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In this edition...
A high level investment conference, ALSIS 2010, brought together local and international investors in Melbourne this week, with 35 Australian and New Zealand life science firms presenting the essentials of their businesses to an attentive audience. All round, it was an interesting and worthwhile event for those who attended. We provide a comprehensive coverage of the event.

ChemGenex Pharmaceuticals, in fact a last minute withdrawal from ALSIS 2010, announced a financing deal with the now well known second tier US pharmaceutical firm Cephalon. The convertible note financing potentially sets up Cephalon to acquire ChemGenex, if it so desires.

The Editors
Companies Covered: ALSIS 2010, CXS

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	5.7%
Cumulative Gain	**206%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

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

Cephalon Sets Up For Chemgenex Acquisition

Cephalon is positioning itself for a potential and likely acquisition of Chemgenex Pharmaceuticals in 2011. Cephalon will provide Chemgenex with a convertible note financing of $15 million, which if it converts will give it a 9.6% stake in the company. The company has also entered into an option agreement with two of Chemgenex's substantial shareholders, to acquire an additional 19.9% stake in Chemgenex.

For Chemgenex, delays in commercializing its product as a result of having to re-file its NDA with the FDA, has caused a funding issue for the company. Stakeholders have likely been reticent in providing further funding. The aim was that licensing of European rights would help fund the product rollout in the US. However, Chemgenex has been spending around $24 million a year and at June 30 had only $12.8 in funds remaining, or on estimates, around three months cash now.

The funding by Cephalon and the potential acquisition next year is a logical and welcome outcome. As seen with **Peplin**, a blowout in planned Phase III costs – Peplin was required by the FDA to double the number of Phase III trials with two Phase III head and neck trials and two Phase III rest of the body trials rather than just one for each – can place companies in vulnerable positions when the biggest cheques need to be written at the final phase of commercialization. Arguably the moving of the goal posts by the FDA has contributed in the delay in commercialization of Chemgenex's lead drug candidate, Omapro, for the treatment of chronic myeloid leukemia.

Cephalon can convert the notes into shares at 50 cents a share. There will be no interest on the note if certain performance milestones are met, namely if patient data collection and analysis from patients in the two pivotal studies, is completed by the end of March next year.

The option to buy 19.9% of the company from **Stragen** and **Merck Sante** is set for a selling price of 70 cents a share. Cephalon will need to exercise this option before 31 March next year or before the data collection and analysis is completed. Chemgenex will resubmit its NDA to the FDA after this data is collected and assessed in 2011.

If Cephalon increases its stake above 19.9%, it will be required to launch a bid for the remaining shares in Chemgenex. Presumably this offer price will be the same as the acquisition price from Stragen and Merck Sante of 70 cents a share. This will equate to a capitalisation of $219 million.

Since the time of the acquisition of the oncology assets from US company **Chemgenex Therapeutics** in 2004, Chemgenex Pharmaceuticals has expended ~ $87 million (including current allocated cash) in commercializing its assets. If the company is acquired for 70 cents a share next year, it represents a successful outcome, although not the stunning outcome many investors were anticipating.

Bioshares recommendation: **Speculative Buy Class A**

The Australian Life Science Investment Summit 2010

The Australian Life Science Investment Summit was held in Melbourne on October 19, 2010. The event brought together 35 Australian and New Zealand life science firms, both public and private, with local and international investors. Company representatives each had a six minute time slot to provide a snapshot view of their company. We provide summaries of those presentations.

ASX Listed Company Presenters

Acrux – Axiron Milestone Payments Total up to US$355 million

Acrux, founded in 1998, is a transdermal drug delivery company that has three products at the registration stage of development and one on the market. Acrux signed a deal with **Eli Lilly** in March 2010, licensing Axiron, a testosterone therapy for men, delivered under the arm from a 'roll-on' dispenser.

On gaining FDA approval, Acrux is entitled to an US$87 million milestone payment from Eli Lilly, followed by another US$195 million with respect to further commercial milestones. It has already received $1 million (of $3 million) from the transfer of manufacturing and $50 million as an upfront payment.

A point to note about the Acrux-Eli Lilly partnership was that Acrux was attracted to the strong leadership position Lilly had established in men's health, courtesy of its sales of the erectile dysfunction drug Cialis. Cialis sales at US$1.6 billion now rival Pfizer's Viagra, even though Cialis entered the market in either second or third place (depending on territory). "Axiron will drop straight into the Cialis machine," said CFO Jon Pilcher.

The small market outside of the US the product a great market potential in those regions as well. It's currently a $1.2 billion global market growing at 20% a year due to an aging population and growing awareness of low testosterone.

Alchemia – FDA Decision Expected Soon

Alchemia was founded in 1995 and listed on the ASX in 2003. The company's lead asset is generic fondaparinux, a once daily anticoagulant used to prevent deep vein thrombosis. An ANDA was accepted for priority review by the FDA in May 2009, with approval anticipated to occur shortly. Fondaparinux is off-patent in the US, however EU exclusivity expires in 2012.

US sales of Arixtra, GSK's branded fondaparinux were $220 million in 2009, an increase of 34% from the previous year. Alchemia has a higher yielding, lower cost manufacturing process. A third player has indicated they can also manufacture the drug although it's unknown what scale they are at, according to CEO Peter Smith.

The FDA has scheduled a review of the third party facility that will 'fill and finish' fondaparinux for November, perhaps suggesting that an authorisation action will be not too far off. Smith says they are not expecting any more questions from the FDA.

Alchemia will receive up to 60% from a profit share arrangement in the US with its partner Dr Reddy's and a royalty from sales outside of the US.

AtCor Medical – Superior Measurement of Central Blood Pressure

Atcor Medical has developed what it argues is the gold standard in the non-invasive measurement of central blood pressure. The company generated sales of $9.2 million in FY2010 from an installed base of 2,100 systems. Gross margins are in the order of 90%.

Central blood pressure management is greater than 50% better than brachial (cuff) measurement in predicting cardiovascular events. This superior performance should translate into significant economic benefits such as reduced hospital admissions.

The company has established itself in the research and pharmaceuticals market and has begun to access the clinical specialists market. An objective is to sell the product to primary care physicians, a market four times the size of the research market.

Atcor expects to return to double digit growth this financial year. Between 2006-2010 the company generated a compound annual growth rate in sales of 23%. There are now over 2100 installed systems. The company currently has 32 employees.

Benitec – DNA -directed RNAi Therapeutics (ddRNAi)

Benitec holds a strong position in the field of RNAi, covering the area of small interfering RNA that is delivered into cells using DNA constructs, and is applicable to offering long-term gene knock-down (or silencing). This is contrast to siRNA that is synthetic and delivers short term down regulation of genes

One ddRNAi construct has completed a Phase I trial in HIV patients. A trial in collaboration with the UNSW in lung cancer is planned, targeting beta-III tubulin. An emerging opportunity exists in the acute pain indication, for terminally ill patients requiring pain relief. Another program in the area of hepatitis B is partnered with **Biomics** in China.

CEO Peter French said the recent patent win in the US has re-established Benitec as a major player in this space. There four key patents in this filed in the world and Benitec owns one of those French said this technology can cure disease associated with gene up-regulation.

BioDiem – Commercialising a Live Flu Vaccine

Biodiem is commercialising a live attenuated influenza vaccine (LAIV) and a peptide to treat retinal disease. The LAIV product is delivered intra-nasally and can be manufactured in both egg and cell-based systems. The LAIV can induce three types of immune response – mucosal, systemic and cell-mediated. More than 100 million doses of the vaccine (egg-based manufacture) have been administered in Russia, demonstrating safety and efficacy.

A pandemic (H1N1) vaccine (egg-based manufacture) was launched in India in July 2010, through a sub-license to the World Health Organisation.

A Phase II trial of the cell-based manufactured vaccine has been completed. The LAIV has been licensed to **Nobilon/Merck** (who

At a Glance – ALSIS 2010 Presenting Companies

	ASX Listed Presenters		Cap ($M)	Share price	Cash (latest) ($M)	Sales - Year - latest - ($M)	Platform Technology	Services	Diagnostic/Detection	Device Developer	Therapeutic Developer	Biologic	Small Molecule	Cell/Tissue Therapy	Vaccine/Immunotherapy	Manufacturing	Drug Delivery	Recommendation
1	Acrux	ACR	**$434**	$2.66	**$59**	$55					●		●				●	Speculative Buy Class A
2	Alchemia	ACL	**$102**	$0.54	**$15**	$0					●		●					Speculative Buy Class A
3	AtCor Medical	ACG	**$11**	$0.11	**$2**	$9		●	●									Speculative Hold Class A
4	Benitec	BLT	**$17**	$0.04	**$1**	$0					●							Speculative Buy Class B
5	BioDiem	BDM	**$14**	$0.14	**$4**	$0									●			Under Review
6	Bionomics	BNO	**$91**	$0.29	**$13**	$2					●		●					Speculative Buy Class A
7	Biota	BTA	**$166**	$0.93	**$105**	$65					●		●					Speculative Buy Class A
8	Biotron	BIT	**$11**	$0.09	**$2**	$0					●		●					Speculative Buy Class B
9	Circadian Technologies	CIR	**$28**	$0.60	**$32**	$1			●		●	●						Speculative Buy Class A
10	CogState	CGS	**$17**	$0.25	**$3**	$10		●	●									Speculative Hold Class A
11	Genetic Technologies	GTG	**$11**	$0.03	**$3**	$11		●	●									Speculative Hold Class B
12	Living Cell Technologies	LCT	**$47**	$0.17	**$3**	$0					●					●		Speculative Hold Class B
13	Mesoblast	MSB	**$582**	$2.31	**$32**	$0					●			●				Speculative Hold Class A
14	Nanosonics	NAN	**$210**	$0.93	**$21**	$1	●			●						●		Speculative Hold Class A
15	Patrys	PAB	**$15**	$0.08	**$7**	$0					●	●						Speculative Buy Class B
16	Phosphagenics	POH	**$81**	$0.11	**$8**	$5					●						●	Speculative Buy Class B
17	Phylogica	PYC	**$11**	$0.05	**$1**	$0	●	●										Speculative Buy Class B
18	Progen Pharmaceuticals	PGL	**$19**	$0.31	**$15**	$2					●							Under Review
19	pSivida	PSD	**$105**	$5.66	**$17**	$0					●						●	Under Review
20	QRxPharma	QRX	**$91**	$0.89	**$13**	$0					●							Speculative Buy Class A
21	Starpharma	SPL	**$153**	$0.64	**$23**	$1	●		●		●						●	Speculative Buy Class A
22	Sunshine Heart	SHC	**$15**	$0.03	**$2**	$0				●								Speculative Buy Class B
23	Tissue Therapies	TIS	**$55**	$0.40	**$4**	$0			●		●	●						Speculative Hold Class B

	Private Presenters		Funding sought ($M)	Funds raised ($M)	Cash (latest) ($M)														
1	Applied Physiology									●									
2	Cystemix		$1.8	$7.6	$0.87						●		●						
3	Dimerix			$1.4			●	●			●		●						
4	Echidna Surgical Solutions									●									
5	Gamma Vaccines		$9.0												●				
6	Hunter Immunology		$10.0	$5.0	$3.20						●				●				
7	Innate Therapeutics		USD$10	NZD$50							●	●			●				
8	Vaxxas										●				●		●		
9	Neural Diagnostics		$6-$8						●										
10	Percutaneous Cardio. Solutions		$3.0	$0.5						●									
11	Photonz		NZD$6.3	NZD$5.6												●			
12	Velacor Therapeutics		$1.0	$2.9	$0.11						●		●					Add. $2.5 million funds u/w	

developed the cell based manufacturing capability), with the exception of Japan, North America and Russia and the CIS. Partners are being sought for the US and Japan.

Merck is closing down the Nobilon Boxmer facility, which puts Biodiem's LAIV project in some doubt.

Bionomics – BNC105 in Two Phase II Trials

Bionomics is developing BNC105 to treat cancer, with a Phase II trial (in conjunction with Afinitor) underway in renal cancer patients and another Phase II underway in patients with mesothelioma. BNC105 is a vascular disruption agent.

Another drug candidate, BNC210 is being evaluated in Phase I trial to treat symptoms of anxiety and depression. In a Phase I trial completed, reduced levels of cortisol where recorded in patients taking BNC210, which is a function of lower anxiety.

The renal cancer trial is enrolling 152 patients in the US, with interim data expected in Q1 2011. The mesothelioma trial is enrolling 60 patients in Australia with interim data expected in H1 2011. Both kidney cancer drugs on the market are currently generating sales of close to $1 billion a year. Alimta, used to treat mesothelioma generated sales last year of $1.7 billion.

One of the other believed advantages of BNC105 is that it enhances the effects of chemo or radiation therapy.

Biota – Guidance on Inavir Sales

Biota provided guidance on expected Inavir sales in Japan. **Daiichi Sankyo** is targeting to sell 2.5 million courses by 31 December ($125 million at $50 per course) and 10 million courses ($500 million) in the second year. Patent protection goes out to 2027. Bioshares estimate is that Biota receives around a 4% royalty rate. In *Bioshares* view, interest in rest-of world rights to this drug will be significantly greater if this compounds gains early traction in Japan. We expect management will hold off transacting rest-of-world rights until that occurs. The flu season peaks in Japan in February. Biota is anticipating Inavir royalties this financial year.

Patent protection on Relenza goes out 2014 in the rest of the world and out to 2019 in Japan. The patent around the Relenza inhaler goes out to 2027.

Biotron – Conducting a Phase II Trial of BIT225 in HCV Patients

Biotron is developing BIT225, a small molecule drug that targets the p7 protein which has a critical roles in the production of HCV virus in infected cells. The company has completed a Phase I program, finding that the drug candidate was well tolerated up to 600mg with no dose limiting toxicities. The Phase Ib trial showed that the drug candidate significantly reduced viral levels in three of the six patients.

A Phase IIa trial is underway in 24 subjects positive for the HCV Genotype 1. Patients are administered standard of care (interferon and ribavarin) and either 200mg or 400 mg or placebo twice daily for 28 days. Results are due by the end of 2010.

The market potential for BIT225 rests with a large patient pool globally of 170 million infected persons, coupled to trend towards combining drugs for therapy where different mechanisms of action that can address the problems of mutation and drug resistance. The global market for HCV is $2.7 billion and is expected to grow to more than $10 billion according to CEO Michelle Miller.

Earlier this year the company raised $2.7 million. The company has a strong patent position according to Miller with five patent families filed.

Circadian Technologies – Developing Diagnostics and Anti-Angiogenesis Antibodies

Circadian Technologies is developing antibodies that target VEGF-C and the VEGFR-3 receptor in the areas of cancer and eye disease.

The targets are involved in blood vessel formation and by inhibiting the targets, tumour blood supply can be cut off.

VGX-100, a VEGF-C antibody is at the pre-clinical stage of development as are antibodies developed under license to Imclone Systems. Circadian expects to file an IND for VGX-100 in H1 2011 and commence a Phase I trial in H2 2011.

Circadian is also developing diagnostics, with its Cancers of Unknown Primaries diagnostic, licensed to **Healthscope**, in late stage clinical validation, with a market launch expected in Q1 2011. CEO Robert Klupacs told investors to 'watch this space' over the next two to six months.

CogState – A Profitable Cognition Testing Company

Cogstate is a profitable company that was founded in 1999 and now employs 42 people. Sales for FY2010 were approximately $10 million.

The company's core business is the provision of cognition testing to pharmaceutical companies running clinical trials. Its second area business is that of sports testing by providing a quick and efficient web-based tool for managers and doctors to assess the cognitive function of players following concussion.

The company launched a joint venture, **Axon Sports**, with Quixote Investment LLC in August 2010 to access the US sports market. Cogstate estimates the US market is worth between US$150-US$175 million pa.

According to CSO Paul Maruff, a hysteria is spreading through the USA from concussion in contact sports.

Genetic Technologies – To Launch the Brevagen Non-familial Breast Cancer Test

Genetic Technologies has continued to develop its cancer diagnostics and genetic testing focus with the planned launch (in the US) of a first-in-class risk test for non-familial (sporadic) breast cancer, Brevagen. The test combines a population risk score with seven genetic risk factors. The test has been validated in over 16,000 patients.

The market driver for the test is that of 1.6 million breast biopsies conducted each year in the US, 1 million deliver an indeterminate outcome. Brevagen offers sufficient improvement to reclassify about 25% more accurately so that preventative treatment can be commenced. Such treatment (e.g. Tamoxifen) can be effective in 50% of all potential breast cancer cases.

The company has three core businesses: genetic testing for groups such as the Department of Immigration, Legal Aid and the police; licensing revenue from its gene patents; and a global diagnostic business. In that last business, the company sells in-licensed genetic test in the Asia pacific region from TrimGen, Rosetta Genetics and Response Genetics. It is also about to launch its proprietary Brevagen test in the US.

CEO Paul Macleman said the company expected to have more positive cash flows than not going forward.

Living Cell Technologies – Moving Towards a Pivotal 50 Patient Study Data Set.

Living Cell Technologies (LCT) is developing encapsulated porcine cells for the treatment of Type 1 diabetes, using islet cells and neurodegenerative diseases such as Parkinson's and Huntington's diseases, stroke and hearing loss using choroid plexus cells.

The company has completed a Phase I/IIa in Russia and is conducting a Phase II trial in 12 patients in New Zealand. All up the company will aim to expand its data set to 50 patients by 2012, sourcing patients in other countries.

A benefit from Living Cell Technologies' encapsulation technology is that immune-suppression is not required, as is the case with various other cell transplant products.

From a safety perspective, the company has found from cell implants to date, that no significant adverse events have been observed and that no evidence can be found of animal to human infections.

The company says it needs 50 patients in its pivotal study gain approval. The company is targeting a global launch in 2014 to generate revenue of $50-$60 million a year, increasing to $80 million a year from 500 patients in 2015.

Mesoblast – Three Advanced Cell Therapy Products

Mesoblast is a regenerative medicine company which listed on the ASX in 2004. The company is developing therapies from a class of adult stem cells known as mesenchymal precursor cells. The company has six products in clinical development, led by a bone marrow transplantation (BMT) product, a congestive heart failure treatment and a spinal fusion treatment.

With the BMT product, the Mesoblast technology is used to expand cells obtained from cord blood. In its latest trial, 80% of patients transplanted achieved 100 day survival with sustained engraftment compared to a 38% rate of 100% engraftment obtained from analysis of a registry database. The product has the potential to reduce Graft-Versus-Host Disease. A Phase III trial will commence in 2011 under an orphan drug designation. A BMT product could be launched in 2014. A product for the treatment of heart disease could be launched in 2015/2016 and a product for spinal fusion also in 2015/2016.

The company expects to commence Phase III trial of its Congestive Heart Failure product Revescor and spinal fusion product NeoFuse in 2012. The competing product on the market Infuse is restricted to use in a subset of fusion operations in the spine. To date there have been no safety issues with Mesoblast's NeoFuse therapy.

The company is anticipating being in the clinic for the treatment of invertebral disc repair, eye diseases and diabetes in 2011.

Nanosonics – Trophon EPR Progress

Nanosonics has developed the Trophon EPR device for disinfection of ultrasound probes. The point-of-care system is rapid and environmentally friendly and is capable of disinfecting a wide range of materials, using nebulised hydrogen peroxide.

The device is not yet FDA approved. However, the company has appointed GE Healthcare as its distributor for North America. The product is now listed on the Queensland Governments tender panel for three years and the district healthboards in Auckland are adopting Trophon EPR as the standard. A 200 unit order is being fulfilled for the iMed healthnetwork, Australia's largest private diagnostic imaging network.

Patrys – Phase I Trial of PAT-SM6 Begins

Patrys is a developer of natural antibodies for the treatment of cancer, isolated from human sources. The human body generates cancer killing antibodies on a regular basis, targeting cancer cells. Patrys has four human antibodies in development, each of which target receptors not targeted by any other antibody drugs in development or on market.

The limitation to harnessing human antibodies in the past has been an inability to manufacture and purify the proteins. However, Patrys has overcome that problem, achieving yields of 1g/L.

The company has commenced a Phase I trial of PAT-SM6. The company also has a four target/product with CSL and has identified one target to date. Patrys's patent position covers the antibody, the novel targets it finds, and its manufacturing process.

Phosphagenics – Generating Revenues in CY2010

Phosphagenics is commercializing the TPM transdermal delivery system, which exploits the properties of two forms of alpha-tocopheryl to assist the passage of molecules across the skin. The lead pharmaceutical application is for the development of a pain drug patch.

The company has launched a range of OTC skin care products, as well as cosmetic and dermatology products, which are on sale in an Australian pharmacy chain.

– Cont'd over

Phosphagenics expects to generate revenues of $6 million in CY2010 and greater than $8 million in CY2011.

Phylogica – A Peptide Drug Discovery Platform

Phylogica is a exploiting a technology platform derived from the drug-like properties of peptides sourced from bacteria that live in extreme environments.

Phylogica generates revenue from providing drug discovery expertise and library resources on a fee-for service, target by target basis, in addition to gaining royalties and payments on the successful completion of various milestones. It stands to receive a mid single digit royalty as well as milestone and R&D payments. The company generally stands to receive around $2 million each time it moves into preclinical tox studies. One issue with peptides is the short half-life although this can be extended through pegylation.

Long term value for investors stems from developing multiple product discovery and development relationships. The company is positioning itself for a trade sale in 18 months time.

Progen Pharmaceuticals – Advancing PG545 to a Phase I Trial

Progen Pharmaceuticals is a cancer drug developer and a manufacturer, through its PharmaSynth operations. Better known for its development of PI-88, which it has licensed to Taiwanese company, **Medigen Biotechnology Corporation**, the company is now focusing on the development of a next generation anti-angiogenesis compound, PG545.

Compared to PI-88, a semi-synthetic compound that is made of up 40 different chemical groups, PG545 is a synthetic single molecular entity. The compound is designed for systemic administration with a weekly dosing schedule. PG545 is a heparanase and VEGF inhibitor.

Progen intends to commence a Phase I trial in advanced cancer patients of PG545 in late 2010, file a US IND application by Q2 2011 and commence Phase II trial in 2012. The company is looking to sell its Cellgate assets.

pSivida – FDA Decision on Illuvien Expected Late 2010/Early 2011

pSivida has developed two sustained release product for treating back of the eye diseases that have reached market. These are Vitrasert for CMV and Retisert for uveitis. A third product, Ilivien, for diabetic macular edema (DME), is under priority view by the FDA. The company has licence agreements with **Pfizer**, **Bausch & Lomb** and **Alimera Sciences**.

The current treatment for DME is laser therapy which has limitations and there is no currently approved drug. The condition affects 1 million people in the US.

The company's Phase III trial of Iluvien has enrolled approximately 1,000 subjects with 24 month data showing that 40% of severely affected subjects gained three or more lines of visual benefit.

An FDA decision is expected in late 2010 or early 2011. The product has been given priority review by the FDA. An FDA approval would trigger a US$25 million milestone payment from Alimera Sciences. Approval by the FDA will open up other opportunities for using the delivery mechanism in other parts of the body. In the last financial year the company was profitable.

QRxPharma – MoxDuoIR NDA Filing Expected Q1 2011

QRxPharma is developing immediate release, IV and controlled release formulations of MoxDuo, a combination of two well known pain drugs, morphine and oxycodone. MoxDuo IR is being developed for the acute pain market, MoxDuo IV for the hospital setting and the MoxDuo CR for the chronic pain market.

The data from completed trials of MoxDuo IR shows that the compound delivers better pain relief with fewer side effects, consistently showing between 50% to 75% reduction in side effects.

The Phase III evaluation of MoxDuo IR is nearly finished and the company anticipates filing an NDA with the FDA in Q1 2011. A market launch is planned for 2012.

The recent bid by **Pfizer** for **King Pharmaceuticals** for $3.7 billion highlights enormous interest in this space according to CEO John Holaday. The company's MoxDuo IR is a potential 'game changer' said Holaday.

Starpharma – "Unashamedly a Platform Technology Company"

Starpharma is a platform technology company exploiting dendrimer chemistry to develop products such as Vivagel as a treatment for bacterial vaginosis (Phase II underway), prevent HIV and genital herpes and as a condom coating. The condom coating product is partnered to **SSL** (the maker of the Durex brand condom), with SSL being bid for by **Reckitt Benckiser**.

The Vivagel coated condom could deliver significant royalty income to Starpharma, given that SSL has an approximate 40% share of the global condom market, but depending on how much of SSL's product range winds up with Vivagel incorporated in the final product. Royalty revenue is expected to commence in CY2011, with estimates in the $20-$25 million range p.a. within a few years. Starpharma receives a double digit royalty. SSL has conducted market research in 57 countries on the proposed product.

The company has partnered its technology with many other firms, to investigate and develop agro-chemical, drug delivery and diagnostic applications.

Sunshine Heart - Feasibility Trial of the C-Pulse Heart Assist Device

Sunshine Heart was founded in 2000, becoming a Delaware corporation in 2002 and then listing on the ASX in 2004. The company is commercializing a non-blood contact heart assist device that wraps around the aorta, and compresses and decompresses on a counter pulse to assist blood flow. The device is targeted for treatment of Class III heart failure patients.

The company is currently conducting a feasibility trial in 20 patients, with 16 implantations made to date. The company has revised the surgical procedure from a full sternotomy to a minimally invasive procedure, shortening the time patients spend in hospital. Sunshine Heart is aiming to develop a fully implantable (both cuff and device driver) by 2012.

The company is intending to register for the Nasdaq market in 2011. GBS Venture Partners and CM Capital own 52% of the company. On the back of the 20 patient study the company will seek to gain CE Mark approval in Europe. The company expects to complete the 20 patients by the end of 2010.

The implant procedure is currently reimbursed in the US $154,000 to hospitals. SHC receives $54,000 for each device it uses in its US trials.

Tissue Therapies – Developing VitroGro for Wound Healing

Tissue Therapies listed in 2004, as a spin-out of the Queensland University of Technology. The company is developing VitroGro, a protein-based product that includes vitronectin, for treating wounds and burns. Latest study results showed 5 out of 30 venous ulcers completely healing in 24 days, with 50% healing after six months treatment. The average ulcer duration prior to the trial was 11 months, and the average length of compression therapy was nine months. The product has a device classification for approval purposes.

The company has now begun discussions with potential commercial partners, with an objective of sales commencing at the end of 2011. CEO Steven Mercer said the therapy is extraordinarily efficient and the clinical results received to date were exceptional. The product is ready to be used in the forthcoming trial.

The product will be used both as a stand-alone treatment and will also be incorporated into existing products. The product is very durable, retaining activity after freezing and gamma irradiation. The company is aiming to make this product the default for wound treatment globally.

Private Company Presentations

Applied Physiology – ICU Patient Monitoring

Applied Physiology was formed in 2004, based on work initiated in 1999 by Professor Geoff Parkin at Monash University. The company has developed a suite of patient monitoring systems that are designed for use in the critical care setting (e.g. intensive care units).

Its lead Navigator lead product displays information about pressure and flow in the circulatory system, so that key cardiovascular parameters (e.g. resistance, volume of blood flow and heart performance) are displayed on the one screen. The device connects standard monitors and draws a 'map' of the patient in relation to a 'target zone', in which an active object such as red dot can signal whether the patient's status is in the specified zone.

The company is establishing 10 reference sites in Australia and Europe while it develops relationships with both patient monitoring device companies and cardiac output device companies.

Applied Physiology has completed a 112 patient, multi-centre, randomized, open study of the Navigator system in the critical care setting, which demonstrated that the navigator device was non-inferior to standard ICU therapy. The Navigator system is TGA certified and CE marked.

The company anticipates completing a Series C fundraising round in 2011.

Cystemix – Cancer Drug Developer

Cystemix was founded in 2002 as a spin out of the University of NSW. Cystemix is developing compounds that block adenine nucleotide translocase (ANT), focusing on primary liver cancer and triple negative breast cancer. ANT is involved with tumour cell metabolism.

There appears to be no competition for ANT targeted cancer drug development, forming a basis for clinical and commercial potential.

The company's lead compound GSAO has completed a Phase I programs. Cystemix is seeking to raise $1.8 million to advance development of next in line PENAO compound, including oral formulation development, conduct a Phase I trial and file an IND in the US.

Dimerix – Tackling Opportunities in the $60 billion GPCR Drug Space

Dimerix was founded in 2004 as a spin-out of the West Australia Institute for Medical Research. Dimerix is a platform technology company that has the potential generate revenues in multiple ways by exploiting an opportunity that has emerged with the class of drugs that bind to GPCR receptors, which make up 40% of all current approved drugs and accounted for $60 billion in sales in 2009.

It was once thought that GPCR drug bound in a one-on-one fashion. However, research has uncovered a more complex situation in which a drug could bind to a GPCR receptor which co-incidentally pairs with another receptor, a process called heteromerisation. This complexing can initiate effects in addition to the intended drug pathway (disease modulation) effect.

The company has developed an assay that can determine if and to what degree heteromerization takes place. This assay is useful in charactering existing drugs more fully by revealing other pathways that may act on (to deliver either positive or negative benefits). It can also enable new drug developers to elucidate these other pathway effects. This is very helpful information used at the start of the drug development process.

The technology offers up the possibility of improving existing drugs, or re-purposing existing drugs in new beneficial target effects are discovered. An important advantage is that many drug development expenses do not need to be repeated.

The company can generate revenues through providing screening and profiling services, and library access fees. The company recently signed a service agreement with Takeda. It is also developing a fixed dose drug-drug combination therapy (of two existing drugs) to treat diabetic nephropathy, with plans to file an IND in 2011.

Dimerix raised $1.4 million in February 2009 from new and existing investors and has flagged a September 2011 fundraising.

I Echidna Surgical Solutions – A Novel Orthopeadic Pin

Echidna Surgical Solutions is an orthopedic products developer. Its main product is an orthopaedic pin which could be suitable for the treatment of long bone, clavicle and rub fractures.

The company is planning to complete cadaver trials this year, followed by a clinical trial in 2011 and the gaining of product approval also in 2011.

Gamma Vaccines – A Universal Influenza Vaccine

Gamma Vaccines was founded in 2009, based on research at the ANU. The company is developing a broad-spectrum influenza vaccine that can give immunity against different strains of Influenza A. A specific strain Influenza virus A/PC (a H3N2) strain has been shown to provide protection against a H1N1 strain.

The point of difference with the Gamma Vaccines is that, as its name suggests, the vaccine is inactivated using gamma radiation instead of with formaldehyde or UV radiation.

Gamma Vaccines intends to take its vaccine through to the Phase II stage of development. However, it also sees an opportunity in the Avian influenza market, targeting the global poultry market.

Gamma Vaccines outlined an investment plan to raise $8 million for the human vaccine program and $1 million for animal health and licensing activities.

Hunter Immunology – HI-164OV, an Immunotherapy for COPD

Hunter Immunology's is developing a treatment for Chronic Obstructive Pulmonary Disease (COPD). Its lead product, HI-164OV, is an enteric coated table containing killed Haemophilus influenza bacteria. The killed bacteria stimulate an immune response which protects airways from infections that cause exacerbations.

In a completed Phase II trial in 38 patients, administration of HI-1640V resulted in a 56% decrease in antibiotic use, a 37% drop in the duration of exacerbation episodes and a 90% decrease in exacerbation caused hospitalizations.

The company is conducting an expanded trial (Phase IIb) in 340 patients with moderate to severe COPD, with a final report due in 2012.

Hunter Immunology is looking to raise up to $10 million to support the completion of the Phase II trial, file an IND, manufacture GMP material under scale-up and conduct further tox, formulation and mechanism studies.

Innate Therapeutics – Treating Progressive Multiple Sclerosis and Other Diseases

Innate Therapeutics (Auckland) has developed an immune modulating particle technology. Its lead product MIS416 is in a Phase Ib/IIa trial in patients with secondary progressive multiple sclerosis (SPMS). The company expects to move MIS416 into a Phase I cancer adjuvant study,

MIS416 is a rod shaped microparticle that incorporates the ligands for the TLR9 and NOD2 receptors, which are involved in two immune system pathways. MIS416 appears to reduce the blood levels of the proteins (adhesion molecules) that destroy the myelin sheath that surrounds nerves, which is the underlying problem of MS.

Innate Therapeutics is seeking US$10 million to support ongoing Phase II development. Currently seven patients have been receiving therapy for up to two years on compassionate grounds. There have been no safety issues with some symptoms of disease having been reversed in some patients with progressive MS. It expects to report on its current Phase IIb trial at the end of 2011. The company has raised $40 million to date and is currently valued at $15 million (some of the previous funds were used for other now failed programs).

Vaxxas – Vaccine Patch System

Vaxxas is a spin-out of the University of Queensland. The company has developed a vaccine patch delivery system. The company claims a 150 fold increase in efficacy compared to needles and syringes used in animal models, and is 10 fold better that micro-needles, gene guns, intradermal and other patch systems.

Neural Diagnostics – CNS Diagnostic Technology

Neural Diagnostics was formed in 2005. The company has developed the EVestG device which non-invasively captures and measures vesitibular hair cell field potential, offering higher sensitivity to CNS status than that obtained by EEG. The device could be used to diagnose or bring greater analytical insight into CNS conditions such as schizophrenia, Parkinson's Disease or different forms of depression.

Percutaneous Cardiovascular Solutions – Mitral Valve Replacement

Percutaneous Cardiovascular Solutions has developed a mitral valve replacement (the JT valve) that can be implanted by catheter. The device solves the problem of fixing the valve in a section of the heart called the mitral annulus.

The medical condition the JT Valve addresses is mitral regurgitation, a condition which affects 40% of congestive heart failure patients.

To give some colour to the commercial opportunity open to PCS, in 2009 Medtronic acquired Ventor for US$325 million and CoreValve for US$700 million. Ventor was developing a transcatheter

Bioshares Model Portfolio (22 Oct 2010)

Company	Price (current)	Price added to portfolio	Date added
Phylogica	$0.047	$0.053	September 2010
Sunshine Heart	$0.027	$0.036	June 2010
Biota Holdings	$0.93	$1.09	May 2010
Tissue Therapies	$0.40	$0.21	January 2010
QRxPharma	$0.89	$0.25	December 2008
Hexima	$0.45	$0.60	October 2008
Atcor Medical	$0.11	$0.10	October 2008
Impedimed	$0.86	$0.70	August 2008
Mesoblast	$2.31	$1.25	August 2008
Circadian Technologies	$0.60	$1.03	February 2008
Patrys	$0.08	$0.50	December 2007
Bionomics	$0.29	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$5.75	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.18	$0.66	September 2007
Starpharma Holdings	$0.64	$0.37	August 2007
Pharmaxis	$2.85	$3.15	August 2007
Universal Biosensors	$1.50	$1.23	June 2007
Acrux	$2.66	$0.83	November 2004
Alchemia	$0.54	$0.67	May 2004

Portfolio Changes – 22 October 2010

IN:
No changes.

OUT:
No changes.

transapical aortic valve and Corevalve had developed a transcatheter, transfemoral aortic valve replacement.

The company is seeking up to $3 million to support further development.

Photonz Corporation - Manufacture of highly-purified EPA (Omega-3)

Photonz Corporation has developed a novel method for the manufacture of eicosapentaenoic acid (EPA), a long chain fatty (Omega-3) acid. EPA is harvested from fish oil and is formulated in gel capsules for diet supplements and included in additive in foods such as infant milk formula.

A related chemical is docosahexaenoic acid (DHA). Nasdaq listed Martek manufactures DHA using a fermentation approach. Martek is capitalised at US$774 million.

However, the high value opportunity for Photonz is the therapeutic products market, which requires highly purified forms of EPA as a pharmaceutical ingredient. The drug Epadel was approved in Japan in 1990. **Amarin** is conducting a Phase III trial of AMR101, a partially synthetic EPA.

The market driver for drug formulations of a highly purified EPA derive from the hypothesis that co-administration with statin dugs delivers even better cardiovascular disease management outcomes. However, the investment appeal of Photonz is that it has the potential to address security of supply concerns for EPA drug makers who rely on limited marine-based supplies.

Photonz uses fermentation techniques to produce EPA from a proprietary strain of micro-algea, which is the original organism of production in the marine food chain. The company has made significant progress in increasing production yields of EPA, more than doubling previous best published yields of approximately 7.5 mg/L/h to approximately 19 mg/L/h.

The company is moving develop a scale-up production in a 600 litre prototype with DSM in Italy. It is aiming to sign its first forward supply agreement in June 2011. The company has raised NS$5.6 million to date and is seeking NZ$6.3 million in funding.

Velacor Therapeutics – A Therapy for Alzheimer's Disease

Velacor was spun out of the University of Melbourne in 2005. The goal at foundation was to develop a compound comprising of therapeutic quantities of selenium (a trace element) for the treatment of prostate cancer by targeting the PP2a phosphatase complex. However, the company has shifted its therapeutic focus to treating Alzheimer's disease and conditions in which the tau protein is implicated.

The company intends to show proof-of-concept in a Phase II study of patients with Alzheimers disease, by dosing AD patients with VEL105, a formulation 40 times the standard OTC dose of selenium. Ethics approval has been granted for the trial. In pre-clinical studies an 84% reduction in tau tangles was observed.

Velacor is majority owned by an Angel investor group. Existing investors are underwriting a $2.5 million capital raising, in addition to seeking another $1 million from new shareholders.

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

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, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics

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