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In this edition...
Calender year 2010 is closing out as a momentous quarter for Australian biotech. This week, Mesoblast inked a deal with Cephalon, one of the biggest Phase II deals ever done. The up-front component of the deal of US$130 million and equity component of US$220 million is unsurpassed in Australian biotech.
Universal Biosensors has opened up on its next product, a pro-thrombin time test to aid patients taking the warfarin anti-coagulant, which it is seeking to partner. UBI suggests this product could access a $2.5 billion market.
While Immuron has a long history as an ASX-listed biotech (formerly Anadis) it is now has a clearer focus on medical food applications of orally administered polyclonal antibodies.
The Editors
Companies Covered: IMC, MSB, 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)	19.0%
Cumulative Gain	**245%**
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.

Mesoblast Stuns Market With US$350 Million Up-front Deal

(Now That's More Like It Cephalon!)

Who would have thought that title for the biggest deal in Australian biotech would last for such a short time. Two weeks after **Acrux** secured a US$87 million milestone payment for the approval of its transdermal testosterone product, Axiron, Mesoblast has stunned the market with multi-product deal with **Cephalon** for the commercialisation of its adult stem cell platform. It is one of the largest Phase II stage biotech deals ever completed, with a total potential deal value of $2.05 billion.

Deal Terms

Upfront

Under the terms of the deal, Cephalon will pay Mesoblast US$130 million as an upfront payment. The first US$100 million of that is expected to be received a few days after the deal was announced. The US$30 million balance will be received after shareholder approval is received for the equity investment Cephalon will also make in Mesoblast. The challenge for Mesoblast will be to spread its revenue with future costs so that it does not pay tax on revenue that will be going towards product development.

Equity Investment

Cephalon will make a US$220 million equity investment in Mesoblast at $4.35 per share. Around half will be acquired as new equity in Mesoblast and half has been acquired from existing shareholders. Cephalon will own 19.9% of the merged Mesoblast-Angioblast Systems entity with around 270 million shares that will be on issue.

The exact number of shares that will be on issue after the merger is completed is still unknown, with some Angioblast shareholders still to decide over the next 10 days whether to take some of their shares in cash (at $1.70 per share) or in equity. Under the terms of the Mesoblast-Angioblast merger, shareholders in Angioblast were entitled to take payment in Mesoblast shares, or 85% MSB shares and 15% cash, to allow for payment of tax obligations. It is likely those shareholders will now elect to take payment in MSB shares given the strong run in the stock since the merger was announced.

Royalty and Product Application Rights

The alliance with Cephalon includes use of Mesoblast's adult stem cell technology for the treatment of congestive Heart failure, heart attack, Parkinson's disease, Alzheimer's disease and for use in bone marrow transplantation on a worldwide exclusive basis. The deal does not include the areas of orthopedics, diabetes, eye diseases and immune based inflammatory diseases (such as arthritis).

Mesoblast will maintain manufacturing rights and will enjoy a 'significant' component of product sales, by effectively selling the manufactured product to Cephalon.

– Cont'd over

Milestone payments
Potential regulatory milestone payments under this deal that Mesoblast could receive total US$1.7 billion. This is for four cardiac products, four neurological disease treatment products and one bone marrow product.

Comments
This is an outstanding deal for Mesoblast. The company will have around $250 million in cash after the deal. There will be no restrictions on how the funds are to be used by Mesoblast, although Cephalon will gain immediate representation on the Mesoblast board with its COO Kevin Buchi.

Cephalon will now be responsible for all clinical development of the relevant programs after they have completed Phase IIa development. Mesoblast is unencumbered in commercializing the technology in the other applications outside of this alliance.

The alliance does not affect the merger between Mesoblast and Angioblast Systems. It is anticipated that Cephalon will be the end marketer of the stem cell products at least in the US.

Manufacturing
Mesoblast is seeking to form a manufacturing strategic alliance, whereby a third party would build and pay for its manufacturing facility, similar to how many antibody drugs are manufactured. Some of the funds raised through the Cephalon deal (perhaps up to $20 million) will go towards refining the manufacturing processes, including the cell media and cell culture process.

Retaining control of manufacturing is an incredibly important and astute decision by Mesoblast. It helps maintain the company's strong position and remain an integral part in the process chain. It also allows Mesoblast to slice and dice the application of the technology for other indications and to ensure quality control standards are maintained within the one facility and by the one operator.

Cephalon Partner
Cephalon is developing quite an interest in Australian biotech. The company's first foray into this sector was in its failed bid for **Sirtex Medical** in 2003. It has since acquired **Arana Therapeutics** at a very good price for the acquiror, has an option to acquire up to 30% of **Chemgenex Pharmaceuticals**, will likely be a bidder for **Bionomics** in *Bioshares* view, and now holds a major alliance with Mesoblast, on what should be seen as very attractive terms, this time to Mesoblast shareholders.

Mesoblast CEO Silviu Itescu said that mid-tier pharmaceutical companies such as Cephalon are hungrier and more aggressive to get the deal done than larger pharmaceutical groups which are prepared to wait longer and pay a fuller price. This transaction has the potential to be a transformational deal for both Mesoblast and its partner Cephalon.

Funding risk removed
The funding risk for Mesoblast has been effectively removed. Cephalon will fund all late stage programs for the indications it has licensed, and Mesoblast will now have the funds to explore all other opportunities and progress the orthopedic applications, including spinal fusion.

Recommendation
We recommend shareholders take some profits following the very strong run in the company's share price. Mesoblast will be capitalized at $1.26 billion once the merger with Angioblast has been completed and the Cephalon equity investment. Exceptional opportunities have become more attainable for the company. We suggest investors monitor the stock for more attractive price entry points.

Bioshares

Fortrend's Equity Facility

It may be of interest to investors and biotech companies about the Fortrend Securities Equity Standby Facility. It differs from a convertible note offering that has become very popular over the last two years in the biotech sector, however has some similarities as well.

At least seven life science companies have gained access to this facility. These are Agenix, Immuron, Avita Medical, Prima Biomed, Acuvax, Iatia and IM Medical.

The company generally offers $5 million in funding over three years. This loan amount can not exceed 30% of the company's market value and generally not more than 15% of the company's value is raised in any one year.

Forstrend supports additional capital raisings and helps promote the company to other investors. Funds are raised at a 10% discount to a weighted average of the company's share price. The maximum draw-down volume allowed at any one time is five times the daily weighted average of the stock turnover of the preceding 15 days.

Unlike convertible note facilities, there is no interest payable and equity is issued on draw down. Similar to convertible notes, the facility allows companies to raise money at their discretion, when their share price is strong, and no prospectus is required.

Fortrend has provided facilities worth $155 million in total, with the maximum facility put in place being $30 million. The company generally requests some early draw-downs. A change in management can activate an exit clause from the arrangement.

Bioshares

Universal Biosensors – Still For Sale … At The Right Price

Universal Biosensors (UBI: $1.65) is positioning itself to capitalise on an aging population that more and more will live with chronic diseases. These chronic diseases, such as diabetes, need to be managed through accurate monitoring and treatment. Diabetes currently is the largest point-of-care testing market in the world, worth $10 billion a year.

However interim CEO and Executive Chairman Andy Denver, told a **BioMelbourne Network** audience this week that the company is always for sale if the right price is offered for the business.

The company has a current manufacturing capacity of 750 million glucose strips a year, with a second manufacturing line almost completed that will double that capacity. **Lifescan** (UBIs partner for blood glucose testing applications) currently sells around 4 billion strips a year and presumably the aim is to transition users to the new low cost system.

'Unsurpassed Accuracy'

According to Denver there are two reasons that will prompt this transition. The first is cost. The second is feature driven, such as improved accuracy or lower blood volumes required. The first product made by UBI, the glucose testing product called the OneTouch Verio, is labelled in Australia as providing 'unsurpassed accuracy'.

Denver made the point that it is a very competitive environment in medical devices and diagnostics, as opposed to pharmaceuticals where a drug's properties are what deliver the competitive advantages.

UBI receives one cent for each strip that Lifescan sells that uses the UBI technology. UBI also receives a manufacturing fee for the strips that it makes. The product is currently sold in Australia and the Netherlands. Our expectation is that a wider rollout in Europe should occur first in 2011 then followed by release into the US.

According to Denver, the OneTouch Verio is 'exceeding expectations' of Lifescan.

Prothrombin time test

The next product for UBI will be the prothrombin time test (PTT). This test is used by people on chronic warfarin treatment and the test is used to help calibrate dosing. This is currently a $500 million market and is expected to increase to $1.2 billion a year by 2020.

Denver said that self testing by people taking warfarin has shown to result in a 30% reduction in mortality. Denver said the global potential market for self-testing is around $2.5 billion a year. UBI is currently in discussions with partners to license this product. It wants a similar deal to the type it currently has with Lifescan for blood glucose monitoring.

UBI's product has been tested against the leading product on the market, called Coaguchek XS and made by **Roche**. It is understood that this Roche product has about 80% of the market. The PTT product is an electrochemical cell type product, similar to glucose test. It is significantly easier to make that a quantitative point-of-care immunoassay, such as the test for CRP (a marker of inflammation). The PTT manufacturing system is expected to be on-line this month at the company's plant in Rowville in Melbourne. Its manufacturing process should offer significant cost benefits over competing products.

UBI employs around 100 people. Denver said that companies such as UBI represent the 'future wealth of the nation' with the company representing an economic footprint (at its current stage of development) of between $100 - $200 million.

In the first nine months of 2010, the company has generated $11.1 million of revenue, including $6.1 million of product revenue. Its net loss for that period was $5.1 million. It has $25 million in cash and has raised a total of $71 million to date. More funds could be raised in the future to expand manufacturing if required.

In September this year the company's CEO stepped down. The search is continuing for a new CEO, with the company seeking a person with strong manufacturing experience, as well as the ability to architect the company's strategy, to negotiate and maintain deal flow, and the ability to attract and retain talent within the company.

UBI is capitalised at $262 million and held cash of $25 million at September 30, 2010.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Immuron – Expanding Product Opportunities

Immuron (IMC: $0.068) is a Melbourne-based company that is developing over-the-counter medicines (OTC), medical-grade food products and potentially fully developed ethical drugs, by vaccinating dairy herds to produce polyclonal antibodies.

The polyclonal antibodies are harvested from bovine colostrum, a unique milk that is expressed at the time of birth that is abundant in nutrients necessary for developing the 'uneducated' immune system of the newborn mammal. These antibodies are easily prepared for oral administration.

Travelan

Immuron developed the Travelan product, for the treatment of traveler's diarrhea. Travelan was approved by the TGA in 2004 and received a medical food authorization for the US market in 2005.

This product was licensed to **Nycomed**, which holds Australia and New Zealand marketing rights, which commenced distribution in February 2010. Immuron and Nycomed are looking to develop new formulations of Travelan for treating minor gastro-intestinal disorders. Nycomed is also seeking to gain the rights form Immuron to expand into other territories. In the US, the product is marketed by **Alaven Consumer Healthcare**. However, sales of Travelan did not commence in the US until March 2009. It is sold in South Africa through **Pharmaco.**

Travelan provides protection against Enterotoxigenic *E.coli*, a cause of traveler's diarrhea. We estimate cumulative Travelan related income to be in the range of $1.3 million to $1.5 million. We conclude that sales of Travelan have, to date, been disappointing.

What are Polyclonal Antibodies?

Polyclonal antibodies, unlike monoclonal antibodies which bind to a single site on a target, attach to many different parts of a designated target.

Polyclonal Antibodies – The Driver

The driver for pursuing the development of polyclonal antibodies through the dairy herd 'manufacture' is that the cost of goods becomes very low for medical food grade products.

Immuron estimates that monoclonal antibodies for pharmaceutical applications costs $50,000 per gram for injection. In contrast, polyclonal serum in gram amounts for injection costs $1,000 per gram, but more decidely, Immuron's polyclonals cost $1 per gram (in tonne quantities), developed for oral use.

To date, Immuron has completed six harvesting runs or campaigns as a seasonal activity. It has shown it can produce up to three tonnes of polyclonal product up to GMP standard. Each colostrum harvested provides about 400g of colostrum.

Corporate History

Until December 2008, Immuron was known as Anadis, having listed in April 1999. The company has always had been focused on developing immune-system enhancing products from bovine colostrum. However, the company also operated a toll-manufacturing business, which it sold in February 2008, following years of losses. The CEO who oversaw the business for most of that time, Conor Graham, stepped down in April 2007.

The appointment of a new US based CEO, Zeil Rosenberg, was somewhat short lived, with his tenure lasting from November 2007 to July 2009. In September 2009, the company's former General Manager, Grant Rawlin, was appointed CEO.

In November 2007, the company formed a joint venture ("Immuron") with **Hadasit** , the commercialization arm of the **Hadassah Medical Organisation** (Israel). The Hadassah organisation operates two medical centre hospitals that support more than 1000 beds.

More recently, Immuron acquired intellectual property from Hadasit relating to Oral Immune Modulation technology. Payment was by way of Hadasit gaining a 19.99% stake in Immuron (now 17.96%).

– Cont'd over

Immuron - Financials

Year	Revenue ($M)	Profit/Loss ($M)
2000	$0.32	-$0.99
2001	$0.84	-$1.55
2002	$2.19	-$1.70
2003	$3.43	-$1.28
2004	$4.28	-$1.16
2005	$5.10	-$1.66
2006	$4.11	-$3.56
2007	$4.29	-$3.28
2008	$0.32	-$3.20
2009	$0.55	-$2.62
2010	$0.50	-$1.90

Note: Functional foods business w as sold 25/2/2008

Immuron History - Selected Events

30/04/1999	Lists on ASX as **Anadis**
4/05/2004	Travelan Registered with the TGA
12/10/2005	Travelan authorised for US market
12/04/2007	CEO Connor Graham resigns
6/08/2007	Cross-licenses with Immucell
14/11/2007	Forms JV ("Immuron") with Hadasit
26/11/2007	Appoints Zeil Rosenberg as CEO
26/02/2008	Sells functional foods business
18/06/2008	Prof. Colin Chapman rejoins the board
4/12/2008	Name change to **Immuron**
20/04/2009	Initiates new arrangements with Hadasit
17/07/2009	Zeil Rosenberg resigns as CEO
3/09/2009	Acquires technology from Hadasit
	Hadasit take 19.99% stake
19/09/2009	Grant Rawlin appointed as CEO

Professor Yaron Ilan assumed the role of Chief Medical Officer following the deal although he retains his position as Director of the Department of Medicine A.

The Oral Immune Modulation technology meant that Immuron could develop products that target other diseases and conditions such as metabolic syndrome, non-alcoholic steato-hepatitis (NASH), HCV and influenza infection, and with the more specific advantage of generating a T-cell response (in contrast to standard vaccines stimulating a B-cell response.)

Immuron IP now covers colostrum harvest methods and apparatus, vaccine preparation and production, and the above mentioned T-cell system (and its use in various conditions) in several forms.

Other barriers to entry that potential competitors face include large scale systems for collection of bovine colostrums and know-how involved in processing the collected material.

The patent covering Travelan expires in 2024. Patents covering oral immunotherapy and the treatment of liver disease have priority dates of 2008 and 2009 respectively,

Product Development Programs

Immuron is developing IMM 124-E to treat NASH and metabolic syndrome, IMM 308 to treat clostridium difficle infection, IMM 243 for HIV, and IMM 255 for influenza.

NASH (fatty liver disease) is an interesting product opportunity for Immuron. NASH is grouped with simple fatty liver disease, advanced fibrosis and end-stage cirrhosis. It affects about 3% of the normal population, about one fifth of the obese population and half of the morbidly obese population. The target market is large and globally significant. To date, all attempts by other companies to develop a product to treat NASH have failed.

Immuron has completed a Phase I/IItrial in NASH patients, with ten patients administered two oral tablets a day equivalent to 200mg of IMM 124-E and another group administered two capsules a day equivalent to 100mg of IMM 122-I. This was a 30-day safety trial, which showed the treatments to be safe and well tolerated.

IMM 124-E and IMM 122-I were shown to decrease insulin resistance, decrease lipid levels (in 70% of patients) and increase regulatory T cells (in 70% of patients).

The company is planning to progress IMM 124-E into a Phase III trial. This trial will recruit 60 patients and take three months to complete. Degree of inflammation and fibrosis and quantity of liver fat will be measured by MRI scans and biopsy. If sufficient reduction in these parameters is achieved, then the company will seek to gain approval for the product as a medical food.[*Editor's note: Immuron also plans to seek approval under an NDA in order to sell a fully re-imbursable product.*]

Board and Management

The CEO of Immuron is Dr Grant Rawlin. The board comprises Professor Colin Chapman (Chair), Professor Roy Robins-Browne, Simon Sallka and Dr Elane Zelcer.

Risks

The main risks faced by Immuron (and hence for investors) relate to funding, production assets, clinical development and commercial focus.

The company held cash of $1.8 million as of June 30, 2010. The company will need to access significant further funds in the very near future. We note the company did have a draw down funding facility with Fortrend Securities although this lapsed in June this year.

The company relies on access to dairy herds as for sourcing colostrum. Diversification across different geographical areas would mitigate production source risk, should dairy herds become subject to specific diseases. However, this issue would come in to the foreground as the company builds revenues from the launch of many more products.

While the company has access to Hadassah research facilities, our view is that over time other clinical management capabilities would need to be accessed or even developed internally. A strong clinical development base would support moves by the company to develop products with improved marketing and labelling claims.

The company trimmed back its executive team, following the departures of Zeil Rosenberg and Oren Fuerst. However, a prudent measure for the company would be to appoint (when funds permit) a Chief Commercial Officer, to take responsibility for the commercial product development goals of the company.

Summary

The current day Immuron should not be confused with the Anadis of old. A clear date of separation of the old with the new is when Hadasit transferred its oral immune-modulation technology in exchange for a 19.99% stake in September 2009.

The departure of Connor Graham in 2007 and the decision to sell the functional foods business marked the end of the 'old' Anadis. The transition into a business focused more simply on therapeutic products and medical foods began with the joint venture with Hadasit in 2007.

The Hadasit transaction added a suite of additional products derived from hyper-immune colostrum technology to Immuron's Travelan product (and others), and coupled the IP to Immuron's dairy herd manufacturing base in Victoria.

Immuron is capitalised at $21 million, and held cash of $1.8 million at June 30, 2010.

Bioshares recommendation: **Speculative Hold Class B,** to be reviewed when further funding has been accessed.

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Bioshares Model Portfolio (10 Dec 2010)

Company	Price (current)	Price added to portfolio	Date added
Phylogica	$0.050	$0.053	September 2010
Sunshine Heart	$0.030	$0.036	June 2010
Biota Holdings	$0.96	$1.09	May 2010
Tissue Therapies	$0.49	$0.21	January 2010
QRxPharma	$1.16	$0.25	December 2008
Hexima	$0.37	$0.60	October 2008
Atcor Medical	$0.08	$0.10	October 2008
Impedimed	$0.80	$0.70	August 2008
Circadian Technologies	$0.65	$1.03	February 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.30	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$6.08	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.15	$6.60	September 2007
Starpharma Holdings	$0.82	$0.37	August 2007
Pharmaxis	$2.91	$3.15	August 2007
Universal Biosensors	$1.67	$1.23	June 2007
Acrux	$3.55	$0.83	November 2004
Alchemia	$0.62	$0.67	May 2004

Note CUV 10 for 1 share consolidation

Portfolio Changes – 10 December 2010

IN:
No changes.

OUT:
We will take some profits and remove Mesoblast from the portfolio at $4.68

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