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In this edition...
Universal Biosensors is gaining traction now that J&J has taken the covers off their jointly developed blood glucose monitor. One Touch Verio is regarded by J&J as an important new product.
The chronic obstructive pulmonary disease drug market is emerging as a hot area, even though current drugs are top sellers. New drug development for COPD is relatively uncongested giving local companies Pharmaxis and the privately-held Hunter Immunology a good shot.
Wound healing company Tissue Therapies is making good progress in the clinic, delivering some compelling data with recent clinical activity. Tyrian Diagnostics is patiently waiting for manufacturing to be scaled up for its wheat quality test.
The Editors
Companies Covered: PXS, TIS, TXD, UBI

	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)	-3.4%
Cumulative Gain	**200%**
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.

J&J Right Behind the UBI Developed Glucose Test Strip Platform

If you were in any doubt regarding **Johnson & Johnson's** commitment to the new glucose monitoring platform developed by Universal Biosensors (UBI: $1.75), then just listen to a recent briefing by J&J (see link on recent UBI release), or keep reading for a summary of key points. This is the first major briefing J&J has given on its diabetes business in two years.

Lifescan (diabetes group subsidiary of J&J) Group Chairman, Michel Paul, said that UBI gives J&J the capability to find new solutions for patients worldwide. "(Our) next product delivers outstanding accuracy with no coding. The new strip platform is called One Touch Verio ('verio' meaning truth), a platform that promises to deliver excellent accuracy and precision in diabetes monitoring. Far more than just a strip, the One Touch Verio system provides a picture of blood glucose levels and delivers better insights to the diabetes patient. This way the patient is able to make better decisions daily about their medical management, their meals and their activities.

"This no coding strip uses a glucofilter technology along with an algorithm that eliminates interferences. One Touch Verio is a brand we will build upon for many years to come, delivering exceptional value to our customers and their healthcare professionals around the world," said Paul in the briefing.

The global medical devices and diagnostic industry is worth US$350 billion a year. A Citigroup Global Markets report stated that J&J's MD&D division is not just the largest but the fastest growing and highest margin medtech business in the world today. A Morgan Stanley report states that it expects J&J to file the Once Touch Verio system for approval in the third quarter of 2010. The product has been released in The Netherlands.

In 2009, UBI dropped the development of its first glucose test stop platform, going straight through to the Mark II version. This second version, which is now on the market, discriminates between glucose and other sugars such as maltose, galactose and xylose. Glucose test strips that utilise glucose dehydrogenase pyrroloquinone quinine (GDH-PQQ) can react with non-glucose sugars and lead to false positive readings. Between 2004-2008, the FDA received about 12,000 reports of serious injury from errors in blood glucose meters.

The Diabetes Epidemic According to J&J

Paul said diabetes is a global epidemic. Over 50% of people with diabetes in the developed market are not achieving optimum blood glucose control. J&J is currently number two in the world in diabetes care and is positioned to lead the world in glucose control. Its diabetes business unit is growing at a double digit rate and is gaining market share.

The Diabetes Market

Throughout the world there are 114 million people living with diabetes and this number is expected to escalate to 150 million by 2014 (with around 40% of those living in developed

2010 Thredbo Biotech Summit Speaker List

Speakers
Jon Pilcher & Hugh Alsop
Acrux Ltd

Jason Armstrong, CEO, Primed

Brendon Coventry, University of Adelaide
(Associate Professor inSurgery)

Rob Crombie, C2CC

Jackie Fairley, CEO, Starpharma Holdings

Tim Grogan, CEO, Dimerix Pty Ltd

Peter Howard & Andrew Gaffney
Middletons

Phil Kearney
Merck Sharp & Dohme

Phil Magistro, Chief Commercial Officer
QRxPharma Ltd

Tom McCarthy, CEO
Spinfex Pharmaceuticals

Speakers
Brad O'Connor, CEO, Cogstate Ltd

Greg Roger, CEO, ASDM Ltd

Iain Ross & Peter French, Benitec Ltd

Darren Shafren, CSO, Viralytics Ltd

Brigitte Smith, GBS Venture Partners

Shane Story, Wilson HTM

Mark Pachacz, Bioshares

Panelists

Remy Bernarda, Blueprint Life Science Group

Michael Lusis, Wilson HTM

Matt McNamara, IB Managers

Scott Power, RBS Morgans

Deborah Rathjen, CEO, Bionomics

Speakers
Dr Suku Thambar, CSO of PCS Pty Ltd
(Interventional Cardiologist)

Paul Watt, CEO Phylogica Ltd

Simon Wilkinson, CEO
Innate Therapeutics (NZ)

Nick Woolf, Non-Executive Director
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Peter Bradley, Innate Therapeutics

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market regions). In China one in 10 people potentially have diabetes, whether diagnosed or not, due to adoption of western diets and increasingly sedentary lifestyles. The vast majority of people with diabetes in emerging markets such as China and India are not diagnosed or do not have good control of their diabetes according to Paul.

The American Diabetes Association and the European Association for the Study of Diabetes say that current day management has failed to achieve and maintain the glycemic levels most likely to promote optimum healthcare status for people with diabetes. According to Paul, "It is the responsibility of the world's largest medical device company to address these issues on a global basis."

When left uncontrolled over a long term, the complications with diabetes can be devastating said Paul. Therapies alone are not enough. Therapy enablers like glucose strips are needed.

Importance of Control

Early control of diabetes is important in children because of the phenomena called metabolic memory, where good early control of diabetes can have a lasting effect on the person.

Currently one in 10 US healthcare dollars is used to treat diabetes and its complications. Paul said the US healthcare system does not have the budget for an uncontrolled diabetes population.

A person without diabetes costs the US healthcare system US$3,000 per year. A person with diabetes whose condition is well managed costs the US healthcare system US$6,000 a year. With moderate complications those costs move out to US$10,000 a year and blow out to $24,000 a year when the person gets to a stage when severe complications occur.

Lifescan has a fourfold strategy to grow its business. Top of that list is the launch of the new glucose test strip platform according to Paul. J&J estimates that the global market for self-monitoring of blood glucose will grow to US$10 billion by 2014.

Bioshares recommendation: **Speculative buy Class A**

Bioshares

The COPD Market – An Update

Although Pharmaxis (PXS: $3.12) is focused on achieving approval for Bronchitol for cystic fibrosis, a longer term objective is for Bronchitol to be launched into the much larger COPD market. The COPD market is huge, with an estimated 210 million people suffering from COPD in 2005, and 3 million deaths estimated for the same year, according to the World Health Organisation.

What is COPD?

COPD is a progressive lung condition characterised by non-reversible changes to the airways in the lungs, with less air flowing in and out of the lungs. This is because the airways become less elastic, the walls between the air sacs are destroyed, the airways become inflamed, and more mucus is made, which causes clogging of the airways.

A major co-factor for COPD is smoking, however also include other airborne particles such as pollen, dust and pollutants. Mild COPD is classified when a patient has 80% lung function (forced expiratory volume, FEV1). Moderate COPD is classified between 50%-80% FEV1. Severe COPD is less than 50% FEV1 and very severe COPD is defined at less than 50% FEV1 coupled to chronic respiratory failure or less than 30% FEV1.

Current Drug Treatments

There are three classes of treatments for COPD. Bronchodilators are designed to relax the muscles around the airways with the intention of making breathing easier. They can be long or short acting. Steroids are administered to manage inflammation although their well established side effects of causing high blood pressure, osteoporosis, cataracts, glaucoma and diabetes, limit the long term use. Thirdly, antibiotics are administered for infections when they arise.

Some of the leading drugs approved for the treatment of COPD, such as Advair and Symbicort, are also approved as asthma medications.

In 2008 the FDA approved **GlaxoSmithKline**'s (GSK) Advair (also known as Seretide – fluticasone and salmeterol inhaled powder) as a treatment for exacerbations associated with COPD. Fluticasone is a corticosteroid and salmeterol is a long acting beta-2 agonist (LABA). Advair is a taken (inhaled) twice a day.

Advair generated sales of $US7.7 billion for GSK in 2009, and provided the bulk of the revenues within its respiratory franchise of US$10.8 billion. Sales are split roughly 50:50 between asthma and COPD.

AstraZeneca sells a similar product, Symbicort, which combines budesonide (a corticosteroid) and formoterol (a LABA). Symbicort achieved revenues of US$2.3 billion in 2009, contributing to total respiratory sales of US$4.1 billion.

Two LABAs have been approved by the FDA as COPD treatments, but not asthma, and not in combination with a steroid. These are Brovana and Perforomist

Boehringer Ingelheim markets Spiriva (tiotropium bromide) as a once daily treatment for COPD. It is not approved for the treatment of asthma. The company reported sales of €2.4 billion for the drug in 2009, which represented an increase of 16% from the previous year. Spiriva is a long-acting muscarinic antagonists (LAMA), and is also meant to function as a bronchodilator.

Considering the combined sales of Advair, Symbicort and Spiriva alone (US$13.5 billion), it is easy to gauge the financial attractiveness of respiratory medicine, including the sub-category of COPD. For example, Advair is GSK's biggest selling drug.

Why the Concern with LABAs and Corticosteroids?

In a study that compared the incidence of asthma related deaths in a group of 13,176 subjects who were dosed with salmeterol over 28 weeks compared to a group of 13,179 patients on placebo, there were 13 deaths reported versus 3 in the placebo group.

The FDA advised in March 2010 that LABAs should not be used without a corticosteroid to treat asthma. However, the FDA did not apply the new ruling to COPD patients. That said, the safety profile of both LABAs and corticosteroids are now regarded with far less satisfaction than in the past.

It should also be noted that roughly a quarter of patients do not respond to treatment with steroids. Add that to the long term negative effects of administering steroids, then it would appear that the longer term prospects for co-administered LABAs and steroids are diminished.

Emerging Medicines

In May, **Novartis** commenced two Phase III trials of QVA149, an inhaled dry powder which combines a fixed dose of the LABA QAB149 (indacaterol) and the long-acting muscarinic antagonist (LAMA) NVA237 (glycopyrronium bromide). This drug was licensed from to Novartis from **Sosei** and its co-development partner **Vectura Group** in 2005, in a deal worth up to US$375 million in addition to royalties. QVA149 is designed for once a day administration.

GSK and **Theravance** are developing a once daily LABA (vilanterol trifenatate) and inhaled corticosteroid (fluticasone), Relovair. The first of five Phase III COPD trials, in more than 6,000 patients, commenced in October 2009. GSK is also developing bifunctional muscarinic antagonist-beta2 agonist (MABA) with Theravance.

Locally, privately held **Hunter Immunology** is developing HI-164OV as an orally administered immunotherapeutic to treat COPD, with a Phase III trial in the planning.

Recent Deals

It is worth noting several recent transactions in the COPD space. Starting with **Nycomed**'s registration phase deal last year (August 2009) with **Forest Labs** for Daxas (roflumilast), a key US territory only deal covering a once daily, oral delivery PDE4 enzyme inhibitor was inked with a US$100 million down payment. Daxas may be the first PDE4 to make it to the market. Overall potential earnings from the deal were not stated. Forest Labs sells Aerobid, an inhaled steroid drug.

– Cont'd over

Selected Recent Deals in COPD

							Payments - US$ M			
Date	**Company**	**Company/Licence**	**Product/Program**	**Stage**	**Indications**	**Description**	**Upfront**	**Research**	**Potential**	**Royalties**
1/06/2010	Orexa	Ortho-McNeil-Janssen	OX-CLI, OX-ESI programs plus one not disclosed	Advanced pre-clinical	Asthma, COPD	Small molecule/ arachidonic acid	$10.00	$21.50	$564.00	Yes
11/01/2010	Galapogos	Roche	Multiple Novel targets		COPD				$573.00	Yes
10/08/2009	Nycomed	Forest Labs	Daxas (roflumilast)	MAA/NDA filed deal US only	COPD	Once daily, **oral**, PDE4 enzyme inhibitor	$100.00		N.S.	Yes

Subjects administered Daxas experienced exacerbations at a rate of 1.14 events per year compared to rate of 1.37 per year for patients on placebo, a reduction of 17%. Forest signed the Daxas product after a PDE4 compound (oglemilast) it had licensed from **Glenmark** failed in Phase II trials.

More recently, two pre-clinical deals were signed, both valued in total potential dollar terms at near the US$550 million mark. **Roche** signed up **Galapagos** to hunt for targets in the COPD area, and **Ortho-McNeil-Janssen (Johnson & Johnson)** licensed two advanced pre-clinical programs from **Orexa**. What is interesting about these two deals is that neither Roche nor J&J are known for respiratory medicine capabilities, let alone COPD.

Pharmaxis and COPD

Pharmaxis is not yet conducting clinical studies of Bronchitol in the target indication of COPD. However, in the longer term, and assuming the company is successful in developing Bronchitol as a useful treatment for cystic fibrosis, then the opportunity to transition Bronchitol into COPD will increase in likelihood. However, we expect that it would have most benefit in addressing mucus build up in COPD sufferers.

At the very early research phase, Pharmaxis is developing PXS TPI1100 (inherited from Topigen) for COPD. PXS TPI1100 is an inhaled, phosphodiesterase (PDE) inhibitor that targets PDE isoforms 4B, 4D and 7A. Many other PDE drugs in development only target PDE4. By targeting both PDE4 and PDE7, an improved drug profile may possibly be achieved in managing inflammation. Pharmaxis' view is that some of the side effects of systemic administration of PDE4 inhibitors will be ameliorated because it will be delivered by inhalation.

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Tyrian Diagnostics – Tests for Wheat, Food Quality, TB and COPD

Tyrian Diagnostics (TXD: 1 cent) has entered into a formal manufacturing and supply agreement with **Bayer CropScience**. Tyrian has developed an agricultural diagnostic test for Bayer which measures the quality of wheat, called the ReadRite test. The test uses Tyrian's proprietary point-of-need diagnostic platform, called DiagnosticIQ, which is particularly good at processing coarse input materials such as ground wheat. The technology can deliver a result in a disposable cartridge, or a quantitative test when required through a portable digital reader.

The ReadRite test was launched in Canada in May last year. In the first nine months of this financial year, Tyrian has generated receipts from customers of just over $1 million, with most of this from sales and R&D and payments from Bayer. Tyrian has been manufacturing small quantities of the test for Bayer in-house. The formalisation of the manufacturing agreement with Bayer will allow Tyrian to assign a contract manufacturer to make larger quantities of the test. Tyrian will now receive a royalty and manufacturing margin, allowing the company to make a clear profit on this product line.

Tyrian is developing a second test for Bayer, being an undisclosed food quality test. The market for this test is much larger than the ReadRite test. The company is expecting to reach a major development milestone this year, with the product reaching the market at the earliest in late 2011 if all goes well.

Tyrian's longer term goal is to build its novel diagnostic products in the respiratory diseases area with shorter term revenue coming from its agricultural product tests. The company is working on a molecular diagnostic test for active tuberculosis. The company believes it has an excellent biomarker and may be in a position to validate this test in 2010. If it can, the company will look to partner the test commercialisation.

COPD Diagnostic

The company is also working on a novel test to diagnose chronic obstructive pulmonary disorder using biomarkers. This condition is currently diagnosed by measuring lung function.

Tyrian Diagnostics had $4.1 million in cash at the end of March which should be sufficient for at least one year's funding. The company is making good progress on commercialising its agricultural product tests with the blue sky linked to success in the development of novel biomarkers in the healthcare respiratory space. The company is capitalised at $5 million.

Bioshares recommendation: **Speculative Buy Class C**

Bioshares

Bioshares Model Portfolio (18 June 2010)

Company	Price (current)	Price added to portfolio	Date added
Sunshine Heart	$0.038	$0.036	June 2010
Biota Holdings	$1.20	$1.09	May 2010
Tissue Therapies	$0.21	$0.21	January 2010
QRxPharma	$1.15	$0.25	December 2008
Hexima	$0.27	$0.60	October 2008
Atcor Medical	$0.14	$0.10	October 2008
CathRx	$0.30	$0.70	October 2008
Impedimed	$0.60	$0.70	August 2008
Mesoblast	$1.92	$1.25	August 2008
Circadian Technologies	$0.60	$1.03	February 2008
Patrys	$0.11	$0.50	December 2007
Bionomics	$0.28	$0.42	December 2007
Cogstate	$0.23	$0.13	November 2007
Sirtex Medical	$5.40	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.24	$0.66	September 2007
Starpharma Holdings	$0.55	$0.37	August 2007
Pharmaxis	$3.12	$3.15	August 2007
Universal Biosensors	$1.75	$1.23	June 2007
Probiotec	$1.35	$1.12	February 2007
Acrux	$1.90	$0.83	November 2004
Alchemia	$0.57	$0.67	May 2004

Portfolio Changes – 18 June 2010

IN:
No changes.

OUT:
No changes.

Tissue Therapies – More Compelling Results

Tissue Therapies (TIS: 20.5 cents) is developing a novel wound healing technology, called VitroGro. The company has completed two clinical trials with compelling results. Those compelling results continue to emerge, with data from five more patients treated with VitroGro now available.

In one patient, who's venous ulcer had not healed after 27 months of expert care, and the second patient who's ulcer did not respond to expert care for 19 months, both achieved 100% healing of their wound after 24 days of treatment with VitroGro.

A third patient achieved 75% healing after no response to expert therapy for two months prior to treatment with VitroGro. Overall, the average reduction in venous ulcer surface area was 39%.

To date 27 patients in Canada and Australia have now been treated in the previous two clinical studies and this additional group in Western Australia. The additional results follow from a request from Professor Michael Stacey at the Vascular Research Laboratory to continue treating patients with existing supplies of VitroGro that Tissue Therapies retained, following completion of previous clinical studies.

Tissue Therapies is completing commercial scale manufacture of VitroGro which is being made through a different, but more economical process. Product from this batch is expected to be ready in June. Another clinical study will be conducted by year's end in three sites in Australia and three sites in the UK.

Tissue Therapies seeking to have the product approved in Europe in the first half of 2011 and on the market in the second half of 2011. Under mutual recognition agreements, that could then see the product approved in Canada, New Zealand, East Asia and South America. Approval in the US may require a second trial.

The company is currently in discussions with potential marketing partners and is aiming to secure a deal by year's end. The company's business plan is to maintain manufacturing control, which was a very wise strategy.

It is unheard of that none of the patients don't get any worse, according to a UK wound healing expert Professor Keith Harding, in a chronic skin ulcer trial such as the VitroGro trials, says CEO Steven Mercer. Mercer says the product is becoming very predictable. Before the trials started, Mercer did not believe this level of results could be achieved.

Tissue Therapies is capitalised at $28 million with $6.5 million in cash, enough we estimate for at least 18 months funding. By that stage the company is anticipating a marketing deal and product launch in Europe.

Bioshares recommendation: **Speculative Buy Class B**

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, CathRx, BioMd, Tissue Therapies, Viralytics

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