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In this edition...
Bell Potter's annual Life Sciences Conference was held this week, with several presenting companies reinforcing key points on strategy and market developments. Mesoblast emphasised the expanding number of therapeutic opportunities available for its stem cell therapy. QRxPharma cautioned investors against just looking for a binary decision from the FDA for its MoxDuo IR application in June. Starpharma spelt out the benefits of an SPA granted by the FDA for Vivagel. Phosphagenics is ensuring its oxycodone pain patch is ready for a Phase III trial in 2013. Tissue Therapies is keenly waiting for the European approval of VitroGro.
The Editors
Companies Covered: Bell Potter Life Sciences Conference (BNO, SPL, MSB, POH, QRX, GID, RVA, TIS), GTG, PRR

	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 - current)	-6.9%
Cumulative Gain	**221%**
Av. annual gain (11 yrs)	**17.8%**

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

Report – The 2012 Bell Potter Life Sciences Conference

Bell Potter Securities held its annual Life Sciences Conference this week. The broker has become the most active investment bank in the sector. Its Managing Director, Alastair Provan, said his firm has raised over $400 million in the last two years delivering investors a gain of 30% on their investment. Bell Potter has over 300 retail advisors across Australia with around $20 billion in funds under advice.

One of the traditional exit paths for venture capital funds' mid-to-late stage biotech companies has been to list in the US. However with that path largely closed, the ASX is now actively targeting US VCs to consider having their investee companies list on the ASX, according to ASX General Manager of Equity Markets, Richard Murphy.

The ASX listed life science companies that presented included Mesoblast, Reva Medical, GI Dynamics, Starpharma Holdings, QRxPharma, Bionomics, Phosphagenics and Tissue Therapies. We provide the following summaries of the key points made by the CEOs of these companies.

Mesoblast – An Expanding Therapeutic Universe

Mesoblast CEO, Silviu Itescu, said its partner, Teva Pharmaceutical Industries, is currently the world's largest generics company but wants to become one of the top six global pharmaceutical firms. He believes this is one of the reasons the Mesoblast technology is an important part of that strategy.

The recent approval by Canadian regulators of a stem step product from Osiris was a positive step for the stem cell industry, with the approval evidence that regulators know how to regulate this emerging class of therapeutics said Itescu.

Mesoblast has delivered its stem cell therapy into 150 people with no safety issues. According to Itescu, another major advantage of this technology is that safety can be confirmed in one Phase III trial, and from there, the company can leverage this common safety aspect of the therapy into many other potential indications. For new indications, it can move straight into Phase II studies.

The company has now commenced enrolling patients in its Phase II Type 2 diabetes trial using an intravenous dose. The company intends to expand into other treatment areas including rheumatoid arthritis, where the patient could potentially be put into remission by simultaneously shutting down all over-active immune pathways.

Mesoblast is targeting blockbuster markets, including diabetes, disc repair and heart failure. In congestive heart failure, there are 670,000 new patients each year in the US alone, adding to the existing 6.2 million pool of patients. Mesoblast will target the more at-risk population, where ejection fraction is less that 40%, which should allow it to command a higher reimbursement price.

Intervertebral disc repair is expected to become the lead application in the orthopedics area, which Itescu said could be a blockbuster product. He said the company can do the Phase III study on its own, with no urgency to partner, although it will need a distributor.

Mesoblast is capitalised at $1.9 billion.

GI Dynamics – Implanted Device for Obesity & Type 2 Diabetes Management

GI Dynamics is a US medical device company that listed on the ASX last year raising $80 million.

GI Dynamics is commercialising the EndoBarrier system, which is a plastic sleeve that is inserted into the first 60 cm of the duodenum past the stomach. The bypassing of section of the duodenum triggers a reaction in hormones that over 12 months have been shown stimulate weight reduction by 20%, reduce HbA1c levels by 2.2% (which is very meaningful) and to also help sustain the control of glucose. The therapy is initially being targeted for people with both Type 2 diabetes and obesity.

The product is currently on the market in Europe (UK, Netherlands, Germany and Austria) and in Chile. The company had $62 million in cash at the end of March and will commence a major clinical study in the US late this year.

The device sells for €3,350. To date 14 centres of excellence have been established. The company has treated 600 patients to date. It is training surgeons now and educating clinicians about the technology. The company has 10 people based in Europe.

The company is building the case for reimbursement, gaining local reimbursement first (there are hospitals in the UK reimbursing the product and one payor in the Netherlands). A ramp up in sales is not anticipated until the company gains national reimbursement in a number of countries.

CEO Stuart Randle said that retention rates were around 80% in the trials because if the device moved it had to be removed. In practice the retention rate is around 90%, with some patients experiencing discomfort for the first two weeks.

The EndoBarrier is approved only as a 12 month implant. The benefits of the therapy have been observed for at least six months after the device is removed.

GI Dynamics is capitalised at $252 million.

Reva Medical – Bioresorbable Stent Developer

Reva Medical CEO Bob Stockman said he believes that his company and **Abbott Laboratories** are the two front runners in the filed of bioresorbable coronary stents. According to Stockman, the market is worth $4.6 billion in annual terms. He said the company has the best resorbable stent of those in the market and in development.

Stockman said that what makes the Reva drug eluting stent better than any others is that it can be imaged using an x-ray (others can't) and its (mechanical) strength. The Reva stent also has a greater expansion range than the Abbott stent.

Bioresorbable stents restore the natural movement of the artery by reducing regrowth, potentially reducing blood clots associated with permanent stents and potentially reducing the need for anticoagulants.

Abbott commenced sales of its stent in Europe at the end of last year, with the device having been tested in around 1,000 people. The device is being sold for around €4,500, about six times the price of existing stents.

By contrast, Reva is considerably behind. It started its pilot clinical study in December last year and has enrolled 18 patients. There have been no adverse events in the first cohort. This trial is expected to enrol between 25-50 patients and will finish at the end of June.

Reva plans to enroll 200 patients across 30 sites in its pivotal study using its next generation stent, called ReZolve2, which is thinner and stronger. This is the device the company intends to bring to market. The company is aiming to get CE Mark approval in Europe by mid 2014. A US trial will require up to 2,000 patients and is planned to start in 2014.

Once Reva has completed 200 implants, **Boston Scientific** has the first right of refusal to license the product. If Boston Scientific takes up that option, Reva would be entitled to receive 50% of sales. Otherwise Reva can license it to another group.

In March this year there was a $24 million sell down by some existing shareholders including **Domain Partners** and **Saints Capital**. Boston Scientific was previously a shareholder however it sold out its holdings in 54 private companies to raise funds.

Reva is capitalised at $232 million. It had cash assets of US$58.8 million at the end of March.

Phosphagenics – Oxycodone Patch Headed for Phase III Trial in 2013

Phosphagenics is the first group to put the oxycodone pain drug into a transdermal patch format. It has successfully completed a Phase I trial. Its Phase III trial is due to commence in the first quarter of 2013. It will run for 12 weeks with results expected at the end of 2013.

The company is conducting physician surveys, competitive analysis, branding strategy, reimbursement strategy and economic modelling.

The company has developed the patch in conjunction with **3M Drug Delivery Systems**. The company expects to complete patch development and testing this year. Abuse resistance safeguards have been incorporated into the patch, such that 18 chemical steps would be required to extract the oxycodone from the patch.

The human skin also acts as a natural barrier to substance abuse. CEO Esra Ogru said that regardless of how many patches a person

places on their body, the reservoirs in the skin prevent the rapid euphoric effects from occurring.

Delivery of oxycodone via the skin also removes the gastrointestinal side effects of oxycodone which include constipation, headaches and dizziness.

The company intends to license the oxycodone program during or at the end of Phase III studies. The market for oral oxycodone drugs, for chronic pain management, is currently valued at $3.5 billion.

Starpharma – SPA Award Mitigates Risk for Vivagel

Starpharma CEO Jackie Fairley said Starpharma had secured the ultimate in risk management by negotiating a Special Protocol Assessment with the FDA for the company's Vivagel therapeutic for the treatment of bacterial vaginosis.

The SPA was received in just 45 days. The SPA also delivers a far higher degree of certainty for any potential partner. Fairley said the company will seek to license the product.

Current Phase III trials underway are expected to be completed at the end of this year. Royalties from sales of between 20%-30% can be expected if the product gets to market and is then licensed. The existing market for the treatment of bacterial vaginosis is over $300 million and for prevention the market is estimated at being worth over $1 billion a year.

The agreement reached with the FDA was that the current Phase III trials can follow the treatment regimens from the Phase II trials. Of interest is that the trial will be comparing Vivagel against a placebo and not the current standard of care which involves antibiotic treatment.

Vivagel has shown to be as effective as antibiotic use, but without the toxicity associated with the antibiotics. Vivagel is not absorbed into the bloodstream because it is such a large compound.

Starpharma is working on many other applications of its dendrimer chemistry platform. Fairley expects a number of deals to come into to public domain in coming months. Its chemistry scaffold has been shown to increase the solubility of the cancer drug taxotere by up to 8,000 fold. The annual market for this drug is $3 billion a year. Normally detergents are added to the drug to make it soluble. However this triggers allergic reactions and patients are required to take corticosteroids to dampen the side effects.

Incorporating its chemistry in existing drugs could extend patent life for pharmaceutical companies. The company has shown it can conjugate the dendrimer to insulin achieving prolonged suppression of glucose in an animal model. The concept is that insulin may only need to be taken once a day or even less frequently if it has a longer duration in the bloodstream.

In the agrochemicals industry, the amount of liquid that needs to be transported could be reduced by 70% due to the solvents required to make the active chemicals soluble. These solvents are also often flammable. These solvents could potentially be removed by changing the chemical properties using Starpharma's chemistry scaffold.

One of the drivers in the company's share price has been the buying from overseas funds. **M&G Investments** in the UK last year increased its stake in Starpharma to 6.7%, owning also just over 10% of Mesoblast and 19% of Ansell.

QRxPharma – FDA Decision for MoxDuo IR Expected in June

There are not many new drugs that are approved each year. There are around 100 listed Australian biotechs and between 800-1,000 in the US but last year only 35 new drugs were approved by the FDA. QRxPharma is hoping to be one of those companies next month when the FDA gives a decision on its new pain combination therapeutic, MoxDuo IR. A decision is expected around 25 June, give or take a week.

QRxPharma's partner **Actavis Group** is expected to start selling four different doses of the drug in the third quarter of this year (3mg/2mg, 6mg/4mg, 9mg/6mg and 12mg/8mg combinations of morphine and oxycodone). It has a sales force of 120 people ready to begin product sales.

Watson Pharmaceuticals has made a bid for Actavis, which will, if successful, make it the third largest generics business in the world. That acquisition will not be completed until the fourth quarter of this year, by which stage MoxDuo IR will be well into its launch.

In the US, if Actavis can achieve a 2.5% market share, that would translate to $680 million in sales. However there is also a larger market opportunity if the combination use of other pain drugs with paracetamol (e.g. Percocet = oxycodone + paracetamol) is restricted to less than 325mg of paracetamol and if the pain drug Vicodin (hydrocodone + paracetamol) becomes a Schedule II drug (tighter prescription procedures), the same as other oxycodone products, reducing that drug's competitive advantage considerably.

CEO John Holaday said the FDA decision will not be a binary decision. The FDA may or may not have some other items for QRxPharma to address. However the dialogue with the FDA has been very positive and site inspections have gone well.

In the second half of this year the company will start a Phase II trial with an controlled release version of MoxDuo (CR). In the first quarter of next year, MoxDuo IR will be filed for approval in Australia, Canada and Europe.

Holaday said the company has a strong IP position around its technology, with patent terms running until 2029.

Bionomics – Commences Phasel/II Ovarian Cancer Trial for BNC105

Bionomics has now started another study with its lead cancer drug BNC105. The company will enroll up to 134 women with ovarian cancer to see how effective its vascular disrupting agent (VDA) is in treating this very late presenting disease. The trial will be conducted in Australia, New Zealand and the US.

Bionomics' VDA works by destroying the blood vessels from inside the tumours. The trial will combine BNC105 with two existing chemotherapy drugs carboplatin and gemcitabine. CEO Deborah Rathjen said the company's drug candidate was shown to work very well in combination with these drugs in preclinical studies.

In a preclinical lung cancer model, the drug produced stunning results said Rathjen, with all animals surviving.

This Phase I/II trial is expected to be fully enrolled by the end of the year. Rathjen said BNC105 is the most significant program in the company's pipeline. Bionomics is also conducting a Phase II study with BNC105 in renal cancer (with results expected in early 2013).

The company is aiming for multiple revenue streams in the future from the drugs it is developing.

The company's second program, IW-2143, for the treatment of depression and anxiety, has been partnered with **Ironwood Pharmaceuticals**. "Ironwood has not lost a beat", said Rathjen, in developing this compound, forcefully driving the program forward since it partnered with Ironwood in January this year. Ironwood already has more people working on the program than Bionomics employs said Rathjen.

Ironwood has a pipeline that needs this program stated Rathjen. One of the reasons Bionomics partnered with Ironwood is because Ironwood clearly spelt out how it would develop the drug, and that it would get top priority (after its lead program, linaclotide).

Ironwood has an IND meeting scheduled with the FDA in a few weeks and it is currently studying how a Phase IIb trial could be structured.

Bionomics strategy is to target blockbuster markets. Its latest program, alpha 7 nicotinic acetylcholine receptor, is developing a potential treatment for Alzheimer's disease, schizophrenia and ADHD. Rathjen said this drug candidate, if successful, could potentially be given to every person over the age of 60 (to maintain healthy cognitive function).

Bionomics is set to receive US$14 million in funding from Ironwood by January 2014. The company has $18 million in the bank and has no need for fresh capital.

Tissue Therapies – When Plan B Becomes Plan A

Tissues Therapies VitroGro wound healing product is treated as a device by regulators because it temporarily replaces part of the normal skin extracellular matrix. Anything that temporarily or permanently replaces a body structure is deemed to be a device.

VitroGro consists of four proteins that occur naturally in the skin. These are vitrronectin, fibronectin, collagen III and insoluble phase growth factors. Tissue Therapies has combined these all on the one protein that is made by recombinant engineering. Tissue Therapies CEO Mercer said the regulators like recombinant proteins because they are not derived from animals.

This year the company is looking to sell thousands of dollars of product and move into the tens of millions in 2013. Mercer said the company had 370,000 vials of its product ready to ship in Europe.

Mercer said the company's Plan A had been to partner with a major group to sell VitroGro. Plan B was to used third parties to manufacture, distribute and sell, where Tissue Therapies would coordinate the whole process. Plan B became Plan A because after modeling the commercialisation, it did not make sense to license the product.

The company has to some degree de-risked its launch by maintaining control of commercialisation. Deals can sometimes go wrong, which is certainly a valid point.

Tissue Therapies has spent the last year working on reimbursement. It will take three to six months to get reimbursement in the various countries in Europe. From next month the company will also establish and maintain a patient registry.

Mercer said diabetic and venous ulcers, which VitroGro can treat, become significant morbidity issues. About 80% of non-trauma related amputations are due to diabetes. It becomes a vicious cycle for patients where chronic wounds become painful and start to smell, forcing the patient to stay at home and not be active, only compounding the problem. The three-year survival after amputation for a non-healing diabetic ulcer is only 50%.

In the company's most significant trial in 44 patients, in patients with venous ulcers that had not healed for three years, 43% achieved 90%-100% healing using VitroGro! Only 18% showed no improvement.

Venous and diabetic ulcers are a very large market, valued at US$14 billion a year and growing at 15% a year, with the USA making up 3% of that market. The incidence of diabetes in some countries is now at 25%.

Tissue Therapies is waiting for approval in the next month in Europe, at which point it will start to sell the drug into Germany, the UK, Austria, Netherlands, Switzerland and Northern Italy.

In the third quarter of this year it will start a randomised, double blind venous leg ulcer trial in the US, which is expected to take two years to complete. Depending on revenue from VitroGro in Europe, the company plans to then also start a two year US trial in diabetic foot ulcers, also randomised and double blinded.

Bioshares recommendations: -
Mesoblast (Cap'n - $1.9 B) : Speculative Buy Class A
GI Dynamics (Cap'n - $252 M) : Speculative Hold Class B
Reva Medical (Cap'n - $232 M): Sell (high market cap relative to state of progress)
Phosphagenics (Cap'n - $179 M) : Speculative Hold Class A
Starpharma (Cap'n - $448 M) : Speculative Hold Class A
Bionomics (Cap'n - $112 M) : Speculative Buy Class A
QRxPharma (Cap'n - $260 M) : Speculative Buy Class A
Tissue Therapies (Cap'n - $82 M) : Speculative Buy Class A

Bioshares Model Portfolio (25 May 2012)

Company	Price (current)	Price added to portfolio	Date added
Osprey Medical	$0.40	$0.40	April 2012
QRxPharma	$1.80	$1.66	October 2011
Mayne Pharma Group	$0.310	$0.435	September 2011
Somnomed	$0.82	$0.94	January 2011
Phylogica	$0.045	$0.053	September 2010
Biota Holdings	$0.78	$1.09	May 2010
Tissue Therapies	$0.51	$0.21	January 2010
Atcor Medical	$0.07	$0.10	October 2008
Bionomics	$0.31	$0.42	December 2007
Cogstate	$0.295	$0.13	November 2007
Sirtex Medical	$5.96	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.85	$6.60	September 2007
Pharmaxis	$1.02	$3.15	August 2007
Universal Biosensors	$0.60	$1.23	June 2007
Alchemia	$0.435	$0.67	May 2004

Portfolio Changes – 25 May 2012

IN:
No changes

OUT:
No changes

Genetic Technologies' Price Surge

Genetic Technologies (GTG: $0.17) share price surged 129% this week (from 8.3 cents to a high of 19 cents) due to a combination of company related announcements and unsolicited press coverage in the US.

The company announced it had executed four credentialing contracts which allow for the expedited adjudication of (reimbursement) claims for its Brevagen breast cancer risk assessment tool. The four preferred provider organisations (PPO) who signed the contracts represent an aggregate of 13 million covered lives.

Genetic Technologies also announced that year-to-date average monthly unit sales for April were up 48% on a comparable basis. The company was mentioned in a CNBC news segment and was mentioned on the TV show 'Good Morning Texas'.

Genetic Technologies is capitalised at $79 million.

Bioshares recommendation: **Speculative Hold Class A**

Prima Biomed CEO to Step Down

Prima Biomed's CEO has decided to step down as CEO at the end of August. He will be replaced by Matt Lehman, who is currently the company's Chief Operating Officer. Although Lehman is very experienced in clinical trial management, he will need to build his capital markets expertise.

Rogers has done an excellent job to bring what was a sidelined program to a stage where it is being investigated in a 1000 patient, global ovarian cancer trial. The trial is scheduled to be completed in March 2015. After four and a half years at the helm, Rogers decided it was the right time to hand the reigns to a person with skills that reflects the company's current clinical focus.

Prima has cash to support the company's activities until 2014.

Prima Biomed is capitalised at $155 million.

Bioshares recommendation: **Speculative Hold Class B**

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada, Bioniche

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