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In this edition...
While it may appear to be a quiet period for the biotech sector, investors should be prepared for a busy wrap-up to the year. The fate of a select number of companies rests on the actions of drug regulators. Pharmaxis is waiting on EMA approval for Bronchitol, Acrux on FDA approval of Axiron (which could come sooner rather later) and Alchemia on the FDA approval of its generic fondaparinux. And interestingly enough the future of Universal Biosensors (where CEO Mark Morrisson has retired) rests in part on the clearance by the FDA of the One Touch Verio blood glucose meter. We also discuss Mesoblast's continuing search for new opportunities based on its adult stem cell technology and we update readers on Sunshine Heart.
The Editors
Companies Covered: ACL, ACR, BTA, MSB, PXS, SHC, 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)	-5.1%
Cumulative Gain	**175%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

10 September 2010
Edition 376

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

In The Hands Of The Regulators

The fate of three of Australia's leading biotech companies are now in the hands of the regulators as they wait for final marketing approval to bring their drugs to market. Pharmaxis, Acrux, and Alchemia should all find out in the next three months whether their products will receive approval to be sold to patients in international markets. While it has been a quiet six months for the biotech sector in Australia, it should be a very busy and positive run into the end of the year in 2010. (At the time of release of this publication, Biota Holdings has also just announced approved of its drug (Inavir) in Japan.)

Pharmaxis Hires Contract Sales Force for EU

Pharmaxis (PXS: $1.98) is expected to hear from the European drug regulator by year's end regarding its marketing application of Bronchitol for the treatment of patients with cystic fibrosis. Our expectation is that the company should receive the green light to start selling its drug in Europe in early 2011.

In advance of the receipt of a European marketing authorization, Pharmaxis has been in the process of establishing a marketing capability across the EU. In addition to its direct employment of a small number of staff, primarily UK-based, Pharmaxis has opted to hire marketing personnel from **Quintiles**, a global contract pharmaceutical industry services organisation. The contract is for six years.

Quintiles employs product managers who hold detailed market access knowledge pertaining to each of the member states of the European Union. Quintiles will provide sales, staff charged to Pharmaxis at a daily rate. Quintiles will be responsible for sales call rates, and will also provide the IT infrastructure in support of the sales force.

The advantage of using a contract sales force is that Pharmaxis can place sales staff in individual European countries in a timely manner, given that not all countries will be market-ready following authorization. For example, in the UK and Germany, sales can commence almost immediately following EMA approval without Pharmaxis reaching agreement on a selling price for Bronchitol, which is required in France, Spain and Italy. Pharmaxis expects sales of Bronchitol to commence in the UK and Germany in 2011 Q1.

It is also a much quicker way for Pharmaxis to access knowledge of specific in-country marketing requirements and characteristics, which could take Pharmaxis much longer to accumulate under its own management.

And in contrast to the distributor model of sales, use of a fixed-cost sales force allows Pharmaxis to collect a margin that would otherwise flow to a distributor.

Under the Quintiles arrangement, Pharmaxis expects to have about 30 staff dedicated to the sale of Bronchitol in 14 European countries, with, for example, six dedicated to Germany. Under its own management, Pharmaxis oversees five staff in the UK, with one person expected to be added to cover Ireland.

– Cont'd over

Acrux: FDA result on Axiron Sooner than Expected

Acrux is waiting for approval of its Axiron product from the FDA. The company filed its NDA (new drug application) on 27 January this year. That means the company should get a decision by 27 November this year, plus or minus one week.

The FDA's target regulatory review timeline for new drug applications is 10 months. Looking at the NDA decisions for 'new molecular entities (NMEs)' over the last year indicates that regulator is hitting the target to within one week (see table). There have been 12 NMEs approved over the last 12 months by the FDA.

In six of those cases, a decision was received by the regulator within one week of the 10 month assessment target set by the FDA from the date of filing. Three companies were granted priority review, with approval received between six to nine months from filing. One drug, Victoza from Novo Nordisk, was approved after 22 months, however there were 86 additional data/document submissions required by that company. Two other companies (Novartis and Chemische Fabrik Kressler) had problematic submissions where the original NDA was filed in 1999 and 2002. However, these NDAs were finally approved in the last year three and eight months respectively after the final submission of the complete response letter.

On approval of Axiron, Acrux stands to receive a US$87 million milestone payment from its partner Eli Lilly. There is also a US$3 million payment due once manufacturing has been transferred to Eli Lilly for the Axiron product. That translates to 60 cents per Acrux share. Acrux has indicated it will pay a dividend for financial year 2011 if Axiron is approved.

Will Eli Lilly Acquire Acrux?

The bigger question for Acrux investors is whether Eli Lilly will seek to acquire Acrux if the Axiron product is approved. We would argue that such an event has a high probability of occurring. The impact on Eli Lilly's EPS (earnings per share) would be lower if the company was acquired. The cost of a potential acquisition would go onto Eli Lilly's balance sheet and be amortised over say 15 years. That's a $40 million a year amortisation charge on Eli Lilly's Profit and Loss statement assuming an acquisition price of around $600 million. If Eli Lilly continues its licensing arrangement, it will have to pay Acrux US$90 million on approval (and transfer of manufacture), a further US$190 million of potential milestone payments, and an estimated annual royalty of US$100-120 million a year based on global sales of Axiron of between US$500-600 million a year.

In March this year Eli Lilly licensed Axiron from Acrux paying it an upfront payment of US$50 million. On the back of that deal Acrux delivered a net profit for the last financial year of $46 million with cash of $58 million. To have acquired Acrux before Axiron gains approval would have been too large a risk for Eli Lilly. However an

– Cont'd on page 4

FDA NDA Approvals in last 12 months for NMEs (Novel Molecular Entities)

Company	Product	Disease application	Month approval	Month NDA filed	Time to approval	*Notes*
Ista Pharmaceuticals	Bepreve	Ocular itching with allergenic conjunctivitis	Sep-09	Nov-08	10 months (less 4 days)	
GSK	Voitrient	Advanced renal carcinoma	Oct-09	Dec-09	10 months (and 1 day)	
Celgene	Istodax	T-Cell lymphoma	Nov-09	Jan-09	10 months (less 7 days)	
Novo Nordisk	Victoza	Adjunct to diet and exercise for type 2 diabetics	Jan-10	Mar-08	22 months	*86 document submissions*
Shire Human Genetic Therapies	VPRIV	Gaucher disease	Feb-10	Aug-09	6 months	*Priority review*
Orphan Europe	Carbaglu	Enzyme NAGS deficiency	Mar-10	Jun-09	9 months	*Priority review*
Chemische Fabrik Kressler & Co	Asclera	Varicose veins treatment	Mar-10	Jul-10	8 months (from submission of complete response letter)	*NDA originally submitted 1999*
Novartis	Zortress	Prevent kidney transplant rejection	Apr-10	Jan-10	3 months (from submission of complete response letter)	*NDA originally submitted 2002*
Bayer Healthcare	Natazia	Contraceptive	May-10	Jun-09	10 months (precisely)	
Sanofi Aventis US	Jevtana	Hormone refractory metastatic prostate cancer previously treated with docetaxel regimen	Jun-10	Mar-10	3 months	*Priority review. No current available therapies*
Vistakon Pharmaceuticals	Lastacaft	Prevent intching associated with allergic conjunctivitis	Jul-10	Sep-09	10 months (precisely)	
Laboratoire HRA Pharma	Ella	Contraceotive failure	Aug-10	Oct-09	10 months (and 1 day)	

Mesoblast – Continues to Open Up New Product Opportunities

With many biotech companies having downsized their operations in Australia in the last two years, Mesoblast (MSB: $2.40) is one company that continues to grow, taking advantage of the pool of experienced biotech personnel in Australia, and more specifically in Melbourne. The growth is expected to accelerate as investors vote on the merger with its sister company, Angioblast, and as the product opportunities move to pivotal stages of clinical assessment.

Mesoblast (with Angioblast) is currently conducting six Phase II trials in Australia and the US in three different applications with another program expected to move into Phase III testing in coming months.

Treatment Available in Australia

Mesoblast is seeking to launch its products first into smaller markets that can be more readily accessed, then into broader target markets. The first commercial application using its adult stem cell technology is an autologous (patient's own) product in Australia for the treatment of serious non-union bone fractures. Mesoblast now has approval to manufacture its product and patients can now access this treatment.

In 2008 Mesoblast released results from trial of 11 patients with serious bone fractures that had not healed for a median period of 10 months. Using Mesoblast's autologous stem cell treatment, eight of those patients achieved successful bone union.

Making this product available in Australia is more of a goodwill gesture than about making a profit. Patients will need to have a bone marrow sample taken under a local anesthetic and the cells will need to be extracted and expanded, which will take about four weeks in the laboratory. Mesoblast founder Silviu Itescu believes this will be the world's only regulated stem cell product available.

Second Target Market – Elite Athletes

The next closest product application the company is investigating is the use of an autologous adult stem cell product by elite athletes. The idea is that athletes would have their stem cells extracted, expanded and banked prior to injury. When the athlete sustains a stress fracture, those mesenchymal precursor stem cells would be available for immediate use. The benefit of banking the cells upfront is that treatment could be given immediately rather than waiting four weeks for the cells to be extracted and expanded.

The business model may include an upfront fee and an annual storage fee. Stress fractures are becoming increasingly common in AFL and a second issue is that players are returning too soon after a stress fracture and re-fractures occurring.

Third Target Market – Expansion of Cells in Bone Marrow Transplants

A large and accessible near term market application is in the area of bone marrow transplantation. In patients with bone marrow cancers (such as leukemia or lymphoma) the bone marrow is destroyed using chemo or radiation therapy. After therapy the bone marrow needs to be rebuilt with a healthy bone marrow transplant. The problem is that only 30% of patients can find suitable matches. The hematopoietic cells from cord blood has a much lower chance of being rejected (graft versus host disease) and does not need to be matched. However the volumes of these cells from this source is so low that they do not engraft well.

Angioblast (which currently holds the commercial rights to this application) has shown that the mesenchymal precursor stem cells can stimulate the hematopoietic cells from cord blood to expand 40-fold.

There are about 30,000 patients globally each year who need a bone marrow transplant, however only one third find a suitable donor. At $50,000 per treatment, that equates to a $1.5 billion market opportunity, two thirds of which is currently unserviced. It's also a very accessible market, with only 30 transplant centers in the US.

Angioblast expects to start a Phase III trial by early 2011. The company is seeking to structure the trial design through a Special Protocol Assessment with the FDA. This may delay the start to the Phase III trial however gives the company more confidence that the FDA will approve the product based on achieving agreed clinical milestones.

Data from the Phase II trial in 25 patients indicates that a pivotal trial could be achieved with somewhere between 120-240 patients. It's possible that only one Phase III trial may also be required. The endpoint is likely to be either changes in three-month mortality or engraftment rate.

The Phase III trial would cost between $10-12 million. Mesoblast says it has sufficient cash to fund this trial.

This could see the product on the market in the US in 2013 if all goes to plan. In Europe the regulatory pathway may have less onerous requirements for delivering a patient specific therapy.

Heart Failure Areatment Application

The next product application is in using the stem cells for the treatment of heart failure. The commercial rights to this application reside with Angioblast. Itescu believes the market for heart failure is 20 times larger than the bone marrow transplant market. There are 600,000 new patients each year who suffer heart failure in the US which are added to the five million patients already in this category. The stem cell therapy could be suitable for 40% of those people.

A Phase III cardiac trial may require as few as 250-500 patients and is within Mesoblast/Angioblast's capabilities to conduct in 2011 although further funds would likely need to be accessed for this trial.

Business Model

The business model for Mesoblast/Angioblast is to maintain manufacturing for any al1ogeneic (off-the-shelf) products it develops. It is currently looking to secure a contracted third party to

– Mesoblast cont'd

assist with developing such a manufacturing facility. All allogeneic products could then be manufactured at the one facility and delivered to marketing partners for various applications.

Merger and Business Consolidation

Currently the orthopedic applications for the adult stem cell technology reside with Mesoblast. The cardiac disease and bone marrow transplant applications are held by Angioblast. Mesoblast currently owns 32.6% of Angioblast. Mesoblast is currently seeking to merge the two businesses, with an EGM to vote on the merger to take place on 22 September.

Mesoblast is currently recruiting in four spinal fusion trials in the US and one trial in knee reconstruction in Australia. Angioblast is currently recruiting patients in one Phase II trial in the US in patients with recent heart failure.

Management Capabilities

Mesoblast/Angioblast has positioned itself as one of the world's leading commercial stem cell players. It is moving towards not only having the technical and management capabilities but also the international financial support to deliver on its well thought out business model. Earlier this year the company appointed Graeme Kaufman as an in-house advisor. Kaufman previously worked alongside Brian McNamee at CSL and more recently at Circadian alongside Leon Serry.

Funding

At 30 June Mesoblast held $32 million in cash. The recent capital raising has seen several UK funds invest in Mesoblast, with those funds now owning between 10-12% of the company. That international funding should offer important financial support to Mesoblast as it seeks to commercialise its many opportunities.

Summary

Based on the current share price and if the merger proceeds, the company is capitalised at $564 million. If Mesoblast/Angioblast is successful in just one its core applications, then its value will justify multiples of its current share market capitalisation.

Bioshares recommendation: **Speculative Hold Class A**

Bioshares

– Cont'd from page 2

acquisition after FDA approval leaves only the marketing risk for Eli Lilly. It would also allow Eli Lilly to regain most of the US$50 million up front payment it made earlier this year.

Other Reasons

There are other reasons an acquisition of Acrux by Eli Lilly would make sense. Eli Lilly has licensed a number of animal healthcare drug candidates from Acrux that are nearing approval. And there are a suite of other development assets that Acrux holds. One of those is a testosterone product for women, called Luramist, to treat low libido.

The second is the Evamist/Ellavie product, a spray-on hormone replacement product for women to reduce symptoms from menopause. The US rights to this product are licensed to KV Pharmaceutical. KV is in all sorts of problems, having been hit with $26 million in fines, a closure of its manufacturing facility, sacking of its CEO, the laying-off of more than three quarters of its staff and is now facing a US$100 million law suit for breach of supply. Its Evamist HRT product is current selling 18,000 prescriptions a month. However, rights to Evamist may revert to Acrux if KV is unable to commercialise that product. One issue that has been raised by the FDA with this product is the transfer of the pharmaceutical to others, specifically to 8 children and two dogs so far. KV is seeking to better address this issue.

That same product is called Ellavie outside of the US. Acrux is commercialising that product outside of the US, having licensed it to partners in South Africa, Australia, South Korea and Switzerland. That product is currently being assessed by European regulators with a decision expected this year. Both the Luramist and the Ellavie products could be of interest to Eli Lilly, although it currently does not have a female health products group.

Tough times for Eli Lilly

It's been a tough year for Eli Lilly. In August this year its Alzheimer's disease drug candidate semagacestat crashed out in a Phase III trial, throwing some serious questions on the amyloid beta link to Alzheimer's disease. In the same month it lost a patent ruling around its ADHD drug Strattera, which generates sales of around US$600 million a year. The loss may reduce market exclusivity by seven years. In July this year Eli Lilly lost a patent case around its cancer drug Gemzar, which generated sales of US$1.36 billion last year. The decision reduces the market exclusivity by two and a half years. Both were method-of-use patents.

The company faces a number of patent expiries and has indicated it will shed 500 jobs in help reduce its cost base by US$1 billion a year. An Acrux acquisition would potentially allow Eli Lilly to build a very strong mens and womens health drug business.

Alchemia Approval Imminent

The timeline for approval of generic drugs is quite a different matter to New Drug Applications. According to the Director of the Office Of Generic Drugs in February this year, there was a backlog of nearly 2,000 ANDAs (generic drug applications) lodged at the FDA. This extended the generic approval time by five months in 2009 over 2008, and by 13 months from 2005 to 2009.

No doubt this delay has been due to the flood of low cost generic manufacturers coming to market in recent years, drawn to the generics businesses with the raft of major drug patent expiries in process.

This backlog has pushed out the approval time for Alchemia's generic drug fondaparinux which was submitted for approval in March 2009. Our last revised estimate for approval of this drug

– Cont'd over

Sunshine Heart Improves Implantation Technique

Sunshine Heart has continued to refine the surgical techniques required to improve the attractiveness of its C-Pulse heart assist device to cardiologists who manage congestive heart failure patients. The C-Pulse device is an inflatable cuff that wraps around the aorta, and assists (through deflation and inflation) the pumping of blood from the heart. Two major features of the device are that it does not contact blood, diminishing the risk of blood clots forming, and unlike LVADS, it can be turned off without risk of death. The device sells for US$54,000. To date, thirteen patients have been implanted in the current feasibility trial.

In late August, it announced that a patient had been implanted using a minimally invasive thoractomy procedure. With this procedure, the device was inserted through a small incision between a patient's ribs, similar to minimally invasive aortic valve replacement.

The driver for shifting the surgical implant procedure from an invasive sternotomy (a major opening of the chest cavity, about 20 cm in length) to a minimally invasive one, initially as a mini-sternotomy and now as a thoractomy is two-fold.

The ultimate targets for the C-Pulse device are patients with Class III heart failure, a patient group estimated to number 500,000 in North America. However, cardiologists appear to have been reluctant to expose their Class III patients to invasive surgery given that they are likely to face a similar high-risk surgery following deterioration into the final stage of heart failure (Class IV). From a risk-management point of view, cardiologists have not been convinced of that the advantages of the invasive surgery have outweighed the benefits.

With the development of a less invasive surgical technique, risks, such as those relating to infection are likely to have decreased.

A second driver for a less invasive technique is time-to-discharge. In keeping with protocols established with LVAD implants, C-Pulse patients have been discharged about 10 days after surgery. With less invasive techniques, the time-to-discharge has been decreased to 3-4 days. This is an economic driver of significance in the US healthcare system.

Device Improvements

Sunshine Heart has improved and will continue to improve and refine the C-Pulse device, focusing on reducing the weight and size of the device driver and battery system.

Pivotal Trial Design

Sunshine Heart is considering the design of its Phase III pivotal trial. Such a trial could take the form of a superiority trial, in which the device is compared alongside standard of care, or it could be a non-inferiority trial, in which the device is compared to another implant such as the Heartmate II.

The superiority trial would require 260 patients and take 2-3 years to complete, whereas the inferiority trial would take 1-2 years to complete, enrolling 175 patients.

Funding of the pivotal trial is a significant issue for Sunshine Heart. However, should the feasibility trial indicate economic advantages of the C-Pulse are possible, coupled to device improvements, then funding concerns may ease. Sunshine Heart has stated that it would seek a US stock exchange listing in 2011.

However, the device can be submitted for European approval following the completion of the Phase I trial, with approval potentially being achieved by 2011 Q3. Revenues could also flow from the continued implantation of the device through initiation of a registry system.

Summary

Sunshine Heart has, under its new CEO Dave Rosa, made up for lost time in the clinic. The company has taken a more pro-active approach in managing trial sites, with a greater emphasis placed on field management to ensure recruitment is maintained as a priority at clinical trial sites. Rosa expects the feasibility trial enrolling 20 patients to be fully recruited by the end of September or October at the latest.

Sunshine Heart is capitalised at $14 million and retained cash of $3.9 million at June 30, 2010.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

– *Cont'd from previous page*

was for early September 2010 and our current view is that approval of this drug should be imminent.

Biota Holdings Inavir Gets Approval

At the time of publication, Biota Holdings' partner Daiichi Sankyo received approval to market Inavir in Japan. Inavir is a long acting flu drug which needs to be taken once every five days. It will go up against Relenza and Tamiflu in Japan in the coming winter. The seasonal influenza market in Japan we estimate is worth around US$100 million a year.

Bioshares recommendations:
Acrux – **Speculative Buy Class A**
Alchemia – **Speculative Buy Class A**
Biota – **Speculative Buy Class A**
Pharmaxis– **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (10 Sept 2010)

Company	Price (current)	Price added to portfolio	Date added
Sunshine Heart	$0.026	$0.036	June 2010
Biota Holdings	$0.89	$1.09	May 2010
Tissue Therapies	$0.23	$0.21	January 2010
QRxPharma	$0.93	$0.25	December 2008
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.12	$0.10	October 2008
Impedimed	$0.78	$0.70	August 2008
Mesoblast	$2.28	$1.25	August 2008
Circadian Technologies	$0.58	$1.03	February 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.28	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$4.82	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.22	$0.66	September 2007
Starpharma Holdings	$0.56	$0.37	August 2007
Pharmaxis	$1.98	$3.15	August 2007
Universal Biosensors	$1.51	$1.23	June 2007
Acrux	$2.16	$0.83	November 2004
Alchemia	$0.50	$0.67	May 2004

Portfolio Changes – 10 September

IN:
No changes.

OUT:
With a major shareholder pulling out and many challenges still ahead for the company, we have removed CathRx from the portfolio.

Management Change at Universal Biosensors

Universal Biosensors (UBI: $1.50) has announced the retirement of its CEO Mark Morrisson. Chairman Andrew Denver will become Executive Chairman and act as an interim CEO while a search is conducted for a new CEO. Morrisson will continue to work with the company for a transitional period.

While we understand genuine personal reasons have played a role in the stepping down of Morrisson, we suggest that the event signals that the company is maybe up for sale.

The company has achieved a major commercial milestone with the commencement of a global product launch by its blood glucose meter partner (One Touch verio), Johnson & Johnson. However, a US approval and launch is pending.

Drivers for a Sale

There are several major shareholders of UBI who possess strong reasons for seeing the company sold in the near term.

According to the last Top Twenty Shareholders statement from UBI's 2010 Annual Report (CY) report, the Principals Cornerstone Fund Pty Ltd held 22.6 million shares, PFM Cornerstone Group held 13.8 million and Brisbane-based venture capital group CM Capital held 14.1 million shares. However, the Principals Cornerstone Fund Pty Ltd recently divested at 4 million shares, reducing its holding to 18.651 million shares.

At UBI's current share price of $1.505 these holdings are worth $28 million, $20 million and $21 million respectively.

The Principals Cornerstone Fund Pty Ltd is a vehicle that holds shares on trust for UBI directors Denis Hanley, Andrew Denver, Colin Adam and former director Charles Kiefel. Kiefel was replaced by Marshall Heinburg in January 2010. Heinberg is the Senior Managing Director and Head of Investment& Corporate Banking at Oppenheimer and Co, a US investment bank. This appointment could also be viewed as a step towards a sale of the firm.

PFM Cornerstone Group is an investment company, of which the directors are Denis Hanley, Andrew Denver, Colin Adam, Charles Kiefel and Jeffrey Goodman. In addition to investments in UBI, it has interests in CathRx, SpeedX and SunDay Solar Technologies. PFM Cornerstone posted a loss of $3.3 million FY2009 and $23.3 million in FY2008.

PFM Cornerstone has a 22.1 % stake in CathRx, a holding of 24.3 million shares, which is valued at the current CathRx share price of 18 cents at $4.2 million. We estimate that PFM Cornerstone invested $16 million in CathRx when it underwrote a capital raising in 2007 (a total of $27 million was raised at $2.20 per share) and $3.4 million in the most recent capital raising. This would leave PFM Cornerstone sitting on an estimated paper loss of at least $15 million.

This week, CM Capital sold almost its entire stake in CathRx. CM Capital sold 12.78 million shares, yielding $1.8 million dollars. According to CathRx's 2009 Annual Report, CM Capital held 13.9 million shares. We estimate that CM Capital has invested at least $10 million in CathRx.

Also worth noting is CM Capital's holding in Sunshine Heart, in which it has invested an estimated $10.2 million, and which its current holding is valued at $3.6 million.

In summary, the weakened investment positions of substantial shareholders in other stocks can be argued as evidence of a move to position UBI for sale in the near term.
Bioshares recommendation: **Speculative Buy Class A**

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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