ISSN 1443-850X

Companies covered: CGS, SOM,MX1

	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 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - current)	26.7%
Cumulative Gain	**834%**
Av. Annual gain (14 yrs)	**19.3%**

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

Individual Subscriptions (48 issues/year)
$440 (Inc.GST)
Edition Number 670 (21 October 2016)

Bioshares

21 October 2016
Edition 670

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

Cogstate Signs Record Quarter of Contracts

Cogstate (CGS: $1.13) has delivered is best quarter to date, with a record US$17.3 million ($22.6 million) of contracts signed in the September quarter (up 246% over the previous quarter). Revenue for the quarter also reached a new record, at $11.1 million, up 82% over the previous corresponding period. The company now has a backlog of work valued at $55.5 million, with sales locked in for this financial year of at least $28.7 million.

From a cash flow perspective, the company had a net cash out flow of $2.5 million. However, the company should have very strong cash receipts in the current quarter, with $2.9 million due to be received this month and $7.8 million due to be received in November.

Cogstate is now signing larger contracts, with its customers having more confidence in the company's ability to deliver its cognition testing in larger clinical studies. Cogstate is now the largest company in the computerised cognition testing market. However it provides the more traditional 'pencil and paper' testing as well.

Cogstate expects to deliver a profitable first half of this financial year and will update the market with expectations for the full year once half year results have been released. We expect full year sales will exceed $37 million. The profit figure at this point is difficult to predict given changes expected to occur with the company's business over the next six months.

First, the company is planning to appoint three senior staff over coming months. It currently employs over 150 people, with around three quarters based in the US and the balance in Melbourne. The second unknown for the company is its 'Healthcare' application, which is the use of the Cogstate test for the US (and other major regions) as an Alzheimer's early diagnostic aid for the potential prescription of new Alzheimer's disease drugs that may reach the market.

If one of the many Phase III trials underway delivers positive results from the end of this year, starting from Eli Lilly, then plans to develop its community-based test for the US market prior to a market launch of an Alzheimer's disease drug will likely accelerate rapidly. Cogstate expects to provide a “more detailed business plan in respect of the Healthcare business” following half year results, which not surprisingly will be after the Eli Lilly EXPEDITION-3 results are released.

At this year's AGM, CEO Brad O'Connor said that the company delivered a good profit for the quarter and that there should be very good receipts for the December quarter.

With respect to the company's core clinical trials business, O'Connor said that shareholders can expect to start to see some steadiness in the company's business given the long-term nature of its contracts that are building. The company has a backlog of clinical trial revenue out to 2022 and some contracts the company is bidding for are for a duration of eight years.

Cont'd over

Resurgence in Alzheimer's Disease R&D

There has been a resurgence in the field of Alzheimer's drug development in recent years following positive Phase Ib data from Biogen and positive retrospective analysis from combined Phase III data from Eli Lilly's trials with its drug candidate solanezumab.

Technology evolution now allows plaque in the brain to be imaged in patients prior to death, which has taken off the blindfolds from drug developers; in Eli Lilly's previous trial, around 25% of patients recruited had no plaque build-up and therefore no confirmed disease. Eli Lilly's trials showed also that while its drug was not effective at treating mid-late stage patients, there was signs of efficacy when patients were treated earlier.

Finding a treatment for Alzheimer's disease has now moved to treating patients earlier in the progression of disease, and patients are only being enrolled into trials if they have confirmed plaque build-up. The FDA is also playing its part in helping drug developers, given the near 100% failure rate so far in Phase III studies. The FDA has now accepted that even slowing progression of the disease will be a positive outcome.

Over the next two and a half years, 16 Phase III studies in Alzheimer's disease being conducted by 15 companies are expected to be completed. The first of those will be Eli Lilly's solanezumab trial in December this year (in 2,100 patients), and then idalopiridine which is being developed by Otsuka Pharmaceuticals and Lundbeck.

Idalopiridine is being evaluated in four Phase III programs involving 2,500 patients. Recruitment is expected to be completed in Q1 2017. Idalopiridine does not seek to inhibit amyloid plaque or tau build up but stimulates multiple neurotransmitter systems. It is a selective antagonist of the 5-HT6 receptor which is expressed in multiple regions in the brain associated with cognition.

In Eli Lilly's previous two Phase III trials with solanezumab in 2,050 patients with mild-moderate disease (EXPEDITION-3), the compound showed no benefit in the first Phase III trial (EXPEDITION-1). However, an analysis of the patients with mild disease showed an improvement in one measure of cognition. The second trial (EXPEDITION-2) was then changed to recruit only patients with mild disease. Although that trial showed an improvement, it was not statistically significant. But pooling the data from the first two Phase III trials did result in a statistically significant benefit in cognition.

In other positive analysis from this trial, patients in the placebo arm were offered treatment with solanezumab. An interesting finding was that those who received solanezumab first continued to see a delay in declining cognition that paralleled the decline in those who received placebo first. However there was a clear delay in the time to decline because of the earlier treatment with solanezumab.

Part of the way through the EXPEDITION-3 trial, Eli Lilly decided that it would change the primarily endpoint to be just changes in cognition, and that changes in function would still be assessed, bust as a secondary endpoint. This is because in patients with early stage Alzheimer's disease, there is more of a deterioration in cognition rather than function, with patients still able to cook and drive a car for instance. How the FDA will view this change will be a measure of whether the regulator is prepared to significantly lower the bar to get the first disease modifying Alzheimer's drug onto the market.

An aging population and Alzheimer's being a disease of aging still with no available therapy will continue to burden health care budgets from this devastating disease. Last year there were 5.3 million people in the US suffering from Alzheimer's, of whom 5.1 million were over the age of 65.

There are two main implications for Cogstate. The first is that any further positive developments in the R&D area of Alzheimer's, particularly with respect to positive Phase III study results, will aggressively stimulate further clinical trials in this field. The second is that if a drug does get approved, an accessible patient screening tool will be required to find out which patients are likely to have disease, and which patients will be need to be confirmed as having plaque build-up using a PET scan in conjunction with an injectable imaging agent.

Bioshares

– Cogstate cont'd

At the company's 2016 AGM, the company indicated that the level of work it was bidding for was 10 times higher than in 2015. That has continued to grow, with the number of current proposals up 60% - 70% over 2015. The company is now bidding on not just more studies, but on more later stage studies as well.

Cogstate is capitalised at $126 million. It retained $4.7 million in cash at September 30, 2016.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Can Micro-X Compete in the Mobile X-Ray Market?

Micro-X (MX1: $0.46) is developing an ultra-light weight mobile X-ray system, called the Nano, a version for military use (the Rover) and a mobile back-scatter device for the detection of threats such as explosive devices.

The Technology – Size Counts

We understand that Micro-X's Nano weighs about 80kg, which qualifies it as an ultra light weight product, by comparison to contemporary mobile X-ray systems.

Existing mobile X-ray units range from 375kg to 575kg in weight. GE Healthcare's AMX-IV weighs 477 kg, its Optima 220 ,453 kg; Cuattro's Arcus 542 kg; Agfa's DRX-DX, 550 kg; Carestream's DRX-Revolution, 575 kg; Siemens Mobillet Mira, 375 kg; and the Shimadzu's DaRt Evolution, 420 kg.

The mass of these machines, which is also a correlate of the physical space the systems take up, limits where and how they can be deployed in medical settings, as well as influencing cost and price.

Less expensive and compact mobile X-ray systems could be placed in medical clinics including in doctors' consulting rooms and in aged care facilities, delivering significant price advantages against existing systems.

Micro-X has sought to achieve weight savings in the first instance by applying carbon nanotube technology towards the task of X-ray emissions.

Unlike conventional tungsten cathode emitters, the carbon nanotube approach uses an array of vertical carbon nanotubes that are activated as soon as a voltage is applied to them, much like the firing of many tiny electron guns.

The approach not only means that a much smaller electron emitter is used, but that less energy is needed. This has meant that the weight of the power components in Micro-X's Nano have also been able to be reduced.

Other weight savings have also been achieved through the use of composite carbon fibre in the system's main arm (and elsewhere) and because fewer moving parts are used.

Xinray Relationship

The carbon nanotube technology has been developed by Micro-X's US partner Xinray, in which it holds a 30% stake. Micro-X has an option to increase this to 40% by the end the year.

Micro-X holds commercial rights from Xinray for the application of carbon nanotube technology in the field of mobile radiography for medical, dental or veterinary uses.

OEM Relationship with Carestream

In August 2016, Micro-X announced the signing of a five year exclusive development and supply agreement with Carestream Health for an OEM product i.e. the Nano will be branded as a Carestream product.

Global Installed Base & Turnover Market

Micro-X has assessed the turnover of the installed base of X-ray systems to be in the order of 2,600 units per annum in the US and Europe. The number increases to 10,000 if territories in Asia and South America are included. The figures presumably also do not include new market opportunities for ultra-lightweight mobile X-ray systems.

Mobile X-ray systems currently range in price from US$140,000 to US$240,000. Micro-X believes the Nano will be a product that can be price competitive, selling for less than hlaf the price of current mobiles. In addition to the product's fundamental design and components contributing to its cost advantage, the adoption of just-in-time and auto- and aerospace- industry assembly approaches will also contribute to favourable margins for the Nano.

Medical Equipment – Capital Goods Suppliers

A general risk associated with medical equipment companies that supply capital goods is that the sales cycle is long, with the process from lead to contract taking about six months. Annual budget cycles can influence the timing of sales and receipts, however, end-of-year financial year 'unspent budget' spending can often provide a fillip for equipment suppliers. Group procurement tenders may seek savings through the bundling of products, which go against companies lacking relevant items to include in a bundled offering.

Therefore, income streams for these capital goods suppliers into the medical world may be lumpy, with stress placed on their cash flow and working capital requirements.

Cash and Funding

Micro-X raised $20 million through its IPO (December 2015). The company held cash of $4.2 million at the end of June quarter. Funds expended on a non-recurring basis include investments in Xinray (US$5 million, $6.9 million), on prototyping and product design and engineering, and the fit-out of facilities at the company's assembly site in Adelaide. The company recorded R&D spending for FY2016 of $17.9 million (FY15, $7 million) and posted a $10.7 million loss.

Micro-X has access to a $3 million loan from the South Australian government, with $2.6 million received to date. It anticipates receipt of an R&D Tax Incentive refund of $8.2 million for relevant FY16 spending, in addition to income from early orders from Carestream and defence work.

Summary

Micro-X appears to be leading the way in bringing a breakthrough product into the mobile X-Ray market. The nanotube X-ray technology it has accessed should deliver persuasive cost savings and expanded benefits to operators of mobile X-ray systems, as well as open up new markets in aged care and defence. It should be competitive.

The possibility of situating mobile systems in additional treatment

Cont'd over

Bioshares Model Portfolio (21 October 2016)

Company	Price (current)	Price added to portfolio	Recommend-ation	Cap'n ($M)	Date added
Factor Therapeutics	$0.070	$0.054	Spec Buy B	$51	September 2016
GI Dynamics	$0.022	$0.024	Spec Buy B	$10	May 2016
Adherium	$0.360	$0.495	Spec Buy A	$61	March 2015
Bionomics	$0.430	$0.295	Spec Buy A	$207	March 2016
Reproductive Health Science	$0.075	$0.150	Spec Buy B	$6	December 2015
Rhinomed	$0.019	$0.032	Spec Hold B	$15	December 2015
AirXpanders	$1.305	$0.745	Spec Hold A	$308	September 2015
Osprey Medical	$0.375	$0.695	Spec Buy B	$97	September 2015
Clinuvel Pharmaceuticals	$7.02	$4.15	Spec Hold A	$335	December 2014
Innate Immunotherapeutics	$0.720	$0.190	Spec Buy A	$160	November 2014
Opthea	$0.700	$0.160	Spec Buy A	$105	November 2014
Impedimed	$1.650	$0.245	Spec Buy A	$618	December 2013
IDT Australia	$0.220	$0.260	Spec Buy B	$55	August 2013
Viralytics	$1.240	$0.300	Spec Buy B	$298	August 2013
Somnomed	$3.95	$0.94	Buy	$225	January 2011
Cogstate	$1.130	$0.13	Spec Buy A	$134	November 2007

Portfolio Changes – 21 October 2016

IN:
No changes

OUT:
No changes

Somnomed DeliversSolid Quarter; Positive News for France

Somnomed (SOM: $3.95) delivered another solid quarter of growth. Unit sales of the company's oral splints for the treatment of sleep apnea and bruxism increased by 16.9% for the September quarter over the previous corresponding period (PCP).

Revenue increased by slightly lower at 13.4% to $10.9 million. The company incurred a net operating cash loss of $1.6 million for the quarter, which is seasonally weaker due to the northern hemisphere holiday period.

The North American region continues to grow well, with a 20.5% increase in unit sales, with a surprising rebound in licensee sales which had been falling in recent quarters. Europe also showed strong growth at 19.4% higher than the PCP.

There was very positive news in France, which will introduce full reimbursement from the start of next month for any mandibular splints, such as Somnomed's, and fully reimburse the fitting procedure.

Mandibular splints will now also be recommended as a first line therapy in France for patients with mild-moderate sleep apnea. France is the largest CPAP market in Europe. France will join Sweden and Holland where mandibular splints are used as first line therapies. In those two countries, mandibular splints have captured around 50% of the market.

Somnomed is planning the opening of its first Sleep Centers America sleep treatment clinic, which is 84% owned by Somnomed.

These clinics will provide fitting of the Somnomed devices direct to the patient.

The first clinic is expected to be operating at the start of next year. A COO and CEO have been appointed for SCA and the new CEO for the Somnomed business, Derek Smith, started last month. Somnomed has previously expected to have five sleep centres opened by mid 2017.

Somnomed is capitalised at $225 million. The company held cash of $16.3 million at the end of September.

Bioshares recommendation: **Buy**

Bioshares

– Micro-X cont'd

settings and improving care in existing settings, where a more compact and cheaper device can be used more effectively, should make the Nano an attractive offering.

Furthermore, the availability of lower-priced systems may mean that hospitals and other organisations can buy more units, thus introducing efficiences across a hospital campus.

Micro-X is capitalised at $55 million. We maintain a **Speculative Hold Class B**, pending an improved understanding of the company's cash outgoings (including the exercise of its option to acquire a further 10% of Xinray) until the Nano is launched in Q1 2017, matched against income, and the receipt of a 510k clearance from the FDA.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Tips from a Small Cap Fund Manager

At the 7th Microcap Investment Conference held this week, fund manager Dean Fergie outlined the approach his fund, Cyan Investment Management, uses to invest in Australian small cap stocks. Although Cyan steers clear of biotech stocks, mainly because Fergie said that his group does not have the expertise to evaluate the investments but also because of the binary nature of the investments (which is true of many drug development companies), his approach and ideas can be applied to any stocks, including biotechs.

One reason worth considering some of Fergie's investment approaches is that Cyan's fund has delivered a 33.8% annual return from inception two years ago while holding around 40% of its investments in cash for much of that period.

Fergie has looked at the average share price performance of ASX stocks and compared that to market capitalisation. Aside from the $5-$10 million micro cap stocks, which can be very illiquid, the best return historically has been achieved in companies with a market value of between $100-$200 million. Cyan focuses its investments on $50- $200 million companies, where decent returns can be achieved and the chance of losing money is greatly reduced according to Fergie.

He steers clear of companies with a market cap of between $25 - $50 million, which has historically delivered lower gains. This can be partly because of reverse mergers at inflated asset prices. At the lower end, companies valued at between $5 - $10 million make a loss each year that on average equates to around one third of their market capitalisation.

With 2,400 companies listed on the ASX, Fergie said there are many 'stars' to find but one of the main roles of a fund manager is to 'not' do things, to 'pass' on many investments. Cyan does not invest in resource stocks, listed investment companies, value stocks or listed venture capital stocks.

He believes in the adage that good stocks aren't cheap and cheap stocks aren't good, and is prepared to pay more for good companies growing quickly.

Fergie made an interesting point with the first investment he made, and it's a helpful point for all investors. He described his first vestment as a company that had revenue growth of 282% in FY2016. It's a market leader in its field that incorporates cloud-based technology. It's business partners include Google, Coles, Carlton United Breweries, Microsoft and McDonalds. It operates in a global market worth $640 billion. It currently only operates in Australia and if it could achieve just 1% of the Australian market, it will generate revenue of $110 million and an NPAT of over $65 million. Some listed comparables have values of $3.5 billion, $3.0 billion and $2.9 billion. Using an average global PE, that company should be worth $1.2 billion if it can achieve just 1% market share. That company was Cyan Investment Management.

The obvious point here is that investors should be very wary of companies listing almost random market penetration rates with no justifiable reason.

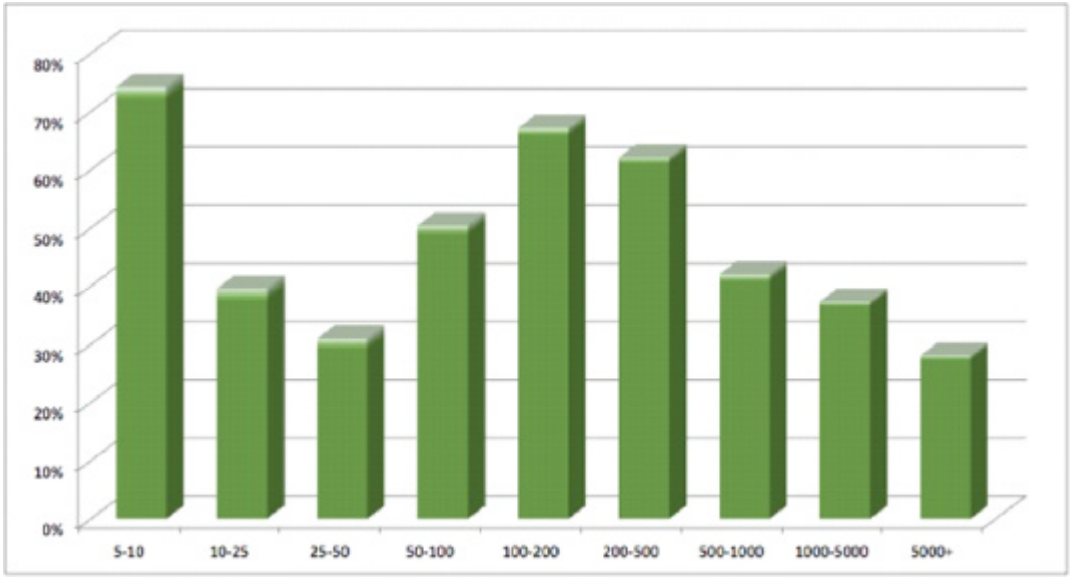
What Cyan looks for in an investment is first a commercially proven product; second scalability (both organic and through acquisition), third, capital structure to fund growth; fourth, realistic business forecasts; fifth, a consistent strategy, which gives Fergie a lot of comfort as an investor.

Cyan looks for companies that have reached the breakeven point. He detailed the Ferris Wheel of Wealth, that starts with rising revenue, rising PE, cheaper capital, organic growth, increasing market value, accelerating investor interest, improving liquidity, ability to raise equity and then accreditive M&A.

Fergie finished with a must watch video of Luke Aitkins, an expert sky jumper who jumps without a parachute. His metaphor is that investments can be very exciting and scary, but you often change your mind about how good an idea it was once you get closer to the ground.

Bioshares

Two Year Investment Return (vertical axis) versus Market Capitalisation



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, LBT Innovations, Viralytics, pSivida, Opthea, Reproductive Health Science, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Antisense Therapeutics, Atcor Medical, Dimerix, Cyclopharm, Adalta

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$440**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$700	2-3 email addresses
	$940	4-5 email addresses
	$1200	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 _____

_____

_____