In this edition...

Wilson HTM held its 6th annual life science conference in Sydney this week, showcasing 12 of the sector's leading companies.

Themes to emerge from the conference included the near term prospects for revenues for a number of companies, as well as a strategy that factors in manufacturing as a key element in value creation and control.

Overall, the conference highlighted the significant opportunities that will occur, (if not already occurring) for investors with an exposure to well structured biotech companies.

The Editors

Companies Covered: ACL, ACR, BTA, CXD, CXS, CST, HXL, MSB, PXS, QRX, SPL, 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 - Current)	63.0%
Cumulative Gain	217%
Av Annual Gain (9 yrs)	20.1%

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Bioshares

16 October 2009 Edition 333

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

Wilson HTM Life Sciences Conference Report

Wilson HTM held its 6th annual life sciences conference this week in Sydney. The conference aims to showcase the twelve best listed life science companies in Australia in the one day with analyst interviews with each company. For the second year in row, the mood at this event was distinctly positive, with a genuine level of heightened anticipation and growing confidence towards the Australian biotech sector.

Alchemia – Move Into Profitability Expected by End 2010

Alchemia is one of the companies that is expected to *move into profitability*, with CEO Pete Smith expecting that event to occur towards *the end of 2010* from sales of its generic blood anticoagulant, fondaparinux. He expects the market for that drug to be US\$250 million a year when their product gets to market and with Alchemia to have the only generic in the market. The current manufacturing process for fondaparinux involves around 60 manufacturing steps, including 15 chromatography steps. It took **Sanofi** originally 10 years to work out how to make the drug and this will be a barrier to other generics. However, Alchemia's patented technology substantially simplifies this process.

With only the one generic on the market, there may only be a 5%-10% discount in the selling price of Alchemia's generic to current Arixtra prices. Based on a more conservative price decline of 20%, the operating profit from drug sales should be 65%-70%, with Alchemia taking 60% of that from its partner **Dr Reddy's**, which is marketing the drug in the US, if certain sales levels are achieved, or 50% if a second generic enters the market, which is not expected. Around 35% of sales are expected to be generated as pure profit.

For Dr Reddy's, Alchemia's fondaparinux has been highlighted by overseas analysts as one of the three top (short term) drivers for that company. Dr Reddy's generated sales of US\$126 million in the US last year. With fondaparinux sales expected to be over US\$100 million, it will not be an insignificant product for that company. (Based on these numbers Alchemia stands to receive at least US\$35 million in profit a year).

Smith said Alchemia had a lot of interest from generic companies before it signed the deal with Dr Reddy's. Dr Reddy's is fifth on the listed in the US in terms of ANDAs filed (generic drug applications in the US), which is one of the reasons Dr Reddy's was chosen. Smith also believes that **GlaxoSmithKline**, which markets Arixtra, remains committed to the drug, having started a 4,000 patient trial (for new indications) recently.

The patents on Arixtra have expired, because of the time taken to get the drug to market initially. Smith previously was a healthcare analyst covering Sanofi as the drug was being developed. The drug had market exclusivity in the US until 2008 and in Europe exclusivity is extended out to 2012.

Alchemia has been approached by two companies in the Asia Pacific region where Arixtra is currently not sold and may license its drug for those regions.

Dr Reddy's will lock in sales contracts in the US as soon as it gets clarity from the FDA on launch date. In the US, 85% of hospital injectables are sold through only seven group purchasing groups (which should allow a rapid market penetration).

Oncology program

For Alchemia's oncology program, which combines hyaluronic acid (HA) with existing oncology drugs, Smith says that for less than \$20 million it can complete a Phase III study which would be enough to bring that product to market, pending favourable results. Phase II studies have shown its therapy, HA with irinotecan, delivers an additional three months progression-free survival in cancer patients. The Phase III study will be funded by fondaparinux revenue.

There are a raft of existing oncology drugs that could be combined with hyaluronic acid for improved performance, as long as they are water soluble. These include carboplatin, cisplatin, Erbitux, 5-FU, doxorubicin.

That the company can not license the drug at the moment does not mean the program does not have potential, according to Smith. Smith cites the drug Abraxane, which was developed by **Abraxis BioScience**. Abraxane is a version of the generic drug Taxol (in a plasma solution). It has made the founder of Abraxis, Patrick Soon-Shiong, the richest man in Los Angeles. Carlo Montagna, who was previously President of **Abraxis Oncology**, is currently a director of Alchemia, and is well placed to guide Alchemia with its oncology program.

Smith made the point that at the end of Phase II trials, Abraxane could not be partnered and could not be sold for a few million dollars. The drug now generates sales of around US\$400 million a year.

It would appear that for about six months worth of future fondaparinux revenue, Alchemia could generate substantial value if its Phase III trial was successful.

(Alchemia is capitalised at \$85 million. It had \$8.3 million in cash as of June, and made a net loss of \$8.4 million in FY2009.)

CathRx – Unmet Need in Atrial Fibrillation

The current cardiac catheter market is worth US\$1.1 billion. It is expected to grow to US\$1.7 billion in the next four years. What is constraining this market at the moment, according to CathRx chairman, Denis Hanley, is the limitations of existing technologies, something that CathRx is seeking to correct.

At the moment only about 2% of patients are receiving ablation treatment for atrial fibrillation (where dysfunctional electrical signals in the left side of the heart causes chronic heart problems that are poorly treated through chronic medication). It affects five million people in the US and will grow significantly with an aging population, with 6% of the US population having this disease. Doctors are unwilling to use interventional catheter treatment because of the complexity of the treatment process and the time taken to perform the procedure (several hours). However with the advent of new technologies, it is becoming more common, and provides a 'cure' to the patient, not just a treatment.

In the US, there is still no product approved for atrial fibrillation, and the company is content to let competitors create the market there.

CathRx has made detailed sales forecasts for the next two years. Hanley says that the company will reach its sales targets. The timing of that is less certain, but to him that is less of a concern. If the sales targets are not reached, then management will change, he said.

Hanley expects that a 5% market penetration will be achieved, with FY2011 being the target, making the company cash flow positive within two years. Generating a set level of profit at this stage is less relevant to Hanley. The catheter industry has seen a recent history of M&A, with advanced diagnostic and ablation catheter companies being acquired for 10 times sales. At forecast 2011 revenues, this places a theoretical future value of around \$220 million on the company, if those sales can be achieved.

Hanley said the technical risk has almost gone with this company, leaving several business risks. If sales targets are not reached, the company may need to raise more funds, likely through a rights issue. Hanley put in \$1 million into the last rights issue earlier this year. CathRx has 43 patent families covering its technology.

(CathRx is capitalised at \$36 million. It had \$7 million in cash at the end of June (receiving \$4 million post 30/6/09), and made a net loss of \$13.4 million in FY2009.)

Nanosonics – Infection is the Driver

Continued infection issues in hospitals are the main driver for Nanosonics, which has developed a disinfection system for hospital equipment. The first product is a small contained chamber for disinfecting ultrasound probes. The platform uses a hydrogen peroxide mist that discards only water and oxygen when finished.

It is estimated that 175,000 people acquire infections each year from healthcare treatments in Australia alone. There are around 6,000 golden staph infections each year in Australia from which there are around 1,200 deaths. Of the infections, 40% are acquired in hospital and most are preventable.

David Radford, CEO of Nanosonics, said its Trophon EPR gives the company a first mover advantage for low temperature disinfection systems. Current practices use gluteraldehyde that needs to be contained in fume cupboards and there have been cases of herpes transmission from existing practices.

Nanosonics started selling its system earlier this year in Australia and New Zealand through two distributors. It also commenced selling Trophon EPR in Europe (in June) through 14 distributors.

Repeat Orders

Nanosonics is now seeing repeat orders from Australian hospitals. It business model is structured that it sells the hardware, but also charges for the hydrogen peroxide consumable canisters. The current facility has a capacity of producing 4,000 Trophon EPR units a year and can outsource a further 8,000 units a year if required.

The ultrasound market is highly regulated according to Radford, will 500 million ultrasound procedures a year and 160 million intracavity procedures each year, placing the potential market for ultrasound disinfection at \$1.5 billion a year. There is no other automated point-of-care product available and some countries, including France and Poland, have now banned the use of gluteraldehydes for high level disinfection.

The company has also received positive feedback from customers, including Dr Michael Cooper, the Head of Gynaecology at the **Royal Prince Alfred Hospital** in Sydney. "The Trophon EPR will make the task of disinfecting ultrasound transducers significantly faster, safer and more convenient." And according to Professor E. Merz, Director of Gynaecology at a hospital in Frankfurt "It is a well known problem that sonographic transducers can become contaminated with pathogenic agents....and turn into a source of infection that is not to be underrated. For this reason, correct handling as well as cleaning and disinfection of the transducers are indispensable."

The next products Nanosonics are developing are for high level disinfection of endoscopes, with the first prototype at an advanced stage. This potential for this market is estimated at over \$400 million according to Radford. Nanosonics has 13 patent families covering the technology.

(Nanosonics is capitalised at \$91 million. It had \$13.8 million in cash at the end of June, and made a net loss of \$8.8 million in FY2009. In the second quarter of 2009 it generated receipts from customers of \$75,000.)

Chemgenex Pharmaceuticals – To License European Rights for Omapro

Chemgenex pharmaceuticals CEO, Greg Collier, expects to license out European rights this year for its lead compound Omapro. The plan is to apply income from a European licensing deal to help fund the rollout of the drug in the US, which Collier believes the company can achieve with a small niche sales force.

A commercial nexus for this program is approaching, with Collier confident of securing a European licensing deal and with the drug on track to gain approval in the first half of next year in the US. Tom DeZao has recently been installed in the US as Chief Operations Officer. DeZao has experience in setting up small sales forces for pharmaceutical products.

While it is a niche market initially, this market for patients with the CML (chronic myeloid leukemia) with the T315I mutation (where Omapro is effective and other approved therapies are not) will continue to grow as CML patients continue to live longer thanks to Gleevec. Although the company can not promote it as such, it is also possible that Omapro will be used off label once approved. Further indications for Omapro will come from patients who have

failed two TKI (tyrosine kinase inhibitor) therapies.

And also of interest will be results from studies where Omapro has been combined with Gleevec. Investigators have submitted an abstract to be presented at the ASH conference in December on combination use of these drugs. Current drugs, such as Gleevec, treat the leukemia in the blood stream but do not effectively treat the underlying disease according to Collier. Omapro may be the first non-TKI drug approved for CML and the only drug that can kill leukemic stem cells responsible for the leukemia says Collier.

Of interest is possible future use of Omapro with Gleevec. Collier says that within five years 50% of patients on Gleevec become resistant to Gleevec, and 20% of those patients will have the 315I mutation (where only Omapro works). Presumably if the stem cells can be knocked out in combination with a highly effective drug such as Gleevec, then the therapy could potentially be used at an earlier stage of disease.

Gleevec – Patents Start Expiring from 2014

Collier said that of interest was that Gleevec was starting to come off patent in 2014. Collier said there had been a lot of pressure from clinicians to combine Gleevec with Omapro. While payors may not support two high priced cancer therapies in combination, the circumstances will be different as one of those (Gleevec) becomes a lower cost generic!

(Chemgenex is capitalised at \$206 million. It had \$17.6 million in cash at the end of June, and made a net loss of \$26 million in FY2009.)

Hexima

One of the key questions facing major seed providers going forward is not how much they stand to make from delivering improved efficiencies to farmers from biotech crops, but how much they stand to lose if they do not own these emerging technologies, according to Hexima CEO Josh Hofheimer.

Emerging biotech crop technologies are crucial for companies such as Hexima's partner, **Pioneer (DuPont)**, to hold and grow market share. Once they know the technology works, how critical is it for them to own it is a key question the seed providers will ask themselves according to Hofheimer. Dupont has lost 15% of corn market share. It is the ownership of valuable traits that drives market share.

Through Hexima's deal with DuPont, Hexima will receive a royalty from increased yields these products deliver. That the seed developers will be marketing the level of the improved yields to the farmers will make it clear what technology providers such as Hexima will stand to receive.

What was critical to DuPont when it signed the deal with Hexima was that Hexima was able to show in actual field trials (in cotton), that using Hexima's antifungal technology, a two to threefold increase in survival was achieved, up to a fourfold increase in lint yield, but also that the lint quality was not diminished.

A key driver according to Hofheimer will be when DuPont expands into the second crop, soy (the initial program is in corn), which will almost double the market application.

Globally it is estimated that disease causes losses of US\$82 billion a year to farmers. The competition for biotech crop technology is becoming more intense (with Hexima holding the most advanced known antifungal technology). Hexima is aiming for 70% disease control in corn.

Bayer/Athenix Deal

Once the technology is derisked, it then becomes critical for the seed companies to own the technology. In August this year **Bayer CropScience** acquired agbio technology company **Athenix** for what was believed to generate a greater than 10-fold return for the private investment made into that company. (Athenix was formed in 2001 and had 65 employees at the time the acquisition was announced.)

(Hexima is capitalised at \$60 million. It had \$30 million in cash at the end of June, and made a net loss of \$11.3 million in FY2009.)

Biota Holdings – Two Programs to Out-license

Biota Holdings is currently looking to out-license two programs: the rhinovirus program for use in people with chronic obstructive pulmonary disorder and asthma; and the LANI (long acting neuraminidase inhibitor) program co-developed with **Daiichi Sankyo**, which is a once a week flu drug (similar to a long acting Relenza drug).

Each year the company reviews over 200 technologies for in-licensing. Its ideal LANI partner will be a major pharmaceutical company with depth and experience in the influenza treatment area.

(Biota Holdings is currently capitalized at \$597 million. It had \$86.7 million in cash at the end of June, and made a net profit of \$38.2 million in FY2009.)

Starpharma Holdings – Vivagel for Condom Coatings

Starpharma partnered with **SSL** to develop microbicide coated condoms in 2007. One of the attractions of the partnership with SSL is that Durex condom sales drives the SSL business, which was not the case with other condom manufacturers the company considered. SSL is also a company where innovation is purposefully managed as a business driver.

The condom coatings program is expected to cost Starpharma \$3 million to reach a point where it will be submitted for approval. The condoms will likely have the claim that the microbicide inactivates virus and no specific claims about prevention of disease transmission.

SSL and Starpharma believe there are no other condoms coated with microbicide agents in development. Nonoxynol-9 was previously used in 40% of condoms before FDA warnings came out. It is still used in 20% of condoms. Consumers are willing to pay a 15%-20% price premium for such condoms. The expectation is that the Starpharma/SSL condoms will be used in around 45% of condoms sold by SSL, which will generate revenue to Starpharma of over \$25 million a year.

The added implied safety benefit of the microbicide condom is expected to help SSL build market share. (It is expected the product will reach the market towards the end of 2010.)

The one program that remains unpartnered for Starpharma is development of the Vivagel product, which is the same active microbicide in a standalone applicator. Potential partners could be condom manufacturers or women's health companies.

(Starpharma is capitalised at \$120 million. It had \$11.6 million in cash at the end of June, and made a net loss of \$4.1 million in FY2009.)

Universal Biosensors Inc (UBI)

UBI's first product, a novel electronic portable glucose monitor and strips, could be registered as early as this year by UBI's partner **Lifescan** (Johnson & Johnson). The minimum registration time for diagnostics in the US is four to six weeks. After regulatory clearance, UBI expects to generate revenue of \$25 million in the first 12 months from Lifescan.

The chairman of UBI, Andy Denver, made the point that more of us will live longer with chronic diseases but can we afford it? The point-of-care diagnostics market, which is the market that UBI is developing products for, is expected to be worth US\$18 billion by 2012.

In 2010 and 2011, UBI expects to be in a position to launch three new products. These are for C-Reactive Protein (a common test for general inflammation), a Prothrombin Time Test (used to calibrate correct warfarin dosage) and a D-dimer test (a common test for blood clots that can cause stroke and heart attack). (Note, all of these tests are currently conducted by pathology groups. The UBI test potentially allows these tests to be conducted by a GP, by the chemist, or at home.)

Denver made the point that people on warfarin therapy are outside the appropriate warfarin range 60% of the time. Warfarin dosage is adjusted every six weeks following a Prothrombin Time Test. The tools haven't been available to measure warfarin levels more frequently (but that is something UBI is seeking to change).

UBI will start negotiating with potential partners for all three follow-on programs this year. There is also the potential for more patient self-testing products to come. UBI has 39 patent families covering the technology. (For all subsequent programs after the glucose monitoring product, UBI has full commercial rights. For glucose, UBI has manufacturing rights and a service agreement which includes a one cent per strip royalty. Currently 16 billion glucose monitoring strips are sold annually worldwide and we believe Lifescan has about a 30% global market share.)

(UBI is currently capitalised at \$265 million. It had \$22.3 million in cash at the end of June, and made a net loss of \$7 million for the half-year ending June 30, 2009.)

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Acrux – Axiron, A Defining Asset

Richard Treagus, CEO of Acrux, said that Axiron (transdermally delivered male testosterone) is a company defining asset for Acrux. Although 80% of the market is in the US, the Brazil and China markets are 'exploding'. Acrux could have done a deal for Axiron at the end of Phase II, which would have validated the program. However, larger drug deals are done on Phase III/NDA (new drug application) stage products.

Acrux is managing the supply of Axiron through its manufacturer, **Orion Corporation** in Finland, which has a lot of experience in making therapeutic hormone products. The Phase III results reported recently by Acrux has triggered strong interest from a variety of potential partner companies.

(Acrux is capitalised at \$287 million. It had \$14.7 million in cash at the end of June, and made a net loss of \$7.7 million in FY2009.)

Cellestis – The Market Opportunity

Cellestis is currently selling 2 million of its tuberculosis (TB) tests each year. CEO, Tony Radford, said the global market is between 50-60 million tests a year. Asked how much of that market Cellestis could achieve, Radford said that achieving 50% of that market was possible. (We estimate that translates to potential sales of \$500 - \$600 million a year in the future).

The Cellestis test is becoming the preferred test, with the skinbased test largely inaccurate according to Radford. This inaccuracy causes unnecessary treatment of latent TB, which is a nine month course of antibiotics. The CDC in the US is expected to announce the Cellestis test as the preferred test. Interestingly, the City of Tokyo currently reimburses all TB screening.

Having captured around 4% of the global market, the rest of the market uses the skin-based test. The ELISPOT test, which is a very complicated test to use, is outsold by the Cellestis test by about 20 to one. Cellestis has only a small sales force, with eight people in the US and eight in Europe. Radford does not expect Cellestis' future gross margin to change significantly.

(Cellestis is capitalised at \$334 million. It had \$19.7 million in cash at the end of June, and made a net profit of \$8.2 million in FY2009.)

QRxPharma – Two Phase III Studies

QRxPharma will now proceed with the two final Phase III studies to bring its first product, MoxDuoIR, an immediate release form of two opioid drugs (morphine and oxycodone), to market. The trials will cost just under \$11 million.

Data from these trials should be available by next July. The trials will involve 550 patients. The company will then file the drug for approval and will seek to negotiate a major licensing deal for its first product.

The MoxDuoIR lead drug candidate has now been trialed in over 440 patients in 10 clinical trials. The combination of the two opioids has a synergistic effect that opens the therapeutic window for patients according to CEO John Holaday, reducing side effects normally experienced at similar analgesic levels and removing the effects of euphoria.

(QRxPharma is capitalised at \$85 million. It had \$17.7 million in cash as of June, and made a net loss of \$8.2 million in FY2009.)

Mesoblast – Multiple Products, Multiple Opportunities

Mesoblast is developing products from adult stem cells, which are harvested from bone marrow. From a population of 1:100,000 cells, the stem cells are isolated and are highly expandible and immunogenic. The company can produce 10 billion adult stem cells from a batch of one million initial cells within six weeks.

Mesoblast founder, Silviu Itescu, said the company can produce products with different concentrations and formulations, delivering multiple products for different partners with distinct pricing points. With these products, Itescu said the technology would be treated more like a device and likely require only single pivotal Phase III trials to get to market.

One new application for which the company has recently generated positive preclinical results, is in intervertebral disc damage, which is a precursor before spinal fusion is required. The preclinical studies have shown outstanding complete reversal of destruction pathology in large animal studies according to Itescu. This is a very large market, with around 20% of the population with some type of intervertebral disc damage, ten times larger than the spinal fusion market. A adult stem cell treatment could sell for \$5000 -\$7000 per treatment. For the knee osteoarthritis program, the company is likely to partner out earlier.

The products being developed by Angioblast are more in sync with pharmaceutical products said Itescu. The current Phase II heart failure trial (in 60 patients) is expected to be finished in the first quarter of 2010. From initial results in patients who were extremely ill with less than 30% heart blood ejection fraction, a 50% improvement was seen in some patients within only three months.

In the non-union long bone repair trial, an adolescent who had been in a car accident with no bone repair after six months, was healed in just 12 weeks with the Mesoblast adult stem cells.

Manufacturing Theme

One theme emerging from the conference was that of companies seeking to maintain manufacturing control of their products. These include **Chemgenex**, **Universal Biosensors**, **Pharmaxis**, **Cellestis**, **CathRx** and **Acrux**. Itescu said Mesoblast can also maintain future manufacturing of its stem cell products, with significant potential profit from that alone.

On a comparison with competitor **Osiris Therapeutics**, Itescu said Mesoblast's cells were 100% homogeneous based on a superior purification process. Mesoblast has sufficient cash at hand to complete its current Phase II programs.

(Mesoblast is capitalised at \$149 million. It had \$15.6 million in cash as of June, and made a net loss of \$12.3 million in FY2009.)

Pharmaxis – Articulating Sales Strategy

Pharmaxis currently has 110 staff. The company's manufacturing facility was under inspection by the FDA at the time of the conference. Pharmaxis has done what no other company has, and that is to place 400mg of a powder into the lungs of patients using particles that have been very highly defined, whereas previously only 40mg has been given to patients with other inhaled drug products.

Pharmaxis' CEO, Alan Robertson, says that there will now be no cystic fibrosis clinician unaware of the Pharmaxis product following presentations of Phase III data of its drug candidate, Bronchitol.

In Europe, the company believes it can sell its product with a sales force of around 25 people. This will be the first product approved for the treatment of CF in Europe in 15 years.

In the USA, a sales force of only 15 or so people will be required to market and sell the product. The product will likely be priced similar to Pulmozyme, which sells for US\$22,000 per year in the US. In Europe, the product will be launched first in the UK and Germany, where negotiation for reimbursement is not required. In the UK however, the company will seek NICE recommendations (for pricing). For the rest of Europe, it must negotiate reimbursement with payors. The price for Pulmozyme in Europe is \$13,000 per year of treatment.

The same drug to treat patients with CF will also be registered for the treatment of bronchiectasis, for which there are no products approved. Pharmaxis is the only company in the world that has completed a positive Phase III trial in bronchiectasis (a degenerative condition of the lung).

Company	Price	Price added	Date added	
	(current)	to portfolio		
Biodiem	\$0.20	\$0.15	October 2009	
QRxPharma	\$1.16	\$0.25	December 2008	
Hexima	\$0.65	\$0.60	October 2008	
Atcor Medical	\$0.17	\$0.10	October 2008	
CathRx	\$0.52	\$0.70	October 2008	
Impedimed	\$0.64	\$0.70	August 2008	
Mesoblast	\$1.10	\$1.25	August 2008	
Circadian Technologies	\$0.75	\$1.03	February 2008	
Patrys	\$0.13	\$0.50	December 2007	
Bionomics	\$0.28	\$0.42	December 2007	
Cogstate	\$0.27	\$0.13	November 2007	
Sirtex Medical	\$5.72	\$3.90	October 2007	
Clinuvel Pharmaceuticals	\$0.33	\$0.66	September 200	
Starpharma Holdings	\$0.58	\$0.37	August 2007	
Pharmaxis	\$2.41	\$3.15	August 2007	
Universal Biosensors	\$1.68	\$1.23	June 2007	
Probiotec	\$2.64	\$1.12	February 2007	
Chemgenex Pharma.	\$0.73	\$0.38	June 2006	
Acrux	\$1.81	\$0.83	November 2004	
Alchemia	\$0.53	\$0.67	May 2004	

In terms of ballpark future sales, Bronchitol could potentially generate sales in the order of \$300 million and Aridol around \$50 million a year according to Robertson.

In the second quarter of 2010 its manufacturing plant will be ready for final inspection. The company expects to file Bronchitol for registration in Europe for the treatment of CF in about two weeks, with approval likely nine months later if all goes well. The recommendation from NICE in the UK should be received about the same time, although the company does not need to receive a positive NICE recommendation before in launches. The NICE decision takes into account health economics assessments, for which Robertson says Bronchitol is well placed.

In clinical trials of CF, 60% of patient achieved meaningful results. Robertson expects every patient with CF could try Bronchitol and 60% should continue using the drug. (Our calculations show that using these numbers, Bronchitol could generate annual sales of \$660 million).

(Pharmaxis is capitalised at \$527 million. It had \$125 million in cash at the end of June, and made a net loss of \$35.2 million in FY2009.)

Portfolio Changes – 16 October 2009

IN:

No changes.

OUT:

No changes.

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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, <i>Bioshares</i> grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.		<i>Speculative Buy – Class A</i> 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.			
Group A Stocks with exis flows.	sting positive cash flows or close to producing positive cash	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			
Buy	CMP is 20% < Fair Value	management or board may need strengthening.			
Accumulate	CMP is 10% < Fair Value	Speculative Buy – Class C			
Hold	Value = CMP	These stocks generally have one product in development and lack			
Lighten	CMP is 10% > Fair Value	many external validation features. Speculative Hold – Class A or B or C			
Sell (CMP_Current	CMP is 20% > Fair Value t Market Price)	Sell			
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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

Bioshares

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

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