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In this edition...
Pattern recognition is a basic skill for all investors so when Japanese pharmaceutical firm Takeda recently announced yet another deal it was time to dig a little deeper. After buying Millennium Pharmaceuticals in April, the company announced a US$150 million licensing deal with RNAi firm Alnylam Pharmaceuticals.

We also investigate progress being made at two very resilient Melbourne firms, Optiscan Imaging and Starpharma. Both companies illustrate how the path to market for promising technologies can be slower than expected, with adoption rates a key issue for Optiscan's/Hoya's flexible confocal endomicroscope.

The editors
Companies covered: OIL, SPL

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - current)	-2%
Cumulative Gain	**103%**
Av Annual Gain (7 yrs)	**17.8%**

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Bioshares

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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Japanese Pharma Goes Shopping

In April, the Japanese pharmaceutical firm **Takeda** announced a bid for Boston-based **Millennium Pharmaceuticals**. Millennium Pharmaceuticals was founded in 1993 as a genomics and screening firm, but began transforming itself into a drug developer from 1999, even as interest in genomics was peaking. One attraction for Takeda in the Millennium asset stable was its marketed myeloma drug, Velcade, which is expected to generate sales in the order of US$350 million this year. Takeda offered a 50% premium on Millennium's share price at the time of the bid and acquired that company for US$8.8 billion.

However, this was not the most recent transaction effected by Takeda. On May 25, Takeda announced that it had signed a licensing deal to access **Alnylam Pharmaceutical**'s RNAi intellectual property, paying US$150 in upfront and near term payments for access to technology that has yet to be validated clinically or commercially.

And also recently on May 21, **Daiichi Sankyo** acquired Germany's **U3 Pharma** for US$235 million, in order to expand its access to antibody drugs and technology. U3 Pharma was founded in 2001 by Axel Ulrich, a former **Bionomics** advisor.

A table listing these and some other recent transactions can be found on the next page.

Why the heightened activity by Japanese pharmaceutical firms?

Why has there been an increase in M&A and licensing activity by Japanese pharmaceutical firms? A recent position statement by the **Japanese Pharmaceutical Manufacturers Association** (JPMA) goes some of the way to explaining the trend.

The JPMA identified an increase in the intensity of global biotech M&A and growth in the globalisation of the pharmaceutical industry occurring at a time when there had been no increase in new drugs emanating from Japan. Furthermore, the size of the Japanese pharma market had shrunk from 20% of the global market to 10% from ten years ago. The JPMA described the current situation as a "crisis". With Japanese pharma firms apparently unable to make headway within the Japanese pharmaceutical and healthcare systems it is no surprise then that a few Japanese companies, led by Takeda, have taken decisive steps to internationalise their businesses.

Another facet of the Japanese pharmaceutical industry is that it is made up of many small companies. There are approximately 470 pharmaceutical manufacturers of which 70 are generic firms. Membership of the outwardly oriented JPMA is a little over 70 companies, and we calculate that about 50 of those are intrinsically Japanese firms (i.e. not foreign subsidiaries). Although mergers between Japanese companies have occurred in the last 10 years, the industry is fragmented and lacks companies of suitable scale. The last great merger was between **Yamanouchi** and **Fujisawa Pharmaceuticals** in 2005, creating Astellas Pharma (Current cap'n: US$22 billion). By way of comparison, **Pfizer**

Cont'd on page 3

Recent Japanese Biotech and Pharma International Transactions

Date	Company	Consideration/Terms	Comments
Takeda			
Acquisitions			
Apr-08	Millennium Pharmaceuticals	US$8.8 B	Velcade seen as attractive drug. Est. CY08 sales ~ US$350m. Plus pipeline and capabilities
Mar-07	Paradigm Therapeutics	Not disclosed	CNS therapeutics
Feb-05	Syrxx	US$270 M	High-throughput X-ray crystallography capabilities plus pipeline
In-licensing			
May-08	Alnylam Pharmaceuticals	US$100 M + US$50 M in near term pmts; US$171 M in MSP	To access RNAi IP; non-exclusive license in two therapeutic fields
Apr-08	Cell Genesys	US$50 M upfront; US$270 M in MSP	W/W rights GVAX immunotherapy
Feb-08	Amgen	US$100 M upfront; US$175 M in MSP; 60% clin dev exp outside JY	JY rights for motesanib diphosphate (AMG706)[oncology, VEGFR1-3 inhibitor]; 50:50 profit share
Feb-08	Amgen	US$200 M; US$362 M in MSP; $340 w/w dev costs	JY rights for up to 13 drug candidates inc. Vectibix (panitumumab)
2/11/2006	Xoma	US$100 M MSP; amended to US$230 M Feb 2007	Monoclonal antibody discovery and development
3/10/2006	Xenon	US$75 M in upfront MSP; US% M in equity	Asian rights for pain compound XEN401
Daiichi Sankyo			
Acquisitions			
May-08	U3 Pharma AG (Germany)	US$235 M (Euros 150 M)	Adds fully human antibodies including U3-1287 (Amgen 888) - anti-HER3
Eisai			
Acquisitions			
Dec-07	MGI Pharma	US$3.9 B	Marketed products and sales force
Astellas Pharma			
Acquisitions			
Nov-207	Agensys	US$375 M (plus $150 M in MSP)	30 proprietary targets; 1 Ph Ib antibody + several pre-clinical
In-licensing			
Nov-05	Xenoport	Upfront US$25 M; MSP of US$60 M	XP13512 a prodrug of gabapentin - neuropathic pain [JY + other rights]
Apr-08	Comentis	Upfront US$80 M; Equity US$20 M; MSP of US$660 M	CTS-211166 - beta secretase inhibitor plus others (Alzheimers disease targets)
Jan-06	Ferring Pharmaceuticals	Not disclosed	Degaralix - GnRH blocker - prostate cancer [JY rights]
Kyowa Hakka			
In-licensing			
Apr-08	Arana Therapeutics	Upfront US$4 M	Co-dev agreement for ART104 for solid tumours; access to mab enhancement technology

MSP - Milestone Payments; JY - Japan

Notes

Daiichi and Sankyo merged in 2005

Yamanouchi and Fujisawa Pharmaceutical merged in 2005 (April) to form Astellas [US$7.2 B merger]

Japanese Pharma Companies
Member Companies JPMA

1 Ajinomoto
2 Asahi Kasei Pharma
3 Aska Pharmaceutical
4 Astellas Pharma
5 Chugai Pharmaceutical
6 Daiichi Sankyo
7 Dainippon Sumitomo Pharma
8 Eisai
9 Fujimoto Pharmaceutical
10 Fuso Pharmaceutical Industries
11 Hisamitsu Pharmaceutical
12 Japan Tobacco Inc.
13 Kaken Pharmaceutical
14 Kirin Pharma
15 Kissei Pharmaceutical
16 Kowa Company
17 Kracie Pharma
18 Kyorin Pharmaceutical
19 Kyoto Pharmaceutical Industries
20 Kyowa Hakko Kogyo
21 Maruho
22 Maruishi Pharmaceutical
23 Meiji Seika Kaisha
24 Minophagen Pharmaceutical
25 Mitsubishi Tanabe Pharma Corp.
26 Mochida Pharmaceutical
27 Nihon Pharmaceutical
28 Nippon Chemiphar
29 Nippon Kayaku
30 Nippon Shinyaku
31 Nippon Zoki Pharmaceutical
32 Ono Pharmaceutical
33 Otsuka Pharmaceutical
34 Pola Pharma Inc.
35 Santen Pharmaceutical
36 Sanwa Kagaku Kenkyusho
37 Seikagaku Corporation
38 Senju Pharmaceutical
39 Shionogi & Co
40 Taiho Pharmaceutical
41 Taisho Pharmaceutical
42 Takeda Pharmaceutical Co
43 Teijin Pharma Limited
44 Teikoku Seiyaku
45 Terumo Corporation
46 The Chemo-Sero-Therapeutic Research Institute
47 Toa Eiyo
48 Torii Pharmaceutical
49 Toyama Chemical
50 Tsumura & Co.
51 Wakamoto Pharmaceutical
52 Zeria Pharmaceutical

Source: Japan Pharmaceutical Manufacturers Association

is capitalised at US$130 billion. One of the company's goals was to post annual sales of more than 1 trillion yen. In its last fiscal year ending March 31, Astellas recorded sales of Yen 972 million (US$9.2 billion). Astellas expects sales to be little changed in the next fiscal year. Again by way of comparison, Pfizer posted sales of US$48 billion in 2007. Astellas is in the top five of Japanese drug firms, with Takeda (Cap'n: $48 billion) ranked number one with sales of Yen 1.4 trillion.

Australian investment implications

In the small molecule area **Biota** is partnered with Daiichi Sankyo, co-developing long acting neuraminidase inhibitors. And **Neurodiscovery** is jointly developing a pain compound, NSL-043, in partnership with **Sosei Group Corporation**.

However, one theme that has emerged from Japanese pharmaceutical firms acquisition and licensing activities is the strong interest in antibody drugs, technologies and targets. Antibody drug discovery and engineering has been an area of interest and strength in Japan for some time, as exemplified by **Kyowa Hakka** this year out-licensing IP and candidates to Amgen and signing a co-development deal with **Arana Therapeutics** for ART 104. **Patrys** has a collaboration with Takeda to evaluate five natural antibody leads that was initiated in March 2007. Takeda also has a small equity stake in Patrys. Both companies in our view may well become acquisition targets of Japanese pharma groups, if their respective products and technologies demonstrate clinical benefit.

Bioshares

The Hoya-Pentax ISC1000 : An Expected Gold Standard in Medical Imaging

Background

Optiscan Imaging has developed an endomicroscope with its partner **Pentax**, recently acquired by **Hoya**. The invention relates to the addition of a microscope to an endoscope used in internal medical examinations. The device allows real time imaging at a cellular level in the body to a depth of 250 microns, which can allow pathology analysis of living tissue without excision. The device, called the ISC1000, was released by Pentax onto the market in 2006.

Optiscan Imaging has developed a new imaging modality that in time should become a universally adopted technology used as the gold standard in internal medical imaging. Its device, the Hoya-Pentax ISC1000, was released in 2006 and currently there are 32 systems installed in Europe alone. How long it will take to achieve universal adoption is one of the key questions on investors' minds.

Two champions of the technology from Mainz, Germany, recently visited Australia and provided a full day update on their experiences with the technology. Endoscopists Professor Ralf Kiesslich and Dr Martin Goetz provided valuable insights into the utility of this technology and their achievements to date in diagnosing disease in real time with this equipment.

Take-up in Australia

In Melbourne there is one installed system used by Professor Finn Macrae at the **Cabrini Hospital**. Hoya's distributor in Australia indicated that the **Western Hospital** in Footscray was looking to acquire the system, switching from Olympus endoscopes to Pentax systems to gain access to the Optiscan confocal endomicroscope system. **Monash Medical Centre** is also considering acquiring a system, and an ISC1000 may be part of a negotiated contract with an overseas endoscopist looking to work in Australia at another hospital. The take-up has been slow but we expect a tipping point will be reached eventually.

At the 'Digestive Diseases Week' industry conference in the USA last week, endomicroscopy was featured in 19 sessions.

Comparisons with other imaging modalities

Around 20 years ago, another imaging system was introduced into the global healthcare system. Called the endoscopic ultrasound, the system is used to detect upper intestinal cancers. Both Hoya and Optiscan market versions of this technology. The relevance to Optiscan is the comparison of global adoption rate of this technology. The two technologies are priced similarly – approximately $250,000 – and there are now an estimated 5,000 endoscopic ultrasound systems installed around the world.

It took about 10 years for this technology to become firmly entrenched in the gastrointestinal imaging market. However, the roll out of this technology was poorly conducted. As an estimate, it may take Hoya seven years to have its technology receive solid widespread global adoption from release (i.e. a further five years). We expect that within the next two to three years we will see sales begin to firmly accelerate.

The accuracy of the ISC1000 is now no longer in doubt with stunning and sufficient data having been generated with this instrument. In 2008 there have been 11 scientific papers highlighting the benefit of endomicroscopy (using the ISC1000) with no papers to date showing that the system produces inferior results.

One of the limiting factors for the technology is cost. A more significant factor is training of endoscopists to a level where they are comfortable in not only using the device, but also comfortable in reading the images. According to Martin Goetz, analyzing the internal tissue at a cellular level using the ISC1000 endomicroscope adds on average 11 minutes to what would normally be a 20 minute procedure.

Applications of the technology

The endoscopists in Mainz currently use the ISC1000 system in 20%-30% of medical imaging procedures. At their training centre, already 300 medical practitioners have completed the three-day training course. So what are the specific applications as outlined by these two practising experts of this technology?

The technology is most useful for conducting *in vivo* histology. Endomicroscopy is always used in conjunction with macroscopy. A standard endoscope camera helps guide the system through the body and provide an initial view of the tissue. Then a technique called chromoendoscopy (use of a dye that is sprayed directly onto the site) can be used to help define the area of interest. This is then followed with the Hoya/Optiscan endomicroscope. A dye is injected into the patient to assist with the imaging. The dye is selected for the application from a range of commonly used imaging agents. There is very low risk with the dyes, with dyes having been injected over 2100 times to date by the team in Germany.

The endomicroscopy technology allows diseased tissue to be imaged to allow better, targeted biopsy, a reduction in biopsies, see-and-treat procedures to be conducted on the spot, detection of precancerous lesions to classify patients into risk categories, and improved resection of diseased tissue. Some of the current applications include detection of colon cancer, gastric cancer, Barrett's Esophagus, celiac disease, liver disease, irritable bowel disease and bladder cancer.

Future uses may include the imaging of bacteria in the gastrointestinal tract, live imaging of tissue undergoing treatment with prediction of response to targeted molecular therapy, and the observation of immunological actions.

Cont'd over

Future product developments

FIVE 1 and benchtop

Optiscan is currently working on 30% smaller scanner for the endomicroscope and on a next generation software upgrade with funding committed from Hoya. The company is selling is research instrument, the FIVE 1, which sells for $96,000. In the first 15 months since release of the device in 2007, 15 systems have been sold. Optiscan continues to receive royalties from sales of benchtop confocal microscopes that have incorporated the company's intellectual property.

Rigid versions - Carl Zeiss Group

The company has formed a partnership with the **Carl Zeiss Group** to commercialise a rigid confocal microscope in an unspecified application and possibly a second. The groups are currently conducting clinical trials and if successful, specific details should be announced. The point to remember is that much of the development work of these systems has now been completed. Rigid systems are standalone systems that do not need to be incorporated into an additional instrument such as an endoscope.

Women's Health

Moving forward the company will seek to maintain full rights further along the value chain. It is investigating using its rigid confocal microscope in the women's health area, to diagnose cervical cancer, endometriosis and ovarian cancer.

Two clinical trials have been conducted in cervical cancer and the system has shown to be 97% sensitive (missed on 3% of positive cases) in detecting disease. Ovarian cancer is a disease that is extremely difficult to detect. If ovarian cancer biomarkers become available (see last week's article on **HealthLinx**) then there will be a need for a better invasive procedure to confirm presence of cancerous or pre-cancerous lesions in the ovary.

Endometriosis affects around 10% of women at some stage of their life. It's a condition that occurs when tissue that normally lines the uterus is found outside of the uterus and grows causing a range of problems. The existing procedure of a laparoscopy is used to diagnose the condition. However, it is often a very frustrating and distressing process to diagnose correctly with several attempts (4-5) often required to detect the lesion. Surgeons have a high seek and treat approach to this disorder. Not surprisingly, a more effective detection method would be very well received.

In the USA, there are approximately 32,000 obstetric gynaecologists with 60% of them conducting at least seven endometriosis diagnostic procedures each month. Physicians have a high dissatisfaction level with existing procedures. Optiscan needs to conduct clinical trials to see if its rigid instrument can detect endometriosis accurately. If it can, then this may become a major application for its technology. There is also a high crossover (60%) in diagnosing clinicians for endometriosis and cervical cancer, giving the technology potentially added appeal if it can be used to assist in the diagnosis of both conditions.

One of the flaws in the flexible endomicroscope business model is that it does not include proprietary consumables. For these women's health applications it is likely that disposable sheaths will form part of the diagnostic instrument.

Men's Health – Robotic surgery

One application that is being explored with an undisclosed collaborator is the use of confocal microscopy with robotic prostate cancer surgery. There are over 700 robots in use in the USA to help surgeons conduct prostate cancer surgery. Real-time cellular imaging may have a role to play in not only imaging cancerous tissue, but also in guiding the robots through delicate surrounding nerve and muscle tissue. Optiscan is planning to conduct trials in two US centers.

Summary

Global adoption of the Hoya/Optiscan endomicroscope is gradual and may well take another three years before we see use accelerate. Training of endoscopists is a limiting factor. There is also some uncertainty as to how aggressively Hoya is prepared to market the technology and partnership risk remains a factor with this stock. Additional reimbursement for a procedure that can reduce the level of biopsy 10-fold will add significant weight to adoption of this technology.

In *Bioshares* view, confocal endomicroscopy has an important place in global healthcare. Whilst it will take time to roll out this technology, in the meantime Optiscan has no shortage of development programs to leverage off its technology base. Looking forward, advantages for Optiscan include the ability to partner later and co-market its rigid systems, much lower development risk with recently established and anticipated programs, and the possibility of an ongoing revenue stream from consumables.

Optiscan is capitalised at $26 million with $4.5 million in cash at the end of last year. Over CY2007, the company generated revenue of $4.7 million. For the first six months of this financial year the company generated a loss of $1.9 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Starpharma's International Investor Appeal

A novel chemistry platform can generate a myriad of uses and commercial opportunities. And so it is now with Starpharma Holdings' dendrimer chemistry scaffolding asset that continues to receive wider interest for a defined chemistry scaffold that can be precisely constructed and manipulated to deliver a seemingly limitless number of functional uses.

Since the beginning of 2007, Starpharma has signed development agreements for its technology with:

– **EMD Biosciences** (siRNA and DNA transfection)
– Undisclosed partner (condom coating)
– **SSL International** (condom coating for Durex condoms)
– **Steifel Laboratories** (improved dermal treatments)
– **Unilever** (dendrimers as imaging agents to assess food structure)

This accelerated interest can likely be attributed to the progress Starpharma is making with its lead dendrimer program, Vivagel, a microbicide being commercialised for the prevention of sexually transmitted diseases.

Vivagel

Starpharma has now completed three safety studies of Vivagel in 134 people with positive results. A fourth expanded safety study is continuing and once completed the company should start two major population-based efficacy studies using Vivagel to prevent HIV (in around 4000 people) and the prevention of genital herpes (in up to 2000 people). These trials will take at least two years to complete and are being funding with more than US$26 million of grants from the US National Institutes of Health.

Closer to market however will be the application of Vivagel as a condom coating. Following safety studies, larger expanded efficacy studies will not be required, only *in vitro* (laboratory) efficacy data will be required, much of which has already been received. It is estimated this product could be in commercial markets within 12-18 months. *Bioshares* estimates potential royalties at $20 million a year from this application.

Commercial Developments

In April this year, Starpharma's partner launched the first commercial dendrimer product which is based on the company's Priostar cell transfection agents. Called 'Nanojuice Transfection Kit', the kit will allow researchers to transfect living cells with DNA. The follow-on product will be similar although will allow the transfection of cells with siRNA.

The real upside with this technology is if it can be applied to siRNA into cells *in vivo*, which is a massive challenge for siRNA drug developers. Starpharma retains rights to *in vivo* applications.

Clinical Developments

The utility of Vivagel in killing pathogens responsible for sexually transmitted diseases has been widened with recent data showing Vivagel is effective against the human papillomavirus (HPV). HPV is linked to the onset of cervical cancer for which the recently launched Gardasil vaccine seeks to prevent. In laboratory tests the compound was shown to be effective against strains that cause genital warts and cervical cancer that are not included through Gardasil vaccination (HPV-5, HPV-6 and HPV-45).

That Vivagel has shown efficacy in laboratory tests against HPV strains, HIV and the herpes virus (HSV-2) increases the appeal of this product for use as a broad spectrum antimicrobicide. Vivagel has also shown to have contraceptive benefits. The lack of an effective microbicide is a key driver for this product.

Summary

Starpharma Holdings is a unique biotech investment consideration with its appeal increasing internationally. Around 25% of the company's shares are now held in the USA with interest growing in the company in Europe and Asia as well. The widespread utility of this technology is now being investigated by several commercial groups giving early validation of the technology's potential.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (23 May 2008)

Company	Price (current)	Price added to portfolio
Cellestis	$2.58	$2.27
IDT	$2.10	$1.90
Circadian Technologies	$0.98	$1.03
Patrys	$0.29	$0.50
NeuroDiscovery	$0.12	$0.16
Bionomics	$0.37	$0.42
Cogstate	$0.13	$0.13
Sirtex Medical	$3.89	$3.90
Clinuvel Pharmaceuticals	$0.42	$0.66
Starpharma Holdings	$0.33	$0.37
Pharmaxis	$1.67	$3.15
Universal Biosensors	$0.95	$1.23
Biota Holdings	$1.01	$1.55
Probiotec	$1.25	$1.12
Peplin Inc	$0.40	$0.83
Arana Therapeutics	$1.02	$1.31
Chemgenex Pharma.	$0.87	$0.38
Cytopia	$0.30	$0.46
Optiscan Imaging	$0.25	$0.35
Acrux	$0.94	$0.83
Alchemia	$0.35	$0.67

Portfolio Changes – 30 May 2008

IN:

No changes.

OUT:

No changes.

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cytopia,Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima

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