



Corporate Update

Half Year Ended 30 Sep 2017



Message from the CEO

'We are accelerating our growth strategy to be a global biotech company'

Peter Bains
President & CEO



March 1996

Head of Global Marketing, SmithKline Beecham plc. (GlaxoSmithKline)

January 2001

Senior Vice President, GlaxoSmithKline International Commercial Development

January 2010

Non-executive Board Director at Syngene International Limited

June 2010

Non-executive Board Director at Sosei Group Corporation

February 2015

Executive Director and CEO at Syngene International Limited

April 2016

COO at Sosei Group Corporation

June 2016

CEO at Sosei Group Corporation

'We are building Japan's first global biotech champion.'

Sosei was established in 1990 with the vision to become a leading global biotechnology company based in Japan, and with the mission to discover, design, develop and deliver new and innovative medicines to patients. Today, we are delivering on this promise.

With strong foundations based on our unique and IP protected GPCR StaR® technology, we are revolutionizing structure-based drug design (SBDD) approaches to developing new and innovative GPCR medicines. For example, in addition to x-ray crystallography, we have begun utilizing cryo-electron microscopy (Cryo-EM) in our drug development process. This exciting technology, co-developed by Heptares co-founder and Nobel Prize winner Dr. Richard Henderson, enables better understanding of large multiprotein complexes. StaR® is enabling us to use both X-ray and Cryo EM techniques in a complimentary manner to obtain the most detailed structural information possible. Deeper structural insights help our scientist in designing safer and more effective drug candidates that target GPCRs.

We are now rapidly advancing a broad and deep pipeline of partnered and wholly-owned product candidates in multiple therapeutic areas, including CNS, cancer, metabolic diseases and other rare/specialty indications. Our leading clinical programs include a proprietary Phase 2 candidate for dementia with Lewy bodies (DLB) in Japan, together with partnered candidates aimed at the symptomatic treatment of Alzheimer's disease (with Allergan) and immuno-oncology approaches to treat cancer (with AstraZeneca). The growing profile of our unique capabilities has also drawn interest from some of the world's leading pharmaceutical and biotech companies, including Teva, Pfizer, Daiichi-Sankyo, PeptiDream and Kymab.

As we look forward to H2 2017, and indeed 2018, we are focused on three major operational priorities;

1. Continue to support clinical progress across all of our Partnered programs
2. Leveraging our world-leading StaR® GPCR discovery engine to expand our wholly-owned pipeline of Proprietary drug candidates, led by the DLB in program Japan (Phase 2 ready), and drive a further six programs to enter Phase 1 clinical studies over the next two years
3. Strengthen our operational capabilities and continue to explore value enhancing opportunities to accelerate our business model evolution



Peter Bains
President & CEO



H1 2017 Sosei Group Business Highlight

'H1 2017 was a year of significant progress for Sosei, and we made important advances across many key areas of our business.'



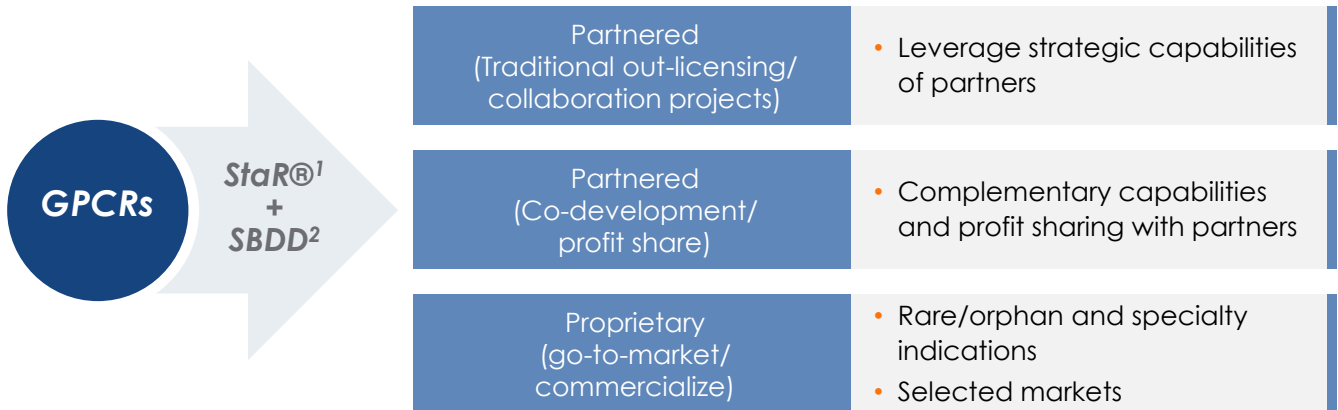
We have rapidly become one of the leading emerging biotech companies based in Japan. Our business model is centered around discovering, designing and developing innovative medicines for patients. FY2017 has so far been a year of great progress for **Sosei**, and operationally we continued to execute on our goals, highlighted below:

- We have made significant progress in each of our Partnered GPCR programs with Allergan, AstraZeneca and Teva, all generating financial milestones during the first half of 2017. These programs continue to validate our StaR® technology and SBDD capabilities, with our first three development candidates all successfully entering first-in-human studies, with no clinical attrition to date. Our M₁ and A_{2A} programs have now advanced into Phase 1b patient based trial
- We have also continued to advance an exciting portfolio of Proprietary GPCR drug candidates, and announced at our half year results that we will look to take up to three candidates per year into clinical testing over the next two years. Our Proprietary GPCR pipeline will now be led by HTL0018318, our dementia with Lewy bodies (DLB) program in Japan, which we will look to take into Phase 2 POC studies in the second half of calendar 2018
- Our GPCR discovery engine, with Heptares Zurich now fully integrated, continues to lead the world in stabilizing GPCR's, thereby enabling SBDD to refuel our preclinical pipeline with innovative and exciting drug candidates.
- We have completed the development of SO-1105, a novel formulation of miconazole, and have submitted the registration package to the PMDA with a view to gaining approval in 2018.
- Our COPD licensing agreement with Novartis continues to be a growing success story providing an outlook of increasing royalty income for many years ahead. Catalysts include ongoing sales growth outside the US market, the addition of US sales following Novartis license in 2016 to Sunovion, sales from China pending approvals under review in that market as well as potential sales that could result from Novartis' ongoing late stage development program for the asthma indication.

Business Model

Our risk-balanced strategy capitalizes on the GPCR opportunity

Creating and capturing more value for shareholders



Reserving the right to choose which strategy is most appropriate for each drug candidate, with a goal to commercialize ourselves in selected indications and markets

¹ Stabilized receptor technology
² Structure-based drug design

Key strategic initiatives

Strategically, we completed investments and negotiations that strengthened our business and pipeline, as well as completing a significant and highly successful global financing:

- We made a strategic 25.6% investment in MiNA Therapeutics, the world's most advanced small activating RNA company (saRNA), and acquired options to acquire 100% of the company subject to our assessment of data from MiNA's ongoing Phase 1/2a clinical study of its lead drug candidate, MTL-CEPBA, in liver cancer. If successful, MTL-CEPBA may provide **Sosei** with a rapid go-to-market drug in an orphan indication. MiNA may also provide us with another important drug discovery engine, and we were encouraged in this view by Boehringer Ingelheim's decision to license several compounds from MiNA as part of a research collaboration with potential milestones of up to EUR307m.
- We successfully negotiated a major amendment to our agreement with Allergan to allow us to develop and commercialize, on a wholly-owned basis, the lead selective M₁ agonist for dementia with Lewy Bodies (DLB) in Japan. DLB is the 2nd most prevalent form of dementia after Alzheimer's disease, with nearly 1 million patients in Japan at present. Dementia is a social and political priority for Japan, and at **Sosei** we are very proud to be at the forefront of research and development in this very important area.
- After the H1 FY2017 reporting date in late November 2017, we successfully executed a Global Offering of shares to international institutional investors, raising close to \$200 million. This significantly strengthened our balance sheet and provided us with a secure financial foundation to invest strategically behind our pipeline in the years ahead.

Message from the CFO

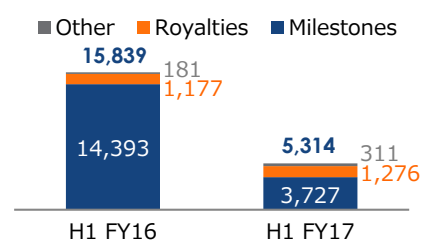
'We are investing and scaling the business'

Andrew J. Oakley
CFO

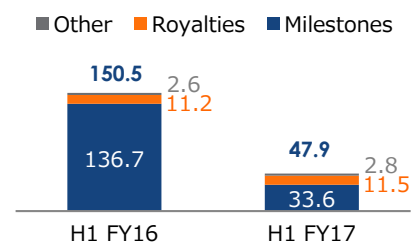


Revenues

JPY (m)



USD (m)

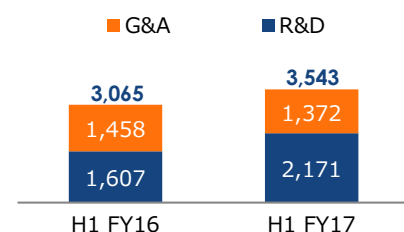


Commentary

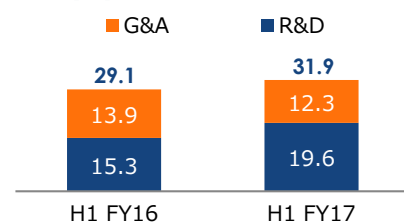
M _R PRGM	<ul style="list-style-type: none"> Muscarinic programs: One-off Allergan upfront \$125m in FY2016
M ₄ SZ	<ul style="list-style-type: none"> \$15m from Allergan upon first healthy patient dosed in Phase 1 trials
A _{2A}	<ul style="list-style-type: none"> \$12m from AstraZeneca – synergy milestone
CGRP	<ul style="list-style-type: none"> \$5m Teva option exercise
COPD	<ul style="list-style-type: none"> Royalties up year on year

Cash Operating Expenditure

JPY (m)



USD (m)



Commentary

R&D	<ul style="list-style-type: none"> Ongoing investment in partnered programs to develop back-up/follow-up molecules Investment behind Proprietary GPCR pipeline Start-up costs related to DLB (Japan) program Deconsolidation of JITSUBO and Activus
G&A	<ul style="list-style-type: none"> Advisor fee in FY2016 for Allergan collaboration Strengthening corporate functions to support operational growth Several key positions filled

Summary of Financial Results H1 FY2017



At the Group consolidated level, **Sosei** delivered a strong first half financial performance;

- Milestone-related revenue for the six-month period ended September 30, 2017 amounted to 3,727m yen. This was a decrease of 10,772m yen compared to the six-month period ended September 30, 2016 (a decrease of 74.3%). The decrease is primarily attributable to an upfront milestone of \$125m received under a licensing agreement concluded with Allergan in April 2016. Milestone-related revenue for the six-month period ended September 30, 2017 is attributable to milestones from AstraZeneca, Teva and Allergan.
- R&D expenses for the six-month period ended September 30, 2017 increased by 564m yen compared to the six-month period ended September 30, 2016 (an increase of 34.0%), and totaled 2,221m yen. For the six-month period ended September 30, 2017, 94.6% of research and development spend was related to our UK operations. The majority of the increase was the expansion and extension of our R&D capabilities to support the advancement of our wholly-owned pipeline.

Given that H1 FY2016 included the substantial \$125m upfront payment from Allergan, we did not repeat the revenues seen in the previous period. We focused on increasing investment behind the expansion our wholly-owned

pipeline, and consequently recorded a net loss for the period of 498m yen, a decline of 11,090m yen for the six-month period ended September 30, 2017

It has been one of the busiest and most progressive half year periods the company has ever had, and now, more than ever, we are well positioned to execute on our growth strategy.

We are grateful for your continued support in helping us to build Japan's first biotech champion. Thank you.

Andrew J. Oakley
CFO

Special feature

The DLB deal with Allergan



In November 2017, we negotiated an important amendment to our 2016 global R&D and commercialization agreement with Allergan. The amendment provides **Sosei** a licence, for the Japanese market, to develop and commercialize HTL0018318, a novel selective muscarinic M₁ receptor agonist as a potential new treatment for patients with dementia with Lewy bodies (DLB).

Initially, we will undertake a Phase 2 proof-of-concept monotherapy study, expected to begin in Japan in H2 CY2018. Allergan has retained the right to develop HTL0018318 in DLB globally.

Importantly, the amendment has provided **Sosei** with a proprietary asset opportunity in Japan, HTL0018318, the same compound that Allergan is advancing in parallel for Alzheimer's disease (AD) allowing us to capitalize on the substantial early clinical progress already made with this compound. Additionally, we have developed an extensive understanding of the DLB opportunity in Japan and, alongside our clinical development capabilities and track record of successful product development in Japan, we believe we can add significant value to the overall muscarinic agonist program through this activity.



About DLB

DLB is the second most common type of degenerative dementia after AD and is characterized by the presence of Lewy Bodies which consist of abnormal deposits of a protein called alpha-synuclein. This leads to inflammation and neurodegeneration in the brain that affects behavior, cognition and motor function/movement. In DLB, the loss of presynaptic cholinergic (acetylcholine-producing) neurons is thought to be a key driver of many of the disease symptoms and appears to be even more pronounced than in AD. As in

Current Treatments

There are currently, no approved therapies for DLB in the US or Europe, while branded donepezil (Aricept®, Eisai), an Acetylcholinesterase inhibitor (AChEI), is conditionally approved for DLB in Japan. Despite this, AChEIs such as donepezil (Aricept®), rivastigmine (Exelon®), and galantamine (Razadyne®), which are approved for mild-to-moderate symptoms of AD disease, are widely used “off label” as the standard of care for treating the cognitive and psychiatric symptoms of DLB.

How it works: the muscarinic M₁ receptor agonist programme for DLB

Muscarinic receptors are a family of G protein-coupled receptors (GPCRs) found in multiple tissues. Stimulating these receptors – in particular M₁ in the brain – has been shown to improve cognitive function in AD patients. However, attempts to develop medicines that selectively target M₁ receptors have until now been unsuccessful because of side effects caused by the activation of M₂ and M₃ receptors. Selective M₁ agonists that do not activate M₂ or M₃ are highly sought after for a wide range of diseases associated with cognitive dysfunction and are therefore expected to have blockbuster potential.

The natural ligand of the M₁ receptor in the brain is the neurotransmitter acetylcholine, the levels of which decline in DLB patients reducing

AD, postsynaptic neurons and muscarinic receptors are preserved in DLB, presenting an important opportunity for our subtype-selective M₁ agonist based approach.

DLB affects up to an estimated 10-30% of all dementia patients. In Japan, where diagnosis techniques and awareness levels are world leading, this represents approximately 920,000 patients at present, a figure that is expected to grow significantly in line with Japan's ageing population.

The clear absence of fully approved and effective treatment options, along with the growing epidemiology driven by an ageing population, means there is an urgent medical need, particularly in Japan, for new approaches to treat patients with DLB.

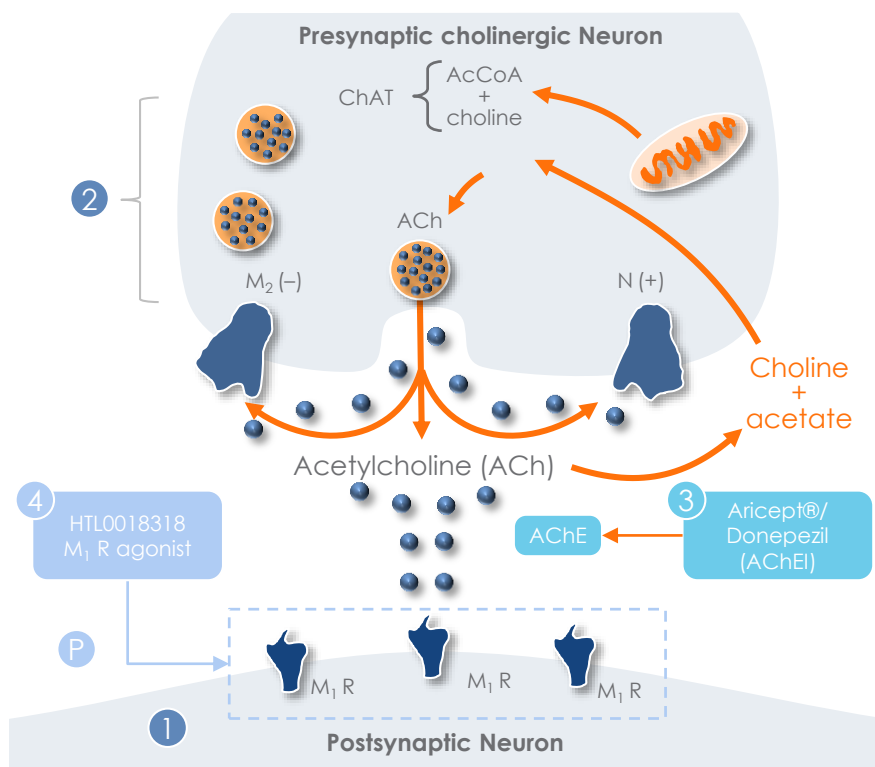
Sosei is proud to be investing significantly in this disease area in Japan, which, as well as a clear medical and patient priority, is also a social and political priority.

the tone on post-synaptic M₁ receptors which is critical to maintain normal cognitive function. Since these post-synaptic M₁ receptors remain intact in the disease a molecule that can directly activate the receptor, bypassing the requirement for acetylcholine, offers great promise as a treatment.

The safety, tolerability and pharmacokinetic profile of HTL0018318 has been assessed in a Phase 1a study, which provided strong evidence of a therapeutic window for the selective M₁ agonist mechanism in general, and for progression of HTL0018318 as a medicine to treat cognitive disorders. Ethnic bridging studies have also been completed, demonstrating the drug candidate is suitable for Japanese subjects.

HTL0018318: A novel approach for symptomatic treatment of DLB

- 1 M₁ receptors in cortex and hippocampus are key in mediating cognitive effects of acetylcholine (ACh)
- 2 The loss of cholinergic neurons in dementia patients leads to decline in cognitive functions
- 3 Acetyl-cholinesterase (AChE) inhibitors (e.g. Aricept®) prevent the breakdown of ACh
 - Effects are limited however, due to dose-limiting side-effects and the loss of endogenous ACh levels as the disease progresses



4 M₁ agonist activates receptor independently of ACh levels

- HTL0018318 derived from StaR® and SBDD, potentially driving comparable pre-clinical effects and a potentially differentiated profile to Aricept®

HTL0018318: Highly selective M₁ receptor agonist derived from StaR® and SBDD

- **Cognitive benefits of M₁ receptor agonism supported** by Lilly's clinical studies of xanomeline¹
- Xanomeline's development stopped due to unacceptable CV and GI side effects linked to stimulation of M₂ & M₃ receptors
- HTL0018318 is a potent muscarinic M₁ agonist with negligible M₂/M₃ receptor agonism
- StaR® & SBDD "designed out" unwanted selectivity over the M₂ & M₃ receptors



Selectivity is crucial. HTL0018318 has a differentiated mechanism of action with the potential to optimize symptomatic benefits in DLB patients

Source: Internal analysis

¹ Bodick et. al. "Effects of Xanomeline, a Selective Muscarinic Receptor Agonist, on Cognitive Function and Behavioural Symptoms in Alzheimer's Disease" Arch Neurol. 1997;54@465-473

Share ownership

(as of Sep. 30, 2017)

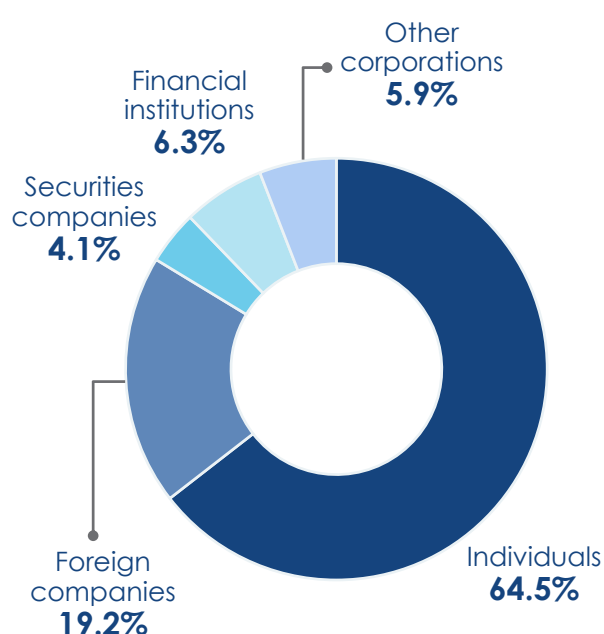
About shares

Total number of authorized shares	37,344,000
Total number of shares outstanding	16,979,984 ¹
Number of shareholders	23,845

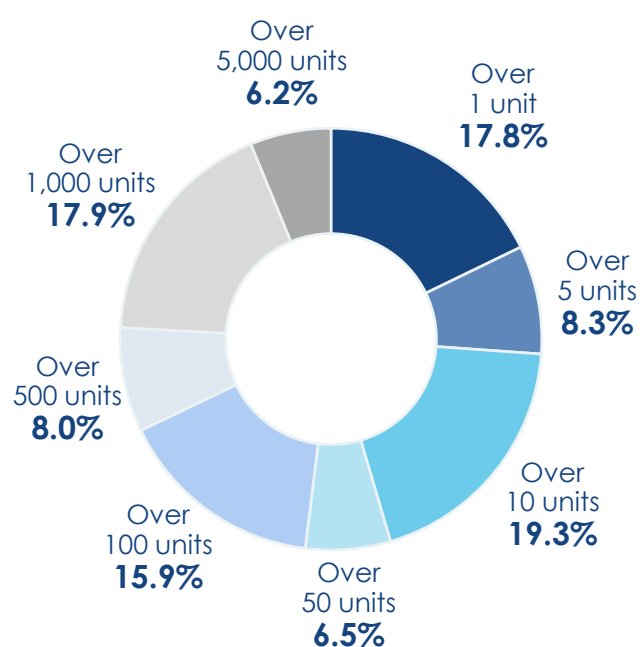
Major shareholders

Shareholders	Number of shares held (Shares)	Shareholding percentage (%)
Daisuke GOMI	1,050,000	6.18
Pfizer Seiyaku K.K.	471,284	2.77
Japan Trustee Services Bank Ltd. (trust account)	439,800	2.59
Shinichi TAMURA	284,100	1.67
TAIYO HANEI FUND, L.P.	272,900	1.60
NOMURA PB NOMINEES LIMITED OMNIBUS-MARGIN (CASHPB)	231,200	1.36
The Master Trust Bank of Japan ,Ltd. (trust account)	213,700	1.25
STATE STREET BANK AND TRUST COMPANY 505019	201,300	1.18
BNY GCM CLIENT ACCOUNT JPRD AC ISG (FE-AC)	175,956	1.03
GOLDMAN SACHS INTERNATIONAL	153,928	0.90

Owner share distribution



Breakdown of distribution by units



¹ Following the successful issue of 2,070,000 new shares as a result of the International Offering in November 2017, the Company's total number of shares is 19,049,984 (as at 31 December 2017)

Location

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