

Special Feature: Overseas Business Strategy



How would you evaluate the success of the acquisition as we look back over the past three years?

Masahiro Sasaki: We are very fortunate to be strongly aligned around our main areas of focus: putting patients first, delivering high quality products to patients and customers, and engaging our employees with a passion to drive performance. These common cultural elements were apparent in early discussions of the acquisition and have only grown stronger and more aligned over the past three years.

Rusty Field: Sawai has developed a deep understanding of the U.S. market and Upsher-Smith business and leaders from both teams have built strong relationships and trust. The U.S. pharmaceutical market is complicated and different than the market in Japan. Together, we have made great strides in understanding our unique business markets and cultures. Upsher-Smith's leadership is committed to living up to the expectations Sawai had when the acquisition was made in 2017.

Masahiro Sasaki: Sawai is likewise committed to driving Upsher-Smith's growth and success. We are also dedicated to working together, which has helped us navigate a challenging business environment. We met and evaluated several types of companies before being introduced to Upsher-Smith. As we learned more about the company, Sawai top management shifted its acquisition approach to a "global" vs "international" view. We recognized Upsher-Smith has its own full capabilities, portfolio of products and pipeline over a long history, and that it would be best managed by its management team in the United States. That is why we introduced a basic policy of respecting autonomy from Day 1, and we

continue to believe that the best decisions can be made locally in the United States.

How does Upsher-Smith's autonomy play out in the management of operations? How do the two companies work together?

Masahiro Sasaki: As we have progressed through the acquisition, leadership roles and decision-making processes have achieved greater clarity, resulting in efficient management of operations. From the start, Sawai clearly and appropriately defined the plan for Upsher-Smith governance, established an effective Board of Directors and deployed leaders to live in the United States to drive the integration and partner on business growth. The clear business structure and dedicated Sawai leaders helped establish a strong decision-making process that allowed us to embark on key business strategies, like the acquisition of migraine assets and investment in our new manufacturing facility.

Rusty Field: There have been many great examples of collaboration between Sawai and Upsher-Smith over the past three years. The R&D, legal, regulatory and commercial teams from both companies have worked on Paragraph IV*¹ development programs. The Quality teams have developed a Global Quality guideline and are sharing auditing activities. Regulatory Affairs leaders at Upsher-Smith have been consulting with Sawai on key FDA issues. The R&D teams are actively involved in sharing formulation and development expertise between the companies to improve development programs and speed to market. This partnership and capacity for teamwork will only grow stronger as we move into the future together.

Masahiro Sasaki: I think it's also important to note the partnership and collaboration with Sumitomo, which has been a very strong and important partner in the development of Upsher-Smith's business. In addition to providing insight and guidance on API sourcing and pricing, as well as other business development activities, Sumitomo has added a key resource in India that has provided a deeper understanding of market dynamics and industry information to help our development programs. Okuyama-san has become a critical member of Upsher-Smith's Strategic Team and is involved in key company strategy decisions. Sumitomo has also been a proponent of additional investment in Upsher-Smith through support of significant asset acquisitions and investments in Upsher-Smith infrastructure that will drive future revenue growth and efficiency of operations.

Upsher-Smith performed very close to original 2018 and 2019 plans, despite extremely challenging market conditions, but was not able to deliver on the original 2020 target set in the Mid-Term plan. What are your expectations going forward? What are the biggest opportunities for the next three years?

Rusty Field: As you note, Upsher-Smith came very close to achieving the Mid-Term plan targets for Net Income in a really difficult U.S. market. The pipeline that was in place at the time of acquisition fell short of expectations due to severe competition. We are now faced with further challenges in FY20 as competition will enter the market on three key Upsher-Smith products – Klor-Con M, Chlorpromazine and Qudexy® XR. We will strive to achieve and exceed our targets for the year by focusing on opportunities, such as the new Keystone manufacturing facility that will be added on to our Maple Grove Headquarters building. The creation of this new facility will be the foundation of Upsher-Smith's manufacturing for decades to come. I also want to point to the expansion of our brand

strategy. In July of 2019, we successfully acquired two important acute migraine medications – Zembrace® Symtouch®, an injectable and Tosymra®, a nasal mist. These products fit perfectly into our existing sales and marketing expertise by building on our existing Qudexy business. While the growth of Tosymra has been slower than expected to start, we have confidence that Tosymra and Zembrace will be powerful growth drivers for the next several years.

Masahiro Sasaki: We are also creating new opportunities across our organizations. For example, Upsher-Smith and Sawai will begin to co-invest in highly complex generics and 505(b)(2)*2 products that can drive long-term growth. This financial investment by Sawai will increase the size and value of the pipeline and drive financial benefits for both companies. Adding Kimura-san to our existing Upsher-Smith Board of Directors, which includes Sueyoshi-san, Yokota-san, Okuyama-san, Rusty-san and me, will help drive the successful implementation of our Keystone strategy. In Regulatory, Upsher-Smith's expertise working with the FDA will help Sawai leverage new business strategies. These are valuable and exciting opportunities.

It sounds like there are many opportunities going forward. What about the challenges of the next three years?

Rusty Field: There will continue to be uncertainty about the U.S. generics market due to continued competitive pressures. Between 2017 and 2019, the U.S. generic market experienced dramatic price deflation. This deflation was driven by a significant increase in the number of generic competitors in the United States and an increase in FDA approvals of new generic drugs. We have seen a decrease in price deflation overall, but significant impacts to important Upsher-Smith products remain possible as more generics enter the market. When Sawai acquired Upsher-Smith in 2017, the value of the pipeline products was much higher than the value of those products today due to the decline of the U.S.

generics market. As a result, when competitors entered into our largest, most profitable product markets and negatively impacted our revenue and margins, the pipeline was not able to drive the needed growth to cover that decline. In short, we must now drive growth from a smaller base of revenue.

How optimistic do you feel about the next three years?

Rusty Field: I feel confident about the future because Sawai and Upsher-Smith are committed to continuing investment in our organic pipeline as a foundation for future growth. Together, we have a strong focus on adding more programs and more complex programs – both generic and small brands – to our portfolio. Increasing complexity adds some risk, but it also adds the opportunity to drive stronger growth. I also feel confident because of the strong partnership between Sawai and Upsher-Smith leaders and teams. Over the past three years, we have learned a great deal about each other, including how businesses operate in both countries as well as how we can leverage our different cultures and communication styles to foster powerful teamwork. Sasaki-san and Okuyama-san are deeply involved in Upsher-Smith's strategy development and oversight of our business, and Upsher-Smith leaders have strong connections to Sawai functional leaders in Finance, Technology, Regulatory & Quality, R&D and Operations. We will only get better as time moves forward.

Masahiro Sasaki: I also feel confident about the future. Upsher-Smith has demonstrated strong financial discipline and ensured its expense structure is appropriately balanced for growth and financial results. For example, in 2019, Upsher-Smith took significant actions to lower overall SG&A expenses to better align our expense structure with our revenue and margin. We will continue to drive efficiencies and cost management to ensure we are positioned for growth. Secondly, we continue to have strong cultural alignment between our people and organizations. Our shared focus on patients first will drive us to overcome



our challenges as we move forward. Patients rely on us for their health and well-being and it is our responsibility to deliver high quality products to them. Across Sawai and Upsher-Smith, our employees' commitment to this mission binds us together and makes us stronger.

How can the new structure of Sawai Group enhance Upsher-Smith's contribution to Sawai Group's value creation?

Masahiro Sasaki: The Upsher-Smith Board of Directors has established a deep knowledge and understanding of Upsher-Smith's business and the U.S. market. The Upsher-Smith Board is deeply involved with key business strategy decisions and this new design will allow the Upsher-Smith Board to be even more agile in response to shifts in the U.S. market.

Rusty Field: The new Sawai Group holding company will also be able to see across the Sawai and Upsher-Smith businesses to identify, foster and develop opportunities that leverage the strength of both businesses. It's very exciting.

*1 Paragraph IV : A company can seek approval from the FDA to market a generic drug before the expiration of a patent related to the brand name drug upon which the generic is based. To accomplish this, it must certify that the patent in question is invalid or it is not infringed by the generic product - this is known as paragraph IV certification. The first ANDA applicant that successfully claims and receives FDA approval may obtain the right to sell the generic drug exclusively for 180 days.

*2 505(b)(2) : 505(b)(2) is a regulatory pathway that allows a sponsor to reference previous studies and information, e.g. safety studies, efficacy studies, literature and other information to seek FDA approval for the development of enhancements to an already approved molecule. These enhancements generally include new routes of administration or new formulations. If sponsors are successful gaining FDA approval, they may be able to gain exclusivity for 3-7 years or longer, depending on the clinical studies required, indication and intellectual patent protection developed by the sponsor.