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# Bioshares

**23 July 2014**
**Edition 560**

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

**Companies covered: Summit Coverage - ALT, IMC, IPD, RNO**

| | 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 - ) | 3.8% |
| **Cumulative Gain** | **367%** |
| **Av. Annual gain (14 yrs)** | **16.4%** |

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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

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## *Reports From The 10th Bioshares Biotech Summit*

The 10th Bioshares Biotech Summit was held in Queenstown, New Zealand over Friday July 18 and Saturday 19 July. More than 170 people registered for the event to hear presentations from a diverse group of speakers. Our coverage of a selection of sessions from the event follows.

### Investment Panel

The Investment Panel comprised Danny Sharp (Director - Corporate Finance, Canaccord Genuity), Scott Power (Senior Analyst, Morgans), Steve Yatomi-Clarke (Director - Corporate Finance, Paterson's Securities), Stuart Roberts (Analyst - Baillieu Holst), Anton Uvarov (Analyst - Forrest Capital), and Eddie Grieve (Senior Manager - Listings and Issuer Services, ASX).

In reviewing recent activity in the sector, Scott Power agreed that it has been a rollercoaster experience. The year started off well, with Benitec and Viralytics raising some good money which was followed by number of companies causing disappointment, so the sentiment really fell out of the sector. Power is now sensing that there are a number of green shoots starting to emerge again. He believes there is a lot more interest in health generally, which is driven at the larger end by the Healthscope float and a couple of aged care providers coming onto the listed market, so the actual sector is getting larger. Power said that we are going to see that increase quite significantly over the next decade as the thematic of an aging population really starts to take hold. There is a lot more investor interest in companies in that space. However, in the near term he believed things are pretty patchy – investors are looking for near term milestones which will drive the share price, as opposed to getting carried away with long term plans.

Stuart Roberts said that he thought the interest level (in biotech) was at its highest level in all of the 12 years he has been doing biotech stock research. Impedimed's gaining of its CPT1 code was noteworthy because previously that was a busted up company which is now on the road to recovery. "Investors have to pay attention to that sort of thing," he said.

Danny Sharp said that from an institutional investor perspective there has been both a combination of opportunity and frustration, with the frustration stemming from the fact that there is not enough choice from an institutional viewpoint in the sector. "We have seen a lot of companies of quality go out too early in terms of being taken out and that has left a quite a void between the $50 million market cap and $500 million market cap groups, which we are working really hard to fill with IPOs and new issues. I think that also that there is a general sense of mis-pricing in the Australian market," he said.

Anton Uvarov discussed the importance of US markets to Australian markets. "Without strong US markets we wouldn't have seen the Viralytics or Benitec capital raisings, or the Bionomics-Merck deal or Shire acquiring Fibrotech. So the fundamental link between the ASX and US markets is very important."

*Cont'd over*

Uvarov said that the US Federal Reserve chairman, Janet Yellen, recently mentioned that the valuations on small cap biotech companies and media companies are quite stretched and the Federal Reserve would like to see some cooling down in the sector. "In my experience it is the first time the Federal Reserve has mentioned biotech. Biotech dropped 5% that day. Fortunately biotech in the US has its own Stuart Roberts, and there were lots of people saying that the Fed should focus on monetary policy rather than the markets."

Continuing with the US-Australia markets discussion, Steve Yatomi-Clark said that one of the problems is to believe that the grass is always greener. "Anything under $200 million is struggling in the US. VCs continue to struggle from what I have seen," he said. Yatomi-Clark sees two-to-three opportunities from the US a week, from companies seeking to raise money in Australia.

Uvarov said that the difference in the valuations (between the US and Australia) can be explained by the general nature of the ASX. "To price Viralytics at the price it could be trading at in the USA, you would need a big volume, and you can't get that on the ASX. That is why Viralytics is trading at where it is right now," he said.

Yatomi-Clark said there are a number of US investors who are waking up to the fact that you can get quality assets (in Australia) at the 'pointy end' of clinical trials, at a fraction of what you would pay in the US. "I am hoping that Viralytics and Benitec will be the thin edge of the wedge," he commented.

### ASX and Listings

Eddie Grieve said that the ASX has had its best IPO year in 13 years. "Things are pretty buoyant, the market is pretty much open for floats." He repeated Power's views that "we have seen a lot of interest in health related type floats, for example Monash IVF. In fact with three IVF companies listed, we are the only exchange in the world with IVF companies listed."

Grieve said the challenge is that we live in a country that has the third largest pool of investment funds in the world. Self managed super funds hold $550 billion in assets and 38% of that goes into ASX stocks. "So there is plenty of money there. The challenge is to get it to come to this sector," he said.

The ASX has over the years looked at the ways to drive the connections between companies and investors. In 2006 the ASX started with the biotech reporting code. The ASX is now in the third year of an equity research scheme. This is a fund made available to cover companies which are currently not covered and now about 160 companies are covered, which previously weren't .

At the end of 2012, the ASX reduced the minimum spread requirement from 400 to 300 shareholders. The ASX originally wanted 200 but ASIC rejected that. The other area of change has been freeing up the placement capacity for smaller companies, so that they can get a mandate to raise up to 25% of issued capital rather than 15%. "Unfortunately the way we implemented that made it quite cumbersome. We are keen to get feedback on how to improve that. It's due for review at the end of this year," said Grieve.

### 12 Month Outlook

Sharp was generally optimistic for the next 12 months, expecting Australian life sciences sector market valuations to increase even while the Nasdaq valuations start to cool off. In his view "there is a huge valuation gap and that must close over a period of 12 months."

Roberts remains bullish on the sector. "It has too much going for it!"

Yatomi-Clark was also positive about the next 12 months. "We are in a much better state of health than 12 months ago. There was a fantastic few months of the window opening and clever companies raised a lot of capital which will give then some oxygen to get some runs."

Power anticipates a lot more interest coming in health and more floats coming through both at the big end and at the small end. Power said "there are lot of these companies sitting on cash and that there are good milestones to come. So the sector should sit much higher. The broader market is a bit toppy, that's general investors being quiet, but they are looking for sectors which will move and health is one of them."

Uvarov said that (in the US) "everybody expects the 3rd quarter and 4th quarter to be strong again. We will see another over performance of biotech compared to the general market . In Australia we will see some good wins in the fourth quarter of this year. We are done with the misses and will be back to the hits."

**Bioshares**

# Presentation Summaries: Immuron, Impedimed, Analytica, Rhinomed

### Immuron – NASH as a Large Market Opportunity

Immuron is on track to start a Phase II trial later this year in the treatment of NASH (Non-Alcoholic SteatoHepatitis) with its oral immunotherapy product. That product is derived from colostrum from vaccinated cows against a particular bacterium, *E.coli*. Immuron already has one product on the market, called Travelan, which in FY2014 sales exceeded $1 million (up from $150,000 in the previous year). The product for the treatment of NASH is a significantly stronger dose of the Travelan product.

NASH is caused by a high fat diet and a sedentary lifestyle said Immuron CEO Amos Meltzer. There are four stages of diseases. The first two are reversible and the second two are not. The first stage is called non-alcoholic fatty liver, which is technically not a disease. However this progresses to NASH, when the fatty liver becomes inflamed. Meltzer said that inflammation is the root of all evil. This inflammation leads to failing liver function.

These two stages, or at least early stage NASH, can be reversed by diet and exercise. However NASH can progress to cirrhosis of the liver, and then liver cancer, both of which are not reversible. One in 10 people with NASH develop cirrhosis of the liver.

What is generating the high level of interest in NASH is that 4%-5% of the population have this disease (with around 25% of the population having the earlier stage of non-alcoholic fatty liver). There is no treatment for NASH. And only nine companies have advanced clinical programs (all round the Phase II stage, including Immuron).

Meltzer said that the size of the problem - and the size of the opportunity - is the same order as that as diabetes. In 2012, 9.3% of the US population (29 million people) had diabetes. By 2025, 25 million Americans are expected to have NASH according to the Centre for Disease Control said Meltzer.

It is believed that the chronic inflammation as a result of NASH leads to a leaky gut which sees bacteria and endotoxins formed as a result that move into the blood stream and into the liver, driving chronic inflammation. Immuron is addressing the endotoxin produced in the gut by gram negative bacteria. It is vaccinating cows with the bacteria that produces the endotoxin in the stomach, harvesting the antibodies produced and present in the colostrum.

The three approaches being trialed to treat NASH are modified bile acids, anti-fibrotics and anti-inflammatory agents (Immuron). The three large companies involved in this space are Abbott Laboratories, Shire Pharmaceuticals (being acquired by AbbVie) and Gilead Sciences. The smaller companies working in NASH are Intercept, Galectin, Conatus, Galmed, Genfit and Immuron according to Meltzer. Meltzer said that Intercept's share price quadrupled overnight (from a market value of US$1.5 billion) in January this year following positive Phase II NASH results. Whilst the share price has retracted somewhat, the company still has a market value of US$4.5 billion.

Meltzer said the Medical and financial community is waiting for a NASH drug. "It is a huge unmet medical need."

Immuron has patents covering the vaccine that gives coverage out to 2023, with two other method of treatment patents. It may also be entitled to a 12 year biologics data exclusivity protection in the US for its product, said Meltzer.

### Impedimed – Getting to CPT1

Impedimed CEO Rick Carreon gave one of the standout talks at the conference. It was an impressive presentation not just because of the clarity in describing the AMA coding process for the code the company will shortly have in the US (termed a Category 1 Code) but because it highlighted the expertise the company has shown in gaining the reimbursement code a year earlier than expected.

The key focus by investors previously for biotech companies was whether they have sufficient capital to commercialise their products. This focus then moved on to whether companies had received FDA approval. Now the biggest question (by investors) is whether a biotech company has a roadmap to get through the reimbursement process. Most companies conduct their FDA approval and reimbursement sequentially. But Medtronic, where Carreon previously worked, actually placed their reimbursement teams in with their R&D teams to start the coding and reimbursement process early.

In 2014, there were 183 submissions for reimbursement in the US, of which 17 received a CPT1 code, the highest level of reimbursement said Carreon, and of those six were for new technologies. Impedimed was one of those six companies with a new technology that will receive CPT1 Coding from 1 January 2015.

Carreon said that most companies spend around two weeks completing the reimbursement submission. Impedimed spent 12 months. Carreon was previously at Medtronic, where if the company received reimbursement in two years, it was considered an outstanding achievement. The average period for smaller companies was between three to five years. Impedimed got its CPT1 Code reimbursement through within two years (Carreon started with Impedimed in July 2012).

But once companies are accepted for CPT1 reimbursement, they still need to go through the RUC (Relative Units Committee) process (for reimbursement pricing), and one of those 17 companies failed this step said Carreon. Impedimed will find out next year what its reimbursement price will be.

#### *Starting The Reimbursement Process*

When Carreon started with Impedimed, the first step was to complete a draft application. The next step was to look at the FDA approved indications and to make sure they tied up with the reimbursement application. However Impedimed had a problem there. Impedimed also had gaps in clinical data.

To help guide it through the process, Impedimed engaged an advisory board of past CPT and RUC members. Carreon said that at Medtronic he could call on around 200 people to assist with a reimbursement application. The reimbursement process started in

*Cont'd over*

*– Impedimed cont'd*

August 2012 under Carreon. However, it was going to take two years for a medical society to sponsor Impedimed's product application for reimbursement, with each society only able to sponsor two applications a year. But in March 3013, an opening occurred with the American Society of Breast Surgeons (ASBS) and Impedimed was ready with its information required to support the application for its product.

The ASBS then submitted the CPT1 application in July 2013. Approval was announced in November 2013. The application passed through the RUC pricing process in February in a closed door meeting.

Between July and October this year, Impedimed will receive the 'descriptor', which spells out details of the services to be reimbursed. This will be important. The application applied for reimbursement for the testing of lymphedema for all cancers, not just breast cancers. If reimbursement is granted for all cancers, then it triples the patient population. In November this year, the pricing of the reimbursement from the closed door RUC meeting will be published. And the new code with be effective from 1 January 2015.

Impedimed currently has a sales and support team of four people in the US. This will likely be increased to 15-30 next year, depending on whether reimbursement is for lymphedema testing in people with all cancers, or only in people with breast cancer.

Remarkably, Impedimed also got the FDA to agree to change the label for its product to a label significantly less prohibitive. Its label previously listed that the technology could be used to detect increases in extra-cellular fluid which is a precursor to lymphedema but strangely a warning that it could not be used to detect or monitor lymphedema as there were no proven clinical studies.

Impedimed showed evidence to the FDA that since 2008, more three million patients with lymphedema could have (had it) prevented. The company indicated (to the FDA) that it would conduct a clinical trial. The company then refiled its 510k application and 94 days later received the label it requested. The company has since started its clinical study.

### Analytica – Direct to Consumer (I)

Ross Mangelsdorf, executive director at Analytica said that in looking for the company's second product to develop (the first being a burette sold through very competitive commercial supply chains) the company wanted a product it could sell directly to consumers. That product is the PeriCoach device, used for the treatment of urinary incontinence in women.

The PeriCoach device has sensors on three sides. The device is inserted and measures the contraction of the two major muscles in the pelvic floor. Other devices being sold for this application do not measure the correct muscles and miss the point said Mangelsdorf. The package comprises of a smart phone app, the device, a web portal and a charging case.

When used, the device gives feedback and encouragement. Information is sent to the web portal. Through the web portal, the patient is given reminders about exercises, and a clinician can also view progress.

For the PeriCoach product, all of the orders will come through online. The stock will be held at the Analytica warehouse, with some stock also held by clinicians. The company conducted market research from consumers on the product, and found that if the GP recommended the product, the patients would likely buy the product.

While not necessary, the company will conduct (further) clinical trials to give the product credibility, particularly in US and European markets.

Analytica has decided to not use a distributor in Australia because it needs to build a clinician (physiotherapist)/GP network, and a distributor would not be able to do this for the company. The company is providing the clinicians with a PeriCoach device and a tablet that displays all of the information. The company is in the process of establishing that network now with a public campaign (to the consumers) in Australia due to commence next quarter said Mangelsdorf.

International marketing will commence in Q2 2015. The company will have a large team at a 3,000 specialist meeting in Washington this week. The company is aiming to sell the same 'one' product worldwide.

The pricing of the PeriCoach will modeled on mobile phone pricing, either an upfront of around $300 or through a subscription system.

With respect to manufacturing, Mangelsdorf said the company can scale up production very quickly because it is using third party contractors.

Responding to a question from an attendee, Mangelsdorf said the company has a product in design for males, which could be used prior to prostate cancer surgery to strengthen pelvic muscles.

### Rhinomed – Direct to Consumer (II)

CEO of Rhinomed Michael Johnson talked first about the elephant in the room, that being compliance (and acceptance and adoption), which applies to every pharmaceutical and biomedtech company on the planet. "It is the major issue that stops you from succeeding," he said.

The way Rhinomed is dealing with compliance is through sport. "Sport is a great way to introduce new technology," believes Johnson. Rhinomed is putting together a credible team in the sports field. Its Chief Medical Officer Dr Mitch Anderson, is a leading sports physician in Melbourne. He has competed in eight Hawaiian Ironman competitions, coming in 10th place in one of those events and has credibility and believes in the product said Johnson. "It's about getting authenticity from the people who actually matter."

*Cont'd over*

*– Rhinomed cont'd*

The Turbine product was launched in January this year. The company is shipping to over 20 countries and has over 17,000 subscribers to the company's database with over 3,000 people having tried the product. The existing product has now sold-out and the company is producing the next version – the Yellow Guernsey version – which is made of even softer material.

Rhinomed started selling to elite riders, with some of the riders in this year's Tour de France using the Turbine product. "The early adopter group acts as an excellent reference set for a much bigger market," said Johnson. The company has moved into the recreational cyclist market, which is a market in the tens of millions of potential users. It has also recently moved into the Health and Fitness market, with a tie-up with Fitness First, for use in spin classes. This represents a potential market of hundreds of millions of people believes Johnson.

Broader acceptance of the device is occurring, with it being used in gridiron training and recently by the Carton Football club in training by players with broken noses. As well as being used in the this year's Tour de France – by riders in teams Trek, Cannondale, Lotto Belisol and Tinkoff-Saxo – the product was also used in the Tour of California and the Giro D'Italia.

Rhinomed is selling online, and is supporting that through specialty fitness and cycling shops , which will expand said Johnson. “The great thing about selling online,” said Johnson “is that everybody pays the retail price, so you don't have to share the margin.”

Rhinomed's cycling customers also snore which represents the next market for Rhinomed. This product will dilate a different part of the nose, compared to the sports product mode of action. It will also sit closer to the tip of the nose to reduce the chances of it being dislodged during sleep. The sleep product will be launched in October/November this year. The key issue in the sleep market is compliance.

There is a huge fall off in the numbers of people who see their GP for sleep issues and are prepared to go and have a sleep study conducted said Johnson. The problem with sleep apnea is that you don't actually know the damage it is doing according to Johnson until it's almost too late.

Diagnosis is also poor, with only 5% of those with sleep apnea having been diagnosed. Johnson says the company's product will be the first up the line (for snoring first). The company will then develop a screening product to see who is at risk of sleep apnea. The company will then be able to push patients to sleep specialists said Johnson. And the key feature of the success of any new product is that you have to make money for the doctor, otherwise your technology will not get adopted.

The next application for the company's device is in the wellness market. There is the potential to include fragrances within the device, that can be used, for instance, for appetite suppression. Fragrances and essential oils can be added for the purpose of relaxation. According to Johnson, a recent study conducted (by others) showed compelling data that fragrances can reduce the anxiety levels of people undergoing (being inserted into) an MRI.

Another program the company is working on (through IDT Australia) is adding the migraine drug sumatriptin to the Rhinomed's nasal dilation system, to deliver the drug to the nasal mucosa. The appeal of this approach is that it bypasses the stomach, which is important because a side effect of migraine is nausea.

The issue with nasal sprays, is that they drip down the back of the throat, and sumatriptin has a hard metallic taste that accentuates nausea according to Johnson. Rhinomed will conduct a bioequivalence study of the drug-device combination. The Rhinomed device would be placed in the nose for 15-60 minutes and can be self-titrated by simply removing the device after a certain period. That program will start later this year or early 2015.

What is behind Rhinomed's strategy, is that the people who used the device in cycling, will also be the same potential customers in sleep, in wellness and in drug delivery products.

This week, the Turbine was also approved by the FDA as a medical device.

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**Bioshares Model Portfolio (23 July 2014)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| LBT Innovations | $0.130 | $0.130 | Jul 14 |
| pSivida | $4.550 | $3.800 | May 14 |
| Invion | $0.063 | $0.089 | February 14 |
| Impedimed | $0.270 | $0.245 | December 13 |
| Analytica | $0.036 | $0.025 | December 13 |
| Imugene | $0.014 | $0.022 | November 13 |
| Oncosil Medical | $0.120 | $0.155 | September 13 |
| IDT Australia | $0.265 | $0.260 | August 13 |
| Viralytics | $0.270 | $0.300 | August 13 |
| Tissue Therapies | $0.270 | $0.255 | March 2013 |
| Somnomed | $1.84 | $0.94 | January 2011 |
| Cogstate | $0.250 | $0.13 | November 2007 |

## *Portfolio Changes – 23 July 2014*

**IN:**

No changes

**OUT:**

No changes

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

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| | $1090 | 6-10 email addresses |

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