

More than
150 attendees have
now registered for

The 10th Bioshares Biotech Summit

[www.bioshares.com.au/
queenstown2014.htm](http://www.bioshares.com.au/queenstown2014.htm)

**Companies covered: IMU, Orthocell, US
Life Science Company IPOs**

	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 - May '14)	26.6%
Year 14 (May '14 -)	2.8%
Cumulative Gain	363%
Av. Annual gain (14 yrs)	16.3%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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 - Editor
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz - Research Principal
Ph: 0403 850 425
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
\$400 (Inc.GST)

Edition Number 556 (20 June 2014)

Copyright 2014 Blake Industry and Market Analysis Pty Ltd. ALL RIGHTS RESERVED.
Secondary electronic transmission, photocopying, reproduction or quotation is strictly prohibited without written consent of the publisher.

Bioshares

20 June 2014
Edition 556

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

US Life Science IPOs Roll On

The US life science company IPO window has remained well and truly open during the first half of 2014, with 50 companies having listed on the main US exchanges, including the NYSE and the Nasdaq. Seven non-US companies listed, including Australia's Parnell Pharmaceuticals, a Sydney-based animal health firm.

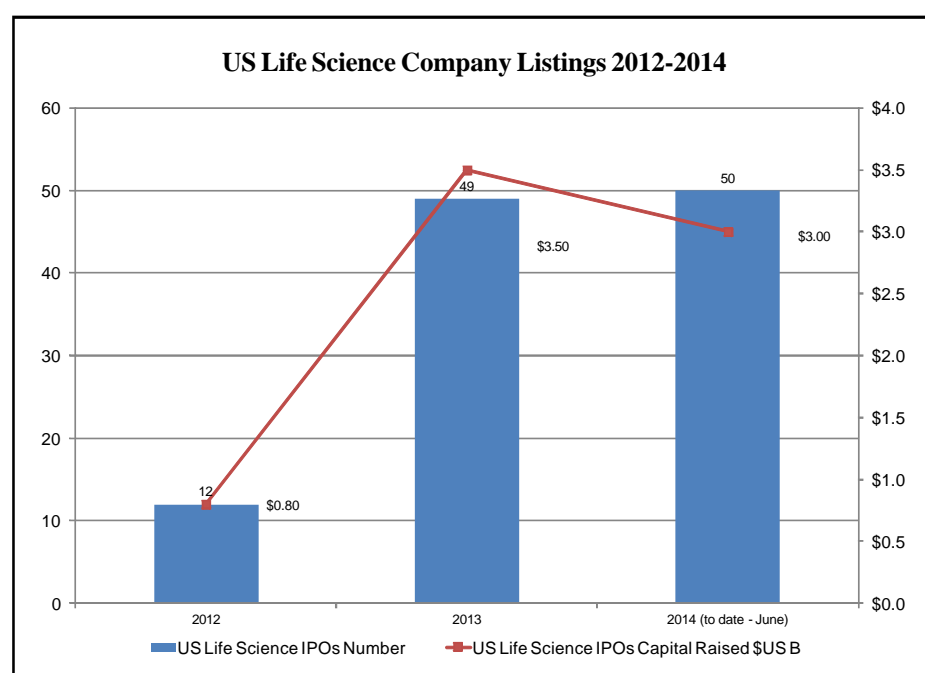
The 50 listings for 2014 have raised \$US3 billion in funding, compared to the 49 companies which raised \$US3.5 billion in 2013. (Please refer to the tables on pages 2-3.)

The average gain of the 50 stocks to date is 23%, with the greatest gainer, Applied Genetics up 154% and the greatest loser, Nephrogenix down 52%.

Therapeutic companies accounted for 33 of the 50 listings so far, raising US\$2 billion. And of this group, companies at the Phase II stage of development raised US\$1 billion, with the median raising being \$US58 million. The median raising for companies at the Phase III stage of development was US\$54 million. Overall, therapeutic product development companies have increased by an average 23% from their offer prices. The best performing group, however, has been the Specialty Pharma group, which posted an average gain of 27%.

With more IPOs in the wings, it is clear that sentiment towards life science companies remains strong in the USA.

Bioshares



US Life Science IPOs 2014 (to date)

	Listing (Pricing) date	Code	Country of Origin	Company Name	Field	Status	Cap. US\$M (at Offer)	Listing Price US\$	Funds Raised US\$M	Current Share Price \$US	Gain Since Listing
Therapeutics											
1	10/01/2014	RTRX	USA	Retrophin	Serious or rare diseases	Market	\$196	\$8.50	\$40	\$11.29	33%
2	20/03/2014	MDWD	Israel	Medi wound	Burns and wounds	Market (EU)	\$285	\$14.00	\$70	\$10.99	-22%
3	5/02/2014	QURE	The Netherlands	Uniqure	Gene therapy	Market (EU)	\$299	\$17.00	\$92	\$12.70	-25%
4	31/03/2014	CARA	USA	Cara Therapeutics	Pain (specific targeting of the mu-opioid receptor)	Phase III (pending)	\$240	\$11.00	\$55	\$17.51	59%
5	13/03/2014	DPRX	USA	Dipexium Pharmaceuticals	Anti-infective (mild infections of diabetic foot ulcers)	Phase III (pending)	\$98	\$12.00	\$33	\$9.57	-20%
6	12/03/2014	AKAO	USA	Achaogen	Anti-infectives	Phase III (pending)	\$201	\$12.00	\$72	\$15.60	30%
7	6/02/2014	EBIO	USA	Eleven Biotherapeutics	Protein engineering platform	Phase III (pending)	\$154	\$10.00	\$50	\$12.04	20%
8	19/06/2014	ARDX	USA	Adelyx	Cardio-renal, GI and metabolic	Phase III	\$250	\$14.00	\$60	\$14.31	2%
9	18/06/2014	ZSPH	USA	ZS Pharma	Renal, cardiovascular, liver and metabolic	Phase III	\$355	\$18.00	\$107	\$28.50	58%
10	6/06/2014	RDUS	USA	Radius Pharma	Osteoporosis	Phase III	\$232	\$8.00	\$52	\$9.73	22%
11	17/04/2014	VTL	USA	Vital Therapies	Cell therapies (acute liver failure)	Phase III	\$253	\$12.00	\$54	\$26.33	119%
12	7/02/2014	ARGS	USA	Argos Therapeutics	Immuno-therapies (Dendritic cells)	Phase III	\$152	\$8.00	\$45	\$7.47	-7%
13	5/02/2014	ASPX	USA	Auspex Pharmaceuticals	Orphan drug diseases	Phase III	\$270	\$12.00	\$84	\$22.73	89%
14	30/01/2014	CLDN	USA	Celladon Corp	Calcium dysregulation	Phase III	\$141	\$8.00	\$44	\$14.03	75%
15	13/03/2014	GLMD	Israel	Galmed Pharmaceuticals	Liver diseases (NASH)	Phase II (pending)	\$144	\$13.50	\$38	\$8.80	-35%
16	8/05/2014	ALDR	USA	Adler Biopharmaceutical	Antibody platform	Phase II	\$299	\$10.00	\$80	\$17.90	79%
17	2/05/2014	ALDX	USA	Aldeyra Therapeutics	Immune-mediated conditions	Phase II	\$41	\$8.00	\$12	\$6.95	-13%
18	2/05/2014	SCYX	USA	Scynexis	Anti-infectives (anti-fungal)	Phase II	\$85	\$10.00	\$62	\$7.81	-22%
19	10/04/2014	CERU	USA	Cerulean Pharma	Oncology (polymer delivery constructs)	Phase II	\$133	\$7.00	\$60	\$5.81	-17%
20	31/03/2014	RARE	USA	Ultragenyx Pharmaceuticals	Ultra-rare diseases	Phase II	\$610	\$21.00	\$121	\$47.49	126%
21	31/03/2014	TRVN	USA	Trevena	GPCR targeted therapies	Phase II	\$180	\$7.00	\$65	\$4.34	-38%
22	27/03/2014	AGTC	USA	Applied Genetic Technologies	Gene therapy	Phase II	\$161	\$12.00	\$50	\$30.46	154%
23	21/03/2014	VSAR	USA	Versatis	Endocrine conditions (long-acting rHGH)	Phase II	\$489	\$21.00	\$126	\$29.75	42%
24	20/03/2014	AKBA	USA	Akebia Therapeutics	Kidney disease	Phase II	\$328	\$17.00	\$100	\$29.17	72%
25	7/03/2014	REPH	USA	Recro Pharma	Pain (non-opioid, alpha-2 adrenergic agonists)	Phase II	\$57	\$8.00	\$30	\$7.82	-2%
26	7/03/2014	AQXP	Canada	Aquinox Pharmaceuticals	Anti-inflammatory (PI3K pathway)	Phase II	\$110	\$11.00	\$46	\$9.11	-17%
27	11/02/2014	NRX	USA	Nephrogenix	Kidney disease	Phase II	\$106	\$12.00	\$37	\$5.71	-52%
28	5/02/2014	GNCA	USA	Genocea Biosciences	Immuno-therapies (therapeutic vaccines)	Phase II	\$207	\$12.00	\$66	\$22.70	89%
29	10/01/2014	GLYC	USA	Glycomimetics	Various diseases	Phase II	\$130	\$8.00	\$56	\$7.83	-2%
30	13/02/2013	CNCE	USA	Concert Pharmaceuticals	Small molecule chemistry - various diseases and conditions	Phase II	\$241	\$14.00	\$84	\$10.46	-25%
31	21/03/2014	RTGN	USA	Ruthigen	Anti-infectives	Phase I (pending)	\$34	\$7.25	\$19	\$5.75	-21%
32	14/03/2014	RXDX	USA	Ignyta	Oncology (kinase inhibitors) (RX/DX strategy)	Phase I	\$168	\$9.15	\$47	\$8.12	-11%
33	30/01/2014	DRNA	USA	Dicerna	RNAi therapies	Pre-clinical	\$249	\$15.00	\$90	\$18.51	23%

Ave. Gain 23%

Funds Raised (33 Co.)	Total	Median	Mean
	\$2,047	\$56	\$62
-Market (3 Co.)	\$202	\$70	\$67
-Phase III (11 Co.)	\$656	\$54	\$60
-Phase II (16 Co.)	\$1,033	\$58	\$65
-Phase I (2 Co.)	\$66	\$33	\$33
-Pre-clinical (1Co.)	\$90	\$90	\$90

US Life Science IPOs 2014 (to date)

	Listing (Pricing) date	Code	Country of Origin	Company Name	Field	Status	Cap. US\$M (at Offer)	Listing Price US\$	Funds Raised US\$M	Current Share Price \$US	Gain Since Listing
Devices											
1	25/04/2014	EVAR	UK	Lombard Medical	Devices (Endo-vascular stent-grafts)	Market	\$178	\$11.00	\$55	\$7.29	-34%
2	16/04/2014	TRIV	USA	Trivascular Technologies	Devices (min. inv. Treat. of abd.aortic aneurysms)	Market	\$232	\$12.00	\$78	\$16.56	38%
3	27/02/2014	LMNS	Israel	Lumenis	Devices (ophthalmic lasers)	Market	\$114	\$12.00	\$75	\$9.46	-21%
4	14/02/2014	INGN	USA	Inogen	Devices (portable oxygen concentrators)	Market	\$289	\$16.00	\$71	\$18.56	16%
5	13/02/2013	AMDA	USA	Amedica	Medical devices (orthopedic implants)	Market	\$70	\$5.75	\$20	\$4.67	-19%

Funds Raised (5 Co.) \$299 Ave. Gain -4%

Diagnostics

1	5/02/2014	BIOC	USA	Biocept	Diagnostics (cancer)	Market	\$45	\$10.00	\$19	\$7.50	-25%
2	23/01/2014	AKER	USA	Akers Bioscience	Diagnostics (rapid POC)	Market	\$27	\$5.50	\$15	\$3.83	-30%
3	18/06/2014	SGNL	USA	Signal Genetics	Diagnostics (Molecular diagnostics)	Market	\$38	\$10.00	\$8.5	\$8.36	-16%

Funds Raised (3 Co.) \$43 Ave. Gain -24%

Specialty Pharma

1	23/05/2014	AGRX	USA	Agile Therapeutics	Speciality pharma (Women's health) (contraception)	Phase III	\$112	\$6.00	\$55	\$7.65	28%
2	10/04/2014	ADMS	USA	Adamas Pharmaceuticals	Specialty pharma (chronic disorders of the CNS)	Phase III	\$263	\$16.00	\$48	\$19.21	20%
3	12/02/2014	EGRX	USA	Eagle Pharmaceutical's	Specialty pharma	Market	\$209	\$15.00	\$50	\$12.78	-15%
4	12/02/2014	FLXN	USA	Flexion Therapeutics	Specialty pharma (anti-inflammatory and analgesic therapies)	Phase II	\$192	\$13.00	\$65	\$13.88	7%
5	6/02/2013	EGLT	USA	Egalet	Specialty pharma (pain) (abuse deterence technology)	Phase II	\$176	\$12.00	\$50	\$14.36	20%
6	6/02/2013	RVNC	USA	Revance Therapeutics	Specialty pharma (botulinum toxin) (cosmetics)	Phase III	\$284	\$16.00	\$96	\$32.48	103%

Funds Raised (5 Co.) \$364 Ave. Gain 27%

Tookit

1	11/04/2014	PRGB	USA	Protea Biosciences	Bioanalytics	Market	\$66	\$1.01	\$44	\$0.98	-3%
---	------------	------	-----	--------------------	--------------	--------	------	--------	------	--------	-----

Funds Raised (1 Co.) \$44 Ave. Gain -3%

Animal Health

1	18/06/2014	PARN	Australia	Parnell Pharmaceuticals	Animal health	Market	\$133	\$10.00	\$50	\$7.80	-22%
2	11/04/2014	PAHC	USA	Phibro Animal Health	Animal health	Market	\$262	\$15.00	\$191	\$20.49	37%

Funds Raised (2 Co.) \$329 Ave. Gain 7%

Total Funds Raised \$9,587 \$3,037

Average Price Gain 17%

Mean \$192 \$61

Median \$179 \$55

Imugene Her-Vaxx Program Update

Imugene (IMU: 0.014) is seeking to achieve something unique; it wants to emulate the function of an existing anti-cancer antibody, Herceptin, with a similar antibody which is produced by the body itself following treatment with a therapeutic vaccine.

What are called Her-2 receptors, are found over-expressed on the outside of breast and gastric tumours. These receptors are part of a family of growth factors that stimulate cancer cells to replicate and spread throughout the body. This growth factor has both an extra-cellular (outside of cell) and intracellular (inside of cell) component. The drug Herceptin, which generates around \$6 billion a year in sales, targets these receptors.

Imugene's cancer vaccine, called Her-Vaxx, includes three peptides that are present on the Her-2 receptor, to stimulate an innate antibody attack against these receptors (and thereby the cancer cells). The researchers behind the vaccine isolated seven peptide candidates for the vaccine that recognised the Her-2 growth factor, of which three were selected that were the most active. The vaccine has also been shown to stimulate a cellular immune response generating cytokine production against the tumour.

This week, one of the technology's pioneers, Professor Ursula Wiedermann from the Medical University Vienna, provided an update to investors on the Her-Vaxx program. Professor Wiedermann has been working on this technology for 12 years. Last year, Imugene acquired the rights to the program and it has become the focus for the company.

If this technology works, it has a number of potential advantages over Herceptin. The main advantage will be the significantly lower cost of the vaccine compared to Herceptin, which costs around US\$70,000 for a year's treatment.

Other advantages include less potential side effects according to Professor Wiedermann. Herceptin is known to cause some cardiac related issues with the Her-2 receptor, which is also present on some cardiac tissue cells. In a Phase I trial with Her-Vaxx, no cardiac related issues were observed.

Phase I Trial Results

A Phase I trial with Her-Vaxx had been previously conducted in 10 patients with end stage breast cancer. Patients received the vaccine treatment on three occasions. The results from the trial showed that five patients achieved stable disease after six months and there were no systemic toxicity issues.

One patient went into remission. There was a significant reduction in regulatory T-cells, indicating the vaccine was initiating an effect. And a T-cell (cellular immunity) and B-cell (antibody) response in the patients was observed. The antibody response against the peptides occurred in eight of the 10 patients. The vaccine induced a lot of antibody production in the patients according to Professor Wiedermann. There were no significant side effects in the patients with negligible toxicity.

Forthcoming Phase II Clinical Trial

Next year Imugene plans to start a Phase II study with Her-Vaxx. First the company will conduct a lead-in study in 15 patients to

optimize the dose for the vaccine treatment, which is expected to start by April next year. That will be followed by a 68 patient Phase II study in patients with relapsed metastatic gastric cancer who over-express the HER-2/neu receptor.

Those patients will be equally divided to receive only the standard-of-care chemotherapy and those receiving chemotherapy plus Her-Vaxx. The Phase II study is expected to start in the September quarter next year. The primary endpoint of the study will be overall survival (expected to be around one year). The secondary endpoints will be immune-related progression-free survival and also the level of immune response.

The reason the trial will focus on gastric cancer and not breast cancer is that Herceptin is the standard of care in patients with breast cancer who are HER-2 positive where it is not for gastric cancer in certain Eastern European countries. Around 20% of patients with gastric cancer over-express the Her-2 growth factor receptor.

Future Applications

Down the track, it is possible that HER-Vaxx could be combined with monoclonal antibody cancer drugs such as Herceptin. It may even have an application as a prophylactic treatment for early disease in those patients with genetic susceptibility to disease progression as well as expanding use to other tumours that over-express the Her-2 receptor, including breast cancer and bladder cancer.

Summary

Imugene is capitalised at \$12 million. The company had \$1.6 million cash at the end of March. Funding will be an item the company will need to address in coming months. The company has recently appointed a manufacturer of its vaccine candidate for its clinical studies and manufacturing is now underway.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (20 June 2014)				Portfolio Changes – 20 June 2014
Company	Price (current)	Price added to portfolio	Date added	
pSivida	\$4.340	\$4.000	May 14	IN: No changes
Invion	\$0.081	\$0.089	February 14	
Impedimed	\$0.190	\$0.245	December 13	OUT:
Analytica	\$0.046	\$0.025	December 13	No changes
Imugene	\$0.014	\$0.022	November 13	Recommendations:
Oncosil Medical	\$0.105	\$0.155	September 13	
IDT Australia	\$0.200	\$0.260	August 13	
Viralytics	\$0.275	\$0.300	August 13	
Tissue Therapies	\$0.300	\$0.255	March 2013	
Somnomed	\$1.45	\$0.94	January 2011	
Cogstate	\$0.300	\$0.13	November 2007	

Orthocell Update

Stem cell company Orthocell is seeking to list on the ASX next month, raising up to \$8 million. Last week, orthopedic surgeon, Mr Raymond Crowe, gave a presentation to investors. Mr Crowe specialises in shoulder and knee tendon reconstruction. He was previously the sports physician to the Melbourne Football Club and the Australian Olympic Ski Team.

Mr Crowe said there is an 'orthopedic tsunami' coming as a result of an aging population. The problem with tendon repair at the moment is that the success rate is only around 60%, which does not make it an appealing area of work. This compares unfavourably to hip and knee replacements, where the success rate is between 95%-97%.

The benefit of the Orthocell cells is that they are grown from tendons (autologous cell repair, using the patella tendon in the knee) and so can only form tendon cells according to Mr Crowe. This is unlike other stem cells, that can, and have shown to, in some cases, form other unwanted cells such as bone that has subsequently needed to be surgically removed.

At medical conferences, all of the focus is on regenerative cells and scaffolds. There are currently no scaffolds on the market that work, although Mr Crowe was very optimistic about the potential of the Orthocell scaffold, which is derived from porcine collagen.

Orthocell's lead product, ATI, for the repair of tendons, costs \$3,200 per procedure, with the scaffold costing around \$2,000.

Orthocell's cells are injected directly to the tendon at the point of damage. If required, a scaffold is used to strengthen the site of damage. To date at least 45 surgeons have used the Orthocell products. A total of 247 patients have been treated, at seven regions in the body.

According to CEO Paul Anderson, the company now has three to five year data on patients treated with its technology. In a study conducted on patients suffering tennis elbow, pain was reduced by 87% following treatment with Orthocell's ATI product, functionality was improved by 93%, and grip strength was increased by 85% following treatment.

Bioshares recommendation: **Pending following IPO**

Bioshares

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

Disclaimer:

Information contained in this newsletter is not a complete analysis of every material fact respecting any company, industry or security. The opinions and estimates herein expressed represent the current judgement of the publisher and are subject to change. Blake Industry and Market Analysis Pty Ltd (BIMA) and any of their associates, officers or staff may have interests in securities referred to herein (Corporations Law s.849). Details contained herein have been prepared for general circulation and do not have regard to any person's or company's investment objectives, financial situation and particular needs. Accordingly, no recipients should rely on any recommendation (whether express or implied) contained in this document without consulting their investment adviser (Corporations Law s.851). The persons involved in or responsible for the preparation and publication of this report believe the information herein is accurate but no warranty of accuracy is given and persons seeking to rely on information provided herein should make their own independent enquiries. Details contained herein have been issued on the basis they are only for the particular person or company to whom they have been provided by Blake Industry and Market Analysis Pty Ltd. The Directors and/or associates declare interests in the following ASX Healthcare and Biotechnology sector securities: ACR, COH, CSL, CZD, NAN, IPD, SOM, SRX, TIS. These interests can change at any time and are not additional recommendations. Holdings in stocks valued at less than \$100 are not disclosed.

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **\$400**

For multiple email distributions within \$630 2-3 email addresses
 the same business cost centre, our \$855 4-5 email addresses
 pricing structure is as follows: \$1090 6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9329 3350

I enclose a cheque for \$ _____ made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card \$ _____ MasterCard Visa

Card Number

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph () _____

Emails _____

