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In this edition...
International interest in Australian biotech assets continues unabated with Inverness Medical Innovations expressing interest in Brisbane-based diagnostic firm, Panbio.

Are there other companies that could also gain the attention of larger firms? There are at least two, IDT Australia and Optiscan Imaging, which we discuss in this issue.

We also update readers on a stock, Clinical Cell Culture, that has disappointed investors over the last 18 months, but has been fixing its problems and moving steadily forward.

The editors

Companies covered: CCE,CXS, IDT, OIL, PBO, PXS

	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 (from 5 May '06)	-1.6%
Cumulative Gain	**174%**
Average Annual Gain	**23.6%**

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Bioshares

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

Offshore Sale of Australian Biotech Continues

It's not only international funds management groups that are expressing a keen interest in the Australian biotech sector. In what will be at least the seventh international acquisition in the sector this year, if it goes ahead, diagnostic group **Inverness Medical Innovations** from the US has expressed an interest in acquiring Queensland diagnostic company, **PanBio**.

The 'formal, conditional indication of interest' values PanBio at $21 million (34 cents a share), which is 31% premium to the company's share price before the indication of interest was announced.

Australian biotech companies are being sold for a number of reasons. Either the business is not well understood by the market and international groups are willing to pay a significant premium to the valuation placed by local investors (e.g. **Vision Systems**), or the management or owners are seeking to exit the business (**Zenyth Therapeutics**, now completed), economies of scale (**Mayne Pharma**) or the management has struggled to grow the business and set and meet expectations (more so the case with PanBio).

The key common parameter with all seven Australian biotechs acquired or being targeted by international companies is that they are businesses that are generating sales revenue from marketed products and services. With this in mind and with a dwindling number of revenue generating life science companies listed on the ASX (with the exclusion of the major life science companies such as **CSL**, **Sigma**, **Resmed** and **Cochlear** that the market appears to understand well), other potential target companies are beginning to become more obvious.

We look at two prime candidates for acquisition, **Institute of Drug Technology Australia** and **Optiscan Imaging**.

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International Acquisitions of Australian Life Science Companies, 2006 (completed/in process)

Company	Acquirer	Date announced	Status	Acquisition Price
Scigen	Bioton (Poland)	January	Acquired 90.5%	$51 million
Bresagen	Hospira (USA)	August	92% ownership	$21 million
Gropep	Novozymes (Denmark)	August	Being completed	$96 million
Vision Systems	Danaher Corporation (USA)	September	72% ownership	$791 million
Mayne Pharma	Hospira (USA)	September	In progress	$2,628 million
Enterix	Quest Diagnostics	September	Completed	$57 million
PanBio	Inverness Medical Innov.	November	Interest submitted	$21 million

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Institute of Drug Technology (IDT) Australia

As life science product companies in Australia have been the target for acquisition by international life science companies, and more specifically specialist drug manufacturers in Australia such as Bresagen and GroPep, it would not be unrealistic to suggest that another Australian specialist manufacturer and services provider, IDT Australia (IDT: $1.80), might also be a target for acquisition.

IDT has been through a difficult period over the last 24 months, with its business model requiring significant re-assessment. Its business has focused in the past on the manufacture of active pharmaceutical ingredients (APIs), which has contributed to as much as 50% of sales. However strong competition from low cost Indian and South American manufacturers has taken a large toll on IDT's core business over the last two years.

API sales now make up only 10% of IDT's total sales. IDT has successfully redirected its business to the manufacture of high containment finished pharmaceutical products. It has also increased its fee-for-service drug development work. And its third business, the CMAX clinical trials facility in Adelaide, has grown with contracts from larger international pharmaceutical groups.

In what must have been a sobering event for the company and its shareholders, the fall in API sales contributed in the first half of FY2006 to sales falling 11% to $11 million. Net profit fell to $651,000. However the company effected a stellar recovery in the second half of the last financial year, with almost a $3 million profit in the second half from sales of $14 million.

Impact of Thalomid

The reason for the turnaround can be attributed largely to the sales of the one finished drug IDT is manufacturing, called Thalomid, for **Celgene Corporation** in the US. Thalomid, or previously known as thalomide, had previously caused birth defects when taken by pregnant women. However it has been resurrected, surprisingly as an effective treatment for multiple myeloma. In June 2005, IDT received FDA approval to manufacture the drug Thalomid on behalf of Celgene. IDT records sales of final product when it is delivered to the customer, which based on the jump in profit in the second half of CY2006, appears likely to have occurred early this calendar year. The company has indicated that the other two business lines have also improved in the second half of FY2006.

IDT does not manufacture the API for Thalomid, but is one of two companies that conducts the formulation and the encapsulation of the finished tablet. Whilst low cost manufacturers in India, China and South America are gaining an increasing share of the API market, a market is emerging for reputable drug manufacturers such as IDT to complete the final product. Although this may be technically less difficult, it is the quality control procedures in place that can check the API quality and deliver secure, finished pharmaceutical product with FDA accreditation, and high containment facilities such as IDT's, that are presenting commercial opportunities in the changing landscape of the pharmaceutical manufacturing industry.

Thalomid sales in this calendar year will exceed US$400 million and are growing at 14% a year. The outlook for IDT as a result is very positive, which is why the company is confident in forecasting strong profit growth for FY2007. Announcements by the company should be read closely and any forecasts made by the company should be taken seriously. IDT is also seeking further finished product manufacturing contracts.

IDT is currently capitalised at $77 million and is trading on a PE of 21.5 with a dividend yield of 4.4% fully franked (although there was a 95% payout ratio over the year). If the last half financial results can be repeated over the coming year, then its prospective PE for 2007 is 13. With the added appeal of being a takeover target, IDT's share price represents a very attractive entry point into this stock.

Bioshares recommendation: **Strong Buy**

Optiscan Imaging

It can take 15 years to bring to new medical technology to market and often five years at a minimum before the product is firmly established in markets throughout the world. This is certainly the experience with Optiscan Imaging (OIL: 47 cents), which has developed the world's first miniaturised confocal microscope for use in real time imaging at a cellular level *in vivo*.

The idea of using fibre optic cable to connect the microscope scanner to the confocal microscope was conceived by Martin Harris (a director of Optiscan) in 1988. The first desktop confocal microscope incorporating the technology was released relatively quickly for research applications, in 1995. Optiscan continues to receive royalty payments from microscope manufacturers who have incorporated this technology into bench top versions, with approximately $1 million a year to be received for the next three years. Recently the company settled to receive $2.6 million in royalty backpayments.

However, it took 18 years (2006) when the technology was officially released for commercial production by Optiscan's partner, **Pentax**, for imaging in patients (a rigid dermal imaging device was released in 2001 although failed to achieve significant market penetration). Given the name 'ISC 1000', Optiscan's microscope technology was incorporated into the Pentax endoscope that provides a quantum shift in the way the disease can be observed in the body.

However, bringing a product to market is just one stage of the commercialisation process. Gaining market penetration and having the technology adopted in widespread use by the market – in this instance by colonoscopists and gastroenterologists – will require time and further investment in product awareness and training.

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Reasons for staggered uptake

Reaching peak sales for a novel medical product, including pharmaceuticals, can take six or seven years. The market will always be broken up into early, medium and late adopters. There are several factors that will delay the uptake of the Pentax/Optiscan device. The first is capital expenditure, with the ISC 1000 priced around US$100,000. The second is training of specialists who will use the device. Specialists will need to become comfortable with viewing tissue at a cellular level and recognising diseased tissue at a cellular level, which currently falls in the domain of the pathologist. However it should be noted, that this device will not seek to totally eliminate the biopsy procedure. The third factor is the need to use an imaging dye which is injected into the patient. However, standard off-the-shelf dyes, as those used in optical imaging procedures, are used with the Pentax/Optiscan device.

To be able to include product claims with the device and to gain its own reimbursement codes, Pentax will need to complete multicentre clinical trials in disease areas. Multicentre trials are expected to be completed in 2008 and specific product claims should be emerging in 2009.

Another limiting factor for the delayed market penetration is the lack of trained doctors to use the device. Approximately 50 doctors have been trained to use the ISC 1000 in Mainz, Germany, and earlier this year an important formal training site was opened at the Johns Hopkins teaching hospital in Baltimore.

The 'Tipping Point' for Optiscan

It's difficult to see the confocal microscope technology not gaining widespread medical adoption but at the same time there remain some commercial risks. At which point will the technology be viewed to have passed the point of commercial viability and sustainability as a standalone product? For Optiscan, an immediate medium term market penetration level can arguably be set at 500 units of the ISC 1000 device.

This calendar year, Optiscan will sell just under 100 microscope units to Pentax (with 47 units sold in the first half of 2007 with 71 scanning units). Optiscan has in the past indicated that it needs to sell 200 units a year to break even assuming no other product income.

At present, on average, 1.5 scanners are sold with every ISC 1000 unit. Traditionally four or five scopes are sold with an endoscope system, allowing the doctor to examine several patients in a day and changing scopes between patients. So whilst one or two scopes are ordered initially, as the ISC 1000 usage increases per system, more scopes will presumably be purchased by the end users. In two years, Optiscan also expects to release an upgraded scanner/scope.

The upside is, if the installed base of ISC 1000 units reaches 500 worldwide, then additional scope sales for existing systems will become an significant revenue stream for the company, resulting in a compounded income stream for Optiscan. In fact, scanner sales may eclipse microscope sales. If we conservatively assume one additional scanner is sold each year for half of the 500 installed systems, and 1.5 scanners are sold with each new system of which 200 are being sold a year, then by the end of 2008, total revenue should be around $19 million a year.

Optiscan's (and presumably Pentax's) target is for more than 500 endomicroscope systems to be sold each year, which would represent about 10% of the total endoscope sales worldwide, and this may take five years to achieve. The recurring revenue stream from additional scanner/scope sales, scanner upgrade (a new version with a faster scanning speed is expected to be released in two years) and scanner replacement sales (each scanner will last only about two years) should not be underestimated.

Importantly, it is also in the miniaturized scanner that patent protection is significantly extended. Core patents over the fibre optic linkage of the microscope to the scanner begin to expire in 2009.

Products in development

As the lead product, the ISC 1000, secures market penetration over the next three years, Optiscan is developing other product offshoots from the considerable development that has occurred with the miniaturized microscope, particularly over the last three years.

The FIVE1

The FIVE1, is a product that has been tailored for the drug development market, for use by scientists in preclinical research. Final product certification is now being finalized, with sales imminent. Overall sales are expected to be modest with this device, generating an anticipated $1.5 million in revenue. The device will be sold by Optiscan directly and the product will sell for around US$100,000.

The rigid microscope

Completion of the development of the miniature confocal microscope with Pentax has delivered a substantially better developed technology that has now been well validated. Importantly this will make the development of follow-on products considerably easier.

Representing a substantially larger market potential is the rigid confocal microscope in development. Initial applications are for use in surgery, in particular tumour resection surgery, to establish immediately whether all tumour traces have been removed from patients who may have pancreatic cancer or prostate cancer or liver disease. The rigid device will allow surgeons to examine the cells in tissues to immediately establish whether any cancer cells remain in the patient. With this type of product, there is the possibility of a number of partnerships or licenses being signed for different applications of the device. Disposable sheaths for the rigid device will also deliver a recurring revenue stream. The company is continuing discussions with potential licencees for the rigid applications.

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Summary

It remains difficult to forecast how quickly sales will ramp up for the company. Sales orders from Pentax moving into 2007 are lower than expected. Market penetration moving forward will benefit from multicentre clinical trials that are necessary to allow Pentax to offer claims of efficacy and for reimbursement of the diagnostic procedures under its own reimbursement code (currently the procedure is reimbursed under a generic code) which should increase adoption and usage.

Since Optiscan was formed in 1994, it has experienced the arduous task of bringing a novel medical imaging modality to market. There have been mistakes, as can be expected, including poor choices in initial market applications of the device. Over the next three years, we have a high degree of confidence that the inflection point the follows over a decade of development activity should occur. This will make the company the target for potential acquirers seeking to leverage the technology and business. The ultimate success for the company is adoption in mainstream endoscopy.

Optiscan is a solid company with strong management. The company has high growth prospects and can be considered as a core long term portfolio holding. Optiscan is capitalised at $47 million, which appears to ascribe little value to the rigid applications for the company's confocal microscopy technology. Last year it generated revenue of $4.7 million with a net loss of $4.0 million. The company had cash assets at the end of June of $6.6 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (24 November 2006)

Company	Price (current)	Price added to portfolio
Acrux	$0.81	$0.83
Alchemia	$0.76	$0.67
Avexa	$0.25	$0.15
Bionomics	$0.21	$0.210
Biosignal	$0.17	$0.22
Cogstate	$0.20	$0.18
Cytopia	$0.68	$0.46
Chemgenex Pharma.	$0.64	$0.38
Evogenix	$0.60	$0.47
IDT Australia	$1.80	$1.80
Optiscan Imaging	$0.47	$0.35
Mesoblast	$1.70	$1.27
Metabolic Pharmaceuticals	$0.82	$0.53
Neuren Pharmaceuticals	$0.41	$0.70
Peptech	$1.28	$1.31
Prima Biomed	$0.056	$0.09
Progen Industries	$3.77	$3.40
Sirtex Medical	$2.65	$1.95
Sunshine Heart	$0.16	$0.19

Portfolio changes

IDT has been added to the portfolio at $1.80

The Bioshares 20 Index

Change from June 30, 2005	**-3.0%**
Change from June 30, 2006	**16.3%**
Change - week ago	**0.1%**

Nasdaq Biotech Index

Change from June 30, 2005	**20.5%**
Change from June 30, 2006	**12.0%**
Change - week ago	**-0.6%**

Clinical Cell Culture Update

Clinical Cell Culture (C3) (CCE: 13 cents) has developed three products that can be used to treat burns, wounds and skin defects. ReCell is a skin cell harvesting device that, using a patient's own cells, can be used to treat small areas (up to 2% of body area) of wounds or burns and also be applied to reconstructive and cosmetic surgery. CellSpray is designed for the treatment of major burns, covering more than 30% of body area, and CellSpray XP is simply a faster version of CellSpray, but for burns over 10%-30% of the body..

Share price history

The Clinical Cell Culture (C3) share price has bounced back recently from a low of 7.9 cents to finish at 13 cents today, a gain of 65%. A closing low of 7.9 cents on October 30 represented a decline of 71% from December 30, 2005. The stock had also fallen 33% from December 2004 to December 2005.

The recent gain in C3's share price may be related to positive sentiment that has occurred as a result of the company's communication activities associated with its annual reporting obligations and also with a share purchase plan it announced on October 30. This fundraising, which is seeking to raise approximately $10 million, (at 6.8 cents per share) is fully underwritten by Bell Potter.

Why the meltdown in the share price?

C3's share price imploded in late 2005 and early 2006 for three reasons. Firstly, a director and one of the company's founders, Dr Fiona Wood stepped down from the board in late November 2005. Normally, the exit of a founder from a biotech board is seen as a desirable event, typically allowing for board members with experience appropriate to the current round of challenges facing a company to join the board. However, in hindsight, this particular departure looks to have unsettled some investors rather than provided assurance of positive directions being taken by the company.

The next event, in December 2005, to shake investor confidence was news that the Therapeutic Goods Administration (TGA) had notified C3 that it intended to reject the company's application of its ReCell product. This was exacerbated considerably by the announcement in January 2006 from the US FDA that C3 would need to conduct a 'substantial equivalence' trial of ReCell, in order to seek approval for the marketing of ReCell in the USA. Such a trial would compare with wound sites treated using ReCell, to sites treated using mesh skin grafts.

Clinical Cell Culture - Key Events

Company Founded	28-Oct-99
ECAT Invested	26-Nov-01
ECAT re-lists as C3	14-Nov-02
Biotech Capital takes 19.99% stake	18-Jun-03
Troels Jordansen appt. CEO (eff. 1/1/03)	10-Dec-02
ReCell receives CE Mark	22-Mar-03
Appoints manufacturers for ReCell	30-Jul-03
Fiona Wood steps down from board	29-Nov-05
TGA notice - to reject Recell appl.	23-Dec-05
2006	
FDA seeks eqivalence data	23-Jan-06
TGA recommends ReCell appl.	3-Apr-06
Fiona Wood rejoins the board	11-Apr-06
CEO Troels Jordensen departs	31-May-06
New CEO - Bob Atwill - appointed	17-May-06
TGA approves ReCell	25-May-06

C3 has previously advised the market that it expected FDA approval to be received by the end of 2005. The January 2006 advice from the FDA meant that launch of ReCell in the US would be delayed by 18-24 months. With such an important market 'quarantined' for such a period, then the interest of some investors cooled considerably.

The US marketing approval trial

C3 is on the verge of accepting its first patients in a clinical trial program of ReCell that will generate data for its US marketing approval submission. The trial will recruit up to 71 patients, however, it will be able to lodge its submission using data gathered from 50 patients. The number of sites in the trial was expanded from five to six. The trial will compare ReCell with mesh skin grafts (MSG). It will evaluate the time to skin closure and cosmetic outcomes. The performance criteria is that ReCell must be shown to be as good as MSG. C3 anticipates completing the trial in June 2007, with approval of ReCell to occur in Q3, 2007.

Analysis

C3 is typical of many Australian listed biotechs that disappoint the market and suffer a significant share price erosion as a consequence. The company has worked solidly in 2006 to reduce its cash burn, inject new management and meet the requirements of several regulators. Whilst progress up to the early part of 2006 was disappointing, there are several elements to the C3 business that continue to merit the attention of investors.

The company has not only achieved product approvals in many territories (the US, Brazil, Russia and Mexico being significant

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C3 - from previous page

exceptions for ReCell), it has also generated modest product sales. ReCell is now approved in more than 40 countries, CellSpray has been approved in six countries and CellSpray XP in eight territories. The company has secured manufacturing services and developed or revisited marketing arrangements and strategies in most approved markets.

The company has matured its understanding of what is required to successfully sell its flagship ReCell product, a product with significant application in the world's cosmetic surgery markets. In early days, it was expected the product would be simple to use, in an off-the-shelf manner. However, the company is now cognisant of the depth of surgeon education required and, for example, to bring attention to factors such as wound bed preparation.

Risks

The ability of the company to grow revenues is an important challenge to the company as it attempts to roll out its products. Despite C3 looking to complete a fundraising through an underwritten share purchase plan, the company's annualised cash burn, reduced as it is to $800,000 per month, will be a burden on its cash reserves, if revenues do not follow as anticipated by the company ($5-$7 million , FY2007). Following the completion of the SPP, we estimate the company will have cash at hand of $14 million, sufficient for 1.5 years worth of operations at current rates of expenditure.

Summary

C3 is capitalised at $48 million, including the shares to be issued under the SPP. Key milestones to monitor will be growth in sales, evidence of repeat orders, approvals for ReCell in Russia, Brazil and Mexico and the completion of the trials supporting its registration objective in the USA by June 2007. While not a short-term potential acquisition target, however if and when C3 generates sustained revenue growth, the company is more than likely to begin to receive the attention of larger medical device companies that have an interest in wound and burn management technologies. We recommend C3 as a **Speculative Hold Class B** and advise eligible shareholders to take up the offer for shares at 6.8 cents under SPP, which expires on December 1.

Recommendation: *Bioshares* **Speculative Hold Class B**

Fast Track Status Granted to Ceflatonin and Bronchitol

Recently, two therapeutic products being developed or by ASX listed biotech companies received fast track status designation from the FDA. **ChemGenex**'s Ceflatonin, a potential treatment for chronic myeloid leukemia and **Pharmaxis**' Bronchitol, a therapy for clearing mucous build up in the lungs of cystic fibrosis patients, both have been permitted to access the 'fast track' interaction mechanism.

This status can be applied to therapeutic products that address an unmet medical need for a life threatening disease. Benefits to the drug sponsor, include receiving FDA input into development plans and the ability to submit elements of a new drug application on a rolling basis.

Receiving feedback during the application process means companies can find out sooner if the intended medicine is satisfying the FDAs requirements.

ChemGenex Appoints VP Oncology

As a sign of its commitment to developing Ceflatonin, ChemGenex has appointed Ian Nisbet as Vice-President Onoclogy. Ian Nisbet was formerly the CEO of **Meditech Research**, prior to its merger with **Alchemia**. Prior to that Nisbet worked at **Millennium Pharmacueticals** in the USA, where he gained considerable experience in cancer drug development. This experience should be of significant benefit to ChemGenex.

Bioshares recommendations:
ChemGenex (Capn - $98 m): **Speculative Buy Class A**

Pharmaxis (Capn - $567 m): **Speculative Hold Class A**

US Food and Drug Administration

Drug Development Designations and Review Status Categories

An Interaction Mechanism	**Review Status Categories**		
Fast Track	Standard Review	Priority Review	Accelerated Approval
intended for a product or claim that addresses an treatment of a life threatening disease with unmet medical need	a designation for an application after it has been submitted for review		intended to make promising products for life threatening diseases available on the market on the basis of preliminary evidence prior to formal demonstration of patient benefit
Benefits:FDA input into development plans; option to submit NDA in parts	sets the target date for actions by the FDA at **ten** months	sets the target date for actions by the FDA at **six** months	utilises surrogate markers (a measurement intended to substitute for the clinical measurement of interest)
Independent of Review Status		intended for a product or claim that addresses an unmet medical need	

Source: FDA - http://www.accessdata.fda.gov/scripts/cder/onctools

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

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