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In this edition...
QRxPharma and its strategic partner Actavis are in a pole position for the combination opioid pain drug MoxDuo IR, courtesy of the FDA forcing the removal by 2014 of almost half the number of scrips written for acute pain opioid drugs in the US. MoxDuo IR looks set to do well from this rare opportunity. Allied Healthcare is developing momentum, driven by progress at Coridon, a novel vaccine technology company in which it has invested. Bluechiip is intent on securing a contract capable of transforming its business. Impedimed has finally hit its 20 million covered lives milestone.
The Editors
Companies Covered: AHZ, BCT, IPD, QRX

	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 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 now commenced	-21.5%
Cumulative Gain	**230%**
Av. annual gain (10 yrs)	**21.2%**

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QRxPharma – Ability to Succesfully Launch Novel Pain Drug Now Clearly Visible

The finalisation of a licensing deal and strategic partnership for the pain drug MoxDuo IR (immediate release), announced between QRxPharma (QRX: $1.83) and global generics firm **Actavis** in December, 2011 is imminent. The deal was struck initially as a binding letter of intent, allowing the two parties to initially agree on key access and royalty terms and then to finalise details covering sales forecasts, co-promotion, management and product supply details by March 15, 2012. Although this target date has not been met, we expect the companies will finalise the deal shortly.

A New Drug Application (NDA) for MoxDuo IR was submitted in July 2011and a decision by the FDA is expected by June 25, 2012. It is anticipated that Actavis will commence sales of MoxDuo IR in 2012 Q3.

The deal with Actavis is important for several reason, the first being that it covers only one territory (the US) and leaves open the rights to other territories around world to be partnered at a later stage. The deal is designed to allow QRxPharma to recover the costs of development of MoxDuo IR once the launch phase of of MoxDuo IR by Actavis has been completed and Actavis has recovered its costs associated with establishing and launching MoxDuo IR. In the launch phase QRxPharma can receive royalties ranging from 10% to 30% depending on sales volumes. In the next phase, or 'premium' phase QRxPharma can expect to receive 50% on cumulative sales up to US$150 million, with the total possible royalty of US$75 million roughly equating to QRxPharma's investment in MoxDuo to date. Thereafter, royalties revert to 10%-30% depending on sales volumes.

The Driver – 100 Million Missing Scrips

The deal with Actavis also includes an option for QRxPharma to co-promote MoxDuoIR, which includes a profit share split and right to manage up to 25% of the sales effort. This deal term has been inspired by, we would argue, the phasing out by 2014 of dose forms of combination pain drugs containing more than 325mg of acetaminophen (better known as paracetamol in Australia) which will expose 100 million scrips per year to competition, out of 210 million written for acute pain opioid drugs. The FDA has clamped down on high dose forms of acetaminophen due to its association with liver damage and toxicity. Such a market opportunity is a rare event in the pharmaceuticals industry.

The deal between Actavis and QRxPharma has substantially elevated the commercialisation prospects for MoxDuo IR because of Actavis' comprehensive knowledge of the pharmaceutical industry in the USA.

QRxPharma is capitalised at $264 million and held cash of $33 million at December 31, 2011.

Bioshares recommendation: **Speculative Buy Class A**

Allied Healthcare Group – Building a Diversified Healthcare Business

Allied Healthcare Group's (AHZ: 3 cents) was spun out of Fortescue Metals Group in 2003. The company's plan has been to build a diversified healthcare business. That plan continues to take shape as the company builds not only its portfolio of product and product development assets, but also its team of experienced biotech managers.

Allied now has three parts to its business. The first is its medical products business – Allied Medical – which it has built up through M&A. This business sells infusion pumps and other devices into hospitals. It generates around $7 million in sales and achieves an operating profit of around $1 million a year.

Its second part is the Celxcel tissue processing technology acquired through its merger with **BioMD** last year. Its lead product, CardioCel, is being developed for the treatment of congenital heart defects in children, and also in the processing of animal tissue used in tissue heart valves.

The third part to the Allied business is its investment in **Coridon**, a novel vaccine platform that uses a number of technologies to deliver potentially not only preventative, but also therapeutic vaccines (see *Bioshares* 424). There is potentially some significant upside in this investment, and the implied message is that the company may have access to substantial funds in the future from its Fortescue shareholder base, should it decide to take any vaccine programs through to the end of product development.

Expanded Management Team

In recent months, Allied has beefed up its management team. Julian Chick, who was formerly head of Avexa, is now the company's Chief Operating Officer. Bob Atwill, who was formerly the head of Clinical Cell Culture (now Avita Medical), has been put on as an Executive of the parent company and CEO of its majority owned Celxcel.

Coridon Investment

Coridon was founded in 2000 by Professor Ian Frazer from the University of Queensland. Coridon has been working on a herpes virus (HSV-2) vaccine and this program is expected to move into a Phase I study in the second half of this year. The company has achieved some very promising results in animal studies conducted by Professor David Koelle at the University of Washington in Seattle. Professor Koelle is considered an expert in the field of HSV.

The animal trials showed that the vaccine was 100% effective in preventing 500 times the lethal dose of the virus. It was also shown to have an effect in clearing the virus from the reservoirs where the virus can lie dormant.

The escalating dose Phase I study will be conducted in Queensland and will involve around 15 subjects.

DNA vaccines have the ability to not only prevent but also to treat infection. Success in a Phase I study should deliver a higher than normal inflexion value as there should be some clear data on the effect the vaccine is having on antibody production and also T-cell activity. Success in this trial will also deliver proof-of-concept of the Coridon platform, which can be applied to many other vaccines.

Coridon is also seeking to start a Phase I this year study for its Epstein Barr Virus vaccine (linked to glandular fever), and it recently announced an early stage program to work on a Human Papillomavirus vaccine. Frazer was one of the inventors of Gardasil, which is a preventative vaccine in use against HPV.

At June 30 last year, Allied had a 23.9% stake in Coridon. It has an option to increase its stake to 55% with a total investment of $6 million.

Celxcel – Dealing with Calcification

Celxcel has developed a way to process animal tissue as used in a variety of biomedical applications. The processing technology removes any active animal constituents but importantly what it leaves is a scaffold matrix that delivers less calcification (thereby less stiffening of the implanted patch) than other products, and an ability for healthy surrounding tissue to integrate with patch (e.g. achieving blood vessel growth). The first product is called CardioCel.

Allied is looking to get TGA approval to sell the patch in Australia in the next 12 months. A successful trial was completed with the patch in South Africa in treating pediatric heart defects. After treatment of heart defects, there is an application for processing biological heart valves, where the company is receiving increasing interest from heart valve manufacturers. Less calcification of tissue heart valves will deliver longer lasting valves. From there, other potential uses include in pelvic floor repair, treatment of hernia, and even providing a matrix in which to deliver stem cell therapy.

Allied owns 77% of Celxcel.

Capital Raising

At the end of last year, the company had just $0.6 million in cash. This week the company announced it would raise up to $6.36 million, before costs. Of that, the company has received a commitment $2 million through a private placement, and a rights issue to raise the remaining $4.36 million is to be conducted with RBS Morgans as the lead manager.

Summary

Allied Healthcare Group is an interesting biotech play. Its medical device business has the potential to deliver the company with sales in the tens of millions of dollars. It believes the Celxcel business can deliver sales in the hundreds of millions of dollars, and the vaccine technology of Coridon could deliver billion dollar products. And this commercialisation game plan has access to some very successful mining investors on its register.

Bioshares recommendation: **Speculative Buy Class B**

Impedimed Reaches 20 Million Covered Lives

Impedimed (IPD: $0.50) markets the LDex U400 device, which is approved by the FDA to aid the clinical assessment of lymphoedema of the arm in women and the leg in men and women. It is also only approved for use with patients who have had lymph nodes removed, damaged or radiated in the axilia (armpit) or pelvic areas.

The LDex device uses bioimpedance spectroscopy to measure fluid that builds up outside cells but within tissue in arms and legs. The device reports a ratio based on differences between limbs.

Lymphoedema can be managed through the use of relatively inexpensive pressure bandages. However, the very early detection at the sub-clinical stage, which is what the LDex device is capable of aiding, can have a major effect on disease progression and with appropriate treatment, see patients restored to baseline measures.

20 Million Covered Lives Target Now Reached

The company has now achieved its target of securing 20 million covered lives in the US, having recently had a Health Maintenance Organisation (HMO) and a Third Party Administrator (TPA), both as yet unnamed, agree to include the use bioimpedance spectroscopy as a medical policy, i.e. to reimburse the products use.

The actual running total of covered lives is 23.4 million lives, up from 13.8 million when last reported by Impedimed in December 2011, when a Pennsylvania health plan responsible for 1.6 million covered lives became the first private health insurer to support reimbursement of Impedimed's LDex device.

The HMO, which is ranked in the top ten of HMOs according to Impedimed, will launch clinical guidelines that address the issue of breast cancer *survivorship*, an increasingly important concept because there are more than 2.6 million breast cancer survivors in the US, with 250,000 new cases occurring annually. The driver favouring Impedimed is that the cost of chronic care is increasing as more women survive breast cancer.

The guidelines will specify the use of bioimpedance spectroscopy as an aid in the clinical assessment of female patients, in a pre-emptive care model.

Unlike insurance companies which HMOs only provide care through doctors or their practise groups that have agreed to treat patients according to the HMOs' guidelines.

Investors should note that while the company has obtained a medical policy determination, Impedimed has yet to reach a supply agreement with the HMO.

The gaining of coverage as evidenced by the publication of medical policy by insurers or HMOs is necessary for companies wishing to commercialise therapeutic products, medical devices and diagnostics in the US.

US Health Insurance

In the US, private health insurance schemes cover an estimated 152 million people through employer programs, with another 25 million through other schemes. The US government provides insurance through its Medicaid and CHIP programs to 37 million people and covers 47 million people over the age of 65 through Medicare. The balance of 50-55 million are uninsured.

Amongst the major private health insurance companies are Aetna (18.2 million covered lives), Wellpoint (34 million), Kaiser Permanente (8.7 million), United Healthcare (18 million), Humana (10 million) and Cigna (9 million).

What's Been Holding The Insurers Back?

Impedimed has focused on achieving coverage decisions from the major US health insurers such as Aetna, Humana, Cigna and Wellpoint. These organisations have typically wanted to be satisfied that Impedimed's LDex product, or more to the point the very early detection of lymphoedema, offers a long term benefit.

Impedimed has also been educating groups on the difference between early detection of lymphoedema using the LDex product and the monitoring of lymphoedema on progressive basis, which the LDex system is not designed to do.

Some data from the nuclear medicine field that Impedimed only recently became aware of has been added to the body of information Impedimed presents to insurers on the long term benefits of early detection. A randomised study by Campisi (2002) (n=50) showed that where lymphoscintigraphy was used to aid early detection, 8% of subjects in the treatment arm developed lymphoedema compared to 36% of patients in the control arm, five years after the assessment was made. However, it should be noted that the Campisi study was too small to deliver statistically significant results.

Summary

Impedimed is making slow progress towards its goal of generating an income from its LDex U400 and related products. In hindsight, the company should have initiated, along the lines of what it proposed in its 2007 prospectus, a sufficiently powered, long term, randomised clinical trial of its LDex system with breast cancer patients so that as it has engaged with US insurance companies it has had credible data from its own technology to put in front of insurers. The company has been somewhat hobbled by needing to rely on data from other approaches, such as perometry and lymphoscintigraphy to demonstrate the benefits of detecting lymphoedema at an early stage in breast cancer patients, which are in our view are not a commercial threat to the far more convenient LDex system.

Impedimed is capitalised at $78 million and retained cash of $12.1 million at December 31, 2011.

Bioshares recommendation: **Speculative Hold Class A**

Interest Builds in Bluechiip's Tracking Technology

Bluechiip (BCT: 21 cents) believes this year will see the company start selling product into global markets and in coming months it may see adoption of the technology by some Tier-1 bio-banking organisations. Bluechiip has developed a technology that will compete with RFID (radiofrequency identification) and bar-coding.

Bluechiip's technology uses sound waves made from differently resonating chips as an identification tool. The key advantage to the technology is that it can be used in extreme temperatures, where RFID and barcoding has limitations. Samples that are barcoded can be difficult to read when frosted over. RFID can not operate below -25 degrees C. There have been cases where biological samples, including IVF sperm samples, have been lost because of inadequate labelling systems.

There are other advantages of the Bluechiip system, including the ability to deliver a historic temperature record of samples, reduced handling because multiple samples do not need to removed to locate one particular sample, and can improve overall storage and handling efficiencies.

There are three parts to the Bluechiip system: the chips, which can either be attached to storage containers or embedded in the container during manufacture; the chip reader; the development of which is almost complete with the company close to initiating third party commercial manufacture; and the software for the reader.

The company can manufacture its chips now through a major chip manufacturer in Italy, although a final manufacturing equipment investment will be required (around $1.3 million) to manufacture larger commercial quantities.

The company believes there is such interest in the technology that the pace of commercialisation is now being pulled by the market. One major contract could be a major differentiator for the company according to the company.

The company is in discussions with major bio-banking groups, some of the largest in the US, as well as manufacturers of the storage vessels used in this industry, that may look act including the company's chips in their product ranges.

Two trials have recently completed with the Bluechiip technology in the US. One was by American Type Culture Collection, a major bio-banking organisation, and was done in conjunction with Corning Life Sciences, which is a consumables supplier. The second trial was conducted by another major bio-banking service provider. The company is confident its technology performed well against existing technologies in these trials, which were very rigorous in their testing.

Challenge to Supply Product at Scale

The challenge for Bluechiip is to co-ordinate the manufacture of its products with its limited budget, but at the same time convince its potential customers that it can deliver sufficient product at large commercial scale.

Bluechiip recently raised $1.2 million. It had $0.5 million at the end of last year. The company expects also to receive an R&D rebate in excess of $0.75 million this year, which gives the company currently access to funds estimated at $2.2 million.

Bluechiip believes the uptake of the company's technology by some major bio-banking organisations may be very rapid. That one major contract will be a differentiator for the company is a reasonable expectation, with other companies likely to follow suit. A major contract will be a transformational event for the business.

There appears to be strong interest in the technology, which offers clear points of difference to competing approaches and we expect product sales to commence at some level over coming months.

Milestones to Monitor

- Results from two trials
- Commercial orders and strategic partnerships/contracts
- Commercial manufacture of readers
- Installation of final manufacturing equipment line in Italy for chips

Bluechiip listed last year at 25 cents a share. It is capitalised at $13 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (16 March 2011)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.83	$1.66	October 2011
Mayne Pharma Group	$0.285	$0.435	September 2011
Acrux	$3.90	$3.37	June 2011
Bioniche	$0.62	$1.35	March 2011
Somnomed	$0.97	$0.94	January 2011
Phylogica	$0.049	$0.053	September 2010
Biota Holdings	$0.85	$1.09	May 2010
Tissue Therapies	$0.37	$0.21	January 2010
Atcor Medical	$0.07	$0.10	October 2008
Impedimed	$0.50	$0.70	August 2008
Bionomics	$0.48	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$5.35	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.81	$6.60	September 2007
Pharmaxis	$1.23	$3.15	August 2007
Universal Biosensors	$0.75	$1.23	June 2007
Alchemia	$0.480	$0.67	May 2004

Portfolio Changes – 16 March 2011

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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada

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