and other activities during the 2Q ended 30 September 2011 include:

NorLevo® 0.75mg TABLETS
NorLevo®, the first emergency contraceptive launched in Japan and is being distributed through ASKA Pharmaceutical distribution network.

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. Novartis intends to launch NVA237 as a once-daily monotherapy for COPD in 2012 and as a combination (QVA149) with its once-daily LABA, indacaterol, in some territories in 2013.

In September 2011, Novartis filed NVA237 for marketing authorisation with the European Medicines Agency (EMA) under the brand-name Seebri® Breezhaler®, triggering a $5M milestone payment to Sosei.

The same month, Novartis presented new NVA237 Phase III data at the ERS congress. The GLOW1 and GLOW3 studies in COPD patients showed that NVA237 significantly increased patients' lung function compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance.

The GLOW1 study met its primary endpoint by showing that NVA237 50 mcg once-daily produced a significant improvement in lung function of 108 ml in trough FEV_1 (forced expiratory volume of breath in one second) after 12 weeks in patients with moderate-to-severe COPD compared to placebo ($p<0.001$). Moreover, NVA237 had a rapid onset of action, with a 93 ml improvement in FEV_1 compared to placebo at five minutes after the first dose ($p<0.001$).

NVA237 significantly prolonged the time to first moderate/severe COPD exacerbation compared to placebo, and reduced the percentage of hospitalizations. Significant improvement in breathlessness was seen at 26 weeks compared to placebo, accompanied by a significant improvement in health-related quality of life and reduction in the use of rescue medication.

The GLOW3 study investigated the effects of NVA237 50 mcg once-daily on exercise endurance in moderate-to-severe COPD patients. The study met its primary endpoint by showing a significant 21% improvement in exercise endurance relative to placebo at the end of the study (i.e. Day 21), with a significant 10% increase from day one (both $p<0.001$).

Both studies showed that NVA237 was well-tolerated, with a similar incidence of adverse events for patients treated with NVA237 and placebo.

In October, Novartis announced that in the US, NVA237 will require additional clinical data to support submission. They confirmed that, as a result of questions from the FDA, they were exploring the dosing regimen of the product.

The change to the timing of US NDA of NVA237 is likely to impact timing of the NDA submission for QVA149 in the US, though we continue to believe that QVA149 could be the first once-daily LABA/LAMA combination therapy on the market for COPD. The dual activity of a beta-adrenergic agonist ($beta_2$-agonist) and a muscarinic antagonist could result in a potent bronchodilator with convenient once-daily dosing. This would address a large and unmet need for COPD sufferers where patient compliance is a key consideration.

Novartis commenced Phase III studies with QVA149 in May 2010, triggering a $7.5M milestone payment to Sosei. Novartis expects to present Phase III data at a major respiratory conference in the second half of 2012 and to file the

product in Europe and the rest of the world the same year. The first product launch is expected in 2013.

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 the monotherapy and combination product. In addition, royalties will be received on product sales in the event of successful product launches.

APNT (Activus Pure Nano-particle Technology)

Sosei Group's 100% subsidiary, Activus Pharma entered into a Joint Development Agreement with Toa Pharmaceuticals and its subsidiary Nitto Medic. Under the terms of the agreement, both sides will jointly conduct research and development to assess the feasibility of developing various ophthalmic solutions applying APNT. Once a product has been identified for development, a separate agreement towards commercialization will be executed.

Also, Activus was awarded a grant from the New Energy and Industrial Technology Development Organization (NEDO), an Incorporated Administrative Agency under the Ministry of Economy, Trade and Industry (METI) as a part of their FY2011 Innovation Promotion Programme.
Using Activus Pure Nano-particle Technology (APNT) and surface-modified nanoparticle technology, Activus is focusing on development of high value-added products that would solve the problems existing formulations are facing. To explore the potential of APNT in treatment of ophthalmic diseases, Activus has signed a collaboration agreement with Gifu Pharmaceutical University and is now working on the development of novel posterior eye segment medication. Posterior eye segment disease such as diabetic retinopathy and age-related maculopathy is the primary cause of blindness and other visual impairments in middle age. An effective and easy-to-use medication has still not been invented, and the development of an innovative treatment is anticipated.

In-licensing

Sosei Group's wholly owned Japanese subsidiary, Sosei Co., Ltd. acquired development and commercialization rights to Loramyc® (development code: SO-1105) in Japan from BioAlliance Pharma. Loramyc® is an antifungal agent, administered as a muco-adhesive buccal tablet for the treatment of oropharyngeal candidiasis in immunocompromised patients. Loramyc® has been registered in 26 European countries, in South Korea, and the United States. Clinical studies are expected to commence in Q4 2011 fiscal year.

Sosei Group Corporation

Consolidated Financial Results (Unaudited)
(Yen Millions)

	6 months ended 30 September	
	2011	2010
Net sales	804	709
Cost of Goods Sold	194	49
Gross Margin	610	660
Selling, General and Administration		
Research & Development (R&D)	100	122
Amortisation of goodwill	794	794
Other SGA	401	285
Total SG&A	1,295	1,201
Operating profit/(loss)	(685)	(541)
Non-operating income/(expenses)	(68)	(77)
Income/(loss) before taxes	(754)	(618)
Income tax (charge)/credit	(1)	1
Net income/(loss)	(755)	(616)
Average number of shares outstanding	118,338	117,913

Consolidated Balance Sheet Data (Unaudited)
(Yen Millions)

	30 September 2011	31 March 2011
Cash, cash equivalents and short-term investments	1,189	1,751
Goodwill	6,220	7,014
Total assets	8,331	8,991
Total liabilities	339	335
Total stockholders' equity (excluding impact of foreign exchange gains & losses and Stock Acquisition Rights)	6,513	7,269

Forecast for the Fiscal Year Ending March 31, 2012

The financial forecast for the year ending 31 March 2012 was revised downward, mainly due to the expected delay of the milestone payment related to NVA237 filing in the US and currency fluctuations.

(Yen Millions)

	Original forecast	Revised forecast	Increase (decrease)
Sales	1,780	876	(904)
Operating profit/(loss)	(1,470)	(2,167)	(697)
Net profit/(loss)	(1,470)	(2,167)	(697)