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February 11, 2010

What Financial Crisis? Australian Biotech Enters Golden Era (Part 2 of 2)

PERTH, Australia - As Australia's biotech sector comes of age, it is beginning to attract the attention of multinational companies, as evidenced by stepped-up merger and acquisition activity and rounds of new funding in the last six months.

In the [first part](#) of this story, *PharmAsia News* explored the maturing of the biotech sector, as well as the challenges of the venture capital industry, in Australia. In this second part, some of the top biotech companies and deals are highlighted.

Medicines Australia estimates that local pharmaceutical companies contribute \$7 billion a year to Australia's economy and export \$4 billion a year to markets including South Africa, New Zealand, Taiwan, Korea and Thailand.

M&A activity in the last year has been notable for Australia. Arana became a wholly owned subsidiary of Cephalon, which paid shareholders AU\$1.40 per share while acquiring a 90-percent stake in Arana ([PharmAsia News, June 11, 2009](#)).

Arana's lead compound ART621, a new-generation TNF alpha blocker, was in Phase II trials for rheumatoid arthritis and psoriasis at the time of the acquisition. Arana had steady revenue streams from licensing agreements with Abbott and Centocor, which use Arana's anti-TNF patent for antibodies **Humira** (adalimumab) and **Remicade** (infliximab) to treat moderate to severe RA, Crohn's disease and other inflammatory diseases.

"People have argued that the Cephalon purchase of Arana was on the cheap side, but they did buy at the bottom of the market and they gave them a 70-percent premium on the share price. If they bought it today, it would cost them a lot more," AusBiotech CEO Anna Lavelle told *PharmAsia News*. "Arana was cashed up and that was attractive, and it was a good buy."

"Now, from an Australian point of view, we would have liked a little more cream in the deal, but they're consenting adults and they signed on the dotted line, so there must have been enough there to make it worth their while," she added.

Danish firm Leo Pharmaceuticals scooped up dermatology biotech Peplin in a deal worth about \$287.5 million in cash. In the case of Peplin, the purchase price amounted to a 72 percent premium to the company's Aug. 31 closing share price of AU\$0.60. Peplin's lead product, a gel called PEP005 (ingenol mebutate), just finished Phase III clinical trials for treatment of actinic keratosis, a common skin lesion, on both head and non-head extremities. AK lesions can lead to cancer if they are not treated, but current therapies are cumbersome and not effective enough (["The Pink Sheet," Sept. 7, 2009](#)).

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Lavelle said VCs are more interested in looking at late-stage Australian companies while Big Pharma is more interested in the early-stage companies.

"More global companies [are] coming to Australia to acquire and invest in Australian companies," Geoff Brooke, co-founder and managing director of GBS Venture partners, said in an interview. "The financial crisis affected companies mostly by bringing prices of public companies down, but they've come back with a vengeance."

Top picks for 2010 for biotech companies include Acrux, Alchemia, Biota, Chemgenix, Starpharma and Pharmaxis.

Biota To Report \$AU56 Million In Relenza Royalties

Anti-infective developer Biota, the originator of flu drug **Relenza** (zanamivir), has had a phenomenal year with royalties following the H1N1 pandemic last year. Biota Feb. 5 reported \$AU32.6 million in royalties from GlaxoSmithKline for Relenza for the quarter ended Dec. 31, 2009. For the first half of 2010, for which the Australian calendar year begins July 1, Biota will report AU\$56.7 million in Relenza royalties.

Biota partner Daiichi Sankyo submitted a new drug application for manufacturing and marketing approval in Japan Feb. 1 for its long-acting neuraminidase inhibitor flu inhaler laninamivir (CS-8958), which it co-owns with Biota ([PharmAsia News, Feb. 2, 2010](#)).

Biota was in acquisition mode in November 2009, when it announced it would acquire the antibacterial assets of Prolysis Limited in exchange for AU\$10 million in Biota shares. The same day, the company announced it would also acquire the antibacterial assets of Boston-based MaxThera for \$1.2 million in cash and \$300,000 in Biota shares.

"Biota's strategy was to broaden its pipeline while keeping into anti-infectives and antibacterial, and [the acquisitions] were consistent with that strategy and we were looking for assets that had novel validated targets and also the capability, and both companies were experts in the antibacterial space," Biota Business Development VP Leigh Farrell told *PharmAsia News* in an interview.

"We think they're good deals for Biota in the current market conditions, and they're also good for the companies because they get to get their products on the market."

He said Biota's business model is based on acquiring early-stage assets and then exiting at proof of concept. The company does not plan on taking products to market.

"We spend a huge amount of time interacting with our potential customers to understand first, their decision-making process, and second, what would [they] want to have in the bag to convert to a licensee?"

Biota also has a global research collaboration and licensing agreement with Boehringer Ingelheim to develop and commercialize Biota's nucleoside analogs designed to treat hepatitis C, for which Biota could receive up to \$102 million.

Pharmaxis Going It Alone

RBS Morgans healthcare analysts placed Pharmaxis on its list of key picks for Australian companies in the life sciences sector for 2010, along with ChemGenex, Alchemia, and QRxPharma.

Pharmaxis is unique as far as Australian pharmaceutical companies go because it is not seeking a partner to launch its products and has brought its pipeline to maturity on its own.

AusBiotech CEO Anna Lavelle said that Pharmaxis "is one of the darlings" in the country right now.

An equity offering in May 2009 raised \$55 million, and at the end of September the company had a cash balance of about \$113 million, CEO Alan Robertson said.

"We met the challenge of building a quality profitable business here and we have Bronchitol and Aridol and behind that we have a pipeline of products that are now working their way through the clinical trial program," the CEO said in an earlier interview. "So no, we're not thinking about partnering."

Pharmaxis announced Feb. 9 that it completed the acquisition of Canadian company Topigen for 3.2 million Pharmaxis shares. The Topigen portfolio includes a number of candidates for respiratory disorders based on its multi-targeted oligonucleotide technology. Lead candidate TPIASM8 is in Phase II trials for moderate to severe asthma.

Last month, Pharmaxis reported positive results on its Phase III trial of Bronchitol for cystic fibrosis ([PharmAsia News, Dec. 4, 2009](#)).

Bronchitol received orphan drug and fast-track review status from U.S. FDA and the European Medicines Agency. Bronchitol is poised to be first out of the gate for bronchiectasis.

Meanwhile, despite a positive recommendation from U.S. FDA's Pulmonary-Allergy Drugs Advisory Committee Nov. 20 for approval of Pharmaxis' bronchial test **Aridol** (mannitol), the agency issued a complete response letter Dec. 24, citing packaging and testing issues discovered at a contract manufacturing site during the preapproval inspection, Robertson told investors during a Jan. 28 earnings call. He said he anticipates approval in the first half of 2010.

Platform Company Starpharma Banking On Dendrimer Nanotechnology

The only technology platform company listed on the ASX, Starpharma is one of the larger cap firms leading the way in Australia, according to analysts.

"We see ourselves as having a number of important differences in the sector: we have \$2 million in recurrent royalty revenues from licensing deals and our U.S. office is already cash-flow positive, and we have the ability to add to those revenue streams in an incremental sense," Starpharma CEO Jackie Fairley said in an interview, while adding that the company has a broad portfolio of technologies and is not relying on one or two drugs to sustain the company.

"We're looking to generate returns for our shareholders on our platform and whether that comes in agrichemicals, diagnostics, animal health, human pharmaceutical drug delivery or in fact **VivaGel**, any of those are fine."

Lead product **VivaGel** is a vaginal microbicide gel in clinical development for preventing sexually transmitted infections, including genital herpes, HPV and HIV infection.

VivaGel is the only example of a dendrimer as a drug, Fairley said, noting that other pharma programs are for drug delivery programs or diagnostics. The dendrimer binds with the receptors of the surface HIV virus or genital herpes virus and serves as an entry inhibitor, and the viruses are unable to bind to human cells and replicate.

In the case of drug delivery, the dendrimer is a scaffold onto which small molecule drugs, monoclonal antibody fragments or constructs for siRNA delivery can be loaded.

Starpharma has already racked up a licensing deal with SSL International, the manufacturer of **Durex** brand condoms, for marketing rights to a condom coated with VivaGel in most markets, including Europe and the U.S. Starpharma estimates it will receive more than \$100 million in royalties on sales, further milestone payments and developmental support.

The company also raised capital in 2009 to fund bacterial vaginosis trials, which would be a new application of VivaGel. Vaginosis is roughly a \$350 million market, with about 20 million women in the U.S. alone infected. Fairley said existing treatments are conventional antibiotics, which have a very low cure rate and a very high rate of recurrence.

Starpharma announced another deal with Eli Lilly on Feb. 2 under which Starpharma will fund a collaborative R&D program to create improved drugs incorporating its delivery technology to be commercialized by Lilly for human drugs. The company earlier announced a deal with Lilly's animal health division Elanco for drug delivery research collaborations.

Other partners include GlaxoSmithKline for drug delivery technology and Siemens, Aldrich, Merck and Qiagen for medical technology.

Starpharma signed an agrichemical deal in November with an unnamed multi-billion dollar U.S.-based agrichemical company.

All three deals use the company's dendrimers to improve existing products for partners, Fairley said.

ChemGenex Awaiting U.S. FDA Approval Of First Product Omapro

Melbourne-headquartered ChemGenex was at the mercy of the forces of nature earlier this week when the Feb. 10 U.S. FDA Oncologic Drugs Advisory Committee meeting scheduled to review the company's **Omapro** application for chronic myeloid leukemia was cancelled due to the massive snowfall in Washington ([PharmAsia News, Feb. 10, 2010](#)).

ChemGenex, which also has offices in Menlo Park, Calif., is going for a second-line indication for patients with CML who have failed to respond to **Gleevec** (imatinib) and who have the Bcr-Abl T3151 mutation. Omapro is also under review in Europe for CML.

The company earlier announced a \$137 million licensing deal with Hospira to license, develop and commercialize Omapro (omacetaxine) in Europe, the Middle East and parts of Africa ([PharmAsia News, Dec. 18, 2009](#)).

ChemGenex CEO Greg Collier told *PharmAsia News* that the company is putting all its efforts into Omapro.

"The way I look at Australian biotech," Collier said, "is that we've matured significantly over the past five years and when you start to look at companies like us - like Pharmaxis, like Acrux, like Starpharma - companies that are moving into late-stage clinical development ... there's about 10 of us leading the way to show the Australian industry that you can get to this stage of development and you can build a serious company from an Australian base, which will hopefully attract more investments here and help some of the other companies through the process."

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