

In this edition...

How diverse is the Australian life sciences sector? Very is the answer. This week we introduce readers to two very different companies. Labtech Systems has developed an automated laboratory instrument for use in pathology labs. The product is close to seeing its first commercial revenues.

In stark contrast, Hexima, an ag-biotech company, is still a good number of years away from revenues. The times appear to suit Hexima, with global demand for better crop protection technologies on the up.

But both companies are a product of quality Australian research, and both are worthwhile investment propositions, given the appropriate investment horizon.

The editors

Companies covered: ACL, HXL, LBT

	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)	0.21%
Cumulative Gain	108%
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.

Hexima – A Compelling Long Term Ag-Biotech Play

Hexima (HXL: 86 cents) is a Melbourne-based agricultural biotechnology company that is developing crop protection technologies that offer benefits of increased yields and a reduced reliance on biocidal and chemical approaches to the management of insect pests and fungal infection. Hexima was founded in 1998, listing in August 2007. The company raised \$40 million through its IPO, at an issue price of \$1.25.

Hexima's technologies involve genetic modification to deliver new plant characteristics or traits, such as insect resistance. The most prominent crop-plant GM technology on the market is the insect resistance trait delivered by several genes obtained from the bacterium *bacillus thuringiensis* (Bt). These genes encode for toxins that kill certain insects.

The company's focus in Australia has been on cotton, one of the two GM crops that can be grown in Australia. (GM canola was recently approved for planting for the 2008 season by the Victorian and NSW governments.) However, internationally, the company's chief focus will be the commercialisation of the technology in US corn and soybean crops, the Brazilian soybean crop, followed by North American canola and cotton and finally Brazilian corn crops.

The area of crops planted around the world with genetically modified seed totalled 114 million hectares in 2007, an increase of 12% from the previous year. Of this, 57 million hectares were planted in the US, 19 million in Argentina and 15 million in Brazil.

The most planted crop in the US is corn, with 38 million hectares planted, of which, in 2007, 27 million was planted with GM corn. To put these figures in a context of global grain production, 208 million hectares of wheat were planted globally in 2006/07 (11.6 million Australia) and 304 million hectares of coarse grains (including barley, maize (corn), sorghum, oats and triticale) were planted (6 million in Australia).

According to Croppnosis, in 2007 the estimated global market value for biotech crops was US\$6.9 billion, or 16% of the \$42.2 billion crop protection market. This same US\$6.9 billion represented 20% of the US\$34 billion global seed market. This market value estimate includes the sale of seed plus technology fees.

Drivers

There are several drivers that compel the development of superior crop technologies, including GM technologies. An obvious factor is growth in global population which is tied to a finite supply of arable land and more recently, the beginnings of a long term trend in the depletion of global water resources. In other words, crop producers will need to find better ways to increase crop yields using the same amount of land and with less water.

Cont'd over

A second factor is demand for animal protein, brought about by a rise in living standards in countries such as China, where demand for animal protein has increased significantly. Animal protein such as pork and chicken is largely produced using feed grains.

Another recent driver is energy related. For example, the US government has mandated, under Energy Independence and Security Act of 2007, that ethanol use in transport fuels will be 34.1 billion litres for 2008. This represents around one quarter of US corn production.

A fourth factor is that innovation in the large international crop seed companies has been poor. None of the 'new' GM-derived plant traits currently marketed the large crop seed firms were developed in-house.

Hexima's technologies

Hexima is developing a suite of plant technologies. The technologies have been licensed from the University of Melbourne (insect resistance or PI technology) and La Trobe University (cyclotide, defensin and chymotrypsin).

The first of these is an insect resistance technology, NaPI, that originates from studies of natural insect resistance in the ornamental tobacco plant, *Nicotiana glauca*. Hexima scientists discovered six proteinase inhibitors (PI) which are peptides that can not be digested by insects. Hence, incorporation into plant DNA confers the property of insect resistance.

The second technology is based on molecules called defensins that were discovered in the female sexual tissue of *Nicotiana glauca*. These molecules have been shown to inhibit fungal pathogens.

A third technology is the Multi-Gene Expression Vehicle. This technology allows the delivery of several genes in a single construct, or in the one piece of DNA. The technology decreases the time required to develop plants with multiple traits.

Field Trials

Field trials have been conducted in Australia with the NaPI technology in cotton, all reporting positive results. An initial trial of fungal resistant cotton has also been completed. A key next step for the company is to conduct field trials in North America.

Commercialisation Strategies

Hexima intends to out-license plant traits it develops to international ag-biotech firms, such as **Monsanto, Bayer, Dupont/Pioneer, Syngenta** and **Dow AgroSciences**. These companies are equipped to market seed products to agricultural producers and control most of the industry.

Hexima is in discussions with a number of large ag-biotech firms concerning the initiation of collaborative development agreements, the first of which may take place in the next 12 months.

The first commercialisation agreement is not expected until 2010 at the earliest, until field trials in certain markets (especially the USA) have been completed.

Hexima's initial product opportunities in US corn and soy are likely to involve the inclusion (stacking) of Hexima's unique insect resistance technology with other traits developed by a partner.

The company is not particularly focused on the Australian market because of slower rate of acceptance of GM technologies by elements outside of the agricultural sector.

Obligations and Agreements

Hexima has licensed the insect resistance technology from the **University of Melbourne**, to which it is obligated to pay a sliding scale royalty from net revenues received by Hexima. The royalty will decrease as Hexima increases its expenditure on the technology. At the time of the company's IPO, Hexima would have been obliged to pay the University of Melbourne 5% of net revenues received of greater than \$1 million.

La Trobe University is the licensor to Hexima of the cyclotide, defensin and chymotrypsin technology.

Balmoral Australia

Balmoral Australia has licensed the PI and defensin technologies for the purpose of developing pharmaceutical applications, particularly in the area of cancer treatment. Balmoral has paid \$1.8 million to Hexima for research in this area over a two to three year period. Should the research be successful, Balmoral has agreed to license back any IP generated under the agreement back to Hexima.

Patents

The Hexima patent portfolio includes eight families. However, it is the US market that is perhaps the most significant in terms of IP protection required for Hexima's technologies. Hexima's granted US patents covering the NaPI technology (insect resistance) run to 2013-2014 in the US and for the anti-fungal technology, to 2022.

Board and management

Hexima has recently appointed a new CEO. The new appointee is Joshua Hofheimer. He is currently a partner with the international law firm Sidley Austin LLP, and is part of that firm's IP and Commercial Transactions Practice. According to Hexima, Hofheimer has significant experience with both start-ups in the agricultural science and biotechnology sector and with global agribusiness leaders. Hofheimer's appointment reflects the company's recognition that it needs to be build the appropriate capabilities to successfully partner its technologies and maximise returns for shareholders.

The chairman of Hexima is Steven Skala, who is Vice-Chairman of **Deutsche Bank AG** (Australia and New Zealand). Other directors include Hugh Morgan, a former CEO of **Western Mining**, Professor Jonathan West and Professor Adrienne Clark, a founder of the company.

Risks and issues

The current Hexima board includes several prominent and outstanding scientists and business leaders. However, in keeping with the decision by the board to hire a new CEO with skills and expe-

rience in the key North American markets, the company could also consider the addition of board members with international ag-biotech business skills.

Although there are powerful and positive global drivers that support the development and commercialisation of ag-biotech crop enhancement technologies, countervailing pressures in the form of anti-GM lobby groups exists, which do not necessarily act in an informed and rational manner. The actions of such groups can and have biased governments and regulators against new crop technologies to make decisions that are not based on the best available information and in fact generate less than best outcomes for many food consumers around the world.

A much more serious risk for Hexima is in regards to partnering with larger international firms that control seed distribution channels. Alignment through commercial agreements with such firms does not guarantee that the commercial considerations of a company such as Hexima are satisfactorily met. The risk is that a future partner may license in a technology with the intent of 'burying' the technology away from competitors and even progress an internally derived project. This class of risk is not trivial because companies such as Hexima effectively have no choice but to partner with one of the large seed companies because of their domination of distribution and marketing relationships with agricultural producers.

One factor in Hexima's favour is that company is well funded, with cash expected to cover five years of operations. A comfortable cash position is strategically important for small firms that engage with larger firms in a partnering process.

Another risk for companies that develop patent protected plant traits is the illegal use of seed stock in countries with weak patent, legal and economic systems. The implication for Hexima is that when it partners with a company, it does so with a company that can address intellectual property breaches by third parties.

Summary

Hexima is a stock for investors with a long term investment horizon. That said, an emerging global food crisis has the potential to shift many companies in the ag-biotech sector into the forefront of the investment universe much sooner than one might normally expect. Hexima's antifungal technology is a significant element of its potential value, given that no GM antifungal technologies are on the market, and none in development targeted at major crops such as soy, corn, cotton or canola.

Hexima is capitalised at \$64 million. At March 31, the company held \$36.5 million in cash. The company's strong cash position is another very positive feature of this stock.

Bioshares recommendation: **Speculative Buy Class A**

Alchemia Update: Heparin deaths cause surge in synthetic alternative Arixtra

Data released this week has shown that Arixtra sales for **GlaxoSmithKline** surged in March in the USA, up 66% over February to US\$20.4 million. The increased demand for Arixtra is due to the safety concerns over non-synthetic based heparin products from China, derived from pig intestines, that have been linked to almost 100 deaths.

This unfortunate event is important news for Alchemia, which is expecting to release the first generic to Arixtra in the USA next year, called fondaparinux. Arixtra is a purely synthetic heparin drug and we expect demand for this drug should continue to rise sharply in coming months with the increased sales penetration to hold firm.

Based on the last month's sales, Arixtra is generating annualised sales of US\$245 million in the US now. Alchemia expects to gain at least 40% market share through its marketing partner **Dr Reddys**. Investors are waiting for Dr Reddys to file its Abbreviated New Drug Application (ANDA) in the US, which is expected by mid year. Coupled with the recent sales surge in Arixtra, an ANDA filing should see a solid rise in the company's stock price.

Alchemia closed the week at 41cents, no change from a week ago.

Bioshares recommendation: **Speculative Buy Class A**

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LabTech Systems' First Instrument Due For Commercial Release

LabTech Systems (LBT: 20 cents) was formed only four years ago and listed on the ASX in 2006 at 20 cents a share. LabTech Systems has had a rapid path to success, with the company's core product due to reach the market around August this year. Its success has also been supported and enabled by the recently cancelled AusIndustry Commercial Ready Grant facility, with the company securing \$2.8 million in grant funding since March 2007.

LabTech has developed an automated instrument system that conducts robotic processing of agar plates used in commercial pathology laboratories to grow and test for the presence of bacteria in patient samples. Samples from patients are sent to pathologists to test for the presence of bacterial infection. The samples are spread onto a sterilized petri dish that contains growth media (agar and nutrients). These agar plates are then incubated for a set time at a set temperature, after which the colonies of bacteria are counted. The colonies are then extracted and the specific bacterium is identified using currently available laboratory equipment (such as the BioMerieux Vitek 2).

Processing of human specimens in a laboratory onto agar plates is a manual procedure and time consuming. One laboratory technician can process around 35 plates an hour, or 280 plates a day. This is a tedious and repetitive task for a microbiologist to conduct for whom there is an undersupply.

LabTech has developed an automated system to conduct this function, called MicroStreak. The system can process 180 agar plates an hour or just under 1500 samples over eight hours.

In April last year Labtech Systems signed an exclusive licensing deal with **BioMerieux** in France to commercially manufacture and sell LabTech's instrument. Under the terms of the deal, LabTech will receive \$12 million in up front and milestone payments, of which just over \$5 million has been received. BioMerieux has renamed the instrument the PREVI-Isola.



LabTech's MicroStreak, or renamed by BioMerieux as the PREVI-Isola, due for commercial launch in August 2008

Origins of Technology

The concept was originally developed by the **Institute of Medical and Veterinary Science (IMVS)** in Adelaide by John Glasson and Lachlan Smith. The invention covers a novel streaking device for distributing a pathology sample on the agar plate growth media and the automation of such a system. The invention is covered by patent applications; in the US, patent application number 20070202564, filed in July 2006, just prior to the company's listing on the ASX. Glasson is the Chief Scientist of the clinical pathology group at IMVS, which employs around 100 people.

LabTech Systems has licensed the technology from IMVS, to which it pays a royalty for any revenue it receives from sales of the MicroStreak technology. The royalty obligation is 3% of gross sales in Australian, and for countries outside of Australia it is 3% of gross sales for the first three years from the date of the first commercial sale in the relevant country. After three years the rate increases to 7%.

Commercial Arrangements

In September 2006, LabTech engaged **Invetech** (a subsidiary of **Vision Systems**, now **Danaher Corporation**), to construct a beta prototype that would be suitable for mass production. In May last year it signed a manufacturing contract with **Leica Biosystems**, also part of Danaher Corporation, to produce the MicroStreak instrument.

The finished product was displayed last month at the European Congress of Clinical Microbiology and Infectious Diseases in Spain and was apparently very well received. Commercial launch of the product is expected around August this year. It is expected that Leica Biosystems will manufacture the instruments for BioMerieux. Its manufacturing capacity is expected to be in excess of 200 instruments a year.

Labtech is approaching a handover of the complete program to BioMerieux in mid-2008.

LabTech Royalties

The PREVI-Isola may sell for in excess of \$100,000. BioMerieux will target mid-sized pathology providers initially. Pricing will be decided by BioMerieux and may be greater than or less than the figure above, and might include leasing or hire purchase options.

LabTech will not receive a royalty from sales of the hardware, but it will receive a good ongoing double digit royalty stream from sales of the MicroStreak applicator, a plastic consumable that is used to distribute each patient sample onto the agar plate. This applicator will be manufactured by a third party for BioMerieux and will be sold for around 20 cents each. LabTech Systems has ensured there will be systems in place that will allow it to closely audit the production volumes and sales of the applicators. LabTech will also receive a minimum royalty payment in certain regions.

Cont'd over

BioMerieux – The Partner

BioMerieux appears to be an excellent choice for LabTech as a partner. It has an existing global sales and distribution network in place selling instruments and consumables to pathology centers. The PREVI-Isola is a very nice fit with its existing product line. It will slot into the pathology process just before the Vitek bacteria identification and antibiotic susceptibility testing platform, of which it has sold several thousand to laboratories around the world. Overall, Biomerieux has an installed global instrument base 38,000 systems of its product range. BioMerieux owns 10% of LabTech Systems.

The Market

Medium sized pathology labs can process 500 agar plates a day with larger centers processing up to 1500 samples a day on agar plates. An estimated two billion plates are processed globally each year, with between 30-40 million plates processed each year in Australia. The consolidation of the pathology industry, as led in Australia by groups such **Sonic Healthcare** and **Gribbles Pathology**, is seeking to introduce efficiencies into processes from systems such as this newly developed PREVI-Isola.

For each 200 installed systems that are operating at 500 plates a day, we estimate LabTech Systems will receive \$800,000 a year in net royalties. The company is expected to release sales forecasts in coming weeks. At an installed base of 1000, the company, we estimate, would be generating \$3 million in net royalty income.

Or alternatively, 10% of the global market equates to \$40 million a year of applicator sales, from which Labtech would receive a healthy double digit royalty stream.

System Benefits

The MicroStreak system can replace up to four technicians and the payback time can be quick for pathology groups. Not only does the system have operational efficiencies, but a paper published last month in the *Journal of Clinical Microbiology* highlighted that this technology can produce 44% more usable colonies per agar plate than standard culture processes. This provides the benefit of better identification of bacteria in a sample containing several different pathogens.

With less operator input, the system is also arguable less prone to operator error. The system also reduces the required laboratory space to process the tests.

Other applications

Following the handover of this project, LabTech will look to develop subsequent automated instruments for use in the pathology industry. This may also include larger and smaller versions of its MicroStreak technology.

Risks

There are two key risks with this company. The first is partnering risk. There is a possibility the relationship between BioMerieux and LabTech could have difficulties moving into the future, particularly as competing technologies emerge, of which at present there are few that challenge this technology.

The second major risk is marketing risk. Whilst there was strong interest in the technology at the recent trade show, pathology groups will need to be convinced to make the investment in this expensive hardware, even though the payoff to users would appear quite obvious. The cost may slow take up of the technology, although this could be alleviated if leasing programs are offered by BioMerieux.

The technology is only supported by patent applications, with no granted patents to date.

Financials

LabTech Systems is capitalised at \$20 million (excluding 36 million options) and has an estimated \$5.4 million in cash following the \$1.6 million milestone payment from BioMerieux last month. The stock's 12 month high is 29 cents. The company generated a net profit of \$965,000 last financial year.

Management and board

The CEO / Managing Director of LabTech Systems, Lusia Guthrie, has a background in pathology management. The company's board includes Bob Finder as Chairman, who was previously CEO of **GroPep**.

Summary

Labtech has proven it can successfully manage the development of an automated laboratory system. In coming months it will hand over its first product and program to its international partner. We believe the product will receive strong demand from pathology groups around the world, although it may take up to five years to achieve peak sales.

More important to Labtech is the installed base, with the company receiving royalties from sale of consumables only, which is a somewhat novel but sensible approach, allowing the company to enjoy continued upside from the global use of this technology. Serious competing technologies will likely emerge in the future, but existing technologies appear inferior.

Following handover in August, the company's expenditure will fall considerably as the company considers its future development programs. Labtech is a quality company that has shown it can successfully develop instrumentation for the life sciences industry.

Labtech is capitalised at \$20 million.

Bioshares recommendation: **Speculative Buy Class B**

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Bioshares Model Portfolio (16 May 2008)			
Company	Price (current)	Price added to portfolio	Date added
Cellestis	\$2.50	\$2.27	April 2008
IDT	\$2.10	\$1.90	March 2008
Circadian Technologies	\$0.96	\$1.03	February 2008
Patrys	\$0.29	\$0.50	December 2007
NeuroDiscovery	\$0.14	\$0.16	December 2007
Bionomics	\$0.35	\$0.42	December 2007
Cogstate	\$0.13	\$0.13	November 2007
Sirtex Medical	\$3.95	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.43	\$0.66	September 2007
Starpharma Holdings	\$0.36	\$0.37	August 2007
Pharmaxis	\$1.55	\$3.15	August 2007
Universal Biosensors	\$0.86	\$1.23	June 2007
Biota Holdings	\$1.09	\$1.55	March 2007
Probiotec	\$1.22	\$1.12	February 2007
Peplin Inc	\$0.44	\$0.83	January 2007
Arana Therapeutics	\$1.06	\$1.31	October 2006
Chemgenex Pharma.	\$0.92	\$0.38	June 2006
Cytopia	\$0.30	\$0.46	June 2005
Optiscan Imaging	\$0.26	\$0.35	March 2005
Acrux	\$1.02	\$0.83	November 2004
Alchemia	\$0.41	\$0.67	May 2004

Portfolio Changes – 16 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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