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Sunshine Heart is close to completing its feasibility trial of its C-Pulse device in 20 patients. However, the next trial, a much larger on, will require signifiicant funding, hence the plans for a $21 million capital raising and a Nasdaq listing.
We include coverage of the recent Wilson HTM conference, noting that ChemGenex's European partner Hospira looks to be modifying its regulatory strategy for that region with Omapro.
One stock worth re-focusing on is Imugene, now that is has re-licensed its vaccine technology for pigs and chickens, this time to Novartis Animal Health.
Halcygen Pharmaceuticals has changed its name to Mayne Pharma Group.
The Editors
Companies Covered: ACR, CXS, IMU, MYX (formerly HGN), PXS, SHC

	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)	12.7%
Cumulative Gain	**226%**
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.

Sunshine Heart to Raise up to $21 Million for Pivotal Year in 2011

Sunshine Heart is developing the C-Pulse device, a cuff that wraps around the descending aorta and inflates and deflates, assisting the function of the heart.

Sunshine Heart (SHC: 2.6 cents) is currently raising funds through a non-renounceable rights issue that will bring in $10.4 million after costs if fully subscribed. The company will also seek to raise up to $11 million in a private placement. The rights issue is being managed by **RBS Morgans**.

Venture capital groups **GBS Venture Partners** and **CM Capital**, which own 52% of Sunshine Heart, have indicated that they will take up their rights to subscribe for further shares in Sunshine Heart, which represents $5.6 million. The company has already received commitments of $3.7 million in the placement from US institutional shareholders.

The institutional shareholders have committed on the basis that Sunshine Heart will list its shares on the Nasdaq stock market by the third quarter of 2011. Sunshine Heart will need to raise a further $40 million to bring its product to market, and it's expected those funds will be raised in the US when listing.

Financial Risk Key for Sunshine Heart

There's still quite a bit of risk associated with Sunshine Heart, with perhaps financial risk being the greatest. The company has now implanted 16 patients in its 20 patient global feasibility trial. The progress appears to be very good, with a full report expected in mid 2011. The C-Pulse device appears to be working well, with infection problems the main issue but one that is manageable.

Bringing mechanical heart products to market can be a very expensive process and macro economic conditions need to be suitable. **Ventracor** found out the hard way, with the company falling victim to funding issues related to the Global Financial Crisis. **Heartware** has managed to get through the GFC, list its company on the US stock market and today enjoys a market capitalisation of $1.2 billion.

Assuming the full $21 million will be raised, Sunshine Heart will have a market capitalisation of only $34 million with around $22 million in cash.

The share market success Heartware is enjoying is presumably driving the interest from US investors and also driving the strategy to follow Heartware with a US share market listing. However, for this all to proceed to plan, financial markets stability will need to be maintained, and Sunshine Heart we believe will need to see its market capitalisation exceed $80 million if $40 million is to be raised in the second half of 2011 to fund the pivotal program.

The main driver of the company's capitalisation will be the results from the current feasibility trial. Sunshine may seek approval to gain additional data from enrolling more pa-

tients (around 15 in and outside of the US). The data from the 20 person feasibility study the company believes should be sufficient to submit for European CE Mark approval, with Heartware gaining European approval from only 23 patients. This filing for European approval may also drive interest in the stock.

Busy Year ahead in 2011

Following the current capital raising, Sunshine Heart should have sufficient funding to take it to the end of 2011. If the full $21 million is not raised, the company will scale back some of the R&D programs ensuring the current trial proceeds without restriction.

Sunshine Heart is expecting to have an extremely busy year in 2011. The first milestone for 2011, following completion of enrolment of the 20 patient feasibility study in 2010, will be completion of the changes to the cuff design (that wraps around the aorta) to better facilitate the new minimally invasive surgery (MIS) procedure, and the completion of development of an external single unit battery pack and driver (pump).

Currently the driver weighs around 5 lbs and the battery 3 lbs. The aim is to bring the new combination unit down to less than 5 lbs. The company believes that the new device will be accepted by regulators for the pivotal study.

The next major milestone will be the release of the 20 patient feasibility study data, around mid year. The company then anticipates starting the pivotal 250 patient study in the third quarter of 2011, with a Nasdaq listing around the same time. In the fourth quarter the company is seeking to achieve European CE Mark approval. The company has drafted an ambitious to-do list for the year ahead.

Feasibility Study

The feasibility study underway will provide information on changes/improvements in heart ejection fractions, changes in cardiac pressure, changes in the 'six minute walk', which is how far patients can walk in six minutes, a treadmill test, blood analysis and also qualitative measures to assess changes in quality of life.

The feasibility trial will deliver results six months after the last patient is implanted, and those results should be available around mid 2011 if the final four patients can be enrolled this year.

There has been some important positive feedback from surgeons/cardiologists. These include: "This is a very basic procedure that any surgeon can perform"; "I would implant this device in 30% of my Class III/IV patients"; "We were sold when we saw the difference on the table"; and "Minimally invasive tools will boost expansion".

There has also been very positive feedback from patients implanted with the device. Our expectation is that the six month data from the feasibility study will deliver very positive results.

Pivotal Study

The pivotal study is expected to enrol somewhere between 250 – 300 patients, although the final trial protocol has yet to be set. The trial will be randomised with the control arm receiving existing medical therapy. The aim will be to have most patients implanted using the MIS procedure although this can not be guaranteed.

The company is currently reimbursed for devices used in trials in the US in most cases, particularly where the patients are covered under Medicare (over 65 years of age) and where private insurers agree to coverage. The company receives a reimbursement of US$54,000, with the procedure reimbursed under the LVAD category to the value of US$150,000 to the hospital.

Crucial Advances for Sunshine Heart

The Sunshine Heart C-Pulse device has needed to achieve at least two major technical advances. The first was that its device could be implanted through minimally invasive surgery (MIS), rather than requiring a full sternotomy (splitting of the chest). That has now been achieved with the last four patients implanted in the feasibility study using the MIS procedure.

Under a sternotomy procedure, the patient needs to stay in hospital for around 10 days. Using a MIS procedure, that hospital stay can be cut down to four days (as was the case with the last patient implanted with a C-Pulse), which is similar to that for a pacemaker implant procedure. The reduced complexity of the procedure and decrease in hospitalisation time makes the procedure more appealing and more widely accessible.

The C-Pulse device has the potential to be a successful product, however to become a billion dollar product like the pacemaker industry, the product needs to be made fully implantable i.e. there is no drive line across the skin. In the fully implantable system, power and control would be delivered across the skin, rather than through the skin. The company expects to demonstrate feasibility of the implantable prototype within 18 months.

Bioshares view is that the aim of the current product being developed is to deliver an approved proof-of-concept device that is not fully implantable, and that the real value of the product, and to any group seeking to acquire the company, would be for the implantable system that has no cables crossing the skin.

Aside from the discomfort in having cables coming through the skin for the patient (similar for the LVADs), the point where the cables cross the skin is also the principle point of infection, which for LVADs and the C-Pulse remains high, at around 25% of patients. In a fully implantable system, most of these infection issues should not occur.

Summary

Next year will be a crucial year for Sunshine Heart. The stock has the capacity to deliver multiple fold gains. However, the major risk for the company remains that of funding, and whether the company can list in the US next year and raise capital to fund its pivotal study. If capital markets remain open to capital raisings and the appeal of the LVAD companies remains high, then Sunshine Heart has a good chance of achieving its ambitious milestones for 2011.

Bioshares recommendation: **Speculative Buy Class B**

Wilson HTM Life Sciences Conference Wrap

Investment group **Wilson HTM** held its 7th life sciences conference in Sydney earlier this month. The entry of Wilson HTM into the biotech sector in Australia around eight years ago can not be underestimated with the group facilitating one of the the largest flows of capital into the sector, raising in excess of $500 million by its investment banking group, and also running investment funds with a strong interest in local biotech stocks.

With that in mind the comments from Wilson HTM Executive Chairman Steve Wilson in opening the conference are worth noting. Wilson stated that his group was proud and keen to continue its association with an 'embryonic' industry and emphasising that it is an exciting place to invest in.

The Chinese are now joining the west on lifestyle decadence and this is an industry that should and is being subsidised by taxpayers through scientific research said Wilson.

Wilson also said that investors can make money and outperform the broader market through investing in life science stocks. Since 2006, the life science stocks that Wilsons has raised money for have outperformed the ASX300 by 53%, Wilson stated.

The title of this year's Wilson's conference was "A Reason to Believe". However Wilson HTM analyst Graeme Wald believes that the sector is now delivering and perhaps the title should have been "We Told You So". And that is perhaps one of the most important points for investors.

Chemgenex Pharmaceuticals

Chemgenex Pharmaceuticals is a very clear example of how long it can take to deliver new products to the market, in this sector. CEO Greg Collier opened by noting that his involvement with Chemgenex had now been for 15 years.

One of the appeals of the company's leukemia drug, Omapro, is that it kills leukemia stem cells, where the existing drugs on the market do not get into the bone marrow to reach the stem cells.

As of this month, there are now three drugs (TKIs – tyrosine kinase inhibitors) approved to treat chronic myeloid leukemia as a first line therapy. Patients eventually develop resistance to all of these TKIs. Omapro works through a different mechanism and so offers an alternative treatment to patients with resistant disease.

Chemgenex's approach to getting its drug to market was a 'speed-to-market' strategy, bringing Omapro to market first by focusing on a subset of patients with a particular mutation. The difficulty in measuring this mutation accurately has proven this not to be a good speed-to-market strategy. The company is now refiling its application with the FDA as a third line treatment for patients who have failed two TKIs.

The positive side to going for the two TKI approach is that the market is larger. The delay also gives the company more time to get key opinion leaders on side.

With regards to European approval, the company is now considering aligning its European submission with the US, by seeking approval for treatment of patients who have failed two TKI treatments rather than those with the T315I mutation. European approval will likely deliver a milestone payment, although may not be as high as analyst forecasts of $25 million.

Collier said that following the receipt of a $15 million convertible note from **Cephalon**, the company has sufficient cash to last to the end of 2011. The recent deal with Cephalon now sees that company with a 'footprint' on 30% of Chemgenex, which would trigger a formal takeover of the company if those options are exercised.

Pharmaxis

Pharmaxis CEO Alan Robertson was back on deck having recovered from illness. Robertson showed now signs of slowing down with a 45 minute, 37 slide presentation and Q&A with investors.

A peculiarity from the company's second Phase III cystic fibrosis trial result appears to have been resolved. In that trial, the company achieved a p-value of 0.059 (results need to be less than 0.05 or else are not considered statistically significant). The first Phase III trial delivered unquestionable statistical significance of 0.001.

It appears that the primary endpoint was narrowly missed due to the improvement in lung function of the placebo group between screening and commencement the trial (baseline). Competing drug Pulmozyme was assessed on an average of the screening and baseline values. If that approach is taken with the Pharmaxis Phase III trials in CF, then the p-values are 0.0002 and 0.0075, both clearly statistically significant.

In *Bioshares* view, regulators however do not like post hoc reassessment of data using a method different to that which was originally agreed to. However, combining data from the first and second trials in their original data format we believe should be sufficient to support approval both in Europe (potentially this year) and in the US in 2011. Approval is also expected in Australia very soon.]

It should be remembered that cystic fibrosis is a life limiting disorder. According to Robertson, the average of age of people with CF in the Ukraine is only five. Ten years ago someone with CF would live to only the early 20's and the average age now is approaching 40 years. There is a rapid decline in lung function between the ages of 14-22, and by the age of 25, half of people with CF are no longer alive.

Robertson believes that if you can treat a person with CF earlier enough, then there's no reason that person should die from respiratory failure. Usage of Pharmaxis' Bronchitol should see antibiotic use decline.

– Cont'd on page 5

Imugene Re-licenses Pig and Chicken Vaccines

Imugene (IMU: 6.7cents) is the only animal health biotech listed on the ASX. The company has developed a vaccine technology (which originated from the CSIRO), with a primary focus placed on the development a vaccine to treat Porcine Reproductive and Respiratory Syndrome (PRSS) in pigs.

Until December 31, 2010, the company has partnered its vaccine technology (pig and poultry) with French company **Merial**, but because that company was slow in developing the technology, Imugune elected to regain its rights to the technology.

After a nine month period of new partnering discussions, Imugene has licensed the technology (pig and poultry) to **Novartis Animal Health,** which is managed from Basel (Switzerland), Archwood (Iowa) and Greensboro (North Carolina).

Specific royalty rates were not disclosed. However, we understand that royalty rates for the vaccine are better than those achieved in the first deal with Merial, and are in double-digit territory. The company has received an initial sign-on fee of US$1.5 million, and Novartis will pay development costs and other milestone payments to Imugene.

Also recently received by Imugene from Merial were data files, scientific records and lab books. The timely receipt of these documents is relevant to the re-starting of the program with Novartis.

A PRRS vaccine challenge trial in 75 pigs was completed in the US in July 2010, with results positively replicating results from an earlier US-based trial. This trial was conducted using a manufacturing cell-line that is expected to simplify the vaccine's registration pathway.

Although the stock was in a pause position while a new partner was being sort and licensing negotiations were underway, we expect the stock to offer an attractive upside in the next twelve months. Since 2003, approximately $10 million has been invested in the company, with more than $4 million received in licensing and related payments. The company possesses a platform technology with patents extending the life of potential products out to 2028.

Significantly, the market opportunity for an easily administered but effective PRRS vaccine has not changed, with the economic costs of PRRS greater than US$500 million per annum (in 2005) in the US continuing in the absence of an effective treatment. Worldwide losses are estimated to be in the order of US$1 billion each year.

Imugene had $700,000 in cash at September 30 and has since received the US$1.5 million payment from Novartis Animal Health. The company is capitalised at $9.6 million.

Bioshares recommendation: **Speculative Buy Class B**

Halcygen Pharmaceuticals – Name Change to Mayne Pharma Group (MYX)

Halcygen Pharmaceuticals (MYX: 66.5 cents) received approval at its AGM to change its name to Mayne Pharma Group. The company's new ticker code is MYX. The move is designed to reflect the greater role played by the company's pharmaceutical operations that it obtained when it acquired the Mayne Pharma International assets from **Hospira** in November 2009. These assets include the former **FH Faulding** plant in Salisbury, Adelaide. Management describes the acquisition as having 'exceeded expectations'.

With eight months of operations from the acquisition at hand, Mayne Pharma Group reported total revenue for FY2010 of $36.7 million and NPAT of $3.3 million. The company has announced a 2 cent normal dividend and a 1 cent special dividend. The company said at the AGM that it would aim to maintain a 25% – 30% payout ratio. However, that would be subject to internal investments and to potential M&A activities.

The company expects to pay down the remaining US$5 million of the US$10 million loan taken out to fund the acquisition of the Hospira assets in FY2011.

SUBA-Itraconazole

SUBA-Itraconazole is a compound that has been engineered using the Mayne Pharma Group's SUBA technology, which improves the bioavailability of the active drug ingredient. The systemic compound treats a number of fungal infections. It will compete with Johnson & Johnson's Sporanox. The advantage of SUBA-Itraconazole is that a lower dose (50%) can be administered to achieve that same distribution (bio-availability) of Sporanox.
US Phase II trials have now been completed and the company is planning to hold discussions with the FDA in March 2011.

The company said that SUBA-Itraconazole is in the final stages of dossier preparation, with a filing to be made with the European Medicines Agency in the next two-to-four weeks, and with approval expected in about nine months time.

One investment concern for Mayne Pharma is that revenues from Doryx (a 150 mg formulation sold in the US by **Warner Chilcott**) will decrease significantly in the second half of 2011 when a 30-month stay on a generic competitor's challenge expires. Doryx is a delayed release antibiotic. Sales in the US of Doryx exceeded US$200 million in 2009.

The company is addressing this threat in several ways including through the development of new formulations of Doryx. It filed a provisional patent covering new formulations of minocycline, the active pharmaceutical ingredient (API) of Doryx in September this year. The strength in Mayne Pharma Group is that it owns three technologies that can be applied to provide protection to drugs by improving bio-availability of the API, controlling release of API and masking the taste of the API.

Mayne Pharma Group is capitalised at $100 million, holding cash of $18.5 million at September 30, 2010.

Bioshares recommendation: **Buy**

Bioshares Model Portfolio (19 Nov 2010)

Company	Price (current)	Price added to portfolio	Date added
Phylogica	$0.045	$0.053	September 2010
Sunshine Heart	$0.026	$0.036	June 2010
Biota Holdings	$1.01	$1.09	May 2010
Tissue Therapies	$0.51	$0.21	January 2010
QRxPharma	$1.00	$0.25	December 2008
Hexima	$0.36	$0.60	October 2008
Atcor Medical	$0.11	$0.10	October 2008
Impedimed	$0.84	$0.70	August 2008
Mesoblast	$2.95	$1.25	August 2008
Circadian Technologies	$0.64	$1.03	February 2008
Patrys	$0.11	$0.50	December 2007
Bionomics	$0.32	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$6.05	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.18	$0.66	September 2007
Starpharma Holdings	$0.75	$0.37	August 2007
Pharmaxis	$2.71	$3.15	August 2007
Universal Biosensors	$1.52	$1.23	June 2007
Acrux	$3.06	$0.83	November 2004
Alchemia	$0.57	$0.67	May 2004

Portfolio Changes – 19 November 2010

IN:
No changes.

OUT:
No changes.

Acrux Update

Acrux (ACR: $3.06) (and its licensee **Eli Lilly**) is waiting on approval from the FDA for its testosterone lotion product, Axiron. Our previous calculations indicated that approval should come through, if indeed it is approved, on 27 November plus or minus one week. So that places our expected approval as either the coming week or the week following.

Our recommendation to readers is to start taking some profits if approval is achieved and the share price approaches $4.00. If that price is not achieved, there should be plenty of reasons to stay in the stock and Acrux will remain a very attractive long term investment proposition.

The positive news flow to be expected in the next six months includes: includes receipt of a US$87 million milestone payment from Eli Lilly should Axiron be approved; potentially an interim dividend payment; the global launch of Axiron; approval of Ellavie (the transdermal HRT product) in Europe; and approval of the animal health products in the US from the partnership with Elanco (Eli Lilly).

There is also potentially further upside from a potential acquisition premium should Eli Lilly decide to acquire Acrux.

Bioshares recommendations: **Speculative Buy Class A ; Take some profits at $4.00**

Bioshares

– Wilson HTM coverage (from page 3)

Pharmaxis will be meeting with the FDA shortly before it files its NDA, and it expects an accelerated review with approval within six months, if all goes well.

In terms of the competition, Roche's Pulmozyme currently generates sales of US$460 million a year. It is dosed once to twice a day using a nebulizer for 15 minutes a day although in practice takes longer with set up and cleaning. It achieves an improvement in lung function of 6% over six months. Bronchitol achieves a 6%-8% improvement over six months and takes up to five minutes administer through a portable inhaler. At 12 months that improvement is sustained at 8% (no data for Pulmozyme).

Other competition includes **Inspire Pharmaceuticals** Denufosol, also in Phase III trials. However this requires treatment through a nebulizer three times a day and achieves only a 2% improvement in lung function at six months.

Bioshares recommendations:
Chemegenex Pharmaceuticals – Speculative Buy Class A
Pharmaxis – Speculative Hold Class A

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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 or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "**Take Profits**" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

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

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C
Sell

Corporate Subscribers: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron

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