ISSN 1443-850X

In this edition...
Universal Biosensors is moving steadily forward on the development of its next product, a point-of-care test which helps patients control their administration of the oral anticoagulant warfarin. UBI has an objective of partnering the product this calendar year.
Immuron is seeking to carve out an opportunity in the treatment of a progressive stage of fatty liver disease, better known as NASH. The company expects to have a big second half if it can commence and complete a Phase IIb trial in NASH.
On the finance front, several biotech companies have terminated covertible note funding arrangements as funding from other sources has improved.
We also have included our mid-week Special Edition coverage of Tissue Therapies.
The Editors
Companies Covered: IMC, UBI, TIS

	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 - May'11)	45.4%
Year 11 now commenced	-1.9%
Cumulative Gain	**313%**
Av Annual Gain (10 yrs)	**21.2%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.
Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph:03 9348 9317
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
$350 (Inc.GST)
Edition Number 408 (20 May 2011)
ISSN 1443-850X

Bioshares

20 May 2011
Edition 408

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

Universal Biosensors – Prothrombin Time Test the One to Watch for 2011

As the first product for Universal Biosensors (UBI: $1.15) continues to be launched into various markets around the world, the R&D focus now for the company is on the development of its second product, a point-of-care/home test for patients on chronic warfarin therapy. This prothrombin time test (PT test) is used to measure coagulation capacity in the blood.

The company's first product is electronic glucose test strips that are being sold by the company's partner **LifeScan** (Johnson & Johnson). Globally about 16 billion of these strips are sold each year and we estimate that LifeScan has a 25% market share, selling around 4 billion strips a year. UBI manufactures the new strips at its facility in Rowville. It receives around US one cent per strip that LifeScan sells using the new technology, whether UBI manufactures it or not.

In calendar year 2010 (which is also the company's financial year) the company generated $6.4 million in service revenue ($2.8 million last year), which includes the one cent per strip fee and also any other R&D service work it conducted for LifeScan.

UBI also receives a manufacturing fee for making the glucose strips for LifeScan, which totaled $11.7 million last year ($132,000 in the previous year). As the volume increases, its manufacturing margin increases. In 2010, the company generated only a $958,000 operating profit from manufacturing, however with increased volumes, the last quarter of last year alone generated an operating profit of just under $1.5 million.

There is a step change benefit from UBI's manufacturing process for the strips, which cost about 20% of what other manufacturers' costs are that use a batch screen printing process rather than the UBI continuous throughput system. The difference arises from the core electrode interference technology that underpins UBI. About 20 people are required to make the UBI product. In contrast competitors require an estimated 500-600 people to make the same amount of product, illustrating in stark terms the manufacturing efficiency benefits that the UBI platform has to offer.

The glucose test, called OneTouch Verio, has now been launched in 90% of the European market (Spain, France, Italy, the UK and Germany), and is approved for sale in the US but has yet to be launched in that market.

In the company's annual report, UBI states that it anticipates that in the future LifeScan will manufacture all or a large portion of the new glucose strips itself. However if it does it will still be required to pay UBI the one cent per strip service fee, which equates to US$40 million a year if LifeScan was to convert all four billion strips we estimate it sells. UBI currently has the capacity to manufacture 750 million strips a year.

LifeScan also has the right to buyout the future one cent strip service fee, however LifeScan needs to reach a minimum volume and other conditions need to be met.

UBI says it continues to have a flourishing, ongoing relationship with LifeScan, with daily operational interface between the two companies. It expects to develop other tests for LifeScan in the diabetes area.

PT Test – Regulatory Approval a Goal for 2012

UBI has achieved proof-of-concept with its PT test, with the test comparable to the existing market leading test from Roche, CoaguChek-XS, which as around a 75% market share. The existing market for the PT test is around $400 million a year. There are 30 million outpatient prescriptions written annually in the US, with self testers showing lower frequency of bleeding and clotting.

The reimbursement price of the test is significantly higher, at $5.53 per test in the US, than for glucose strips which sell for around 50 cents each. This potentially affords a much larger profit margin, particular when costs are significantly reduced in a continuous throughput system.

Other companies that manufacture and sell PT tests include **Alere Inc** and **Abbott Point of Care** (a unit of Abbott Laboratories).

As with the glucose test, the PT test is also an electrochemical cell-type test. In our view it is an easier product to develop than other tests UBI is considering, which are immunoassays that require the inclusion of an antibody. However the company says it is progressing well on technical hurdles with these other tests.

UBI has completed the design of the PT strip and it is aiming to submit the product for regulatory approval in early 2012

UBI is currently in discussion with partners regarding licensing the PT test. UBI is seeking a similar deal structure to the one it has with LifeScan. It wants to share the R&D risk and also share the upside. The company is seeking to find a partner for this program this year. LifeScan, which is focused entirely in diabetes, is unlikely to be interested in the PT test.

Summary

UBI continues to be a standout company. Partnering the PT program this year will be the major milestone to monitor for the company.

UBI had 95 staff in Melbourne at the end of March. It had $20.5 million in cash at the end of March. It generated revenue of $18.21 million in 2010 recording a net loss of $6.6 million. UBI is capitalised at $183 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Phase IIb Trial in NASH a Key Driver for Immuron

Immuron (IMC: 6.5 cents) expects to hold a pre- Investigational New Drug application meeting with the US FDA this quarter for IMC-124E, an immune therapy product in development for the treatment of Non- alcoholic Steatohepatitis (NASH).

NASH is a disease state that follows the less severe state of Non-Alcoholic Fatty Liver disease (NAFLD). Steatosis refers to the infiltration of liver cells by fat.

NASH is a liver condition characterised by inflammation and is closely associated with Metabolic Syndrome, which itself is defined by measures of obesity, high lipid (LDL) levels, low HDL levels, insulin resistance and hypertension. If NASH develops into cirrhosis (i.e. the liver becomes fibrotic), then liver function can deteriorate to the point that it fails completely, with a liver transplant required.

The incidence of the disease is very high in morbidly obese people (~50%), moderately obese (20%) and lean people (5%) according Immuron. It is estimated that in the US alone, the 5% figure will increase to 7% by 2025, equating to a population group of 27 million. For this reason, NASH, alongside diabetes and metabolic syndrome, is being described as an epidemic.

NASH is a condition for which there is no effective treatment although some insulin sensitizing agents such as the glitazones have some effect, but with metformin, a long established treatment, having none at all. Vitamin E is thought to also offer some benefit to some patients.

Immuron's therapeutic hypothesis is that administration of IMC-124E can alleviate the symptoms of NASH. IMC-124E, a formulation of hyper-immune bovine colostrum powder, works by addressing at a systemic level the inflammatory state that characterises NASH. The hyper-immune bovine colostrum contains anti LPS (lipopolysaccharide) antibodies, which in circulation induce an immune response with positive effects on markers of NASH.

In a Phase I/II trial, Immuron showed that IMC-124E decreased insulin resistance, decreased lipid levels and increased regulatory T-cells.

Phase IIb trial

The Phase IIb trial planned is expected to take three months to complete and will enrol 60 patients. However, such parameters remain the subject of discussion with the FDA. It also expected to be a randomized trial with three arms, which could eventually form

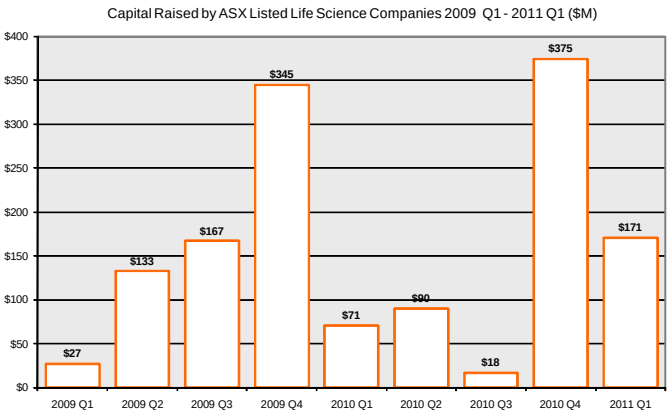
– Cont'd on page 4

Trends in Finance – Biotechs Wind Up Convertible Notes as Funding Conditions Improve

The majority of ASX listed life science firms are compelled to seek capital on a number of occasions post listing to further the development of the products and technologies they are commercialising.

Each quarter Bioshares tabulates the capital inflows for the listed sector. There is often a great a degree of variability in inflows from quarter to quarter. For example, $171 million was raised in the March quarter 2011, following $375 million in the December quarter and $17.5 million in the September quarter.

These figures can be greatly influenced by one or two companies successfully raising very large sums of money. For example, in the March quarter of 2011, **Mesoblast** accounted for $105 million of the $171 million raised, with 23 companies accounting for the remaining $66 million.



Convertible Note Financings

Some of these financings have been small monthly tranches provided by convertible note financing companies, dominated by US-based **Springtree Special Opportunities Fund** and **La Jolla Cove Investors** (LJCI).

Springtree has arranged convertible funding for **Prima Biomed**, **Neuren Pharmaceuticals**, **Healthlinx**, **CBio** and **Living Cell Technologies**.

LJCI has arranged financing for **Cellmid, Bone Medical, Benitec**, **Avita Medical** and **Viralytics**. The Singapore-based **Advance Opportunities Fund** has also provided funds to **Patrys**.

The benefit of this type of hybrid funding has been that companies have been able to maintain operations in the face of tight funding conditions. However, these funding arrangements typically permit the financing party to dispose of shares once they have converted, usually monthly, which can have the effect of depressing the share price if there is no strong buying support for the stock.

Early Terminations

Recently, we have seen several companies wind up their arrangements with these convertible note financiers, commencing with Prima Biomed at the end of March 2011 (announced January) and Avita Medical in May 2011. Springtree had originally agreed to provide Prima Biomed with $25.5 million. At the termination of the arrangement it had supplied $12.2 million in funds.

In exiting the arrangement, Springtree made a $1.25 equity investment (at $0.20 per share) and placed a convertible note of $1.25 million, convertible on March 29 2011 at 90% of the VWAP for a prior specified period , as well as granting options equal to 20% of the number of shares issued on the conversion of the convertible note and exercisable at 150% of the average of the VWAP per share for the 20 business days prior to the date of grant of the options.

Avita Medical announced a conditional placement to raise $9 million and an SPP capped at $2 million at the same time as rescinding its arrangement with LJCI. The terms of disengagement between Avita Medical and LJCI included Avita making a one off US$200,000 cash payment and the issue of 4 million shares to LJCI in exchange for forfeiture of its rights to further convertible notes. However, these shares will be escrowed for 12 months.

Patrys wound up its $15 million funding agreement with Advance Opportunities Fund in March this year after raising $4.3 million at the end of last year through a placement with Wilson HTM and an SPP. The company's CFO Roger McPherson indicated that the company's recent capital raising had given the company the flexibility to close its convertible note funding facility.

Summary

Since 2009 convertible note financings have been used by almost a dozen biotechs to solve funding problems. With three companies now having wound up these arrangements as their capacity for gaining less dilutionary funding has improved, it is worth noting that the exits from these agreements are also not without cost.

Bioshares

Selected Convertible Note Financings

Date	Company	Funding	Financier	Comments
Jun-09	Viralytics	US$6 M	La Jolla Cove Investors	
Jul-09	Prima Biomed	$25.5 M	SpringTree SOF	Terminated
Oct-09	Healthlinx	$7.2 M	SpringTree SOF	
Nov-09	Neuren Pharm.	$6.7 M	SpringTree SOF	
Apr-10	Benitec	US$6 M	La Jolla Cove Inv.	
May-10	CBio	$12.4 M	SpringTree SOF	
Jun-10	Avita Medical	US$6 M	La Jolla Cove Investors	Terminated
Aug-10	Patrys	$15 M	Advance OF	Terminated
Sep-10	Cellmid	US$8 M	La Jolla Cove Investors	
Oct-10	Bone Medical	US$6 M	La Jolla Cove Investors	
Dec-10	Living Cell Technologies	$5.75 M	SpringTree SOF	Paused until July

Bioshares Model Portfolio (20 May 2011)

Company	Price (current)	Price added to portfolio	Date added
Psivida	$3.60	$3.95	May 2011
Bioniche	$1.02	$1.35	March 2011
Somnomed	$1.35	$0.94	January 2011
Phylogica	$0.068	$0.053	September 2010
Sunshine Heart	$0.052	$0.036	June 2010
Biota Holdings	$1.20	$1.09	May 2010
Tissue Therapies	$0.55	$0.21	January 2010
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.13	$0.10	October 2008
Impedimed	$0.60	$0.70	August 2008
Patrys	$0.15	$0.50	December 2007
Bionomics	$0.70	$0.42	December 2007
Cogstate	$0.20	$0.13	November 2007
Sirtex Medical	$5.39	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.80	$6.60	September 2007
Starpharma Holdings	$1.36	$0.37	August 2007
Pharmaxis	$2.93	$3.15	August 2007
Universal Biosensors	$1.15	$1.23	June 2007
Alchemia	$0.63	$0.67	May 2004

Portfolio Changes – 20 May 2011

IN:
No changes.

OUT:
No changes.

– Immuron from page 2

part of a larger pivotal trial. One objective of the trial would be to provide data that could be used to engage with pharmaceutical companies.

The major challenge facing the company in conducting its Phase IIb trial will be recruitment and screening of patients. Some of the symptoms for NASH include lethargy and fatigue and chronic fatigue, which are common with many other conditions.

Diagnosing NASH is challenging because the current best available method is liver biopsy, a technique that is painful and invasive. There is possibly one bio-marker emerging that could help clinicians screen for NASH – CK18 (Cytokeratin) – however it does not appear to be accepted into clinical practice at this stage and it is not planned for use with the Phase IIb trial.

The Phase IIb trial for NASH is one of several more advanced trials the company could conduct with programs in influenza and clostridium difficile also being planned.

IMC-124E Milestones to Monitor

- Pre IND meeting **2011 H1**
- File IND submission **2011 H1**
- Commence Phase IIb trial **2011 H2**
- Complete Phase IIb trial **2011 H2**

Other milestones to monitor include the signing of sales and distribution agreements in many territories around the world for Travelan, Immuron's travellers diarrhea product, which in some areas will be sold as a treatment for residents where diarrhea is a problem caused by inadequate hygiene.

Summary

Immuron is a company in a definite 'change' mode, with its recently installed CEO, Joe Baini, a former executive with **Gilead Sciences**, now driving the company more strongly in a commercial direction.

The company's clearance of its IND filing with the FDA and subsequent clinical trial commencement will be major drivers for this stock. The market opportunity in NASH is compelling, and the bio-pharmaceutical platform that Immuron controls offers potentially impressive benefits with the right products.

Immuron is capitalised at $21 million and retained cash of $1 million at December 31, 2010. The company recently raised $0.5 million through a placement.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Tissue Therapies – Shire plc Snaps Up Advanced Biohealing

[First published on May 19,2011 in Bioshares 408 Special Edition]

In a sudden move, **Shire plc** has announced it will acquire **Advanced Biohealing Inc** for US$750 million in an all cash bid, and move into the field of regenerative medicine. The move gazumps plans by Advanced Biohealing to pursue an IPO, in which it was seeking to raise US$200 million. Shire is capitalised at US$51 billion and posted revenues of US$3.5 billion in CY2010.

The acquisition price of US$750 million appears to offer a healthy premium to the notional IPO offer price of US$15 per share, which had priced Advanced Biohealing at US$600 million (excluding options and warrants). This acquisition echoes last year's licencing deal and equity investment by **Cephalon** with and in **Mesoblast**, in that a specialty pharmaceutical company has made what looks on the surface to be a bold move, but may on closer inspection may prove to be a prescient and well timed bid to build a franchise in an emerging technology area with strong growth prospects.

Advanced Biohealing sells the Dermagraft product in the US, which is used to treat slow healing diabetic foot ulcers (but not yet venous leg ulcers).The product is a bio-engineered skin substitute which uses a mesh scaffold sourced from Johnson & Johnson's **Ethicon** unit.

Dermagraft costs approximately US$1,500 per unit. In the US, Dermagraft is reimbursed by Medicare, 1000 private plans, the Veterans Administration and many Medicaid programs. Advanced Biohealing's revenues have grown from US$9 million in 2007 to US$147 million in 2010. This represents only 5% of the US$3 billion diabetic foot ulcer market in the US.

The implication for Tissue Therapies (TIS: 50 cents) is that it confirms the 'high medical need' in this 'growing and under-penetrated market', as phrased by Shire, for these novel tissue regeneration products. Tissue Therapies is commercialising its own tissue regeneration technology, Vitrogro, which is being developed to treat slow healing wounds, including diabetic, venous and pressure ulcers. And while Tissue's product still needs to gain regulatory approvals in major territories and reimbursement for its product, it is one of a handful of promising new products in the area and one which could potentially compete on price and efficacy or even carve out a role as a valuable adjunct therapy.

The Shire takeover of Advanced Biohealing sends a clear signal that wound healing technologies and products are now very appealing growth areas, which bodes well for Tissue Therapies as it seeks to partner Vitrogro over the next 12 months. Shire stated that it will use this wound healing platform to potentially acquire additional regenerative medicine assets.

Tissue Therapies ($0.50) is conducting a rights issue, which closes today. The company is capitalised at $84 million, including the recent placement and rights issue underway that will raise $15 million.

Bioshares recommendation: Upgraded to
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. 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, Mayne Pharma Group, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$350**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$550	2-3 email addresses
	$750	4-5 email addresses
	$950	6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9329 3350

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph ( ) _____

Emails _____

_____

_____