ISSN 1443-850X

Companies covered: AHZ, ALT, IMU, IPD, OSL, PVA, QRX, SOM, TIS

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - Current)	44.6%
Cumulative Gain	**415%**
Av. annual gain (13 yrs)	**18.7%**

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Bioshares

20 December 2013
Edition 534

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

Admedus Gains Manufacturing Headstart

Admedus (AHZ: $0.14) (formerly Allied Healthcare Group) is acquiring a Perth-based manufacturing facility from Genzyme Australasia, a unit of Sanofi, for a nominal sum. The terms are nominal because Sanofi would have had to undertake a costly decommissioning of the plant. The facility was established for the manufacture of MACI (matrix- induced autologous chondrocyte implant) in 2009. The deal is expected to close on Dec. 31, 2013.

The acquisition moves forward Admedus' plans for scaling up the manufacture of its tissue repair product Cardiocel by 6-9 months. Admedus has taken over the lease of the site, on which an estimated $8-$10 million was invested. The acquisition also included plant and equipment estimated to be worth in excess of $1 million.

Admedus is also in a position to select from staff employed at the site by Sanofi. These staff are trained to GMP standards and have experience with TGA and FDA audits.

Admedus believes the site will allow it to service global markets, worth in excess of $200 million of manufactured product. The company will also be able to undertake product development from the new facility, reducing its dependence on Royal Perth Hospital.

US Approval for Cardiocel Anticipated in 2014

The company has submitted an application to the FDA under the 510(k) approval route. Admedus expects to be able to gain a wider label claim for Cardiocel from the FDA, permitting its use for intra-cardiac repair *and* vessel reconstruction. The vessel reconstruction group of procedures (carotid, femoral, CABG and triple A) is estimated at 400,000 a year in the USA. This is a sizeable addressable market.

In contrast, in Australia Cardiocel is indicated for use as an implant to close and repair cardiac septal defects or injured myocardial tissue. In Europe, the CE Mark allows for the repair and reconstruction of heart defects including treating congenital heart disease and repairing heart valves in both children and adults.

Over the longer term, Admedus intends to develop Cardiocel for hernia repair.

Summary

Admedus has had a stellar run this year, with its shares increasing by 567% from a year ago. High expectations have been built into the Admedus share price, with investors recommended to monitor the company's sales performance and regulatory progress throughout 2014. Admedus is capitalised at $176 million and holds cash and equivalents of $11 million.

Bioshares recommendation: **Sell**

Christmas – New Year Publication Schedule

The next of edition of Bioshares (535), dated January 1, 2014 will be emailed to subscribers on January 2, 2014. The subsequent edition of Bioshares (536), dated January 24, will be emailed to subscribers on January 27, 2014. *(Note, Bioshares is published 48 times a year)*

Imugene Secures Key IP From Pevion

Imugene (IMU: $0.015) has re-negotiated its arrangements with Swiss company Pevion over access to patents relevant to its Her-Vaxx vaccine. Her-Vaxx is a multi-epitope vaccine that may be effective in treating Her2 positive breast and gastric cancers.

Pevion Biotech has assigned its 'Multi epitope vaccine for her2/neu-associated cancers' patent to Imugene and been granted an exclusive global license to its 'Lypophilisation of Virosomes' patent, the field of oncology.

The 'Multi epitope vaccine for her2/neu-associated cancer' patent (which has yet to be granted) expires in 2030 and the 'Lypophilisation of Virosomes' patent expires in 2025. The vaccine patent confers a favourable patent life for a potential product which should lifts its appeal to potential pharmaceutical partners or acquirers.

Pevion's multi-epitope vaccine patent covers the use of a fusion peptide incorporating the same three peptides used in the first generation vaccine developed by the vaccine's inventors at the Medical University of Vienna.

The first generation vaccine links or conjugates the peptides whereas the second generation vaccine fuses the peptides together. It has been found that much stronger immunological response can be generated with the second generation fusion peptide. Pevion also found the order in which the peptides were fused increased the potency of the vaccine.

In both the first and second generation versions of the vaccine, the conjugated peptides and the fusion peptides are linked to a virosome, which is a virus-like particle that is readily recognized by the immune system. Lypophilisation is chemical technique which means the vaccine can be converted to a dry powder for later reconstitution in a liquid form for administration. This represents a commercial advantage because the vaccine would not need to be kept in cold storage.

Deal Terms

Earlier in 2013, Biolife, the vaccine technology company acquired by Imugene, entered into a non-binding letter of intent to gain access to the Pevion IP by way of an initial CHF 200,000 payment, milestone payments of CHF 1 million and CHF 5 million and the payment of 2% of net royalties from Her-Vaxx sales.

The access to the IP has been renegotiated on considerably better and more attractive terms to Imugene, both in terms of fees and the timing of payments.

Development Plan for Her-Vaxx

Imugene will devote the bulk of 2014 to setting up manufacturing for the Her-Vaxx vaccine, and manufacturing material for clinical trials. Phase II trials will commence in early 2015. The company may be required by the FDA to complete some minor testing of the second generation version of the the vaccine prior to commencing clinical trials.

Summary

The securing of rights to the Pevion patents is an important step for Imugene, which it has accomplished on much better terms than originally envisaged in 2013. Not only does it enable access to an improved form of the Her-vaxx vaccine but it delivers access to virosome technology which could be used to deliver drugs into cells (intra-cellular), similar to what Phylogica is aiming to achieve with its peptides.

Imugene is capitalised at $14 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

pSivida: Partner Alimera Moves Closer To Getting Green Light From FDA

pSivida (PVA: $4.78) has seen its share price surge by 70% this week with the FDA indicating pSivida's partner Alimera Sciences can move straight through to labeling claim discussions for its eye drug Iluvien and that an assessment by an FDA advisory committee is now not necessary.

The decision came exactly two months after the FDA delivered Alimera a Complete Response Letter for the third time. Alimera had resubmitted its NDA for the second time with full three year data, then for the third time focusing on patients with chronic DME (more than three years), because this patient population had a more profound effect from the treatment.

The FDA's concerns have been around safety, particularly the need for cataract surgery post treatment in a small subset of patients, and increases in intraocular pressure. Earlier this month in the UK, the National Institute for Health and Care Excellence recommended that the product be reimbursed in the UK in those patients who have already had cataract surgery.

Label Claim To Be Determined

What remains to be determined is the label claim, which means for which patients the treatment will be approved. Alimera will also provide recent commercial safety data from use of the device in Germany and the UK. Iluvien is in commercial use in Germany and the UK, with a launch in France expected in early 2014. Iluvien is also approved in three other European countries.

In Iluvien is approved in the US, Psivida will receive a US$25 million milestone payment from Alimera. It will also receive 20% of net profits from sales in the US and Europe.

Sales of Iluvien in Europe were US$758,000 in the September quarter, up from US$179,000 in the June quarter.

pSivida is capitalised at $108 million. The company had US$16.5 million in funds at the end of September.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Top Six Stock Picks – 2014

Somnomed (SOM: $1.145) (Cap. $51 million)

Sleep apnea treatment company Somnomed continues as one of *Bioshares* top picks, after appearing in last year's Top Six Picks. Why consider this stock? One reason is that the visibility into the company's sales performance is very clear because the company provides both volume and value figures. The company sold 35,841 devices in FY2013, an increase of 16% from the previous year.

In November, Somnomed announced the more than 150,000 people had been fitted with a Somnodent device, with an earlier benchmark of 100,000 being reached in July 2012.

The company has reinvested earnings into market development and marketing, with an emphasis on a medically oriented strategy (~ 8% of sales of $18.5 million in FY13). The downside to this is that investors who look for EPS growth ignore the stock. The upside is that the stock can be bought at very attractive prices with only a modest dilution having occurred with the stock since 2009. The company has 44.7 million shares outstanding, compared to 38 million in June 2009. (The company has issued shares to pay for several acquisitions in Europe.)

In time, the quality of Somnomed's earnings will become more apparent and to a wider audience, an event that could easily lift the stock above the $2 mark.

Impedimed (IPD: $0.245) (Cap. $44 million)

Impedimed is an example of a company that came close to extinction in 2012 but after the imposition of strong fiscal discipline and tremendous efforts to re-work product labelling for its L-Dex non-invasive tool for assessing lymphedema, the company turned a corner.

Why the stock rates as selection for 2014 is that the American Medical Association brought forward by a year the timetable for the issuance of a CPT 1 code for the L-Dex system (to begin Jan 1, 2015 rather than Jan 1, 2016). This means that patients covered in the US by Medicare should largely have insurance cover for lymphedema assessment from Jan 1, 2015. Coverage from private payors is dependent in part from progress Impedimed makes with a trial it is initiating with the L-Dex system.

Impedimed has also strengthened its board, with the company now in a position to leverage the substantial medical device experience of it new board members.

QRxPharma (QRX: $0.62) (Cap. $102 million)

QRxPharma is still working with the FDA to have MoxDuo IR approved as a pain drug. It has received two complete response letters (CRLs), meaning that the FDA could now not approve the company's new drug application in its current form.

The reasons for the knock backs are somewhat innocuous. In the first instance, the FDA wanted to see additional data around respiratory responses from one of its clinical trials. The results from that study, Study 022, were a late addition, and given the importance of that data, the FDA wanted to see the full data.

The second 'knock back' came because QRxPharma could not supply the regulator with validated data within the review period. QRxPharma was waiting for a third party to complete an independent review.

QRxPharma has spent the time in between CMLs improving its cash position – the company recently raised $11.6 million – and signing up partners to sell its product upon approval. The company now has partners to sell the product into Australia, New Zealand, USA, Canada, Israel and South Africa.

The big question is whether the FDA will approve the company's opioid pain combination product MoxDuo IR. The FDA will use an expert advisory panel to help assess the application, indicating the application is more complicated than originally thought. In *Bioshares* view, the likelihood of a positive decision outweighs a third CRL for MoxDuo IR.

Tissue Therapies (TIS: $0.22) (Cap. $58 million)

Tissue Therapies is another company that has battled with a medical products regulator. The company had a stoush with European regulators over whether its product should be treat as a device; first the answer was yes, then no, and now yes. Its share price has taken a pounding in the meantime, with the company having run short of funds in the process.

Cont'd over

Top Six Stock Picks – Performance for 2013

Our Top Six Stock Picks made roughly one year ago posted an average gain of 62%. Strong gains for four stocks (BLT, NAN, PVA and SOM) easily compensated falls in TIS and UBI.

PVA shares bounced back only relatively recently following positive news received by its marketing partner for Iluvien, Alimera Sciences. (see page 2 for discussion). Over the 12months, PVAshares rose 282%.

TIS lost 31% over the year. Despite the challenges this company has had with regulators in Europe, we continue to back this stock and have included it in the 2014 Top Six Stock picks. UBI has been a tremendous disappointment, partly due to actions by its partner Lifescan, but possibly because groups of long term shareholders lost patience with stock and have headed for the exit.

Bioshares 2013 Stock Picks Performance

Company	Code	Price 20-12-2013	Price 14-12-2012	Change
Benitec	BLT	$0.60	$0.38	59%
Nanosonics	NAN	$0.85	$0.49	73%
pSivida	PVA	$4.78	$1.25	282%
Somnomed	SOM	$1.15	$0.83	38%
Tissue Therapies	TIS	$0.220	$0.320	-31%
Universal Biosensors	UBI	$0.465	$0.900	-48%
Average Gain Bioshares Top 6 Stock Picks				**62.2%**
ASX All Ordinaries Index		5261.5	4595	14.5%

Bioshares Model Portfolio (20 December 2013)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$0.620	$0.620	December 13
Impedimed	$0.245	$0.245	December 13
Analytica	$0.025	$0.025	December 13
Imugene	$0.015	$0.022	November 13
Oncosil Medical	$0.120	$0.155	September 13
Invion	$0.085	$0.060	August 13
IDT Australia	$0.375	$0.260	August 13
Viralytics	$0.315	$0.300	August 13
Tissue Therapies	$0.220	$0.255	March 2013
Benitec Biopharma	$0.595	$0.40	November 2012
Somnomed	$1.15	$0.94	January 2011
Cogstate	$0.360	$0.13	November 2007
Universal Biosensors	$0.47	$1.23	June 2007

Portfolio Changes – 20 December 2013

IN:

QRX, ALT and IPD have been added to the portfolio (see Bioshares Top 6 Picks for 2014).

OUT:

Circadian Technologies and Calzada have been removed from the portfolio with uncertainty around those companies following recent management and board changes respectively. Both stocks are under review.

– Top Six Stock Picks cont'd

The company is now in a much better position. The European regulator has reversed its position that Tissue Therapies wound healing product, VitroGro, will be reviewed as a device, so no additional clinical trials are required in Europe. The company has also improved its capital position raising $8.3 million recently .

Tissue Therapies expects to start selling its product into Europe in the second quarter of 2014 once final approval is received. The regulatory risk is now low we believe. The company is ready to start selling the product into five countries across Europe once approval is received.

Our target price on approval is over 40 cents a share with a 60%-80% gain typical on approval. Announcements of launches into individual countries and product sales is also likely to drive the share price higher. On a risk return metric, Tissue Therapies offers good value.

Oncosil Medical (OSL: $0.12)(Cap. $42 million)

Oncosil Medical is aiming to replicate Sirtex Medical with its beta-radiation therapy for the treatment of pancreatic cancer. The company expects to start a pivotal study in the second quarter of 2014.

The trial will recruit 150 patients. Two thirds of the patients will receive the radioisotope covered microparticles delivered via a gastroscope, along with receiving chemotherapy. The remaining one third will receive chemotherapy alone. The company has designed the trial such that an interim analysis can be completed before the end of 2014.

Pancreatic cancer has a very poor prognosis. The company's primary endpoint will be seeking to achieve greater than a two month improvement in overall survival, and a reduction in pain. There is considerable pain associated with this cancer. In a Phase I study over six months in 17 patients, average pain reduction of 35% was achieved. Overall survival was 10 months, which is a 4.3 month improvement over the historical average. The disease was controlled in 82% of patients.

The company estimates the potential market for its radiation therapy to be over US$400 million a year for patients suitable for this treatment. An advantage over the Sir-Spheres therapy from Sirtex, which is used to treat liver cancer, is that the administration of the therapy is significantly easier.

The rate of recruitment into this trial will be a key measure to monitor, as will be the first interim results at the end of 2014.

Analytica (ALT: $0.025) (Cap. $17 million)

Analytica's Pericoach system was approved by the TGA in November. The system integrates a device with a smartphone and clinician portal, such that women can better manage and improve their pelvic muscles. An estimated 30% of child-bearing women experience weakness in the pelvic area and this impacts on continence control.

The market opportunity for the device is significant and even a very modest accessing of the total potential pool of customers could see Analytica generate attractive revenues.

The company has a number of key milestones ahead in 2014, which include gaining FDA certification, the completion of a usability trial, the commencement of high volume production, the commencement and completion of a clinical trial, and the launch of the product at an international conference in Brazil in October.

The company successfully raised $2.2 million in November 2013, overcoming a very weak cash position. While Analytica has the cash to move towards its commercial objectives in 2014, it recognises that additional funds could be devoted to marketing the Pericoach product.

Bioshares recommendations:
SOM – **Buy**
IPD – **Speculative Buy Class B**
QRX – **Speculative Buy Class B**
TIS – **Speculative Buy Class A**
OSP – **Speculative Buy Class B**
ALT – **Speculative Buy Class B**

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: Starpharma Holdings, Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Atcor Medical, Invion, Circadian Technologies, Imugene

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