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Building value through regional licensing; global dealmakers get guidance on Japan

By Michael Fitzhugh, Staff Writer

SAN FRANCISCO – With international dealmaking often a key element of the biopharma asset development adventure, the path to success in Japan took center stage during the first day of Allicense, an annual pilgrimage for the industry's top business development pros.

The total number of ex-U.S. regional licensing deals jumped to an average 95 deals annually from 2011 to 2014, from an average of 51 deals each year between 2007 and 2010, according to a Locust Walk Partners analysis of Thomson Reuters Recap data. While Japanese companies haven't been a dominant force in that mix, as the second-largest single-country market in the world after the U.S. for many indications, they are more and more often becoming the partners of choice among small but fast-growing players looking to fund assets through ex-U.S. deals abroad while retaining domestic rights, panelist suggested.

As potentially attractive valuations push small companies toward the market, drug pricing reforms in the country spurred by Prime Minister Shinzo Abe are simultaneously pulling them, panelists said. Japanese companies facing the prospect of older drugs in their portfolios are losing value more quickly than ever before due to new annual reviews of pricing and reimbursement. That's creating a real need for Japanese companies to open up to innovative biotechs.

Ariad Pharmaceuticals Inc.'s late 2014 deal with Otsuka Pharmaceutical Co. Ltd. to commercialize Ariad's Iclusig (ponatinib) for $77.5 million up front and subsequent milestone-based payments exemplified the trend for panel moderator and Locust Walk Partners Vice President Josh Hamermesh.

With Ariad's plans to commercialize Iclusig in chronic myeloid leukemia (CML) on its own in the U.S. and Europe, seeking partners outside those regions was important, Ariad's senior vice president and chief business officer, Hugh Cole, noted. "Japan was a real cornerstone of that," he said.

Key to the company's success, Cole said, was developing Iclusig up to a certain point on its own in Japan. The company ran its own phase I/II trial in the country, met with Japanese regulatory authorities and brought the product within six months of filing a Japanese new drug application before even beginning to engage in serious talks with potential partners, he said.

"We were coming to Japanese companies with a very well-developed strategy and a well-developed product. It ultimately drove a really competitive process that allowed us to get some attractive terms," said Cole.

Given what panelists appeared to agree is a risk-averse nature of potential Japanese partners, the need for such preparations is critical, noted Steve Engen, Locust Walk's senior vice president for Japan and Asia. The dealmaking process in Japan has to run its course, he said, "percolating" from the bottom up. Achieving speed in that process comes down to answering questions about price, the regulatory pathway and the competition before stepping into anyone's office, he added.

Not everyone is as enthusiastic as Ariad was about the prospects for a Japanese deal. Many Western companies, especially private ones, are worried that if they license to Japan they might be giving away value or hurting their chances to sell their companies later, said Engen, who headed the Japanese operations of Shire Pharmaceuticals plc before joining Locust Walk.

Carving out Japanese rights can actually help in certain cases, he said, pointing to the case of Onyx Pharmaceuticals Inc., which granted Ono Pharmaceutical Co. Ltd. the exclusive rights to develop and commercialize two Onyx proteasome inhibitor compounds, carfilzomib (PR-171) and ONX 0912, for all oncology indications in Japan.

Ono committed to pay Onxy ¥5 billion (US$59M) up front, up to $280M in development and sales milestones in the September 2010 deal, plus double-digit royalties on net sales in Japan, a feat that then-CEO Tony Coles told *BioWorld Today* provided the company with both "value and flexibility." (See *BioWorld Today*, Sept. 9, 2010.)

Onyx was acquired by Amgen Inc. in 2013.

"Japanese companies will have to access Western biotech companies," said Engen.

"If you bring the right story to the right people, you have a very good shot of getting a deal done, especially in this environment," he noted.