

3 March 2010

Sosei Group Corporation

Year End	Revenue (¥m)	PBT* (¥m)	EPS* (¥'000s)	DPS (¥)	P/E (x)	Yield (%)
03/07	740	(4,855)	(46.0)	0.0	N/A	N/A
03/08	709	(4,569)	(41.5)	0.0	N/A	N/A
03/09	153	(2,067)	(19.9)	0.0	N/A	N/A
03/10e	888	(216)	(1.7)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding goodwill amortisation and exceptional items.

Investment summary: A purer play on COPD?

Sosei's investment case is highly reliant on the successful development of COPD therapies NVA237 and QVA149, jointly licensed to Novartis with Vectura. Key development and regulatory catalysts over the next two years should bring significant milestone revenues for Sosei (\$77.5m in milestones are due before US/EU launch). Recurring royalties post-launch should enable expansion of its R&D pipeline through future partnering opportunities that address the Japanese 'drug lag'.

Novartis milestones to boost balance sheet

Sosei has high single product risk on NVA237, which is also one of the constituents of QVA149 (with indacaterol). Progress thus far has been positive with two Phase III trials currently underway that should read out in December 2010 and March 2011, supporting a potential NDA filing mid-2011. Sosei's FY10 cash position of ¥1,711m should be boosted by a \$7.5m milestone once QVA149's Phase III starts in FY11.

Norlevo may provide additional upside next year

Sosei generates ¥100m+ annually from emergency contraceptive Norlevo (SOH-075), which is sold by Sandoz in Australia. Approval in Japan is possible in Q111 (NDA filed September 2009) providing upside to revenues.

Undisclosed licensing deals may also represent upside

Following its restructuring in 2008, Sosei has divested a number of in-house programmes, with others still available for licensing. As no deal terms have been disclosed these may represent additional upside to our forecasts.

Valuation: ¥13.1bn (£88m); but milestones to come

Our Sosei valuation model indicates a valuation of ¥13.1bn (£88m assuming ¥148.5/£), broadly in line with the current market capitalisation. This valuation principally comprises an rNPV of the key drug programmes (which will rise as products advance in the clinic) and forecast net cash for FY10e, but it does not capture the value of potential milestones (\$77.5m over the next two years). We value NVA237/QVA149 on the same basis for both Sosei and Vectura, and consider Sosei as a purer play on these programmes.

Price ¥115,000
Market Cap ¥13.6bn

Share price graph



Share details

Code 4565:JP
Listing MOTHERS
Sector Pharmaceuticals & Biotechnology
Shares in issue 118m

Price

52 week High Low
¥208,000 ¥21,510

Balance Sheet as at 31 December 2009

Debt/Equity (%) N/A
NAV per share (¥) 173,603
Net cash (¥) 2,047m

Business

Sosei Group Corporation is a Japan-based biopharma focused on R&D and drug re-profiling. It is active in licensing – both its proprietary programmes, and external rights for the Japanese market.

Valuation

	2008	2009	2010e
P/E relative	N/A	N/A	N/A
P/CF	N/A	N/A	N/A
EV/Sales	12.2	77.1	13.3
ROE	N/A	N/A	N/A

Revenues by geography

	UK	Europe	US	Other
0%	0%	0%	100%	

Analysts

Lala Gregorek 020 3077 5736
Robin Davison 020 3077 5737

healthcare@edisoninvestmentresearch.co.uk

Investment summary: A purer play on COPD?

Company description: Japanese-UK biopharma

Sosei Group Corporation is a Japan-based biopharmaceutical holding company with two subsidiaries: Sosei Co. Ltd. (Tokyo-headquartered and focused on development and sales) and Sosei R&D Ltd. (the London-based R&D operation). Current CEO Shinichi Tamura founded Sosei in 1990, originally as a technology transfer organisation, but since 1999 it has focused on R&D of in-licensed and in-house programmes (both new chemical entities and re-profiled drugs). As part of its May 2008 strategic restructuring, Sosei closed its discovery capability. It currently has a pipeline of four clinical products: the main value drivers, NVA237 and QVA149, are in late-stage trials and are partnered with Novartis in a \$375m milestone and royalty deal (economics shared 50:50 with Vectura). Sosei is active in partnering, having out-licensed late-stage development programmes and discovery assets, and the in-licensing (and retention) of rights for the Asian market.

Sosei floated on the MOTHERS index of the Tokyo Stock Exchange in July 2004 raising ¥11.3bn (\$104m). Since inception the company has raised c \$157m in equity and has received c \$27m in milestones from partners. Sosei acquired Arakis, a private UK biotechnology company focused on drug reprofiling, for £106.5m (\$187m) through a cash and share deal (£11.7m in cash and the issue of 35,630 new Sosei shares worth £94.8m) in July 2005. The company has 27 employees, four of whom are UK-based, with the CEO dividing his time between Tokyo and London.

Valuation: Reliant on success of Novartis partnership

Our valuation model for Sosei indicates a valuation of ¥13.1bn (£88m assuming ¥148.5/£), which is broadly in line with the current market capitalisation. Our valuation comprises a risk-adjusted net present value (rNPV) of Sosei's key drug programmes (calculated at ¥11bn or £74m), a ¥390m (£3m or three times sales) value to Australian sales of Norlevo and forecast net cash at end March 2010 (¥1,711m or £12m). [NB the same rationale/assumptions are used to value the COPD programmes for both Vectura and Sosei, and value of potential milestones is not captured].

Sensitivities: Drug development, deals and the dollar

Sosei's business is subject to the usual risks associated with biotech company drug development (ie possibility of clinical trial failure or rendering inconclusive/contradictory results, regulatory and commercial risks). Also, Sosei is reliant on Novartis for the clinical/regulatory progress of – and hence financial benefit derived from – NVA237/QVA149, and may also be impacted by SOH-075 approval and commercialisation, upside from existing/future partnerships and currency fluctuations.

Financials: QVA149 milestone to boost cash

Sosei reported nine month 2010 revenues of ¥870m and a pre-tax loss of ¥1,024m (9M09: ¥3,689m), reflecting both the receipt of a milestone from Novartis and the result of cost cutting initiatives following Sosei's 2008 restructuring. We expect Sosei to end FY10 (year-ending 31 March 2010) with cash of ¥1,711m, which is sufficient funding into mid-FY11, in the absence of additional milestones. However, substantial milestones are likely to be received on successful development of NVA237 and QVA149, and approval of SOH-075 – all of which may occur during FY11-FY12.

Company description: Japanese-UK biopharma

Sosei's most valuable assets are the respiratory drugs NVA237 and QVA149, exclusively partnered with Novartis under a \$375m milestone and royalty deal (economics shared 50:50 with partner Vectura). Sosei should receive its next milestone under this deal on initiation of the Phase III programme for QVA149 in COPD later in 2010.

From an investment perspective, Sosei could be viewed as a more leveraged play on COPD therapies NVA237 and QVA149 than Vectura, the UK-based speciality pharmaceutical company focused on inhaled therapeutics and its partner on these programmes. While both companies have an equal share in the economics from the Novartis licensing deal signed in 2005, Sosei could be considered to be a 'purer' play on these programmes than its partner. NVA237 and QVA149 are the main value drivers of Sosei, and it is not exposed to the same regulatory uncertainties that currently surround Vectura's respiratory generics pipeline.

The current status of Sosei's R&D pipeline is summarised in Exhibit 1.

Exhibit 1: Sosei Group R&D pipeline

Programme	Indication	Dev stage	Notes/partners
NVA237 (glycopyrronium bromide)	COPD	Phase III	Partnered with Vectura : worldwide rights exclusively licensed to Novartis . Likely to be second LAMA to reach the market. Uses Breezhaler DPI device. Two Phase III studies underway: 1,065-pt one-year trial with tiotropium as active comparator (results: March 2011) and an 800-pt 26-week placebo controlled trial (results: December 2010). NDA filing mid-2011.
QVA149 (glycopyrronium bromide + indacaterol)	COPD	Phase II completed	Partnered with Vectura : worldwide rights exclusively licensed to Novartis. Aims to be first LAMA/LABA combination to market. Uses Breezhaler DPI device. Phase III expected to initiate mid-2010, with NDA filing due 2011-2012.
SOH-075 (levonorgestrel) – Norlevo	Emergency contraceptive	Registration	Japanese commercialisation agreement with Aska Pharmaceuticals ; exclusive distribution rights (Japan and Australia) licensed from Laboratoires HRA Pharma. Sandoz markets SOH-075 as NorLevo in Australia. NDA submitted in Japan in September 2009, following a positive Phase III trial, which reported that 62/63 pregnancies were successfully prevented in Japanese adult females, with no serious adverse events.
SD 118/NSL-043	Neuropathic pain	Phase I completed	50:50 co-development agreement with NeuroDiscovery/NeuroSolutions for the exclusive rights ex-Japan and Asia, with royalties on sales in Japan and Asia. Oral, re-profiled, small molecule drug. Preclinical and pharmacological profile shows equivalent efficacy to gabapentin, with longer duration of action, and Phase I indicates better tolerability. Potential licensing opportunities being explored.

Source: Edison Investment Research

NVA237/QVA149: Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is an umbrella term that covers a number of chronic inflammatory lung diseases characterised by persistent cough and difficulty breathing, including chronic bronchitis and emphysema. It has an estimated prevalence of 210 million people worldwide and is the fourth leading cause of death globally, with the World Health Organisation projecting that it will become the third leading cause of death by 2030.

COPD is primarily caused by exposure to tobacco smoke and airborne pollutants which damage and irritate the lungs, triggering inflammation and other obstructions (eg mucus overproduction and bronchospasms), ultimately resulting in the progressive narrowing of airways and hampering breathing. Exacerbations of COPD symptoms may result in hospitalisation, and have a profound impact on survival. Despite a US market of \$4.9bn in 2009 (IMS data), there is no cure for COPD, although a number of prophylactic therapies are available.

Inhaled COPD products

Advair (fluticasone + salmeterol, GSK) and Symbicort (budesonide + formoterol, AstraZeneca) are the leading combinations of inhaled corticosteroids (ICS, which reduce airway inflammation) and long-acting beta-agonists (LABAs, which dilate airways). These two combination products dominate both the asthma and COPD markets, although their position in COPD is being challenged by Spiriva (tiotropium, Boehringer Ingelheim/Pfizer), a long-acting muscarinic antagonist (LAMA, also bronchodilators like LABAs), which can be taken once-daily. Boehringer Ingelheim has a strong position in the COPD market having developed the original muscarinic antagonist Atrovent (ipratropium), which has to be taken four times a day, as well as two combination products: Combivent (ipratropium + salbutamol) and Berodual Duovent (ipratropium + fenoterol).

In December 2009, Novartis obtained EU approval for its once-daily LABA, Onbrez (indacaterol, formerly QAB149), using its Breezhaler DPI (formerly known as Concept 1). The registration package consisted of studies in over 6,000 patients, including trials showing Onbrez improved lung function and symptoms of breathlessness compared to tiotropium,¹ formoterol² and salmeterol.³

Almirall looks to be next to the market with a single agent LAMA, aclidinium, with filing planned in the EU in early 2010 and US, in partnership with Forest Laboratories, in 2011/2012. (Almirall and Forest have also recently expanded their respiratory collaboration to include a combination of Almirall's once-daily LABA, LAS100977, with an undisclosed ICS; and Forest has separately licensed Nycomed's PDE4 inhibitor Daxas [roflumilast], which is currently in registration – 20 May PDUFA date – and could become the first oral treatment for COPD.)

Novartis is likely to follow its Onbrez launch with potentially the second single agent LAMA to reach the market, glycopyrronium bromide (NVA237), followed thereafter by its combination with indacaterol (QVA149), which could become the first LAMA/LABA combination to reach the market. The successful development of both NVA237 and QVA149 triggers undisclosed milestones to Sosei.

NVA237 and QVA149 are key programmes within Novartis's respiratory portfolio and should garner a significant share of the COPD market due to their competitive profile versus both marketed and late-stage clinical products. Of the two, QVA149 has greater market potential which is supported by its anticipated superior efficacy and bronchodilatory profile compared with monotherapies (as demonstrated in Phase II studies) resulting from the complementary mechanisms of action of LAMA and LABA. However, NVA237 should also find its niche: Phase II data has indicated that the compound has similar efficacy to tiotropium, but with an improved tolerability profile (reduced anticholinergic side effects) and potentially a more rapid onset of action. Both NVA237 and QVA149 benefit from strong efficacy with once-daily dosing in contrast with aclidinium (a twice-daily product), which should have a favourable impact on patient compliance. The competitive landscape for inhaled products in development for COPD is shown in Exhibit 2.

¹ Fogarty *et al*/Eur Respir J 2009;34 (Suppl. 53):P2025

² Dahl *et al* Eur Respir J 2009;34 (Suppl. 53):E4350

³ Kornmann *et al* Chest 2009;136:152S

Exhibit 2: Inhaled products in development for COPD

Notes: MDI = metered-dose inhaler; DPI = dry powder inhaler.

Name	Developer(s)	Device	Notes
Onbrez (indacaterol)/ QAB149	Novartis	DPI (Breezhaler)	Approved in EU (December 2009) at 150µg and 300µg doses for once-daily use. Filed in US, complete response letter requesting additional data on dosing (October 2009). Two large comparative Phase III studies (INTENSITY: 1,568-pt and INVIGORATE: 3,500-pt) vs tiotropium underway (results: February 2010 and July 2011) and smaller 110-pt Phase III study on inspiratory capacity (results: June 2010). 1,126-pt Phase III study of indacaterol with open label tiotropium (INTRUST2, results: February 2010).
Eklira (aclidinium) LAS34273 (also in combination with formoterol)	Almirall/ Forest Laboratories	DPI (Genuair)	One-year ACCLAIM/COPD I and II studies (once daily) show 60-70ml difference in trough FEV ₁ at 12 and 28 weeks. 561-pt, 12-week ACCORD/COPD I study (bid) indicate significant difference (p<0.0001) in trough FEV ₁ vs placebo at 12 weeks for both 220µg and 400µg doses (84ml and 124ml respectively). 513-pt Phase II bid in combination with formoterol completed. MAA filing in EU 2010; NDA in 2011/2012. 810-pt and 600-pt Phase III studies (ACCORD/COPD II and ATTAIN) investigating two bid doses ongoing (results: July 2011). Comparative Phase II study vs tiotropium and placebo (results: Q110).
NVA237 (glycopyrronium bromide)	Novartis	DPI (Breezhaler)	1,065-pt and 800-pt Phase III studies (results: Dec 2010 and March 2011). Phase II dose-ranging study shows 131ml increase in trough FEV ₁ for the 50µg dose. Phase II studies presented at ERS 2008 show good safety and tolerability, and sustained 24-hour bronchodilation (mean improvement in FEV ₁ of >120ml vs placebo for both 50µg and 100µg doses on day seven), with potentially a more rapid onset of action than tiotropium. Partnered with Vectura. NDA expected in 2011.
BI-1744 CL (single agent and combination with tiotropium)	Boehringer Ingelheim	Respimat	Two Phase III studies as single agent (900-pt and 920-pt; results: October 2010). Two Phase II studies in combination with tiotropium completed.
MFF258 (mometasone + formoterol)	Merck & Co	DPI or MDI	1,000-pt Phase III (results: July 2010). 240-pt Phase III completed. Filed for asthma (July 2009). Royalty due to Novartis.
Fostair (beclometasone + formoterol)/CHF1535	Chiesi/UCB	MDI	1,102-pt Phase III in severe COPD (results: June 2011).
Fluticasone + GW642444	GSK/ Theravance	DPI (Gemini)	Two 52-week 1,560-pt Phase III studies (results: October 2011); 65-pt Phase II study (results: January 2010).
QVA149 (glycopyrronium + indacaterol)	Novartis	DPI (Breezhaler)	Phase III due to start in 2010, filing due 2012. Two Phase II studies completed: data presented at ERS 2009. In a seven-day trial (n=135), mean improvement in trough FEV ₁ vs placebo on day seven was 226ml and vs indacaterol at doses of 300µg and 600µg was 123ml and 117ml. In a 14-day trial (n=225), all three doses tested were safe and well tolerated, with no change in 24-hour mean heart rate or clinically relevant effect on QTc interval. LAMA/LABA combination. Partnered with Vectura.
AVE2635A (ciclesonide + formoterol)	S-Aventis/ Nycomed	DPI	1,145-pt Phase II study completed. 240-p Phase II study completed.
CHF-4226 (carmoterol)	Chiesi	MDI	Three Phase II studies completed.
CHF-5188 (budesonide + carmoterol)	Chiesi	MDI	Intended for once-daily use.
ADC4022 (budesonide + theophylline)	Argenta Discovery	N/A	91-pt Phase II rendered positive results.
BEA-2180 BR	B Ingelheim	Respimat	3 Phase II studies completed.
GW642444	GSK	DPI	576-pt Phase II (was due to complete: March 2009). LABA.
AZD3199	AstraZeneca /Argenta	DPI	500-pt Phase II study of AZD3199 once daily vs 9µg formoterol bid and placebo (results: March 2010). LABA.
PF00610355	Pfizer	DPI	380-pt Phase II study (results: March 2010). LABA.
Budesonide + formoterol	Orion Pharma	DPI (Easyhaler)	Phase III studies for asthma/COPD. Same combination as Symbicort.
Fluticasone + salmeterol	Meda/ Almirall	DPI (Novoliser)	Europe only. Same combination as Advair.
GSK573719 + GW642444	GSK	DPI	100-pt Phase II (results: May 2010). LAMA/LABA.
PT003 (glycopyrrolate + formoterol)	Pearl Therapeutics	MDI	Phase IIb initiation anticipated H110. Phase I/II monotherapy trials complete for PT001 (glycopyrrolate) and PT005 (formoterol).
LAS100977 + ICS	Forest/ Almirall	DPI (Genuair)	Combination of LABA with undisclosed ICS. Development plans not yet disclosed.

Source: Edison Investment Research

The history of NVA237 and QVA149

NVA237 (previously AD237) is an optimised inhaled formulation of glycopyrronium bromide, a long-acting anti-muscarinic used intravenously in anaesthesia and to treat chronic gastric ulcers, and in oral form for sialorrhoea (excessive saliva) and hyperhidrosis (excessive sweating).

Arakis originated the concept of using NVA237 as a bronchodilator; and, following a collaboration agreement in November 2000, it was further developed as a novel inhaled therapy for COPD using Vectura's PowderHale inhalation technology. Under this agreement NVA237 development would be jointly funded by Arakis and Vectura, with both deriving equal benefit from any future returns.

In April 2005, Novartis acquired the exclusive rights to the global licence for NVA237, taking on responsibility for and funding the further development of NVA237 as a monotherapy, and also in combination with its own once-daily long-acting beta-agonist indacaterol (previously QAB149) as QVA149. Later in 2005, Sosei obtained Arakis's rights when it acquired the company in July.

The Novartis deal

In April 2005, Sosei (Arakis) and Vectura exclusively licensed the global rights to NVA237/QVA149 to Novartis in a \$375m joint deal. On signing, Sosei received a \$15m upfront payment, and has subsequently received \$7.5m on initiation of the NVA237 Phase III programme (April 2009). Milestones are booked as recognised on receipt. While the precise terms of the deal remain undisclosed, the economics that are in the public domain are shown in Exhibit 3.

Exhibit 3: Terms of the licensing deal with Novartis

Deal terms	Due after FY09 (ie March 2010)
\$15m upfront and up to \$172.5m in milestones (April 2005). Mid-single digit (ie ~6%) royalty. \$7.5m paid (April 2009) on Phase III initiation with NVA237. Figures represent Sosei's 50% share of \$375m joint deal (with Vectura).	\$77.5m in milestones are due before US/EU launch. \$7.5m milestone due on Phase III start for QVA149 (mid-2010).

Source: Edison Investment Research

The contract period of the Novartis licence extends to the later of the following: a) expiry of all applicable patents held by Sosei and Vectura, and b) 10 years after the first day of NVA237 sale.

In October 2009, Novartis and its partners issued a progress/timeline update for NVA237/QVA149. This confirmed that the NVA237 Phase III trials were on schedule with read out expected in December 2010 and March 2011, supporting a potential NDA filing in 2011. The QVA149 Phase III trial is anticipated to start by mid-2010.

It is also worth noting that Novartis's Onbrez (indacaterol), one of the components of QVA149, is now approved for COPD in the EU, with Novartis receiving a Complete Response letter from FDA on 16 October 2009, requesting additional information on the proposed dosing regimen.

SOH-075: Emergency contraception

Emergency contraception is used to prevent pregnancy following unprotected intercourse by preventing the implantation of a fertilised egg to the uterus, and falls into two main categories:

- hormonal emergency contraceptives (also known as 'morning-after' pills) – which must be taken within 72 hours and generally contain higher doses of hormone than conventional oral contraceptives, and;
- intrauterine devices (IUDs) – which can be implanted up to five days after intercourse.

A World Health Organisation trial published in 1998 established 'levonorgestrel only' products as the gold standard hormonal emergency contraceptive, based on their superior efficacy and side-effect profile compared to other classes of emergency contraceptive (Exhibit 4).

Exhibit 4: Classes of emergency contraceptives

Note: ECP = emergency contraceptive pill, OCP = oral contraceptive pill.

Class	Active ingredient
ECP – progestin only	Levonorgestrel
ECP – oestrogen and progestin	Oestrogen and levonorgestrel
OCP – progestin only	Levonorgestrel or norgestrel
Combined OCP	Oestrogen and a progestin (levonorgestrel, norgestrel or norethisterone)

Source: Edison Investment Research

While the first levonorgestrel-only products were approved by the FDA and EMEA in 1999 (Duramed's Plan B and HRA's Norlevo respectively), there is no comparable product approved in Japan, where emergency contraception is limited to off-label use of multiple doses of low dose combined OCPs.⁴ Sosei's product, SOH-075, is a levonorgestrel-only product developed by Laboratoires HRA Pharma and marketed as Norlevo in more than 60 EU and Asian countries. In April 2001, Sosei licensed the exclusive distribution rights for Japan and Australia, subsequently licensing the Australian marketing rights to Sandoz in December 2005.

Sosei filed the NDA for SOH-075 with the Japanese regulator (Ministry of Health, Labour and Welfare, MHLW) in September 2009, prior to signing a distribution agreement with Aska Pharmaceutical. Under the agreement, Aska will acquire a predetermined but currently undisclosed stake in Sosei via purchases in the market, and Sosei is eligible for upfront and milestone payments of up to ¥300m plus a significant royalty on net sales. However, as the margin on sales is undisclosed (although this is 'significant' compared with the industry standard), this potential revenue stream is not included in our financial forecasts. Sosei bears responsibility for the development and registration of SOH-075, with Aska responsible for sales and marketing. Sosei anticipates Japanese approval by Q111. Peak sales potential is estimated to be within the range of ¥2-5bn (\$20-50m) per annum depending on the pricing obtained.

It is worth noting the MHLW track record with oral contraceptives. Low dose contraceptives were first approved in Japan in June 1999, nine years after initial filing; the delay had been attributed to concerns over side effects, spread of sexually transmitted disease and the environmental effects of hormonal contraceptive use. Ten years later, uptake remains low: the most recent data from a 2009 UN report indicates that 1.0% of Japanese women aged 15-49 who are married or in a long-term relationship are on the pill compared with 18.3% in the US.⁵ This is largely due to a negative perception about the side effect profile of OCPs, the lack of public health insurance coverage and the relatively high cost (around ¥3,000 or £20 a month). Thus, even if SOH-075's approval is in line with Sosei's expected timeline, it remains likely that similar pricing and reimbursement issues will be faced, which may impact potential sales.

⁴ Primary Care Tokyo (www.pctclinic.com/images/Emergency%20Contraception.pdf)

⁵ UN World Contraceptive Use 2009 (www.un.org/esa/population/publications/contraceptive2009/contracept2009_wallchart_front.pdf)

Other assets: Focus on partnering post-restructuring

In May 2008, Sosei announced the outcome of a strategic restructuring and portfolio review which had the aim of extending its cash runway to two years' burn (not including any potential income from new licensing deals) and positioning the company ahead of it becoming sustainably income generative once NVA237/QVA149 is launched. The restructuring involved streamlining operations (closure of the drug discovery unit and the Chesterford facility), cost cutting (reduction in UK headcount) and pipeline prioritisation (decision to sell or out-license UK-generated assets⁶ while retaining Asian rights).

Subsequently, Sosei has continued with development and commercialisation plans for SOH-075 and on partnering. Sosei's partnering activities have been twofold: exploring in-licensing opportunities of late-stage compounds, and the out-licensing/divestment of its early-stage programmes. Sosei's in-licensing activities are expected to concentrate on the acquisition of development and commercialisation rights to late-stage products, or 'drug lag' products which are already marketed in the US/EU, but are not available in Japan. Assets available for partnering or sale are summarised in Exhibit 5, with those already divested in Exhibit 6.

Exhibit 5: Sosei Group assets available for partnering

Programme	Indication	Dev stage
SD118	Neuropathic pain	Phase I complete
AD337	Fibromyalgia	Phase IIa complete
SD726	Lower back pain	Preclinical
SD208	Psoriasis	Preclinical

Source: Edison Investment Research

Exhibit 6: Sosei Group divestments post-restructuring

Date	Programme/Technology	Indication	Dev stage	Notes/partners
Oct 2009	AD923	Cancer breakthrough pain	Phase III	Rights to sublingual fentanyl and administration device assigned to Pharmasol . Sosei will receive sales-based royalties. Previously licensed to Mundipharma under a June 2006 deal: rights reacquired in December 2008 for £2m, plus an additional 20% of net receipts (up to a maximum of £1.5m) on re-partnering.
Oct 2009	SD281 & analogues	Inflammation/ulcerative colitis	Research	Rights assigned to Biocopea Ltd . Sosei will receive payments when the compounds are commercialised.
Mar 2009	Chronotherapeutics patents	-	Research	IP and patents related to chronotherapeutic drug formulations sold to Nitec Pharma .
Nov 2008	RS(+) isomer of mefloquine	Treatment and prophylaxis of malaria	Preclinical	IP and know-how licensed to Treague Ltd . Malaria project terminated in January 2010 after a comparative Phase I study failed to demonstrate superior safety for the single enantiomer compared with racemic mefloquine.

Source: Edison Investment Research

Management

Sosei has a three-person management team consisting of President and CEO Shinichi Tamura, CFO Hidetoshi Torami, and EVP of R&D Akinori Mochizuki. The president and CEO is the only executive director serving on the four-person board of directors and he splits his time between Sosei's Tokyo and London offices. The Sosei board consists of both Japanese and UK nationals, and includes Dr Declan Doogan, interim CEO of Amarin and former Head of Worldwide Development at Pfizer. Sosei employs 27 staff globally, four of whom are based in the UK, and 11 involved in R&D.

⁶ With the obvious exception of NVA237/QVA149.

Valuation

Our Sosei valuation model indicates a value of ¥13.1bn (£88m assuming ¥148.5/£), broadly in line with current market capitalisation. This figure comprises a risk-adjusted net present value (rNPV) of Sosei's key drug programmes (calculated at ¥11bn or £74m), a ¥390m (£3m or three times sales) value to Australian sales of Norlevo and forecast net cash at end March 2010 (¥1,711m or £12m).

The most important component of our valuation is the rNPV which includes Sosei's three key clinical programmes (NVA237, QVA149 and SOH-075), using our revenue forecasts, assumptions regarding the economics of the partnerships with Novartis and Aska respectively, and probabilities of success. (NB We use the same rationale to value the COPD programmes for both Vectura and Sosei; our launch assumptions, probabilities and sales assumptions are the same in both models.) The rNPV also includes a 'base' cost of running the business and uses a 12.5% weighted average cost of capital. Please note that our valuation model does not capture the value of potential milestones (\$77.5m in connection with NVA237/QVA149 over the next two years), as there is little visibility on their breakdown and payment schedules beyond the near-term.

Our assumptions and rNPV model output are summarised in Exhibit 7.

Exhibit 7: Sosei Group core business valuation model

Notes: Assumes FX rates of ¥148.5/£ and ¥91.7/\$

Product(s)	Status	Probability of success	Est launch year	Est peak market share	Current market value	Est maximum royalty	Est peak sales
NVA237 and QVA149	Phase III/II	65%	2012/2013	15%	\$7,000m	6%	\$2,079m
SOH-075 (Japan)	NDA filed	90%	2011	100%	\$30m	30%	\$48m
Total rNPV				¥11,025m			£74m
Marketed products (Norlevo Australia)				¥390m			£3m
F10 forecast net cash				¥1,711m			£12m
Total valuation				¥13,126m			£88m

Source: Edison Investment Research

Sensitivities

Sosei's business is subject to the usual risks associated with biotech company drug development (ie the potential for clinical trials to fail or render inconclusive/contradictory results). There is the possibility that approval timelines exceed expectations (delaying launch) or that the process results in a negative recommendation/not approvable decision. Commercial sensitivities include pricing and reimbursement which may have either a positive or negative impact on sales. Specific sensitivities to the assumptions in our model, both on the up and the down side, are as follows:

- **Clinical and regulatory progress of NVA237/QVA149:** Sosei has high single product risk and is largely reliant on Novartis and the progress of these programmes to provide both near-term funding (from milestone income) and to enable the company to achieve sustainable profitability once launched.
- **Commercialisation of SOH-075:** Given this is potentially a first to market drug, pricing and reimbursement is untested and likely to be a major factor in determining uptake.

Additionally, the market for hormonal emergency contraception may be smaller than anticipated due to off-label prescribing of OCPs and the social acceptability of abortion.

- **Partnering activity:** Assets available for partnering and those divested post Sosei's 2008 restructuring are not included in our valuation. Any economics derived from existing or future deals may constitute upside.
- **Currency and accounting standards:** Sosei's reporting currency is the Japanese yen, and its financials are prepared to Japanese GAAP. However, the bulk of expected milestones (ie from Novartis) are US dollar denominated, hence currency fluctuations may impact revenues either positively or negatively.

Financials

Sosei reported 9M10 revenues of ¥870m, which were significantly higher than the ¥132m booked over 9M09 due to the \$7.5m milestone received from Novartis on the start of the NVA237 Phase III trials. The implementation of Sosei's strategic restructuring resulted in lower operating expenses (¥1,957m at 9M10 vs ¥3,118m at 9M09) reflecting the ongoing progress in reducing both R&D and SG&A spend. These initiatives contributed to a lower pre-tax loss for the period of ¥1,024m (9M09: ¥3,689m) and a net loss of ¥1,025m (9M09: ¥3,534m).

Sosei reports are produced in accordance with Japanese GAAP; hence milestone payments are recognised in full on receipt. This contrasts with Vectura under IFRS, where milestones are recognised over the course of the clinical trial to which they relate.

We expect Sosei to report revenues of ¥888m this year – mainly comprised of the NVA237 milestone (¥695m) with the remainder attributed to Australian Norlevo sales and the Aska upfront payment. Sosei has provided P&L guidance for FY10 (net sales have exceeded sales guidance at end-Q310 due to the strength of yen vs the AUD at that point), which is summarised in Exhibit 8.

Exhibit 8: Latest Sosei Group financial guidance for FY10

	FY10 forecast (¥m)	Comment
Net sales	850	Novartis milestone and Norlevo sales in Australia
Operating expenses:		
R&D costs	366	
SG&A costs	624	
Goodwill amortisation	1,586	Relates to 2005 acquisition of Arakis
Operating income/(loss)	(1,800)	
Ordinary income/(loss)	(1,800)	
Net income/(loss)	(1,800)	

Source: Edison Investment Research

Sosei reported net cash of ¥2,047m for end-Q310 (vs ¥1,769m at end-FY09). We expect Sosei to end FY10 with cash of ¥1,711m, representing sufficient funding into mid-FY11, in the absence of any additional milestones from either Novartis or Aska Pharma. However, substantial milestones are likely to be received on successful development of NVA237 and QVA149, and approval of SOH-075 – all of which may occur during FY11-FY12. Indeed, we expect Sosei to receive a \$7.5m milestone in conjunction with the initiation of the Phase III programme for QVA149 during FY11. Japanese stock market regulations prevent Edison publishing FY11e at this stage. At end-March 2009, Sosei had unrecognised tax losses of ¥8.4bn.

Our financial forecasts are presented in Exhibit 9.

Exhibit 9: Financial results and forecasts

31st March	¥'ms	2007	2008	2009	2010e
		JPN GAAP	JPN GAAP	JPN GAAP	JPN GAAP
PROFIT & LOSS					
Revenue		740	709	153	888
Cost of Sales		(491)	(122)	(122)	(124)
Gross Profit		249	587	31	764
EBITDA		(5,069)	(4,700)	(2,106)	(256)
Operating Profit (before GW and except.)		(5,045)	(4,663)	(2,079)	(226)
Intangible Amortisation		(1,606)	(1,607)	(1,588)	(1,586)
Exceptionals		27	(556)	127	0
Other		(90)	(47)	(510)	0
Operating Profit		(6,713)	(6,872)	(4,051)	(1,812)
Net Interest		190	93	13	10
Profit Before Tax (norm)		(4,855)	(4,569)	(2,067)	(216)
Profit Before Tax (FRS 3)		(6,523)	(6,779)	(4,038)	(1,802)
Tax		284	275	99	10
Profit After Tax (norm)		(4,633)	(4,897)	(2,351)	(206)
Profit After Tax (FRS 3)		(6,240)	(6,503)	(3,939)	(1,792)
Average Number of Shares Outstanding (000)		100.8	117.9	117.9	117.9
EPS - normalised (¥'000)		(46.0)	(41.5)	(19.9)	(1.7)
EPS - FRS 3 (¥'000)		(61.9)	(55.2)	(33.4)	(15.2)
Dividend per share (¥)		0.0	0.0	0.0	0.0
Gross Margin (%)		33.7	82.7	20.5	86.0
EBITDA Margin (%)		(685)	(663)	(1,377)	(29)
Operating Margin (before GW and except.) (%)		(682)	(658)	(1,360)	(25)
BALANCE SHEET					
Fixed Assets		13,659	11,934	10,319	8,720
Intangible Assets		13,445	11,785	10,196	8,610
Tangible Assets		143	112	45	40
Investments		71	38	79	70
Current Assets		9,534	5,470	2,048	1,991
Stocks		0	0	0	0
Debtors		579	562	279	280
Cash		8,955	4,908	1,769	1,711
Current Liabilities		(1,098)	(1,621)	(229)	(227)
Creditors		(1,098)	(1,621)	(229)	(227)
Short term borrowings		0	0	0	0
Long Term Liabilities		0	0	0	0
Long term borrowings		0	0	0	0
Other long term liabilities		0	0	0	0
Net Assets		22,096	15,782	12,138	10,483
CASH FLOW					
Operating Cash Flow		(4,296)	(3,950)	(2,986)	(258)
Net Interest		190	93	13	10
Tax		16	287	47	10
Capex		(115)	(62)	(1)	0
Acquisitions/disposals		0	13	0	0
Financing		3,150	(335)	(97)	0
Dividends		0	0	0	0
Net Cash Flow		(1,056)	(3,954)	(3,025)	(238)
Opening net debt/(cash)		(9,458)	(8,955)	(4,908)	(1,769)
HP finance leases initiated		0	0	0	0
Other		552	(93)	(114)	180
Closing net debt/(cash)		(8,955)	(4,908)	(1,769)	(1,711)

Source: Edison Investment Research

Growth	Profitability	Balance sheet strength	Sensitivities evaluation	
	N/A		Litigation/regulatory	●
			Pensions	○
			Currency	◐
			Stock overhang	○
			Interest rates	○
			Oil/commodity prices	○

Growth metrics	%	Profitability metrics	%	Balance sheet metrics	Company details
EPS CAGR 07-11e	N/A	ROCE 10e	N/A	Gearing 10e	N/A
EPS CAGR 09-11e	N/A	Avg ROCE 07-11e	N/A	Interest cover 10e	N/A
EBITDA CAGR 07-11e	N/A	ROE 10e	N/A	CA/CL 10e	9.0
EBITDA CAGR 09-11e	N/A	Gross margin 10e	20.5	Stock turn 10e	0.0
Sales CAGR 07-11e	N/A	Operating margin 10e	N/A	Debtor days 10e	667
Sales CAGR 09-11e	N/A	Gr mgn / Op mgn 10e	N/A	Creditor days 10e	541
				Address:	
				Kojimachi Tsuruya Hachiman Bldg. 5F 2-4 Kojimachi, Chiyodaku-ku Tokyo 102-0083, Japan	
				Phone	+81 (0)3 5210 3290
				Fax	+81 (0)3 5210 3291
				www.sosei.com	

Principal shareholders	%	Management team
Fidelity Investments Japan	13.9	President and CEO: Shinichi Tamura (Japanese) Shinichi Tamura has been CEO since Sosei's foundation in June 1990. He is the ex-CEO of Genentech Japan, and has previously held various roles in planning and development at Fujisawa Pharmaceutical Co Ltd.
Platinum Asset Management	4.16	
Anima	1.09	
Chuo Mitsui Asset Management	0.13	
		CFO: Hidetoshi Torami (Japanese)
		Hidetoshi Torami has been CFO since December 2008. He was previously the business controller at Honeywell Specialty Materials Japan, and an accountant at Deloitte & Touche.
Forthcoming announcements/catalysts	Date *	Executive VP R&D: Akinori Mochizuki (Japanese) Representative Executive Officer and Executive Vice President Akinori Mochizuki was formerly a research scientist at Fuji REBIO Inc. He holds a PhD in Medical Science from Toho University School of Medicine.
FY09 results	May 2010	
QVA149: Progression into Phase III	Mid-2010	
NVA237: First Phase III trial to read out	December 2010	
SOH-075: MHLW approval	Q1 11	
<i>Note: * = estimated</i>		

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Lincoln House, 296-302 High Holborn, London, WC1V 7JH ■ tel: +44 (0)20 3077 5700 ■ fax: +44 (0)20 3077 5750 ■ www.edisoninvestmentresearch.co.uk
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