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Summary

- Due to both the technological and regulatory requirements, the development of products in the biotechnology sector generally involves significant timelines. As a result, many potential investors in the sector have become frustrated as companies have to raise more cash to support the development of products which remain several years from entering the market and generating sales revenue.
- The route to market for therapeutic products involves extensive clinical testing to establish both the safety and the efficacy (effectiveness) of the products. However once these have been completed to the satisfaction of the various regulatory authorities, the potential profitability of the products is enormous.
- We view it as a very significant development that there are several companies in the sector whose products have nearly completed this clinical development program and consequently have significantly reduced the risk of product failure. These companies have the potential to generate significant revenues in the foreseeable future and, under the current market conditions, we believe offer very good investment opportunities.
- The route to market for medical devices is less challenging however, due to the lower barriers to entry, the market for these products is generally more competitive. For these companies the establishment of strong marketing partnerships or distribution networks is essential to generate the sales revenues from their innovative products.
- In this report, we highlight 14 companies in the biotech sector who are developing therapeutic products or medical devices which are either already generating revenues from product sales or are likely to do so by the end of CY08 (ie: within the next 18 months).

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Figure 1: Companies with Therapeutic Products or Medical Devices That Will Generate Sales Revenue By CY08

Company	Ticker	Price	MCap	Product	Entry	Last Sales	Period	Our View
Therapeutic Products								
Sirtex	SRX	\$2.20	\$122.6m	SirSpheres	On market	\$5.0m	3Q FY06	Positive
Biota	BTA	\$1.38	\$246.2m	Relenza	On market	\$0.7m	1H FY06	Neutral
Peptech	PTD	\$1.27	\$207.5m	TNF α License Royalty	On market	\$14.8m	1H FY06	Neutral
Pharmaxis	PXS	\$2.00	\$353.8m	Aridol	Q2 CY06	N/a	N/a	Positive
Acrux	ACR	\$0.78	\$105.0m	Evamist	Q3 CY07	N/a	N/a	Positive
ChemGenex	CXS	\$0.43	\$70.7m	Ceflatonin	Q4 CY07	N/a	N/a	Positive
Alchemia	ACL	\$1.17	\$146.6m	Synthetic Heparin	Q4 CY07	N/a	N/a	Positive
Medical Devices								
Optiscan	OIL	\$0.51	\$51.1m	Endomicroscope	On market	\$1.3m	3Q FY06	Positive
Psvida	PSD	\$0.59	\$256.9m	Retisert & Vitrasert	On market	\$1.0m	3Q FY06	Neutral
Clinical Cell	CCE	\$0.11	\$24.5m	ReCell & CellSpray	On market	\$0.18m	3Q FY06	Neutral
Brainz	BZI	\$0.50	\$30.0m	Bedside EEG Monitors	On market	\$0.6m	1H FY06	Positive
CathRx	CXD	\$1.50	\$45.1m	Cardiac Catheters	Q3 CY06	N/a	N/a	Positive
Portland	PTD	\$0.33	\$42.4m	Orthopaedic Devices	Q3 CY06	N/a	N/a	Neutral
Visioned	VSG	\$0.02	\$6.2m	Funhaler	Q3 CY06	N/a	N/a	Positive

Source: Company Announcement and IRESS

Therapeutic Products

Sirtex (SRX) \$2.20

(MCap: \$122.6M)

Market Potential of SIR-Spheres

- SIR-Spheres are small radioactive beads that are being used to treat both primary and secondary liver cancer. These beads, when introduced into the bloodstream of a patient, get trapped in the capillary beds that form part of the tumour where they subsequently kill the tumour cells by irradiation.
- SIR-Spheres have been granted approval in a number of countries (US, Europe, Australia, New Zealand, Hong Kong, Malaysia, Singapore and Thailand). However, the majority of sales to date have been in the US due to the cost of treatment (US\$14,000) and the availability of reimbursement. More recently, the Australian government and Private Health Funds have approved reimbursement for SIR-Spheres in Australia.
- In the US, SIR-Spheres are currently approved and reimbursed for the treatment of secondary tumours arising from colorectal cancer. While SIR-Spheres are currently viewed as a last resort treatment following extensive chemotherapy treatments, the clinical data from these patients combined with further clinical testing will support the use of SIR-Spheres as an earlier intervention.
- The growth in sales revenue from SIR-Spheres over the last 3 half years has been very encouraging and in 1H FY06 the company reported an NPAT of \$2.7m

Figure 2: Growth In Sales Revenue From SIR-Spheres

1H FY05	2H FY05	1H FY06
\$5.0m	\$6.9m	\$10.9m

Source: Sirtex Reports

- Primarily this growth has come from increased sales in the US. While the current reimbursement is restricted to non-resectable secondary liver cancers, this is still a considerable patient population. The sales revenue from 1H FY06 would equate only to approximately 700 treatments worldwide underscoring the potential additional revenue opportunities that exist.

Other Products

- In addition to undertaking further clinical trials for SIR-Spheres, the company is also developing alternative mechanisms of tumour ablation including the incorporation of chemotoxic agents (DOX-Spheres) or heat-generation (Thermo-Spheres). These products still require significant development before market entry.

What We Think

- While there are a number of treatments currently in use and being developed for the treatment of liver cancer, the effectiveness of all current therapies is still quite limited.
- Although SIR-Spheres are currently being confined to a limited sub-population of the potential patient market, we believe that the consistent growth in sales revenues from SIR-Spheres reflects a greater awareness and degree of comfort that clinicians are having with this therapeutic approach.
- As the number of unit sales is still very small, we believe there is excellent scope for continued growth in sales revenues in the near term. Furthermore, the reporting of a good maiden profit result in 1H FY06 underscores the potential for SRX to deliver good value over the next 18 months.

Biota (BTA) \$1.38**(MCap: \$246.2M)****Market Potential**

- BTA's lead product, Relenza, is an inhibitor of the influenza virus protein neuraminidase that can inhibit the spread of the virus during the early stages (first 2 days) of infection.
- Relenza is one of two neuraminidase inhibitors on the market. The other drug, Tamiflu, was developed by Gilead and is marketed by Roche.
- BTA licensed Relenza to GlaxoSmithKline and receives a 7% royalty of sales of which 0.5% is paid to CSIRO where the drug was originally developed. The current sales price of Relenza is \$25-30 per course however it is likely that GSK could offer some discount for large stockpiling orders.
- Until concerns of a potential human pandemic of avian influenza, the sales of neuraminidase inhibitors was dominated by Tamiflu (97% of sales) and had a worldwide market size of approximately US\$500m. This market was considerably smaller than initial projections primarily due to patients not seeking medical intervention for 'flu or, in the cases where patients did go to a GP, the reluctance of GP's to prescribe medication to treat 'flu.
- With growing concerns that avian H5N1 virus may mutate and become transmissible between humans, governments, hospitals and individuals have been stockpiling both Tamiflu and Relenza which are currently believed to be the only antiviral drugs that could be effective against the virus.
- While this has led to a significant increase in demand for Relenza, the ability of GSK to meet this demand has been constrained by manufacturing capacity. GSK has stated that they are aiming to significantly increase production of Relenza to meet this demand and have provided guidance that they will be able to produce 15m courses per year by the end of CY06 and possibly up to 40m by the end of CY07.

Other Products

- BTA is developing a Long Acting Neuraminidase Inhibitor (LANI) in collaboration with the Japanese pharmaceutical company Sankyo. This product is scheduled to reach market in 2011 however market entry could be earlier if its development was fast-tracked in reaction to an outbreak of the H5n1 virus.
- BTA is also developing antiviral compounds against Respiratory Syncytial Virus (RSV) in partnership with Medimmune and also compounds against human rhinovirus (HRV) and hepatitis C (HCV).

What We Think

- While the threat of an avian 'flu pandemic has resulted in an increase in demand for Relenza, we believe that the supply constraints will limit the revenue potential for BTA, at least in the near term.
- It is possible that the avian 'flu threat will increase the public awareness of the treatment options offered by neuraminidase inhibitors however we remain cautious on the impact that this will have on long term demand for these products.
- We are expecting a significant increase in BTA's royalty income from Relenza over the reported 1H FY06 result of \$0.7m. However the combination of supply constraints with a lack of clarity on the orders that have been confirmed by GSK have lead us to take a more conservative view of future sales revenues.

Peptech (PTD) \$1.27**(MCap: \$207.5M)****Market Potential**

- PTD's main near term revenue stream will come from royalty payments that the company will receive from Abbott and Centrocortar arising from PTD's patents for TNF α . Abbott and Centrocortar have two antibody products (Humira and Remicade respectively) which target TNF α for the treatment of rheumatoid arthritis and Crohn's disease. PTD's patents for TNF α expire in 2010 and the company is expecting to receive between \$100m-\$130m in royalty payments during that time.
- The company also has two animal health products on market. The first of these is Ovuplant stimulates ovulation and is used in horse breeding management. Ovuplant is currently for sale in Australia, NZ, Canada, Argentina and UK.
- PTD's other animal health product is Suprelorin which is a hormone-based implant that can suppress reproductive function in male dogs. The advantage of Suprelorin over other reproductive controls is that it is reversible and does not result in any behaviour side-effects. Suprelorin is currently approved for sale in Australia and NZ and the company is in the process of gaining regulatory approval for Europe and US.
- The revenue to date from animal health has been minimal with \$0.6m in sales revenue reported in 1H FY06. While there is scope for this to improve, in our view the contribution from the animal health products is likely to be overshadowed by the royalty revenues from the TNF α patents.

Other Products

- The company has two autoimmune/anti-inflammatory products in development however the most advanced of these will only commence phase-1 clinical testing in 1H CY07.
- PTD also has joint venture with an unlisted company, Biosceptre, which is developing a number applications (topical, therapeutic, imaging and diagnostic) for cancer using a unique and specific cancer biomarker.
- PTD has a 34% equity stake in the UK biotechnology company Domantis that has developed technology for generating small and specifically engineered antibody fragments. Because Domantis's technology gets around the existing intellectual property that covers monoclonal antibodies, it has the potential to become a very significant company in the next few years.
- Finally, PTD recently acquired an Australian biotechnology company called Promics which is developing an immunomodulatory drug with a number of possible therapeutic applications.

What We Think

- PTD is in an enviable position in the biotech sector in having a strong current cash position, good cashflow from royalties over the next 4 years and a potentially very valuable equity stake in Domantis.
- We believe that the existing cash and royalty revenue income is fully embedded in the current price. While the equity stake in Domantis could provide significant further upside, in our view the key will be to see what management, and in particular the new CEO John Chiplin does with the company's strong underlying asset position.
- Given the track record of PTD to date and following the recent acquisition of Promics, we remain cautious in forecasting how effective the company will be in building its position from its current strong position.

Pharmaxis (PXS) \$2.00**(MCap: \$353.8M)****Market Potential**

- PXS is developing two products based on an inhalable version of the sugar mannitol which is used in various consumer products such as chewing gum. The first of these products is Aridol which is used to measure airway inflammation for the diagnosis and management of asthma and chronic obstructive pulmonary disease (COPD). The second product is Bronchitol assists with rehydration of respiratory tissues allowing the clearance of mucous in diseases such as cystic fibrosis and bronchiectasis.
- Aridol received approval from the TGA for sale in Australia in March 2006. An application for registration was lodged in Europe in April 2005 and regulatory approval is expected to be received during mid-CY06. Due to specific regulatory requirements, PXS has had to undertake a comparative clinical trial in the US prior to seeking regulatory approval. This trial is in progress and will be completed during CY06.
- There are approximately 50m asthma patients and 30m people affected by COPD in the 7 major pharmaceutical markets. Around 34% of people who are diagnosed with asthma do not have the disease and as a result are inappropriately medicated. With COPD, between 20-25% are able to be treated with inhaled steroid but it has been difficult to identify the responders with the existing tests.
- The company estimates that it will be able to capture 75% of the laboratory market and 30% and 10% of the specialist and primary care providers market respectively. This will equate to approximately 4m tests sold per year. At the current selling price of \$50/test, Aridol should eventually generate revenues of around \$200m per annum.

Other Products

- PXS's therapeutic product, Bronchitol, is currently in clinical testing at centres in Europe, Australia and North America for CF and bronchiectasis and has been granted orphan drug status in Europe and US. It is anticipated that Bronchitol will begin receiving marketing approvals during CY08.
- PXS also has discovery programs for autoimmune diseases such as multiple sclerosis and rheumatoid arthritis and is expecting to commence phase-1 clinical testing on its lead compound, PXS64, in 2H CY06.

What We Think

- As PXS is selling Aridol directly, we believe the company can expect to generate good revenues from the sale of this product.
- In our view, the real value in PXS will come from sales of Bronchitol. As Bronchitol is a product that is likely to have ongoing, long term use from patients who find it provides relief from respiratory congestion, this product has the potential to generate a very secure revenue stream.
- We believe that the earlier sales of Aridol will not only provide initial revenues for the company but will establish the sales and marketing infrastructure as well as familiarity in the market for the use of inhaled mannitol. As a result, we expect that PXS will be in a strong position to secure good sales of Bronchitol when it receives approval for the various regulators.
- With an excellent cash position, a high quality management team and very attractive and low risk product under development, we believe that PXS is one of the premium companies currently in the biotechnology sector.

Acrux (ACR) \$0.78**(MCap: \$105.0M)****Market Potential of Evamist**

- Annual sales of estrogen-only replacement therapies in the US are estimated to be US\$1.4 billion. The current worldwide sales of transdermal estrogen patches and gels are US\$300M.
- Initial market research have indicated that most women would prefer ACR's transdermal system rather than taking capsules, which can result in weight gain, or using patches, which can lead to skin irritation and are cosmetically less appealing.
- Under the current arrangement, ACR will receive a royalty on sales in the US (either VIVUS or a sub-licensee of VIVUS) and can license Evamist to other partners for sales in the rest of the world (including Europe and Japan)

Route to Market

- Having successfully completed the Phase-3 trial for Evamist in May 2006, VIVUS will be submitting its application for marketing approval (New Drug Application or NDA) to the FDA in 2H CY06 with product sales expected to commence in 2H CY07.
- Industry average success rates for NDA applications are 95%. Given the Evamist product is based on an established therapeutic using a novel delivery route, we are confident that Evamist has a high likelihood of being granted marketing approval in 2H CY07.
- The patent covering the technology that underpins ACR's "patchless patch" drug delivery systems provides protection until 2017.

Other Products

- ACR has a further 6 products in clinical development including: Testosterone-MDTS (for decreased libido in women), Nesterone (contraception), Fentanyl (chronic pain relief) and Testosterone-MD Lotion (male testosterone deficiency).
- ACR also has a collaboration in place with Elanco, the animal products division of Eli Lilly, for the development of veterinary products using ACR's drug delivery technology. We believe that a number of products are currently undergoing testing however the ACR is not permitted to disclose the progress of these projects.

What We Think

- ACR has one of the most extensive product pipelines in the Australian biotechnology sector. The positive Phase-3 results for Evamist, including the low level of skin irritation that was observed in this trial, bode well for ACR's other transdermal products and also open the door for further licensing deals in the near term.
- We believe that the company will be actively seeking to extend its licensing deal for Evamist which potentially could also include a co-marketing arrangement in the US between VIVUS and a global partner.
- With sales revenues from Evamist likely to commence before the end of CY07 and a number of potential new licensing opportunities on the horizon, we believe that ACR is in a strong position for significant re-rating over the next 12 months.

ChemGenex (CXS) \$0.43**(MCap: \$70.7M)****Market Potential of Ceflatonin**

- Ceflatonin is under clinical development for the treatment of a blood cancer called Chronic Myeloid Leukaemia (CML).
- The current mainline treatment for CML is Novartis' Gleevec which had sales of US\$2.2 billion in CY05. Approximately US\$650 of these sales were for the treatment of CML while the remaining sales were for off-label use. As 30% of CML patient develop resistance to Gleevec and Ceflatonin has shown excellent efficacy in these patients, Ceflatonin has a target market of approximately US\$200M for CML alone.
- CXS is undertaking Phase-2 demonstration trials for Ceflatonin in two additional leukaemias (MDS and AML) and as a monotherapy for CML which may result in off-label use.
- Under CXS's alliance with Stragen, CXS will receive 49% of profits from sales in Europe in exchange for access to Stragen's proprietary manufacturing process for Ceflatonin. CXS has an exclusive right for Stragen's manufacturing process in all other markets.
- As CML is a relatively rare condition, CXS will be able to sell Ceflatonin directly to clinics with a relatively modest sales force. This is obviously significantly more profitable than entering into a royalty-based licensing arrangement.

Route to Market

- Ceflatonin is currently in a two Phase-2/3 registration trials for the treatment of CML. These trials are expected to be completed by early CY07 at the latest.
- The data from these trials will be used for marketing approval which we would expect to be granted in 2H CY07. As Ceflatonin has been granted Orphan Drug Status in both US and Europe and that there are currently limited treatment options for CML patients who have developed Gleevec resistance, we believe there may be an opportunity that the regulatory review process will be expedited providing earlier market entry for Ceflatonin.

Other Products

- CXS has another cancer therapeutic, Quinamed, that is currently in Phase-2 clinical testing for solid tumours (ovarian, breast and prostate cancer). We expect that CXS may seek to license Quinamed to a pharmaceutical partner for the post Phase-2 development.
- CXS also has discovery programs in metabolism, depression and cancer which may provide further licensing opportunities but are unlikely to provide products in the near term.

What We Think

- We believe that CXS has very good near term cash flow prospects on the basis of its Ceflatonin product. While the near term market opportunity from CML is relatively small for a new drug (US\$100m-US\$200m) the majority of sales revenue will represent cash flow for the company due to being able to sell directly rather than via a licensing/royalty arrangement.
- In our view, even the most conservative assumptions on profits from potential sales (\$20m-\$40m) and the appropriate earnings multiples (8x-10x) would justify a significantly higher market capitalisation for CXS.
- The attractiveness of the Gleevec-resistant CML market has been highlighted by the recent US\$515m deal between Novartis and SGX Pharmaceuticals for the development of new drugs for CML. SGX currently does not have any CML drugs in clinical development.

Alchemia (ACR) \$1.17**(MCap: \$146.6M)****Market Potential of Synthetic Heparin**

- Worldwide sales of heparin in CY04 were US\$3.5 billion with sales growth of 17% over the previous year. The heparin market is currently dominated by Sanofi-Aventis's Lovenox which generated sales of US\$2.5 billion in CY05. Lovenox is a low molecular weight heparin (LMWH) which is extracted by fractionation from pigs intestines.
- ACL's synthetic heparin is a generic version of GSK's Arixtra which loses its market exclusivity in the US in December 2006. ACL's manufacturing process, which uses its carbohydrate technology platform and has patent protection until 2021, involves approximately half the number of steps required to manufacture Arixtra.
- The sales of Arixtra by GSK have been slow to date with only US\$44m recorded in CY05. However, GSK has paved the way for a more market opportunities with approval for a suite of therapeutic indications and the publication of data from an extensive clinical trial where Arixtra showed a very favourable safety profile compared with Lovenox.
- ACL has a manufacturing agreement in place with The Dow Chemical Company, who has already completed pilot scale commercial production of ACL's synthetic heparin, and a marketing partnership in the US with American Pharmaceutical Partners.

Route to Market

- As ACL's synthetic heparin is a generic version of an existing drug, ACL can file an Abbreviated New Drug Application (ANDA) to gain marketing approval. ACL is expected to complete the stability and formulation studies and file its ANDA by the end of the year.
- The time for processing the ANDA is governed by the internal processes and priorities of the FDA and is typically 12 months. We anticipate that sales of ACL's synthetic heparin in the US could commence in late CY07 or early CY08. Arixtra's market exclusivity in Europe does not expire until CY12 and thus market entry in Europe is not expected until much later.

Other Products

- The remainder of ACL's original product pipeline is at research or preclinical stage with drug candidates for cancer and age-related macular degeneration under development.
- However, with the recent acquisition of Meditech Research (ASX:MTR) close to completion, the combined entity will have anti-cancer products using MTR's hyaluronic acid technology in Phase-1 and Phase-2 clinical testing.

What We Think

- We believe that ACL's synthetic heparin represents a relatively low risk and attractive commercial opportunity. From a development perspective, the completion of the pilot scale commercial manufacture removed the last major element of technical risk in the product's development.
- The regulatory path is relatively straightforward as ACL's product is a generic version of an existing, marketed product that has already undergone extensive clinical testing. The only real regulatory risk that remains is the time for the FDA to process the ANDA application.
- While the relatively slow sales of Arixtra may suggest some market risk, we believe that the additional clinical indications that GSK has secured for Arixtra, the very favourable safety data that has come out of the clinical testing of Arixtra, and the ACL's cost advantage (which will allow competitive pricing with respect to Lovenox) should ensure that ACL can generate good sales from its synthetic heparin product.

Medical Devices

Optiscan (OIL) \$0.51

(MCap: \$51.1M)

Market Potential

- Optiscan has developed technology to minaturise confocal microscopes that can be used in both a clinical and research setting. Their lead products are the ISC 1000 flexible, confocal endoscope that has been developed in partnership with Pentax, and the FIVE 1 instrument developed for preclinical research purposes.
- The flexible endoscope market is estimated to be worth US\$1,200m and is dominated by three main players: Olympus (60%), Pentax (20%) and Fujinon (15%). Neither Olympus nor Fujinon currently have a confocal-based endoscope on market which should give Pentax the opportunity to increase its market share.
- The confocal nature of the ICS 1000 endoscope allows it to provide better quality and more informative images. In clinical testing, this improved sensitivity and specificity has resulted in better diagnosis of gastrointestinal cancers and significantly reduced the need for biopsy samples.
- Pentax formally launched the ICS 1000 in March 2006. Optiscan provides the minaturised scanner that is used in the probe and the ICS 1000 confocal control box. OIL recently announced that it had renegotiated the terms of its license with Pentax to allow the receipt of payments at the time of shipping which provides more stable cashflows.
- Pentax has committed to purchasing components for at least 80 units in the first year however if there is sufficient demand, the sales figure could be significantly higher. OIL has indicated that it requires sales of 200 units pa to become profitable.
- OIL exhibited its FIVE 1 research instrument at a trade show in Denmark in November 2005 and has indicated that the product will be on market in mid-CY06, however this is a relatively competitive market and OIL has yet to establish a marketing partnership for FIVE 1.

Other Products

- OIL is also developing rigid endoscopes which have applications in gynaecology, orthopaedics and keyhole surgery. These products are undergoing clinical testing before OIL will seek to establish partnering arrangements.

What We Think

- OIL reported 3Q FY06 sales revenue of \$1.3m from the shipment of 23 endo-microscope systems to Pentax. With the commitment of Pentax to purchase a minimum of 80 units, we can expect an additional \$3.5m in sales revenue by the end of CY06. However, we believe with its established marketing network and traditionally aggressive marketing focus, it is very likely that this figure will be significantly exceeded.
- While it has taken longer than expected to get OIL's confocal technology to market as a flexible endoscope, we believe that there is significant potential upside with the product launch in March 2006.
- We remain more cautious on the near term revenue potential of the FIVE 1 system until such time a marketing and distribution arrangement is put in place with an established player in the research instruments market.

Psivida (PSD) \$0.59**(MCap: \$256.9M)****Market Potential**

- Following the acquisition of the US-based private company Control Delivery Systems Inc for A\$139m which was completed in December 2005, PSD has two products in the market for ophthalmic applications.
- The major product is Retisert which provides long-term (30 month) delivery of the drug fluocinolone acetamide in the back of the eye. This product has FDA approval for treatment of an inflammatory disease called Uveitis which is the third largest cause of blindness in the US where it affects an estimated 175,000 people. The current Medicare reimbursement in the US provides US\$19,345 for implantation and the wholesale price of Retisert is US\$18,250.
- Retisert has also shown good results in a 3 year clinical trial for Diabetic Macular Edema (DME) which affects approximately 10% of diabetic patients. Retisert is licensed to the leading ophthalmology company Bausch & Lomb who have will be responsible for filing any further regulatory applications to the FDA to extend the application of Retisert to DMA. In addition to Bausch & Lomb, in the US Retisert is also co-promoted by Novartis Ophthalmic. PSD receives a royalty on end sales of Retisert from Bausch & Lome.
- PSD's second product is Vitrasert which provides intraocular delivery of ganciclovir for the treatment of patients with AIDS-related cytomegalovirus retinitis. As the incidence of this condition in AIDS patients has been decreasing with improved antiretroviral therapies, Vitrasert is unlikely to generate significant revenues for PSD. Vitrasert is also exclusively licensed to Bausch & Lome.

Other Products

- PSD has a second generation of Retisert in development called Medidur. This product also provides long term delivery of fluocinolone acetamide but is much smaller than Retisert and can be inserted by injection rather than requiring a surgical procedure.
- PSD also has clinical trial in progress for the use of its radioactively-labelled BioSilicon (which is basically porous silicon that is slowly biodegraded) for the radioactive ablation of primary liver cancer and for pancreatic cancer (a process called brachytherapy).
- The company is also developing other applications for BioSilicon including drug delivery, diagnostics and other non-medical applications.

What We Think

- The market potential for the use of Retisert to treat uveitis is sizeable given the limited treatment options currently available. The market opportunity for this product would increase significantly if Bausch & Lome lodges a successful application to the FDA for the use of Retisert to treat DME.
- Clearly Bausch & Lome and, in the US, Novartis Ophthalmic are quality marketing partners in the US. However the time of significant market penetration currently is uncertain as, while the product was launched in June 2005, PSD only received A\$1m in royalty revenue in Q3 FY06. Based on a 10% royalty rate, this would equate to the sale of approximately 400 Retisert devices.
- While we have the view that the acquisition of CDS has provided PSD with some products with good revenue potential, we are less convinced about the fit with PSD's original technology portfolio. We believe that there may be concerns market has regarding PSD's management which could have had a negative impact on the company's share price.

Clinical Cell (CCE) \$0.11**(MCap: \$24.5M)****Market Potential**

- CCE has three tissue-engineered products for the treatment of wounds and other skin defects currently on the market. All of these products are based on an underlying technology to obtain (and in some cases grow) skin cells from a patient and spray them onto a wound so that they can provide additional areas for initiating the healing process.
- Two of the products, CellSpray and CellSprayXP require further growth in tissue culture to provide sufficient numbers of cells. These products are for treatment of significant burns or other wounds that require urgent treatment. CellSpray has been approved for sale in 7 European countries and CellSprayXP has been approved in 5 European countries and are sold for approximately A\$35K and A\$15K respectively
- CCE's ReCell product is for the treatment of smaller surface areas (up to 30cm²) and does not involve any culture step. The application for this product is for smaller injuries and also plastic, cosmetic and reconstructive surgery and sells for approximately \$1,500 per treatment. CCE has indicated that, in the longer term, it expects ReCell to generate over 80% of the company's revenue from product sales.
- ReCell has been approved for sale in a total of 33 countries including its recent approval by the TGA for sales in Australia. Unfortunately, following a review of CCE's 510K application, the FDA has requested further clinical trial data be provided before it is able to consider granting approval for sale of ReCell in the US.
- Following further discussions with the FDA, the trial is likely to require testing in 60 patients at 4 different centres in the US and Europe and will require a 3-month post-treatment follow up. In view of this, it is unlikely that CCE will get a response to its application from the FDA before Q3 CY07. As US market approval for ReCell was expected in October 2005, this has had a significant negative impact on CCE's share price.

Other Products

- With the additional expenditure required for the US ReCell clinical trial, the delay in receiving revenues from US sales of ReCell and the current, low share price making access to new investment capital expensive, CCE has put the development of further products on hold including its EpiGrow project for chronic wound applications.
- The company has indicated that it is conducting due diligence on 2 alternative chronic wound products as well as other advanced surgical skin products to generate short term revenue flow but has not provided any further updates with respect to these opportunities.

What We Think

- CCE has provided revenue forecasts of A\$1.1m-A\$1.4m for FY06, A\$5m-A\$7m for FY07 and A\$12-16m for FY08. With receipts from customers of A\$1.0m at 31 March 06 the first of these estimates should be easily achievable.
- The receipts from customers of A\$117.2K in the last quarter, Q3 FY06, were down considerably on the previous two quarters (Q1: A\$428.3K, Q2: \$413.6K). While this may in part be due to the company having to respond to the FDA's decision, with all products having achieved European approval by September 2005 and with the price of the CellSpray and CellSprayXP products at A\$15K-35K, it appears the demand for CCE's products has been slow to ramp up.
- As CCE is relying on FDA approval of ReCell (Q3 CY07) and sales revenue to provide a re-rating, we believe CCE's price will continue to come under pressure in the near term. An increased focus on sales may deliver the expected revenue figures but we believe that it will be some time before the market feels comfortable that the revenue stream is reliable.

Brainz (BZI) \$0.50**(MCap: \$30.0M)****Market Potential for BRM2 Monitor**

- BZI have developed a bedside EEG monitor which includes analytical software for processing the EEG data. This monitor has initially been developed for neonatal and paediatric use but can be extended to cardiac and adult intensive care patients.
- The benefits of the BRM2 monitor are its portability (reducing the need for specialist facilities) and the reduction in specialist clinical input for interpreting routine EEG data.
- The company is currently finalising data on a software module for Computer Assisted Seizure Detection (CASD). This module will dramatically increase the attractiveness of the BRM2 unit for both adult and childhood ICU units.
- The market potential for these monitors is based on the number of intensive care unit (ICU) beds. In the US there are approximately 21,000 paediatric and neonatal ICU beds and 50,000 cardiac surgery and adult ICU beds. A full install base in an ICU unit would be expected to be one monitor per 3 neonatal/paediatric ICU beds and 1 monitor for every 10 adult ICU beds.
- The BRM2 units typically sell for A\$25,000 with a manufacturing cost of A\$5,000. In addition, each installed monitor generates an ongoing revenue stream from the disposable electrodes (\$1,800pa with GM of 70%) and annual service/support contracts (\$2,000pa).

Route to Market

- The BRM2 already has marketing approval in US, Europe and most other countries with the exception of Japan.
- BZI has agreements with GE Healthcare for distribution in the US and UK. These agreements have recently been extended until October 2007 at which time either party can elect not to continue. In the event that the agreements are terminated at this time, all of the ongoing revenue streams from installed units (disposables and service) are assigned to BZI.
- BZI has already reported sales in US, Canada, Australia and Switzerland and has established sales staff in the US to assist GE with training and education. Reported sales revenue in the 6 months to 28 February 2006 was A\$460,000 which equates to approximately 20 units. We believe the current sales are tracking at around 10 units per month.

What We Think

- We are expecting to see significant growth in sales of the BRM2 monitors over the next 12-18 months as the sales process gains traction. Typically, the initial sales to an ICU involve an obligation-free trial for up to 3 months. The conversion rates from trial to date has been very positive with around 80% leading to sales of one or more units.
- In our view, the full potential of a customer needs to incorporate 1-2 budget cycles of the hospital. Thus, while an initial sale of a few units may result following a site-trial, additional unit sales at the same site are likely once the required capital expenditure and operational costs are included in the ICU unit's budget forecasts.
- We view the distribution relationship with GE Healthcare and the ongoing revenue streams generated from installed units as very positive aspects of BZI's business model. Furthermore, BZI has the option to review the effectiveness of GE as a distribution partner in 18 months and take control if that relationship is not generating the expected sales.

CathRx (CXD) \$1.50**(MCap: \$45.1M)****Market Potential of CXD's Cardiac Catheters**

- Approximately 1 million cardiac catheter procedures are performed each year for both diagnostic and therapeutic purposes. This market is likely to grow due to an increasing use of these procedures and from increased demand from ageing of the population.
- CXD have developed a modular cardiac catheter system which uses a simpler and more robust manufacturing process (resulting in a cost advantage) and provides improved handling properties.
- CXD's cardiac catheters are like to be comparably priced to existing catheters (around \$2,000 per unit). As CXD's catheter does not require clinicians to change their current operational procedures significantly but provide handling improvements, we believe that CXD's product is well positioned to capture some of this growing market.

Route to Market

- CXD have filed for CE Mark (Europe) and TGA (Australia) approval for their first product which is a diagnostic catheter for the right side of the heart. The outcome of these applications is expected during 2H CY06 which, if favourable, will allow sales to commence by the end of the year.
- Marketing partnerships have already been established in UK (CardioCare) and Italy (Manta) and the company is in the process of securing distribution partnerships in Benelux, Germany, France, Japan, Canada and the US. Approval in Canada is relatively straightforward on CE Mark approval is granted. The company plans to file for FDA approval once CE Mark approval is granted.

Other Products

- CXD's first product is a diagnostic catheter for the right side of the heart. The company is in the process of developing two additional product lines which include a therapeutic catheter for the right side of the heart and a diagnostic/therapeutic catheter for the left side of the heart.
- While the development of these products is still be finalised, it is expected that they will enter clinical trialling in 2H CY06 and will obtain regulatory approval in late-CY07 or early CY-08.

What We Think

- From a product perspective, we believe that CXD's catheters will be very competitive as the manufacturing cost advantage will enable them to be priced to existing products but they will offer significant operational advantages to the clinicians.
- As the use of CXD's products do not require major changes to clinicians current operational procedures, we would expect that the barriers to adoption of these new products by clinicians should be relatively low. Furthermore, the 2nd and 3rd generation products have the potential to open up new market opportunities that are currently not available to competitors.
- The critical factor for CXD is the establishment of very effective marketing and distribution channels. We believe that CXD's Marketing Manager (ex-&J and ex-Medtronics) should be well placed to ensure these are put in place but the market will only be able to assess this once sales commence.

Portland Orthopaedics (PLD) \$0.33**(MCap: \$42.4M)****Market Potential**

- PLD has developed a range of prosthetic products for hip and knee replacements. These products have either received or are close to receiving regulatory approval in a number of major markets (US, Europe and Australia) and PLD has established an exclusive 3yr distribution partnership with Plus Orthopaedics Inc., the US subsidiary of the sixth largest joint implants company in the world which has annual sales of \$700m.
- PLD's core product is a hip replacement system that uses a patented Double Threaded Cone (DTC) system for better and more secure placement of the hip implant. This system is particularly applicable to revision reconstructions where an initial device is being replaced. This market segment accounts for approximately 12% of the 700,000 hip replacements that are undertaken world wide. The average selling price for the PLD's revision hip is US\$6,200.
- The company also has a range of products for primary hip replacements in its M-COR range. While this is a much larger market opportunity, it is also a very competitive and fragmented market with over 100 companies offering different products. The average selling price of PLD's primary hip replacement products is US\$3,500.
- PLD has also obtained approval for its patented cup which is an implanted receptacle in which the ball of the hip replacement device sits. In addition the company has licensed a primary knee product from Signal Orthopaedics (MI, USA) and has a range of smaller DTC hip replacements targeting the Asian market.

Route to Market

- PLD's DTC revision hip, M-COR primary hip and Equator Plus cup have approval in the US and Europe and its primary knee replacement has approval in the US. PLD have applied for FDA approval on its revision knee system and expecting the outcome of that application at the end of the year.
- PLD has initiated registration of its products with the State Drug Administration of China and is in discussion with Plus Orthopaedics KK in Japan.

Other Products

- The company is finalising the design of a modular cemented hip replacement product which could also receive marketing approval from the FDA towards the end of the year.

What We Think

- PLD has done an impressive job of expanding its product range beyond its initial DTC core product to a full suite of products for different orthopaedic applications. We also view the engagement of a globally-focussed and established distribution partner such as Plus Orthopaedics Inc and a positive for the company.
- However, we remain cautious on the rate of market penetration and the generation of sales revenue for the company. Many of the products that PLD are offering are in highly competitive markets and will require persuading clinicians to switch from products that they have been using previously.
- Similarly, the DTC system, which appears to have a number of advantages over existing products, will require clinicians to feel comfortable with this system over the systems they have worked with previously.
- In view of this, we believe the ramp up time for generating significant sales revenue for PLD is likely to be 2-3 years from the full launch of its product range.

Visiomed (VSG) \$0.02**(MCap: \$6.2M)****Market Potential**

- VSG's key product is the Funhaler which is a spacer for the delivery of asthma medication to children that includes an incentive device (such as a spinning wheel or whistle) that significantly increases both the compliance and correct administration of medication to asthmatic children.
- The incidence of asthma in children is 12-16% which translates to around 55m cases in developed countries. The worldwide sales of spacers in 2004 was 4m units of which 1.9m were for paediatric applications. As only 8-10% of asthmatic children in US and Australia use spacers, there are opportunities to grow this market significantly.
- The device was initially manufactured using a low throughput process. While this process was not commercially viable, the units produced from this process have sold well indicating that there is a good underlying demand for this product. The company has developed a more cost efficient and scaleable manufacturing process that is on track to commence full scale production by the end of Q2 CY06.
- The new manufacturing process should reduce to production costs and will provide good gross margins. Currently, the Funhaler has been retailing for \$45 with a wholesale price of approximately \$25. On these numbers, we believe that the company can break-even on annual sales of 100,000 units.
- The Funhaler has received marketing approval in its key target markets including US (FDA approval), Europe (CE Mark approval) and Australia (TGA approval). VSG has established distribution arrangements in Australia with Sigma Wholesale, API and Symbion which provides access to 5,000 pharmacies.
- The company has appointed Amcor Medical as the exclusive distributor for Israel and is in the process of finalising distribution relationships in Europe and the US.

Other Products

- The company is looking at expanding its product line with other products that incorporate its patented incentive devices such as peak flow meters to monitor lung function and spirometers. However we do not envisage that these products will be on market in the next 18 months.
- In addition, the company is looking at a number of M&A opportunities to access additional products however at this stage has not been able to provide any detail regarding the market opportunity that these products may afford.

What We Think

- While VSG's product is relatively unsophisticated, we believe that the improved compliance and medication combined with the encouraging initial sales data suggest that it has the potential to provide a solid earnings stream.
- While the annual profits from Funhaler sales are likely to be in the order of A\$2m-4m, we believe that this would be sufficient for a re-rating of the stock from its current market capitalisation.
- We believe that the current management of VSG has provided a very clear market focus to the company and has the potential to build a significantly more substantial company on the basis of the established Funhaler sales revenue and distribution network.

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