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In this edition...
Another week of AGMs has gone by, with investors turning up in greater numbers, and the mood of investors and boards bouyant, although waiting is now a theme as well. Impedimed is waiting for its CPT 1 code application to go through at the AMA in the US; Alchemia is waiting, with its partner Dr Reddy's, for the approval of its generic fondaparinux; and Acrux is waiting to see what the best outcome will be for Axiron. And rather than sit on its hands, Alchemia has also announced a capital raising through an underwritten rights issue.

Reports from the Genetic Technologies, a company that is setting its sights on profitability, and Hexima AGMs are also included in this edition.

The Editors
Companies Covered: ACL, ACR, GTG, HXL, IPD

	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 - Current)	80.0%
Cumulative Gain	**250%**
Av Annual Gain (9 yrs)	**21.9%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au
David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

27 November 2009
Edition 339

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

Impedimed AGM Report

The Chairman of Impedimed (IPD: $0.79) Mel Bridges gave a very upbeat overview of Impedimed's progress and outlook at the company's AGM, held this week in Brisbane. Bridges said that "management had really delivered on important milestones", over the last 12 months with the company having established itself as a world leader in lymphedema assessment.

Between 20%-25% of women undergoing breast cancer surgery will develop lymphedema in the arms, which if not detected early enough can become an irreversible condition.

The company uses bioimpedance spectroscopy to non-invasively detect very early signs of lymphedema. The Impedimed technology allows fluid build up to be recognised four months before symptoms are visible.

The company's instruments are approved in Australia, Europe and the US and the company was the first to gain FDA approval for its instrument to aid in the diagnosis of lymphedema in women following breast cancer surgery. Core patents, which run to 2027, prevent other groups from using this type of technology in this field.

Category 1 CPT Code Filing

For Impedimed, reimbursement is a key factor. The wider and more accessible level of reimbursement, the more successfully and rapidly the technology will be taken up. Earlier this month Impedimed announced that a Category 1 CPT code had been submitted to the American Medical Association, by two US breast cancer surgeons. One of these surgeons is Peter Beitsch MD, a well respected cancer surgeon who is an executive council member for the Society of Surgical Oncology (SSO) in the US and is chair of the SSO Community Surgical Oncologist Committee.

The filing seeks reimbursement for lymphedema testing using Impedimed's bioimpedence technology, called L-Dex, for prospective management of breast cancer patients who are at risk of developing lymphedema.

Significance of Reimbursement

If the filing is successful in achieving this reimbursement for procedures that specifically use the L-Dex technology, then this technology specific code gives the company another level of competitive protection, adding to product patents, regulatory clearance, trademarks and first to market advantage. A Category 1 CPT code, if successful, would specify the reimbursement level from public and private insurers for procedures using this technology (although it is still not guaranteed each insurer would cover this procedure).

Cont'd over

Subscription Changes
Please note, from January 1, 2010, the price of an individual subscription to Bioshares will increase to $350 per 48 issues.

– Impedimed cont'd

A decision on the coding should be received in February next year and if successful, reimbursement under the coding will be in effect from 1 January 2011. Under a Category 1 CPT Code, users are reimbursed generally within two weeks.

The Chairman of Impedimed is clearly impressed with the progress and the calibre of the team at Impedimed. "This is a management team that continues to deliver, deliver, deliver. We have a cracker of a Board (and) we have surrounded Greg with an A1 management team. The best is yet to come".

L-Dex Agreements Signed To Date

To date Impedimed has signed 65 L-dex agreements with breast cancer surgeons in the US. Under these agreements, the surgeons receive the instrument free of charge and pay a per use charge of between US$25-$49 per test (for the U400 instrument), depending on whether the instrument is purchased or under an agreement.

There are around 5,000 breast cancer surgeons with around 2,000 that do most of the work according to CEO Greg Brown. Obviously the aim would be to have a large part of these 2,000 surgeons using the device, with the focus to date being on the top 50 breast cancer surgeons.

Potential Revenue

After three years, we estimate each surgeon with generate between US$27,000 - US$52,000 a year after three years, based on adding 10 new patients each month tested every quarter. With 2000 surgeons using the product, it translates to between US$70 - US$140 million a year after three years of use, depending of the per use price listed above.

The Impedimed technology should be well received by the current US administration that is seeking to reduce healthcare costs. The Impedimed technology offers a pre-emptive care product that can prevent lymphedema moving from a preventable to an irreversible form. There have been several papers published over the last year highlighting the importance of testing for lymphedema following breast cancer surgery.

In March, one study published in the *Journal of Clinical Oncology*, showed that the cost to the healthcare system is on average US$19,000 per patient in the first two years from lymphedema. Pre-emptive testing not only has the capacity to prevent lymphedema, but it also reduces the anxiety in patients concerned about the possibility of developing this condition according to Brown.

Other Applications

Following testing for lymphedema in patients who have undergone breast cancer surgery, other uses include pelvic cancer, patients with oedema and in kidney dialysis (although this application has been licensed to **Fresenius** and the upside for Impedimed is capped).

Summary

The reimbursement from use of this technology is a key for success for Impedimed. There is existing reimbursement under a miscellaneous coding, although this is not a user friendly system and there is no guarantee insurers will cover the procedure under this code.

It is uncertain at this stage whether the Category 1 reimbursement filing will be successful. Under the requirements for a successful Category 1 coding, the technology is strong in some items, including regulatory clearance and use under a miscellaneous coding, and is building its strengths in other specific requirements which include widespread use, professional society support and more than five years of published data. The rate of success of Impedimed is dependent on how quickly the company can achieve top-level reimbursement status.

Impedimed is capitalised at $86 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Acrux AGM Report

A solid turnout and a buoyant mood characterised the Acrux (ACR: $2.45) AGM, held at the Melbourne offices of Pitcher Partners. Chairman Ross Dobinson said that he "could not be happier with the position of the company".

CEO Richard Treagus reviewed the performance of the company over the last twelve months. He said that FY2010 is to be a pivotal year in which the company would generate meaningful returns for shareholders.

Regarding Axiron, a formulation of testosterone developed around a novel transdermal delivery system, Treagus said that the company has been "meticulous in the execution of the clinical and regulatory plan; its progress went according to plan on time and on budget and it exceeded its (anticipated) clinical outcomes".

Axiron is the world's first pharmaceutical product delivered to the armpit. The company expects the product to be on the market in 2011.

Acrux raised $23 million in 2007 for a "compelling investment opportunity" which was the Phase III development program for Axiron. Axiron has been designed as a more convenient and safer method of administering testosterone, requiring less drying time and application time, decreased risk of transference and greater accommodation with daily routines.

The company conducted a Phase III trial of Axiron in 155 hypogonadal men and achieved results that comfortably exceeded the minimum sought by the US FDA. The primary endpoint of the trial was that a minimum of 66.8% of patients maintained testosterone in the normal range. The sudy showed that 76% of subjects achieved the normal range after 15 days, 85% after 60 days and

Cont'd on page 4

Alchemia AGM Report

It was a very buoyant AGM for Alchemia (ACL: $0.66) this week as well, with shareholders very pleased with the progress the company has made and keenly waiting for the pending approval of its generic fondaparinux.

Capital Raising

Alchemia also announced a renounceable rights issue, which is fully underwritten by RBS Morgans Corporate. The company will raise $14.7 million after costs, with the rights issue being done at 53 cents a share, a 26.9% discount to the closing price.

This a sensible move by the company and one that should be favourable to most shareholders. The funds will allow Alchemia to make final preparations for its Phase III HA-irinotecan study in patients with colorectal cancer. However, no patients will be dosed in this trial until the approval of its fondaparinux drug is received from the FDA.

Alchemia is now waiting for the approval of fondaparinux, which should occur this year, although may take to the end of March next year. (Once that occurs, we expect around a 50% increase in the ACL share price within the first month after approval.)

Alchemia CEO Pete Smith was confident of fondaparinux approval, which should generate tens of millions of dollars in revenue for Alchemia. He cited partner **Dr Reddy's**, which has filed the drug for approval, as having all 130 ANDA submissions with the FDA approved. The company's Chairman, Mel Bridges, was confident the approval would come by year's end.

With a royalty stream of what should be at least $30 million, and a Phase III and Phase II clinical pipeline, Alchemia looks set to become appreciably stronger in 12 months time if all goes well.

Fondaparinux took 12 years for a major pharmaceutical company to work out how to manufacture. Without the Alchemia technology, there is no evidence anyone will file another generic for fondaparinux any time soon, according to Smith. Historically it has been shown that with only one generic on the market, a price erosion of only 6% occurs.

Once approved, Alchemia can start work on value creation for shareholders beyond that which fondaparinux offers. With the fondaparinux revenue essentially a royalty stream, Alchemia will be able to focus efforts on other drug development projects. These include: a 330 patient Phase III trial with HA-irinotecan; working on an oral formulation of fondaparinux; a Phase II trial with HA-irinotecan in patients with small cell lung cancer; other opportunities (cancer drug combinations) with the HyACT platform; and work on the company's VAST drug discovery platform, but the work to be funded by external parties.

Phase III HA-irinotecan Trial in Colorectal Cancer

Earlier this year Achemia had a crucial meeting with the FDA regarding its Phase III trial program. It received two critical concessions set by the FDA, which without, would likely have killed this and all other HyACT programs. The first concession received was that only one Phase III trial would be required with HA-irinotecan. The second was that the FDA would accept a 'progression-free survival (PFS)' endpoint rather than an overall survival benefit, which is considerably longer and more expensive to complete.

Once fondaparinux approval is received, the company will start recruiting patients (within four months from now at earliest). The trial may take 12 months to recruit (if recruitment goes well) and results at the earliest could be received by the end of 2011.

The trial will cost less than US$20 million to conduct. If it is successful, it could potentially access a market worth $400 million a year. It is reasonable assumption that this product would receive a favourable review from the FDA if efficacy is achieved, as it improves the efficacy of the irinotecan drug by actively targeting the cancer cells which HA (Hyaluronic acid) binds to, and reduces side effects, as seen in the 80 patient Phase II trial.

The Alchemia board has an experienced advisor in Carlo Montagner, who helped commercialise a similar product, Abraxane, for **Abraxis Bioscience Inc**. Abraxane is an improved version of taxol (taxol in an albumin suspension). The Abraxane product is an example of how incredibly valuable a slight improvement in a generic oncology drug can be. Sales of Abraxane totalled US$229 million for the nine months ending September 30, 2009.

We would suggest there is a good, if not very good chance the Phase III trial will be successful. In the Phase II study, PFS was increased to 5.2 months (with HA-irinotecan) from 2.4 months in the control group (with irinotecan alone), in a result that was statistically significant. Historically, when HA has been combined with Erbitux, which is very expensive and has side effects, PFS is extended out to only around four months.

Success in this trial will not only generate significant revenue in its own right for Alchemia, but it will also validate the HyACT platform – that of adding hyaluronic acid to existing cancer drugs for enhanced tumour targeting – and will almost certainly see it extended to other cancer drugs.

Oral Fondaparinux

Alchemia is working with in international group to re-engineer fondaparinux to make it orally available (currently delivered by subcutaneous injection). Fondaparinux orally almost has no bioavailability. The re-engineered product has 'drastically enhanced' bioavailability of the drug in initial tests. A Phase I trial would not be expensive to conduct and if positive, could generate interest from a partner to develop further, simply from showing absorption of the drug at right levels into the blood stream.

Fondaparinux in Current Territories

In other opportunities, Alchemia may look to commercialise fondaparinux in other territories outside of the US and Europe. Next year the company will start partnering discussions for Europe. The market exclusivity for Arixtra (fondaparinux) in Europe expires in 2012.

Cont'd on page 5

Genetic Technologies – Expanding Cancer Management Offerings

The main theme of the Genetic Technologies (GTG: 4.8 cents) AGM was the casting of the firm as a business with three core revenue generating units: forensics and paternity testing (Forensics); cancer management tools which included molecular diagnostics (Medical); and animal reproductive health management (Animal). The company has set itself a goal to become a leading provider in Australia and the Asia-Pacific region over a three year period in these three areas.

In May, 2009, the company began to build a new leadership team and design a new strategy to turn the company into a profitable business. While the company has generated turnover from its operations of $2.4 million (2005) to $5.4 million (2009), and has also received licensing related income of $41 million since 2005, it has failed to make a profit in this five year period. The company posted a loss of $7.9 million in FY2009, compared to a loss of $5.5 million the previous year.

Licensing income declined in FY2009 by 50%, impacted in part by the lumpy nature of licesing income flows and that fact that the Genetic Technologies' patents are undergoing a re-examination at the US Patent and Trademark Office. The company expects it will achieve higher licensing fees going forward.

Genetic Technologies is the owner of several patents that cover the use of so called non-coding DNA, with numerous firms around the world having taken licenses from Genetic Technologies to afford them the freedom to practise the inventions described in the patents. Currently 38 companies are licencees. However, the non-coding DNA patents are due to start expiring from 2010.

Cancer Management Tools

An stronger focus on marketing cancer management tools was a major component of the AGM presentation. The company has been offering the BRCA1 and BRCA2 genetic tests since it licensed the test from **Myriad Genetics** in 2002, can be used to screen women for their likelihood of developing breast or ovarian cancer. Genetic Technologies also offers tests that guage the risk of bowel and uterine cancer.

This test sits at the beginning of a cancer management continuum, where the task is risk assessment and screening. The company intends to license or develop products that will contribute to differential diagnosis (i.e. knowing what type of cancer is present) through to assessing the stage of a cancer, prognosis, therapy selection and monitoring and surveillance.

As a step towards in-filling its pipeline, Genetic Technologies has recently licensed from **Rosetta Genomic**s, a micro-RNA based diagnostic that can assess Cancers of Unknown Primaries (CUP), labelled miReview. In the USA, the product is marketed by **Prometheus Laboratories** as ProOnc Tumour Source. We expect this product to compete with **Circadian Technologies/Healthscope** CUP diagnostics which we anticipate will be launched in 2010 H1 (see *Bioshares* 338).

Commentary

Genetic Technologies has set out to convince biotech investors of its merits in the most persuasive way possible, by seeking to generate profits. Attention to cost control, while it expands and develops its medical, animal and forensics lines of business, will be critical, as will replacing its licensing income stream.

In our opinion, the timing of Genetic Technologies to launch out and develop a suite of offerings in the area of cancer management is impeccable, given that one of the clearest trends in medical care is towards products that increase the quality and quantity of information across different stages of disease detection and management.

Genetic Technologies is capitalised at $18 million.

Bioshares recommendation: **Wait** for signs of improvement to underlying business.

Bioshares

– Acrux cont'd from page 2

84% after 120 days. The study confirmed that the preferred dose going forward was 60 mg applied once daily.

Commentary

The appointment of investment banker Credit Suisse to manage the post-Phase III commercialisation of Axiron was noted by Acrux chairman Ross Dobinson, who said that the choice of Credit Suisse had " confirmed our belief that this selection will result in the optimal outcome for shareholders".

Although the company iterated its view that it would be profitable in 2009/10, on the back of revenue from signing a partner for Axiron, receipt of a milestone from the Eli Lilly animal health program, fees and royalties from the Ellavie/Evamist product and a potential milestone payment from Vivus for the Luramist female testosterone product, our view is that the Acrux board is leaving all options open for crystalising value created in the firm, not only that relating to Axiron but also to other programs and assets.

Acrux is capitalised at $392 million and held cash assets of $11 million as September 30, 2009. Acrux continues to hold value for investors.

Bioshares recommendation: **Speculative Hold Class A,** with the value of this company due to be re-assessed potentially in the short term from a commercial deal for Axiron.

Bioshares

Hexima AGM Report

Hexima (HXL: $0.50) is a plant technologies company based in Melbourne. The company is developing fungal resistance traits that may eventually be stacked with other traits in crops such as corn, soy, cotton, canola, sugarbeet and potentially at a later stage, wheat and rice.

At the company's 3rd AGM, CEO Josh Hofheimer said that a key objective for the company is to develop and position its fungal resistance technology into a 'must have' trait that it (or its partners) can apply in crop markets where the cost of disease is estimated in excess of US$80 billion. With 12% of the US corn crop lost to fungal disease, a 'must have' trait may be worth as much US$1 billion to corn seed providers and worth as much US$2 billion to corn farmers in the US each year.

The company has established a path to market, through an arrangement with DuPont, a licencee, with corn a lead crop focus. DuPont also has right to the Hexima technology for soy. Importantly, Hofheimer said that if DuPont takes up its rights to progess development of fungal resistance traits in soy, it could be regarded as a strong sign of support for the lead program in corn.

Latest Results in Cotton

In an associated presentation at the AGM, Hexima's Chief Science Officer, Dr Marilyn Anderson, provided details of results from the third year of field trials of Hexima' fungal resistance genes in cotton. Trials in years one and two resulted in a 192% and 276% in cotton lint yield per kilogram per hectare for plants with Hexima's antifungal technology. For the latest growing season, the trial site was larger and was situated in a different geographic region. The result was a 133% increase in cotton lint yield per kilogram per hectare. Such data are convincing by the orders of magnitude in yield they confer, even adjusting for geographical influence (i.e. different disease pressures) and growing seasons separated by time.

What makes the Hexima antifungal technology attractive is that the fungi that infects cotton is similar to those which infect many other crops. If Hexima shows that its antifungal proteins are an effective broad spectrum fungal control technology, then it may in fact have a 'must have' trait at is disposal.

Hexima is capitalised at $40 million and held cash assets of $27 million at September 30, 2009.

Bioshares recommendation: **Speculative Buy Class A**

– Alchemia cont'd

ACS approval

It is expected that in 2010, **GlaxoSmithKline** will receive ACS (acute coronary syndrome) approval in Europe, which globally makes up about 30% of the total heparin products market. This may see the market for Arixtra (fondaparinux) grow even further from the current not insignificant global market worth US$390 million a year.

Alchemia is capitalised at $106 million (prior to the rights issue).

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (27 November 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.21	$0.15	October 2009
QRxPharma	$0.78	$0.25	December 2008
Hexima	$0.50	$0.60	October 2008
Atcor Medical	$0.20	$0.10	October 2008
CathRx	$0.66	$0.70	October 2008
Impedimed	$0.79	$0.70	August 2008
Mesoblast	$1.43	$1.25	August 2008
Circadian Technologies	$0.69	$1.03	February 2008
Patrys	$0.16	$0.50	December 2007
Bionomics	$0.37	$0.42	December 2007
Cogstate	$0.35	$0.13	November 2007
Sirtex Medical	$7.00	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.27	$0.66	September 2007
Starpharma Holdings	$0.58	$0.37	August 2007
Pharmaxis	$2.45	$3.15	August 2007
Universal Biosensors	$1.75	$1.23	June 2007
Probiotec	$2.46	$1.12	February 2007
Chemgenex Pharma.	$0.94	$0.38	June 2006
Acrux	$2.45	$0.83	November 2004
Alchemia	$0.66	$0.67	May 2004

Portfolio Changes – 27 November 2009

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: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd

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