#### In this edition...

'Lessons learned' is a theme in this edition, in which we continue coverage of the 9th Bioshares Biotech Summit. A panel of investment analysts and advisors discussed lessons learned in the last 12 months. Following a series of regulatory setbacks, one view expressed was that companies should now be working much more closely, in the geographic sense, with regulators. Several professional investors talked about how their investment approaches had changed over time in conjunction with challenges experienced on the way. This has led, for example, to Andrew Kelly from Pacific Bioventures, to contemplate starting an evergreen venture capital fund in response to the changing attitudes of institutional investors towards risk. **Companies covered: Summit Coverage** Pt II, IVX, OSL, Telezon

	<b>Bioshares</b> 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)	13.0%
Cumulative Gain	302%
Av. annual gain (12 yrs)	16.6%

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

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Individual Subscriptions (48 issues/year) \$400 (Inc.GST) Edition Number 513 (26 July 2013)

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# Bioshares

#### 26 July 2013 Edition 513

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

# The 9th Bioshares Biotech Summit Reports – Part 2

Our coverage of the 2013 Bioshares Biotech Summit continues in this edition with reports on the 'Investment Panel' session, the 'New Kids on the Block' session and 'Biotech Investment Rules from Three Professional Investors' session

## Investment Panel Session

The members of the investment panel were Matthijs Smith (analyst with Canaccord Genuity), Scott Power (analyst with RBS Morgans), Steven Yatomi-Clark (Director of Corporate Finance at Pattersons), Stuart Roberts (currently operating independently but formerly with Bell Potter) and Danny Sharp (investment banker with Canaccord Genuity).

#### What Lessons Have Been Learned In The last 12 Months?

Matthijs Smith said it had been a horrible 12 month period with some very difficult lessons learned. Historically, much of the risk has been removed once clinical trials (and results) were completed. In the last 12 months, no Australian company has got through the regulatory process unscathed said Smith. This group of companies included Pharmaxis, Tissue Therapies and QRxPharma. The only company that has got through (in recent years) was Acrux (with Axiron). However, that wasn't a completely new drug, requiring only pharmacokinetic studies. All companies are now very nervous when approaching the regulator because a binary event will take place.

Danny Sharp said there has been a shift in the requirements of investors. Ten years ago investors demanded that a company should be in the clinic before they (the funds) would invest. Investors had been expecting this to be a very good 12 months with several companies approaching final approval. Sharp said we've seen the risk curve change again because of what's happened at the FDA. Sharp also believes companies need to be interacting on the ground more closely with regulators than remotely from Australia.

Stuart Roberts argued that biotech companies have been very poor communicators with only Prima Biomed to his knowledge the only one with a Facebook presence. Better communication is one aspect Roberts would like to see the sector improve upon over the next 12 months.

Scott Power said that one thing he has noticed in the last two months is an increased investment into companies with a revenue stream and companies that are also profitable, with the trend only just starting. Companies such as Nanosonics and Somnomed are receiving a lot more interest at the moment according to Power. Anything that represents a forthcoming binary bet, either from the regulator or a clinical trial is very hard work at the moment, he said.

Steve Yatomi-Clark said that the last 12 months will be the new normal from a capital markets perspective, so companies should be ready to raise money at any time.

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#### The US Biotech Market Has Performed Well – Why Not Australia's?

Roberts view was that Australia is going through a transition period. The mining boom has ended, the small resources index has halved and it will halve again. Roberts belief was that a whole lot of risk capital will move from mining to biotech and that the capital window for the biotech sector will open. 'A lot of companies you'll be surprised about and you will be able to take advantage of that in the next 12 months' he said.

Yatomi-Clark said that IPOs represent the third phase (in a turnaround). The first is investors re-entering a market. The second is those investors buying undervalued companies and there is too much value out there at the moment. Investors are busy buying up the existing stocks before the third phase of IPOs. The US IPO market is going through the roof, but that is on the back of a couple of good years. The local sector will need to see at least 18-24 months of solid gains first.

Interestingly, Yatomi-Clark argued that given the turbulence of the last two years, the share registries of biotech companies in Australia are probably as stable as they have ever been because anyone who has wanted to exit will have done so.

# What Is The Sentiment From Retail And Institutional Investors At The Moment?

Sharp is not a believer in the movement of risk capital from one sector, such as mining, into another, such as biotech. 'Either risk is on or risk is off' said Sharp. In Australia, some of the risk capital is allocated to resources and some to biotech. In the last two years, there has definitely been a lot of contraction in domestic institutions playing in the biotech market. 'That creates a fantastic opportunity for those funds still investing in the sector' according to Sharp.

Sharp said that the flip side had been the incredible pick up in interest from funds in the US, Europe and to some extent in Asia. For companies that are able to access that overseas funding, those with a market value in excess of \$50-\$100 million, the pool of funds available has got 'enormously bigger' he said.

Power suggested that things are starting to become easier for companies looking to raise capital. He cited the recent raising by GI Dynamics of \$57 million which was completed at an attractive

price and brought in some overseas investors as well. In the broader health space, Virtus Healthcare raised \$400 million recently and has done incredibly well since it listed in Australia recently. Money is returning to the sector, and Power is particularly interested in the e-health sector, including companies such as Cogstate. Power is also interested in companies where new management has come in, including Neil Fraser's Oncosil and Greg Collier's Invion.

#### Are There Any IPOs In The Pipeline?

Smith said Canaccord is working on an IPO at the moment. Yatomi-Clark stated that Pattersons is looking at several but won't do them all. RBS Morgans is looking at a possible e-health IPO.

In what is a very international investment market, Sharp said investors need to look at the macro trends and for where there is the demand. Two years ago US companies were listing in Australia and now Australian companies are seeking US capital. GI Dynamics raised 40% of its funds from US investors in its recent capital raise. GI Dynamics will eventually transition and list on Nasdaq, said CFO Bob Crane (who was present in the audience). The company also raised an additional 20% of its funds from Europe, mainly London, as well as funds from Asia and Australia. GI Dynamics is very much an international company that just happens to be listed on the ASX, said Crane.

#### Analyst Picks for 2013

Stuart Roberts had the best stock pick in 2012 choosing Neuren Pharmaceuticals. This year's stock picks from the biotech analysts were as follows: Roberts continues with Neuren as a favourite pick as well as GI Dynamics; Yatomi-Clark's picks were Invion (which at the date of publication was up 66%) and Mayne Pharma as a 12 month plus pick; Power chose Allied Health and GI Dynamics; and Smith selected Nanosonics and Osprey Medical.

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Company	Price	Price added	Date added	Portfolio Changes – 26 July 201
	(current)	to portfolio		INI.
Atcor Medical	\$0.110	\$0.082	May 2013	IN:
Circadian Technologies	\$0.230	\$0.270	March 2013	No changes
Tissue Therapies	\$0.145	\$0.255	March 2013	
Benitec Biopharma*	\$0.330	\$0.400	November 2012	OUT:
Nanosonics	\$0.700	\$0.495	June 2012	No changes
Somnomed	\$1.15	\$0.94	January 2011	
Cogstate	\$0.320	\$0.13	November 2007	
Universal Biosensors	\$0.74	\$1.23	June 2007	

Note, 1:25 Reconstruction recently completed

# Biotech Investment Rules From Three Professional Investors

The final session of the 2013 Summit was one in which three professional biotech investors shared with the audience their lessons learnt from years of experience investing in biotech. The speakers discussed their investment processes and how their approaches have changed overtime, what they have learnt from investing in biotech and gave practical examples of how these approaches have been applied to several existing investments.

# Graeme Wald (BioScience Managers)

The first speaker of the session was Graeme Wald of BioScience Managers. BioScience Managers, headquartered in Melbourne, Australia, is a leading life sciences investment firm with more than 30 years experience managing sector specific bioscience funds.

BioScience Manager's first fund, the 'IB Australian BioScience Fund' was established in 2008 and invested exclusively in Australian companies. The fund has delivered a solid performance with a 25% IRR and an overall 70% return for the 60 months since its inception in July 2008. The firm also operates a second fund, the 'OPBM Asia Pacific Healthcare Fund II' concentrating on new ventures in the Asia/Pacific region. With a first close of \$55 million, the firm has invested around 12% of this fund to date.

#### Philosophy

Wald summed up BioScience Manager's philosophy to their investment approach outlining that essentially the firm wants to first, invest in companies that have a clear technological and market advantage; second, have an ability to influence an investee company's success; and third, be confident of an exit via trade sale or (list on a) public market.

#### **Investment Targets**

Wald emphasised that all the investment targets that BioScience Managers identify have to share the following attributes:

- Are developing healthcare products at human clinical trial / proof of concept stage;
- Addressing a market which can demonstrate significant size and growth;
- Have experienced management team and board with a track record of success;
- Have a capital structure that supports a value added exit.

On top of these criteria, the firm also looks for the presence of strong key opinion leaders for a project, and want to know that a company has made a decision as to whether they're going to build or buy their distribution network and how this will be achieved.

Wald mentioned the firm's emphasis on granularity in their investment approach. This means that they want to dig down into the details of a business. Wald said BioScience Managers is supportive of companies with platform technologies on the basis that one understands that it is the products that arise from a platform and not the platform itself that generates the revenues.

#### **The Investment Process**

Wald summarised the IB investment process by highlighting a few of the key processes that BioScience Managers goes through when deciding whether to invest in a company.

First, the firm likes to have input into the management of the investee company. Wald stressed this as one of the major philosophical changes that has been implemented over the last couple of years, and the firm will now almost invariably insists on having a board role in a prospective investee company. This is important on the one hand as it provides a close working relationship between the two entities. However, Wald also stated that of almost equal importance was the signal of commitment for the long term that the role provides.

Second, Wald emphasised on the exit process, stating that BioScience Managers will always have the exit strategy front-ofmind when they start the investment process. The firm likes to take an active and involved approach in investee companies while working towards achieving a high value exit. Examples of this involved approach include advising on the development of business strategies, reviewing scientific and clinical milestones, engagement of international industry experts and the recruitment and mentoring of management teams.

#### Timing

Wald outlined that BioScience Managers will preferably invest when a company is around Phase I (stage of development), help with the development of Phase II/III trials, and will look to exit before completion of Phase III and the commencement of any accompanying regulatory issues. This is partly a risk mitigation strategy, and also because the firm has found that it is during the Phase II/III period that the maximum (proportional) increase in value is achieved.

When questioned about their exit strategies, Wald mentioned that this approach was evaluated on a case-by-case basis and that the firm is not strictly against being involved with a company through to the revenue generating stage.

#### **Case Studies**

Wald finished his talk with an example of an investment that BioScience Managers has recently made – a New Zealand private company called **Nexus6**, that is developing a 'Smartinhaler' device to fit onto any type of respiratory inhaler and can send information back to the clinician about a patient's compliance.

Wald said that Nexus6 was an appealing investment due to the wide variety of current uses for respiratory inhalers giving the device great potential. As well as the fact that the company's management had been extremely quick to respond to technological problems that had arisen during development and to come up with effective solutions.

Wald said that the value BioScience Managers had brought to this deal was to facilitate access for Nexus6 with some of the larger pharmaceutical companies, effectively stimulating the competitive tension, meaning that in a sense, the firm had already prevalidated an exit for this investment.

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#### Andrew Kelly (BioPacific Ventures)

The second speaker for the session was New Zealand-based Andrew Kelly, the co-founder and managing director of BioPacific Ventures – one of the world's largest food, nutrition and agriculturally focused venture capitalists, managing a \$100 million fund that is currently 93% invested in New Zealand and Australian companies, specialising in the convergence of food and health.

Kelly summarised his hard lessons learnt, and some of the things he felt he'd done wrong in a talk entitled 'Four Lessons Learnt From My Last Decade of Venture Capital Experience'.

#### Lesson 1 – Industry Margins

Kelly's first lesson was set back in 2003, when 'we set out to carve out a new niche as a venture capital firm' and BioPacific Ventures was established to invest in food and health companies from both New Zealand and Australia. Kelly stated they like the niche to this day, and are planning to stay active in the sector. However, their lesson learnt in this case was that the food and health industry, perhaps somewhat unsurprisingly – 'is a very hard niche to make a buck!'.

Kelly suggested that the problem was that when compared to the pharmaceutical sector, the lower values and margins in the food industry create difficulties in generating significant returns from investments focused on food-based products. Kelly discussed the importance of clever marketing and product positioning that is required to improve performance of investments in the food and health sector.

#### Lesson 2 – Risk Profile

Kelly's second lesson related to adopting a lower-risk profile than a conventional venture capital approach, a strategy BioPacific Ventures decided to implement when raising the fund in 2003. Kelly stated that this strategy has resulted in them selecting some big, conservative, cash-positive companies such as **New Zealand Pharmaceuticals** to serve as ballast in their portfolio. Kelly described such companies as exhibiting inertia in their financial performance, in that you can be fairly certain not to lose any money from an investment, but at the same time, can also be fairly certain not to realise any substantial gains.

Kelly said that he has learnt that this lower-risk strategy is a good one, with the BioPacific Ventures fund now on track to realise reward from this approach. Furthermore, Kelly emphasised that he felt this more conservative strategy was successful given the economic climate of the last few years, with the approach being particularly well suited to the global financial crisis.

#### Lesson 3 – The Behaviour of Scientists

Kelly's third lesson was more direct as he stated that 'scientists will lie'. Kelly said he had to learn this lesson the hard way through several companies that BioPacific Ventures both had and had not invested in. Kelly emphasised this was a lesson to any scientists in the room that laying the facts out straight from the beginning is the best approach to establishing a successful relationship with any venture capitalist.

#### Lesson 4 – The Venture Capital Model

Kelly's departing lesson was one focused on trying to change the venture capital model – a lesson he confessed to be still actively learning. Kelly discussed the difficulties in the present venture capital market, given the shift of the institutional approach to risk over the last 10 years, and the 'need to return to the whiteboard'. BioPacific Ventures is currently pursuing talks with parties to attract investment again into venture capital. Kelly said they are primarily focusing these discussions on a target audience of multinationals, in an era where the institutions are comprehensively deserting the field.

Kelly closed his talk stating that BioPacific Ventures has now come up with a design that will hopefully yield them an evergreen fund. Kelly outlined that this work-in-progress fund will not necessarily be a fixed pool of \$100 million or similar, but will have greater spending capability, coming from a complementary group of multi-nationals.

#### Steve Gourlay (GBS Venture Partners)

The last speaker of the session was Steve Gourlay of GBS Venture Partners (GBS). GBS is Australia's largest dedicated life science investment manager, investing in companies that have an Australian or New Zealand connection. GBS has multiple funds, and 5 partners based in Sydney and Melbourne, Australia. GBS has to date invested in some 40 or so companies targeting diverse parts of the human body. Gourlay summarised the GBS portfolio by saying that some of these have been great successes, some are a work-in-progress and some have been complete disasters.

GBS is currently investing from a \$123 million fund established in 2008, and is looking to invest in two more deals in 2013/14. Gourlay stated that GBS would like to put \$5 million initially into a deal, with up to \$10-\$12million available over the lifetime of that company.

Gourlay's take home message was to beware of any CEO or founder who is in love with their product. Emphasising that what is preferable to this is a CEO or founder who is instead in love with their market(s).

Gourlay also mentioned the need for good people, and the fact that it is very rare to find a CEO or CMO who is very good at every stage of a drug or device's development. Gourlay said the result of this is that the job of a venture capitalist is not only to fund the company, but also to ensure that the correct management is in place.

Gourlay concluded with an overview of **Hatchtech**, a Melbourne based company developing a novel method for the treatment of head lice. If successful the product will be the first of its kind that works by killing both the larvae and the eggs in a single treatment, a feature that Gourlay emphasised as having considerable potential value. Hatchtech has received \$23 million in funding to date, and is currently looking to raise a further \$12 million to take the product through Phase III trials.

– Emma Senior

## New Kids on the Block

In this session, three companies were profiled that are, in a number of ways new to investors, despite their respective histories of commercialisation and product development. The companies which presented were Oncosil Medical, Telezon and Invion.

#### OncoSil

OncoSil (ASX:OSL) CEO Dr Neil Frazer was in semi-retirement in North Carolina when he was originally called about NeuroDiscovery, the company which would later be rebadged as OncoSil.

Oncosil's product is a medical device comprising of a microparticulate beta radiation source which is injected directly into the pancreas via endoscopic ultrasound. It remains there for three months, confining the radiation dosage.

Oncosil's technology was rescued from pSivida, where it sat on the shelf until being transferred to NeuroDiscovery in Australia.

Frazer said that the radiation not only destroys tumour cells, but also damages pain neurons surrounding the pancreas. Such reduction in pain has been shown in a pilot study, but no large studies have yet been done.

OncoSil's share price has tripled in the last month, from 0.03 in mid-June to 0.09 in mid-July. As of 18 July, their market cap was \$21 million and as of June 30 they had \$3.4 million in cash. A total of \$25 million has already been invested into the technology and OncoSil has two patent families surrounding manufacture and composition of matter.

Frazer laid out the case that pancreatic cancer is a severe and unmet clinical need: there are approximately 280,000 patients diagnosed with pancreatic cancer per annum, of which 90% are dead within a year. Median survival is 4-6 months and less than 5% of patients make it past 5 years. The disease is also considerably painful and treatment options are limited.

The standard of care for pancreatic cancer is gemcitabine, which has a median survival of less than 6 months. Combination therapies can provide an additional 4-8 weeks of survival but with severe side effects. The main surgical option, which is only applicable in 10-20% of cases, has a 5-15% mortality rate.

Systemic radiation therapy is also an option, but causes severe side effects that limit its use. Frazer noted that immunotherapy was coming to the fore but that it was early days with regard to pancreatic cancer. Local radiation therapy of the sort represented by OncoSil's technology, he reported, was safe, well-tolerated and comparatively effective. Pilot studies have yielded positive results with regard to pain management and improved survival outcomes.

Frazer reported that of the 192,000 pancreatic cancer patients in the developed world (45,000 of whom are in the US), about 28,800-47,000 globally might choose the OncoSil microparticle treatment. Their current estimated price is \$15,000 per treatment, with 1-2 treatments per patient being expected.

Frazer explained that this pricing was arrived at largely through comparison with a successful precedent in the form of **Sirtex Medical** and its SIR-Spheres technology. He said that while otherwise their manufacturing process is quite simple, the largest component of their cost of goods is residence time in a nuclear reactor. The product is packaged in Germany.

OncoSil's next steps are to seek CE marking with the EMA (Europe) this year, a pre-IDE meeting with the FDA (US) in Q4 2013 or Q1 2014 and registration with the TGA (Australia) in this first half of 2014.

The company intends to commence a global registration study at the start of next year, which is expected to run for two years and yield data with which to convince healthcare providers to purchase the product. Frazer also said that they are pursuing a global manufacturing alliance with their German partner.

#### Telezon

Telezon (SIM VSE: TLZ) director Dr Michelle Carr opened with the World Health Organisation (WHO) estimate that 8 billion injections per annum (about half of total injections) are infected or unsafe, with needles commonly being re-used 20-30 times. She compared the one million annual death toll of malaria with the number of deaths from infected injections: 1.3 million, with the cost estimated at US\$0.125 per injection or US\$535 million per annum. Needle stick injuries also cost the US upwards of US\$700 million per year said Carr.

Carr characterised the medical needle market as tightly-held but lucrative, with most of the market share being dominated by **Johnson & Johnson** and **B Braun**. She identified a growing global middle class, who are demanding cleaner, safer and more cost effective medical technologies, as being a potential market driver, along with an ageing population and a trend towards squeezed budgets.

Telezon's solution is plastic needle technology. Carr said that Telezon finished its R&D phase 4 four years ago and is now a sales, development and commercialisation company, with their needles being manufactured under contract in Germany.

According to Carr, manufacturing the plastic needles is much simpler than producing metal needles, with Telezon's manufacturing operations taking up relatively little floor space. She also emphasised their technological edge over any potential competition and said that when asked, Braun said that it did not possess the technology to cost-effectively manufacture plastic needles of the lengths that Telezon does.

Carr explained that they opted to bring their SoloFlow draw-up cannula to market first and did so within 15 months because they faced perceptual challenges around plastic hypodermic needles.

The SoloFlow draw-up cannula has been recognised by the WHO and the Serum Institute of India, which has purchased and taken delivery of around 500 thousand units, which has in turn won them coverage and kudos in the media.

Although Telezon had been previously listed on the ASX, Carr said that being a micro-cap company has meant they have found the less crowded SIM VSE a more advantageous place to be, where they can enjoy greater visibility. Carr stated that about \$3.6 million has been injected into the company since 2004, with which they have reached their current position. They are now looking to commercialise the rest of their product portfolio.

#### Invion

Invion (ASX: IVX) was formed from the merger between **CBio** and **Inverseon Inc.** The company has a market cap of around \$16 million, has two drug candidates in Phase II clinical development and is currently running three Phase II trials. Both drug candidates target inflammation. NV102 (nadolol) is being repositioned for inflammatory lung conditions and INV103 (ala-Cpn10) is being developed for autoimmune disease-related inflammation.

CEO Dr Greg Collier highlighted the significant experience of Invion's management team, including that of CMO Dr Mitchell Glass, who also spoke at this year's Bioshares Summit.

Collier said that Invion had secured over US\$4 million in NIH funding for a Phase IIb trial with (orally-delivered) nadolol for asthma. The trial has now begun. This followed a successful Phase II trial with 19 subjects that showed safety and clinically significant reductions in airway hypersensitivity.

He also mentioned that Invion is aiming to start another Phase II orally-delivered nadolol trial for chronic bronchitis in patients attempting to quit smoking. He said that inhaled nadolol development programmes are also progressing for chronic bronchitis and cystic fibrosis but are at an earlier stage.

Collier identified the total prescription respiratory market as being US\$64.6 billion worldwide, with asthma and COPD making up US\$34 billion of that and individual drugs for those indications having sales on the order of US\$3-US\$8 billion per year. Collier indicated that they expect nadolol to have a short path to commercialisation.

Collier also reported that Invion had also commenced a Phase II trial with ala-Cpn10 for lupus under a US IND. He identified this indication as a 'large unmet medical need'.

Cpn10 is a modified human peptide (chaperonin 10) which has been administered to more than 250 patients already and is backed up by preclinical results in mouse models. Invion forecasts sales of over US\$4 billion in the lupus market in the US and five major EU markets by 2020.

When asked about the lessons learned via his time at ChemGenex and Invion, Collier drew attention to the importance of having your own people, the people who developed your drug, be 'in the room' during negotiations with the FDA. He also emphasised the importance of ensuring that meetings with the FDA are face-to-face and of having a first-rate clinical team.

He said that (the ChemGenex) clinical programme was formerly run by consultants and that this was a significant disadvantage when seeking regulatory approval. He also praised the usefulness of having experienced people (such as Dr Glass) around the table who have already been through the process.

– Mike Nelson

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