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Bioshares

2 May 2014
Edition 549

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

Companies covered: ACR, NAN, OSL, Fibrotech

	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)	26.6%
Cumulative Gain	**351%**
Av. annual gain (13 yrs)	**17.3%**

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Oncosil Medical Waits on Green Light to Start Pivotal Study

Oncosil Medical (OSL: $0.09) should get the green light in the next two weeks to commence recruitment into its pivotal study with its pancreatic cancer treatment, called Oncosil. The company will recruit 150 patients over the year and also expects to gain CE Mark approval based on the data it has generated from previous clinical studies.

Similar to the Sir-Spheres product successfully being sold by Sirtex Medical, Oncosil uses a radioisotope to irradiate tumours, but in this case using radioactive phosphorus rather than yttrium-90.

In March the company submitted its application to an Ethics Committee to conduct a clinical trial in Australia. Once approved, that will allow the company to start recruiting into four sites across Australia, with an additional two sites to be added following additional ethics reviews.

Once Ethics Committee approval is received, which is could occur this month, the company will commence recruitment of patients. Treatment of the first patient could take place in August.

The trial will be conducted across 20 sites in Australia, the US, Belgium, the UK and Singapore. Once recruitment starts, the company expects it will take 12 months to achieve full enrolment.

Interim Readout

One of the appealing aspects of the trial design is that the company will be able to gain an interim readout from the first 30 patients after six months. By our estimates this means there could be data released around August next year. Because the trial is unblinded, as it would be unethical to inject patients with a placebo, the company is able to get an interim readout.

This result will be very helpful to the company. It will not look at overall survival, which is the primary endpoint for the trial, but it will look at progression-free survival (PFS) at six months. The control arm will be patients receiving the standard of care, which is chemotherapy treatment, with two thirds of patients receiving Oncosil plus chemotherapy treatment.

Another benefit of the interim readout is that the company can add more patients to the study if the study is showing to be not powered sufficiently to achieve statistical significance.

– Cont'd over

Fibrotech Inks Stunning US$75+ Million Buyout

While the listed biotech sector has been struggling in recent weeks, private Victorian biotech company Fibrotech is to be acquired by Shire for US$75 million plus future milestone payments, which may make the deal significantly larger. Shire gains access to the company's Phase Ia small molecule drug candidate, FT011.

It is a very impressive deal because Fibrotech has only completed Phase Ia studies in healthy volunteers, so no clinical efficacy data has been obtained to date. Fibrotech's lead compound, FT011, is an antifibrotic agent.

Investors in Fibrotech include Uniseed, Brandon Capital Partners and Medical Research Commercialisation Fund. The technology has been developed by researchers at the University of Melbourne, St Vincent's Institute of Medical Research and Bio21 Institute.

It caps off a big 12 months for Uniseed, which is an investor also in Spinifex Pharmaceuticals, which just raised $45 million, and also Hatchtech, which raised $12 million last year and is due to complete a Phase III trial in August for its novel head lice treatment. On the downside, Uniseed is also an investor in QRxPharma, which has seen its share price fall heavily recently following a negative 14-0 FDA Advisory Committee vote.

According to Uniseed CEO Peter Devine, there were a number of aspects to this compound that were appealing to Shire and other groups who were also interested in the technology.

The first was that the compound is a small molecule, a feature which is well known as a drawcard for large pharmaceutical companies. The second was that the mechanism of action has been very well characterised.

Another point of appeal was that the compound showed good and consistent efficacy in animal models for a number of disease applications. The company had also completed a very good toxicology package with the compound showing no safety concerns. And the target that the compound hits, which is undisclosed, is novel.

Devine said this disease space, in preventing fibrosis, is a hot area for drug development. The first indication that Shire will be progressing is GSGS (Focal Segmental Glomerulosclerosis), which is a rare renal disorder that causes kidney scarring in children. This may be an orphan indication which means that Shire might be able to bring the drug to market more quickly than addressing a larger disease area that would require bigger trials. Other potential indications are for treating fibrosis in patients with diabetic neuropathy.

The deal with Shire is an outright sale with future milestones due on achieving undisclosed clinical and regulatory milestones. Fibrotech's CEO, Darren Kelly, who Devine said should be credited with doing a great job with this program, will stay on with Shire for a period of time. Fibrotech has commenced a Phase Ib study and Shire anticipates starting a Phase II study next year.

The lessons for investors said Devine is that it takes a long time to commercialise biotech assets and some of those do fall over, that being the nature of biotech.

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– Oncosil Medical cont'd

Trial Expectations

A better than 15% improvement in PFS over the control arm at the interim readout will be indicative of a positive trend in the trial.

The company has indicated that a meaningful end result in this trial will be a greater than 30% improvement in overall survival. Looking at a previous trial the company completed in 17 patients with the Oncosil treatment, a median survival of 10.3 months was achieved. This is almost a five month improvement what can be expected with chemotherapy alone (a median 5.7 month overall survival).

A follow-up trial was started in six patients but was stopped because of funding issues. In those patients, all were still alive after a year, indication more than 12 months overall survival. That trial was conducted by Psivida. Oncosil has licensed the technology from Psivida and is required to pay an 8% royalty.

Final Trial Readout

If this pivotal trial commences in August and takes 12 months to fully recruit up to an 18 month evaluation period, then final results can be expected in the first half of 2017.

CE Mark approval

While the pivotal study is underway, which will allow registration in the US upon completion, Oncosil also plans to file a CE Mark submission, which will allow the company to market the product in Europe, and then also in Canada, Australia and Singapore under a mutual recognition agreement. The company expects to gain a CE Mark approval in the next 12 months. However it will be the data from the 150 patient registration study that may give the company solid evidence for clinical use of this therapy.

Summary

Oncosil Medical is capitalised at $31 million. The company had $10.3 million in cash at the end of March. Oncosil is building an experienced management team, with the recent appointment of a Chief Vice President of Clinical Research. The company has been able to extract a dormant asset, build an experienced management team and attract funding to place the company in a position to commercialise what can become a valuable commercial asset, as seen with Sirtex Medical.

Bioshares recommendation: **Speculative Buy Class B**

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Acrux Maintains Dividend Policy

Acrux's (ACR: $0.985) share price fell dramatically recently following the company's revision to its expectation of receiving a US$50 million milestone payment from Eli Lilly in FY2014/15.

This particular milestone payment is contingent on global (USA plus Ex-USA) sales reaching an undisclosed figure. Under original deal terms with Eli Lilly, Acrux has received a US$50 million upfront payment, a US$3 million payment on the transfer of manufacturing assets, a US$87 million payment on receipt of FDA approval, and most recently, US$25 million on surpassing a particular sales threshold.

Outstanding milestone payments include the above mentioned US$50 million payment and further payments of US$120 million.

Acrux has paid out approximately $146 million in dividends in the last four years (or 88 cents per share). Acrux is a Pooled Development Fund, which means that dividends paid to Australian shareholders are exempt from income tax and do not not need to be included in taxable income.

Sales of Axiron totaled US$178.7 million for CY2013. However, reported net sales fell by 26% in the March quarter from the previous quarter.

Several factors have been at play in causing substantial decrease in sales. A smaller contribution came from overstocking of Axiron product (by pharmacies) in the December quarter, ahead of a price rise scheduled for the March quarter.

However, the biggest contributor to the decline has been the effect of several retrospective studies published in two journals that claimed testosterone replacement therapy increased the chances of patients experiencing various cardiovascular events, e.g. heart attack.

In response, the FDA said in a Drug Safety Communication in late January that it would be assessing the risk of stroke and heart attack for males receiving testosterone therapy. However, the FDA also advised patients to not discontinue medication without consultation with their doctors.

When the FDA might release results of its investigation is unknown. What is known is that in March, the FDA approved Aveed, an injectable depot formulation of testosterone, which contains 750 mg of testosterone, and is designed for injection first for four weeks and thereafter at ten week intervals.

The FDA placed a boxed warning (Black Label) on Aveed (Endo Pharmaceuticals) concerning the risk of pulmonary-oil embolism and allergic reaction, and stipulated that it can only be administered to men for whom benefits outweigh the risks.

The daily starting dose of Axiron is 60mg, which can be titrated down to 30 mg or up to 120 mg. Dose adjustment is required to restore testosterone concentration in the blood to a normal range of 300 ng/dL-1050 ng/dL. This means that a comparison of Axiron to Aveed (or even many other formulations) on a drug loading basis isn't appropriate.

A feature that does matter is how quantifiable the relationship is between the drug product and the therapeutic amount of drug that becomes available in the blood. Where Axiron differs from its topical competitors is that the product is dispensed and applied with relatively greater accuracy and certainty. A weakness with topical gel products is that the men who use them tend to overapply the gel product.

The Aveed approval offers an insight into the FDA's thinking, in a positive sense, about testosterone therapy, even where the product confers serious potential side effects because of the nature of its delivery. The FDA consistently evaluates drugs and drug classes according to a trade-off between benefit and risk.

Market Share

Axiron has carved out a market share of about 14% of the transdermal gel market. The task of capturing greater market share is dependent on getting patients to switch to a newer drug such as Axiron, which takes much longer because of additional steps involved in switching drugs (such as pathology services for blood testing).

Acrux expects that efforts being made by its marketing partner Eli Lilly to educate and train the back-office staff of medical practises could see a pay-off in increased sales in the second half of this year.

Dividend Policy

According to Acrux's CEO, Ross Dobinson, the company's dividend policy remains unchanged and that the company will be targeting another dividend in August, providing that 'things stay roughly comparable to where they are today.' The company's annual net cash burn is in the order of $5 million, which can funded from the royalties from one quarter's sale of Axiron (at current sales). Dividends, therefore, can in effect be funded from royalties from the other three quarters each of Axiron net sales. However, the intent will be to retain, on an ongoing basis, a cash balance of $10 million.

In our view, a repeat of the most recent 12 cent special dividend, representing a total payout of $20 million is unlikely, with a shift to a lower dividend rate that allows the company to sustain a cash balance of $10 million.

Summary

While the testosterone therapy is in a state of some flux in the US at present, the reality is that is an established therapy, which has been found to be beneficial when administered as prescribed. Axiron has a strong chance of emerging as the leading transdermal testosterone therapy in the longer term.

Acrux is capitalised at $164 million.

Bioshares recommendation: **Buy**

4.7B Reporting Companies – Cash Balances March 31, 2014

Sorted by Survival Index

	Code	Company	Cash Receipts ($M)	Nett Op. Cash Fl. ($M)	Cash End 31/03/14 ($M)		Survival Index	Comments/Events post reporting date
1	ACL	Alchemia	$8.20	$1.28	$14.01	A	**Not App**	
2	BXN	Bioxyne	$1.74	$0.55	$0.91	A	**Not App**	
3	LBT	LBT Innovations	$0.00	$0.16	$0.99	A	**Not App**	
4	LCT	Living Cell Technologies	$9.24	$1.12	$5.77	A	**Not App**	
5	NAN	Nanosonics	$19.91	-$0.07	$23.76	A	**Not App**	
6	HCT	Holista Colltech	$4.85	-$0.12	$1.91	A	11.9	
7	DVL	Dorsavi	$0.55	-$1.56	$15.66	A	7.5	
8	ADO	Anteo Diagnostics	$2.50	-$0.86	$7.99	A	6.9	
9	SIE	Scigen	$5.64	$1.08	$5.32	**CY**	6.0	
10	VLA	Viralytics	$0.00	-$3.60	$26.53	A	5.5	
11	IIL	Innate Immunotherapeutics	$0.00	-$0.75	$7.94	H	5.3	
12	SPL	Starpharma	$5.04	-$5.94	$27.81	A	3.5	
13	CYP	Cynata	$0.00	-$1.23	$5.72	A	3.5	
14	ACW	Actinogen	$0.02	-$0.27	$1.21	A	3.4	
15	AVX	Avexa	$0.00	-$1.38	$5.85	A	3.2	
16	MSB	Mesoblast	$0.00	-$60.16	$241.45	A	3.0	
17	OBJ	OBJ	$0.05	-$1.22	$4.85	A	3.0	
18	OSL	Oncosil Medical	$0.00	-$2.74	$10.34	A	2.8	
19	PYC	Phylogica	$0.69	-$1.55	$5.80	A	2.8	
20	NEU	Neuren Pharmaceuticals	$0.97	-$1.48	$21.94	**CY**	2.8	
21	PAA	Pharmaust	$1.69	-$0.84	$2.92	A	2.6	
22	BNE	Bone Medical	$0.00	-$0.85	$2.95	A	2.6	
23	OSP	Osprey Medical	$0.00	-$2.54	$19.77	**CY**	2.6	
24	PBT	Prana Biotechnology	$0.00	-$7.95	$25.35	A	2.4	Apr 6, raised $16.4 M (pro forma cash = $41.8M)
25	RHT	Resonance Health	$1.56	-$0.27	$0.83	A	2.3	
26	UNS	Unilife	$24.44	-$14.04	$43.04	A	2.3	
27	BRC	Brain Resource Corp	$0.77	-$1.03	$3.12	A	2.3	
28	SUD	SUDA	$8.13	-$1.73	$5.12	A	2.2	
29	PAB	Patrys	$0.58	-$3.69	$10.37	A	2.1	
30	PRR	Prima Biomed	$0.02	-$10.04	$26.74	A	2.0	
31	SOM	Somnomed	$18.30	-$1.21	$3.00	A	1.9	
32	BLT	Benitec	$0.20	-$7.57	$18.40	A	1.8	Part II of $31 M (i.e. $15.75 M) placement received
33	PXS	Pharmaxis	$3.99	-$19.14	$43.71	A	1.7	
34	CDY	Cellmid	$1.21	-$1.50	$3.38	A	1.7	
35	BNO	Bionomics	$2.20	-$7.17	$15.72	A	1.6	
36	CUV	Clinuvel Pharmaceuticals	$0.97	-$4.09	$8.48	A	1.6	
37	GID	GI Dynamics	$0.98	-$10.51	$53.52	**CY**	1.5	Completed A$34.3 capital raising
38	IVX	Invion	$0.22	-$2.64	$5.17	A	1.5	Raised $0.89 from Rights issue
39	RNO	Rhinomed	$0.02	-$1.35	$2.58	A	1.4	
40	QRX	QRxPharma	$0.00	-$8.37	$14.26	A	1.3	FDA Committee voted 14-0 against Moxduo IR
41	TIS	Tissue Therapies	$0.00	-$5.41	$8.78	A	1.2	
42	UBI	Universal Biosensors	$2.20	-$3.37	$19.46	**CY**	1.2	
43	IMU	Imugene	$0.00	-$1.05	$1.67	A	1.2	
44	MLA	Medical Australia	$8.23	-$1.16	$1.77	A	1.1	
45	ANP	Antisense Therap.	$0.00	-$1.85	$2.67	A	1.1	
46	AHZ	Admedus	$5.85	-$5.87	$7.07	A	**0.9**	
47	ISN	Isonea	$0.02	-$7.62	$7.31	A	**0.7**	
48	AVH	Avita Medical	$2.22	-$5.59	$4.98	A	**0.7**	
49	RGS	Regeneus	$1.30	-$5.21	$4.46	A	**0.6**	Expects to receive R&D tax refund of $3M
50	SVA	Simavita	$0.00	-$7.00	$5.84	A	**0.6**	
51	RVA	Reva Medical	$0.00	-$7.19	$14.09	**CY**	**0.6**	
52	IPD	Impedimed	$2.42	-$4.15	$3.10	A	**0.6**	Completed $8.8M placement; SPP to follow
53	GTG	Genetic Technologies	$3.70	-$7.70	$4.99	A	**0.5**	
54	GBI	Genera Biosystems	$0.11	-$0.47	$0.24	A	**0.4**	
55	ALT	Analytica	$0.00	-$1.81	$0.60	A	**0.2**	Completed $1.8M placement; RI to raise up to $1.2M
56	UCM	USCOM	$0.57	-$1.17	$0.37	A	**0.2**	Received $0.37M R&D tax refund
57	BCT	Bluechiip	$0.00	-$1.72	$0.49	A	**0.2**	Access to short term funding facility -up to $0.7M
58	BIT	Biotron	$0.00	-$3.73	$1.02	A	**0.2**	Received $1.7M R&D tax refund
59	MGZ	Medigard	$0.00	-$0.17	$0.02	A	**0.1**	
60	AGX	Agenix	$0.03	-$0.69	$0.08	A	**0.1**	

Legend:

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

A: The SI calculation for these companies is based on the average of the last five quarters of NOCF, annualised.

CY: The SI calculation for these companies is calculated on the average of the last three quarters of NOCF, annualised.

4.7B Reporting Companies – Cash Balances March 31, 2014 (Cont'd)

Commentary

The current analysis of cash balances of 4.7B reporting companies shows that one quarter of the 60 companies reporting under the rule have less than one year's cash at hand to support activities. Some of these companies, such as Regeneus, Uscom and Biotron, expect to, or have received tax refunds from the Commonwealth Government. This scheme has been of significant benefit to many ASX listed biotechs.

Impedimed has since March 31 completed an $8.8 million placement. Although GI Dynamics had a satisfactory SI of 1.5, it chose to reinforce its funding base through a $33.4 million capital raising.

Stocks with funding challenges in front of them appear to be Simavita, Reva Medical, Genetic Technologies and Genera Biosystems.

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Ellex Medical Lasers, IDT, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics and Atcor Medical.
pSivida, a re-domiciled company, does not comply with the 4B Rule.

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing net operational cash flows (NOCF) for the last nine months ending March 31, 2014, annualised, into each company's cash assets as recorded at March 31, 2014. For companies that report on December 31 full year basis, the index is based the last 5 quarters NOCF, annualised, into each company's cash assets as recorded at March 31, 2014. The NOCF is net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less then 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

Bioshares Model Portfolio (2 May 2014)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.056	$0.089	February 14
Impedimed	$0.190	$0.245	December 13
Analytica	$0.029	$0.025	December 13
Imugene	$0.010	$0.022	November 13
Oncosil Medical	$0.090	$0.155	September 13
IDT Australia	$0.275	$0.260	August 13
Viralytics	$0.290	$0.300	August 13
Tissue Therapies	$0.300	$0.255	March 2013
Somnomed	$1.48	$0.94	January 2011
Cogstate	$0.280	$0.13	November 2007
Universal Biosensors	$0.37	$1.23	June 2007

Portfolio Changes – 2 May 2014

IN:

No changes

Recommendations:

OUT:

No changes

Recommendations:

Nanosonics – Strong Uptake Continues in US

In the last six months, Nanosonics' (NAN: $0.77) Trophon disinfection system has been adopted by around 430 new healthcare sites in the US, bringing the total facilities in the US using the system to 1,415.

Sales in the third quarter increased by 14% over the previous corresponding period to $5.2 million, with sales for the last nine months reaching $14.9 million. The company achieved a positive cash flow for the quarter, of $2.2 million, with the assistance of $1.5 million in the R&D tax rebate.

In a conference call, CEO Michael Kavanagh stated that the momentum was continuing in the US and in Europe, the company was starting to gain traction, particularly in the UK, where at least 11 sites have bought multiple units.

The difference between the US and the UK is that UK organisations are slower to sign on to purchases, but when they did, they would buy multiple units. Europe is still in a market introduction phase, said Kavanagh. Over the next six months, healthcare reviews in Scotland and Wales for hospital disinfection processes are expected to be complete which (presumably) may see faster adoption of the Trophon system in those regions.

Of interest was that Kavanagh said that in the US no sites have stopped using the Trophon system. Growth in the US is coming from new sites purchasing the system, as well as some existing groups moving to multiple systems. The average daily use of the Trophon by customers is around four times day, which is consistent with expectations. Currently consumables make up between 20%-25% of total sales, with capital items making up the balance.

Over the longer term, when there is a large installed base (mover than 10,000 units), we expect consumable revenue should dominate overall sales.

In Germany, the company recently signed on Miele Professional as a distributor, which is the market leader in the area of device sterilization.

Costs for the company were stable in the quarter compared to the previous corresponding quarter with some slightly lower travel costs. The company is also using less external consultants and bringing those roles in-house. The company finished the quarter with $23.7 million in cash.

Nanosonics is capitalised at $203 million.

Bioshares recommendation: **Hold**

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

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