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bioMD (BOD)

Breakthrough in soft tissue repair

Recommendation

Spec Buy

Price

\$0.05

Target (12 months)

\$0.18

bioMD (BOD) is developing a technology for tissue engineering with applications in various soft tissue repair situations. We see the potential for early licensing of the technology based on favourable clinical data expected late in 2010. We have a high regard for management. We are initiating coverage with a Speculative Buy recommendation and a target price of 18 cents per share.

Expected Return

Capital growth	260%
Dividend yield	0%
Total expected return	260%

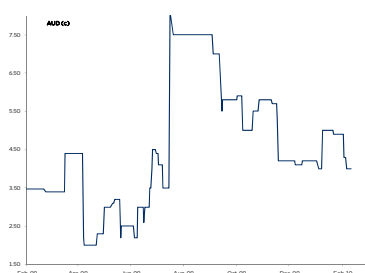
Company Data & Ratios

Enterprise value	\$5.7m
Market cap	\$6.4m
Issued capital	128.8m
Free float	100%
12 month price range	\$0.02-\$0.08

GICS sector

Healthcare Equipment and Services

Absolute Price



SOURCE: IRESS

Disclosure of Interest: bioMD is a corporate client of Bell Potter Securities which is a related entity of Southern Cross Equities. Bell Potter will seek to earn corporate fees from bioMD.

Tissue engineering technology that works

Over the last four years BOD has demonstrated that its ADAPT technology can work well in a variety of soft tissue repair situations. This opens up the potential for the technology to displace existing synthetic products used in soft tissue repair.

A large marketplace

Around US\$700m a year gets spent in the US on soft tissue repair procedures such as heart valve replacement, hernia surgery, and pelvic floor reconstruction. We rate highly BOD's chances of addressing these markets.

A near-term payoff

ADAPT is currently in two Phase II trials – one in heart deformities, the other in pelvic floor reconstruction. With data available on these trials before the end of 2010 we see potential for BOD to be rerated as regulatory approval nears and the company is in a position to license the technology.

Commercial management

BOD's management team of Michael Bennett and Rob Towner have done a good job over the last four years building up the potential of the ADAPT technology and taking it into the clinic, and we believe they have the commercial smarts to license this technology on favourable terms.

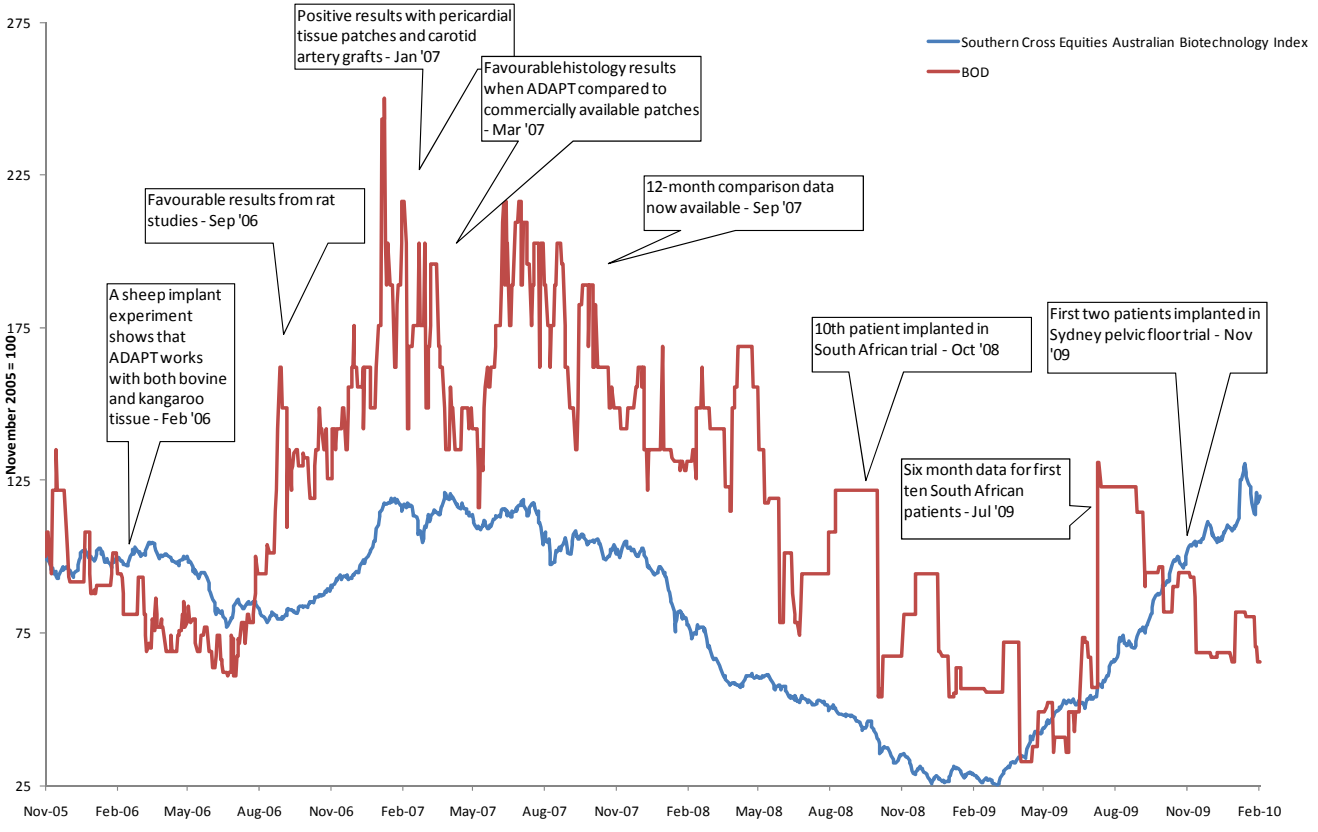
Target price 18 cents attainable with clinical data

In February 2010 BOD announced a 2-for-3 new issue of listed 'piggyback' options at 1.5 cent per option to raise \$1.3m with which to fund clinical development of ADAPT during the course of 2010. This will give BOD \$2.0m cash on hand. We value BOD at \$0.18 per share base case and \$0.42 optimistic case, fully diluted for this options issue. Our target price of \$0.18 sits at our base case valuation. There is potential for the market to rerate BOD as further clinical and pre-clinical data on the utility of its technology emerges during 2010.

bioMD – Breakthrough in tissue repair

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Figure 1 – Major developments for BOD since the company got involved with the ADAPT technology in November 2005



SOURCE: BOD, SOUTHERN CROSS EQUITIES

Nine reasons to own bioMD

bioMD is an early-stage Perth-based biotechnology company developing a soft tissue repair technology known as ADAPT, in which it owns a 77.35% interest. We see nine reasons to own bioMD stock.

- 1 Management is capable.** We have a high regard for bioMD's key people. *Managing Director Michael Bennett* knows the medical devices space well, having worked for most of his career in medical/surgical supplies, first for Ramsay Surgical (an Australian distribution arm of C.R. Bard), then for his own distribution company through the 1980s and 1990s, where he brought a number of new devices to Australia as well as participated in the relevant regulatory approval processes. *Executive Director Rob Towner*, whose background lies in corporate finance for small and emerging companies, and who founded bioMD initially to pursue retractable syringe technology, has done a good job identifying and positioning the ADAPT technology so that maximum shareholder value can be realised. Also, he demonstrated foresight in staying the course with clinical development of ADAPT even through the funding climate for biotech since 2005 has at times been poor. That Towner and Bennett have been respectful of shareholders through that time is evidenced by the fact that only \$7m in equity has been raised since the 2004 IPO.
- 2 The ADAPT technology works.** bioMD has demonstrated through numerous animal studies that ADAPT is suitable for soft tissue repair in a wide range of settings.
- 3 There has been a favourable experience in human trials in the cardiovascular space.** A trial conducted in South Africa in patients suffering various heart deformities has enjoyed success in terms of interim data on the acceptability, functionality and durability of ADAPT patches.
- 4 A trial in pelvic floor reconstruction has opened up a significant market opportunity.** This trial, first announced in August 2009, will see ADAPT used in 20 patients undergoing pelvic floor reconstruction to treat vaginal prolapse. This opens up a large potential market for ADAPT. An estimated 10-20% of women have suffered some kind of vaginal prolapse, and the US market for pelvic floor surgical material is around US\$300m pa.
- 5 The market for soft tissue repair is strong but underserved.** Around US\$700m gets spent in the US on tissue repair solutions for hernia and pelvic floor repair as well as other applications, but there are few biological alternatives such as ADAPT, so we think the product can enlarge the market.
- 6 There is important near term news flow.** bioMD expects to receive results from the two abovementioned trials by the third quarter of this year, which should be favourable in terms of news flow.
- 7 Regulatory approval could come from next year.** We see completion of the trials as opening the way to regulatory approval for ADAPT, first in Australia in 2011, then in the US and Europe.
- 8 There is potential for an early licensing of the technology,** based on the receipt of favourable clinical data, given the demand from major companies in the tissue repair space.
- 9 We value bioMD fully diluted at 18 cents base case / 42 cents optimistic case.** This is based on the potential for licensing. Our target price is 18 cents per share, which sits at our base case valuation.

bioMD's ADAPT product could receive its first regulatory approval next year

ADAPT – A tissue repair breakthrough

bioMD's 76%-owned ADAPT technology is a tissue engineering process, that is, a method of fixing and sterilising animal tissue so that it can be used as implant material in humans. We argue that ADAPT represents a potential breakthrough in soft tissue repair with the potential for significant licensing deals from as early as next year.

ADAPT overcomes a key issue in soft tissue repair. At present there are three main materials used in soft tissue repair – human tissue, animal tissue (mainly bovine and porcine) and synthetic tissue. In all cases what the surgeons want is a biological 'matrix' to act as a scaffold which, placed at the site of disease or injury, allows new vascularised human tissue to grow at the site, thereby effecting repair¹. Generally speaking, animal tissue is better than human tissue because it is easier to source and less likely to provoke an immune reaction in the recipient. And animal tissue is better than synthetic tissue since it naturally has more 'biocompatibility'². The main problem with animal tissue, however, is that it is subject to calcium deposition³, which over time limits its usefulness by causing it to harden and become less flexible⁴. ADAPT-treated animal tissue, by contrast, has about the same level of calcification as regular human tissue, making it much better material in terms of elasticity/flexibility, strength, durability and ability to promote revascularisation when compared with existing biological soft tissue repair products.

We see bioMD benefiting from the rise of stem cell therapies

Tissue engineering is a growth area of modern medicine. Many medical conditions are the result of tissue that has died or been damaged. For example, heart failure is primarily the result of damaged heart tissue resulting from a heart attack while knee osteoarthritis is the result of damage to cartilage in the relevant joint. Consequently the ability to grow new tissue and implant it at the site of disease or injury can help fix the underlying problem for which drugs or devices can treat only the symptoms. The rise of adult stem cell technologies over the last decade has brought this prospect close to realisation, a matter we discuss at length in our 8/1/2010 note on Mesoblast⁵. We argue that the commercialisation of stem cell therapies addressing new billion dollar markets will also create strong demand for the kind of technologies represented by ADAPT, since biological scaffolding will likely be needed for many stem cell therapies so as to speed the healing process. Pre-clinical and clinical work on the ADAPT technology has demonstrated that it can do this, and bioMD is working on demonstrating that ADAPT can function as a good scaffold to grow mesenchymal stem cells⁶.

ADAPT has been in development for around ten years now. The initial ADAPT technology was invented around 1999 by Professor Leon Neethling⁷, a cardiovascular medical scientist originally from South Africa who now does research in the field at Fremantle Hospital in Western Australia. Traditionally,

¹ When human tissue is used the implant is either an 'autograft' (self tissue) or allograft (donated tissue). When animal tissue is used the implant is called a 'xenograft'.

² Many synthetic products are biocompatible in the sense that the body does not reject them. That said, synthetics present potential problems that are not issues when natural products are used.

³ Needless to say, an additional problem with animal tissue is that certain people groups are not enamoured of the idea of pig parts going into their bodies.

⁴ This is because of the body's ability to recognise animal tissue as foreign. For tissue recognised as 'self' the body has mechanisms to prevent this calcification from occurring.

⁵ In our opinion Mesoblast (ASX: MSB, www.mesoblast.com), is the world's leading stem cell company. Our 8/1/2010 note, headlined *Mesoblast – the stem cell opportunity*, is available at the Mesoblast web site. With the note we initiated coverage with a \$3.00 price target. At the time MSB was \$1.66. It's now \$1.85.

⁶ The kind of stem cells Mesoblast is commercialising. See our note on the stock for more.

⁷ Pronounced 'Neet-ling'.

animal tissue has been fixed for implantation purposes using glutaraldehyde, which, by cross-linking, prevents the rapid degeneration of collagen structures in the animal tissue. Glutaraldehyde also prevents tissue digestion by enzymes or bacteria and, by disinfecting the tissue, reduces its potential to provoke an immune reaction. The problem with glutaraldehyde, however, is that it increases its susceptibility to calcification, which ultimately makes the tissue rigid and inflexible. In the 1990s Neethling set out to create a better fixing solution than glutaraldehyde. Working initially with kangaroo tissue, and later with bovine tissue⁸, Neethling was eventually able to markedly reduce the use of glutaraldehyde by first treating the tissue with an alcohol solution⁹. He filed for patent protection of the various steps in the ADAPT process¹⁰ as the technology developed, and brought in bioMD as a major partner in the project in late 2005. bioMD currently owns 77.35% of Celxcel Pty Ltd, which holds the ADAPT intellectual property. We see the lengthy development process for ADAPT as helping to iron out the bugs in the technology. The fact that Leon Neethling remains involved in the development is also encouraging, since it brings substantial intellectual capital that would be hard to replace in his absence.

ADAPT could be used in multiple applications. bioMD sees potential for ADAPT-treated mesh patches to be used in a variety of soft tissue repair situations including healing of burns and skin ulcers, repair of ligaments for joint reconstruction, pelvic floor reconstruction, plastic surgery and vascular repairs. There's also the potential for ADAPT to be used to make 'leaflets' for heart valve repair. We see the widespread applicability of the technology as one reason why a successful licensing deal for ADAPT could happen from as early as next year.

ADAPT could help grow the biologics part of the soft tissue repair market. Around US\$700m a year is spent in the US on various soft tissue repair products, both biological and synthetic. The animal side of the business has been building since the 1970s when porcine and bovine pericardium was first used to create prosthetic heart valves. However the calcification issue has traditionally limited the utility of animal tissue – for example, generally only older patients receive replacement heart valves while younger patients get mechanical valves. We argue that an animal product without calcification issues could seriously grow the use of animal tissue across the soft tissue repair market, and by extension the market as a whole, and that this prospect allows bioMD the potential to negotiate some lucrative deals for the technology.

Some big companies play in soft tissue repair. Currently soft tissue repair is dominated by large American medical device companies such as Bard (Michael Bennett's old employer), J&J, Covidien and W.L. Gore as well as various emerging companies. We see the potential for BOD to license ADAPT to one of these companies, or other companies in the medical device or biotech space looking to expand in the tissue repair area.

There is plenty of upside for BOD. In 2008 Covidien bought the UK's Tissue Science Laboratories for around US\$80m while an American medical device company called Kinetic Concepts bought a tissue engineering business called LifeCell for US\$1.7bn. We think these deals are applicable to bioMD since they represent the kind of upside that medical device companies will pay to control good tissue engineering products and technologies.

ADAPT could help grow the market for biologic products used in soft tissue repair

⁸ Pericardial tissue and carotid artery tissue are the preferred tissues used by Neethling and his team. We understand he chose kangaroo tissue was because of the ethical and disease-management issues associated with porcine tissue and the vCJD issues that have emerged in recent years regarding bovine tissue.

⁹ The alcohol solution - whose main ingredient is ethanol (70%) - removes various unneeded material such as phospholipids, DNA and RNA, and the α -GAL epitope. After this decellularisation process a small amount of glutaraldehyde (0.05% concentration – around 8% of what is ordinarily used) is used to cross-link the remaining collagen. The result is a collagen scaffold which is less likely to calcify, and which, with more advanced cross-linking, has greater biocompatibility.

¹⁰ ADAPT is primarily covered by two patent applications: 1) *A method using potassium dihydrogen phosphate to reduce calcification of tissue*, WO/2000/074692, priority date 3/6/1999, and 2) *An implantable biomaterial and a method of producing same*, WO/2006/066327, priority date 24/12/2004.

A 'derisked' technology

ADAPT has been the subject of numerous animal studies over the last eight years indicating the potential of the technology to work well in patients. We see these studies as having helped to substantially de-risk the technology, allowing it to proceed into the clinic with a fair degree of confidence.

Animal studies have demonstrated the basic effectiveness of the technology

ADAPT has worked well in animal studies

In 2005 and 2006 bioMD conducted three animal studies where the subsequent histology studies showed ADAPT patches to be:

- acceptable – ie. able to avoid an immune response in the recipient of the implant;
- functional – ie. able to avoid fibrosis and thereby stay flexible, while at the same time allowing new cells to form within the structure of the implanted tissue; and
- durable – ie. able to promote revascularisation in the treated area.

Sheep implant studies, in which ADAPT-treated tissues were used as patches to repair damaged jugular veins of sheep over a 150-day period (February 2006 announcement) and a 200-day period (January 2007), showed the basic power of the technology¹¹.

A rat implant study over a 120-day period showed that ADAPT patches worked well over a long period of time¹² (September 2006 announcement).

Comparison studies indicate that the technology works better than commercially available tissue engineering products.

In 2007 a rat study compared ADAPT with two other commercially available patch materials, with favourable results:

- At the 200-day mark ADAPT was performing much better over that period in terms of lower fibrosis and calcification issues (March 2007 announcement).
- The same outperformance was noted at the 12-month point as well (September 2007 announcement)¹³.

ADAPT could be the first 3-D matrix for growing mesenchymal stem cells

bioMD indicated at its November 2009 AGM that it was working on growing stem cells and keratinocytes using ADAPT as the 3-D scaffold for cell expansion. This work, if successful, could lead to the use of ADAPT as a key part of stem cell therapies given the importance of tissue remodelling for a successful outcome. Appreciating the importance of stem cells to the future of medicine, we see this work as being potentially very valuable in terms of the licensing opportunities.

¹¹ The Neethling lab subsequently published the 200-day study. See J Heart Valve Dis. 2008 Jul;17(4):456-63; discussion 464.

¹² The life expectancy of a domestic rat is around 2-3.5 years. 120 days of functionality in a rat is therefore worth something like 7-8 human years.

¹³ Leon Neethling had already done comparison studies of ADAPT in 2004, with favourable results. See J Heart Valve Dis. 2004 Jul;13(4):689-96; discussion 696.

Clinical results from late this year

The heart deformities trial has yielded good six month data

A trial in patients with heart deformities has gone well. In May 2007 bioMD unveiled a Phase II trial of ADAPT where the patches would be used in reconstructive surgery to correct various heart deformities such as atrial and ventricular septal defects, aortic root enlargements and outflow tract reconstructions. The trial, which was conducted at Universitas Hospital in the South African city of Bloemfontein, saw its first patient in May 2008 with the 20th patient reached by February 2009 and the 30th by October 2009. There was initially expected to be 50 patients in all but bioMD is now of the view that 30 patients will generate sufficient data. Patients are being followed up at the six month and 12-month mark and anecdotally we understand that performance of the ADAPT patches has been outstanding¹⁴. Favourable six month data from the first ten treated patients was reported in July 2009, and we expect the 12-month data for the full 30 patients, due late-2010, to mirror this experience.

A pelvic floor reconstruction trial is now underway. This trial, announced in August 2009, will see ADAPT used in 20 patients undergoing pelvic floor reconstruction at St George Public Hospital at Kogarah in Sydney's south. The indication here is vaginal prolapse. The first two patients were treated in late 2009. We expect some favourable news flow from this trial given that patients will be followed up at 6 weeks, 6 months, 12 months and 24 months. Also, the trial should also yield some data on comparability since at present most pelvic floor reconstructions are undertaken using synthetic mesh products.

A hernia trial is being planned - We understand that bioMD is now looking for trial sites to open a third clinical trial, this one in hernia repair. Hernia is probably the biggest opportunity in soft tissue repair given its high incidence in Western world populations, where around 1-2% of the population have had a hernia¹⁵.

Manufacturing expertise is being gained. Tissue for each trial is manufactured at Royal Perth Hospital. The facilities here have allowed bioMD to go down the learning curve regarding tissue manufacturing, as well as build the necessary dossiers to go for regulatory approval of ADAPT from late in 2010. We understand no major issues have occurred in scaling up for tissue production.

bioMD is preparing to seek regulatory approval for ADAPT. In December 2009 bioMD announced that biocompatibility testing of ADAPT was being undertaken by NAMSA, a US contract research organisation that specialises in the safety evaluation of medical devices¹⁶. The NAMSA work was in preparation for the various regulatory filings for ADAPT from late this year¹⁷.

Regulatory filings from late this year. We expect that the heart deformities and pelvic floor trials can complete by October 2010. BOD then intends to go for regulatory approval first in Australia - an application is expected by Christmas 2010 - then in the US in 2011, where a simple 510(k) filing with the FDA is all that will be necessary. This means that the product could be cleared to sell in the US market by the end of 2011. CE marking is also likely to happen in 2011 as well. We expect that BOD can then go for a licensing agreement for the product, although favourable data in 2010 could certainly begin the necessary discussions.

¹⁴ There was no additional calcification at 6 month follow-up, and the patches worked well in a surgical environment.

¹⁵ This is partly a result of high and rising obesity rates.

¹⁶ Northwood, Ohio, www.namsa.com.

¹⁷ We understand most of the required tests have already been completed.

Valuing bioMD – target price 18 cents

We value bioMD at 18 cents base case and 42 cents optimistic case, fully diluted

We value BOD on the basis of a potential licensing deal for ADAPT. To attempt a valuation of BOD we took ADAPT and assumed outlicensing of the technology after completion of the trials planned for 2010. We then conducted probability-weighted DCF valuations of the product assuming it would gain regulatory approval in the US in 2011. We then assumed certain sales levels to be reached at the point of maximum sales growth in year 7, after which sales only rise 5% pa. We assumed royalties are collected for around 13 years after first sales. We valued this royalty stream using a 20% discount rate, a 30% tax rate, and a 0.89 AUD/USD exchange rate. And while we have no concerns regarding clinical success we also assumed an 80% chance of success to account for any potential issues that may arise in the currently ongoing trials as well as regulatory filings. The various valuation parameters are laid out below.

Target price 18 cents. Our ADAPT valuation plus increased dilution from the 2-for-3 piggyback options issue (we assume all options fully exercised) resulted in our valuing BOD at base case \$0.18 per share and optimistic case \$0.42 per share. Our 12-month target price sits at the base case valuation.

The path to a re-rating. We see the path to re-rating BOD to our target price as involving a number of events likely in 2010, namely:

- Pre-clinical data on ADAPT’s ability to help grow mesenchymal stem cells;
- Completion of recruitment for the pelvic floor reconstruction trial and data from that trial;
- 12-month data from the heart deformities trial;
- Publications related to ADAPT in peer-reviewed journals and presentations on ADAPT at major scientific conferences;
- Filing for Australian regulatory approval;
- Favourable data on biocompatibility from NAMSA;
- Continuing licensing discussions with potential partners. At its 2009 AGM BOD indicated that a feasibility study plan was being negotiated with a ‘global heart valve company’.

Figure 2 – Key parameters for valuing ADAPT

Product	Sales at maximum growth rate base (USDm)	Sales at maximum growth rate optimistic (USDm)	BOD remaining expenditure base (USDm)	BOD remaining expenditure optimistic (USDm)	Royalty base	Royalty optimistic	Start of Phase I	Upfronts and milestones base (USDm)	Upfronts and milestones optimistic (USDm)
ADAPT	120	200	3	3	7%	14%	2006	30	50

SOURCE: SOUTHERN CROSS EQUITIES ESTIMATES

Figure 3 - Our valuation of BOD.

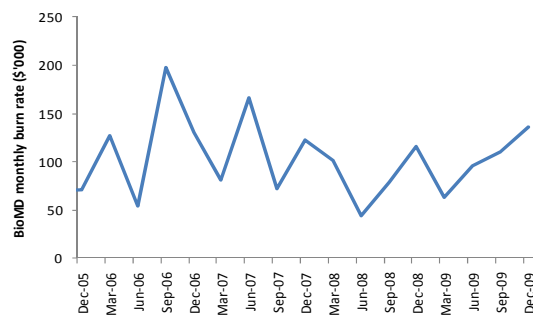
	Base case	Optimistic case
Value of 77.35% of ADAPT technology (A\$m)	41.3	116.3
Cash on hand plus cash from rights issue (A\$m)	2.0	2.0
Cash from future option exercises (A\$m)	14.5	14.5
Total diluted value (A\$m)	57.7	132.8
Total diluted shares (million)	315.5	315.5
Value per diluted share	\$0.18	\$0.42
Share price target	\$0.18	

SOURCE: SOUTHERN CROSS EQUITIES ESTIMATES

Funding the ADAPT opportunity

bioMD's burn rate is modest - At 31/12/2009 BOD had \$0.7m cash after burning around \$100,000 per month since late 2005.

Figure 4 – BOD's burn rate since 2004



SOURCE: BOD

A new piggyback options issue raises the capital to fund the ADAPT trials. In February 2010 BOD announced a 2 for 3 new issue of listed options at 1.5 cent per option to raise \$1.3m with which to fund the ADAPT trials over the course of this year¹⁸. The new options, exercisable at 4 cents, are 'piggyback options', in that:

- if exercised before 30/6/2010, each option yields another option exercisable at 10 cents by 31/12/2012. We assume that the 10 cent options will be listed as well;
- if not exercised before 30/6/2010, the options expire on 30/12/2011¹⁹.

It doesn't cost much to get ADAPT to early revenues. Successful completion of the piggyback options issue will raise cash on hand to \$2.0m from the 1.5 cent option premiums paid. At the current burn rate, augmented slightly to allow the company to step up for a third trial in hernia repair, \$2.0m would fund bioMD until around mid-2011 on our estimates, allowing completion of all three trials, NAMSA testing, and regulatory filing across multiple jurisdictions. In other words, this raising brings ADAPT through to the position where it is market-ready.

Extra funding from the options gives better ability to negotiate licensing deals. While the ADAPT trials can be funded using the initial options premium from the current issue, the issue also provides the potential for extra funding for bioMD:

- early exercise of the options would yield another \$3.4m;
- exercise of the resulting piggyback options would yield \$8.6m.

We see these potential extra funds as giving bioMD the financial resources it needs to negotiate a favourable licensing deal with potential partners, by not being compelled to sign an unfavourable deal because it is running out of money.

Successful completion of the options issue could fund ADAPT through to 'market ready' status

¹⁸ This issue is fully underwritten by Bell Potter Securities, which is a related entity of Southern Cross Equities.

¹⁹ Note – at this stage, the option exercise date is an estimate.

The risks

Biotechnology is risky

The stocks of biotechnology companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology companies in Australia fit this description, the speculative moniker also applies to the entire sector. The fact that biotechnology's intellectual property base lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology ought to be regarded. Investors are advised to be cognisant of this risk before buying any Australian biotech stock including BOD.

BOD is not without risk

We see six major risks specifically related to BOD as a company and a stock:

- 1 **Clinical risk** – There is the risk that either of BOD's current clinical trials could fail to reach their endpoints;
- 2 **Sentiment risk** – Biotech-oriented investors tend to prefer drug development stocks where the lead candidate is in Phase III, rather than a tissue engineering stock such as BOD where the regulatory pathway and commercial payoff may be less well understood;
- 3 **Timing risk** – There is the risk that BOD could take much longer to complete its pelvic floor trial than the timing we have postulated in this note, possibly because of slow recruitment;
- 4 **Partnering risk** – There is the risk that BOD's prospective partners may strike too hard a bargain for BOD shareholders to enjoy a strong return;
- 5 **IP risk** – There is the risk that BOD could find itself locked in dispute over patent infringement should its science be found to lean too heavily on unrelated or unlicensed predecessor science;
- 6 **Burn rate**. The company has raised \$7m in equity capital over the last five years. While we think the current option issue will fund ADAPT through to 'market ready' status, there remains the risk that bioMD may have to make further capital raisings to fund its burn rate in the future should a licensing deal for ADAPT take too long to negotiate.

Appendix I – BOD’s capital structure

Fully diluted, bioMD will have 315.5 million shares on issue after the current piggyback option capital raising.

Figure 5 - BOD’s capital structure

Shares (ASX Code BOD)	128,823,113	Price (c)	5.0
Listed and unlisted options	186,678,626	Undiluted cap (\$m)	6.4
Total diluted shares	315,501,739	F.D. cap (\$m)	15.8

OPTIONS	Number	Exercise price	Expiry date	Cash	Expiry date
Listed (BODO)	6,264,476	\$0.25	30-Aug-10	1,566,119	
Listed (code yet to be determined)	85,882,075	\$0.04	31-Dec-11	3,435,283	'Piggyback options'
Listed (code yet to be determined)	85,882,075	\$0.10	31-Dec-12	8,588,208	Assumes early exercise of 'piggyback options'
Unlisted	5,000,000	\$0.10	22-Oct-14	500,000	
Unlisted	1,250,000	\$0.10	16-Aug-10	125,000	
Unlisted	1,800,000	\$0.10	16-Oct-10	180,000	
Total BOD options on issue	186,678,626	\$0.077	18-Jun-12	14,454,610	

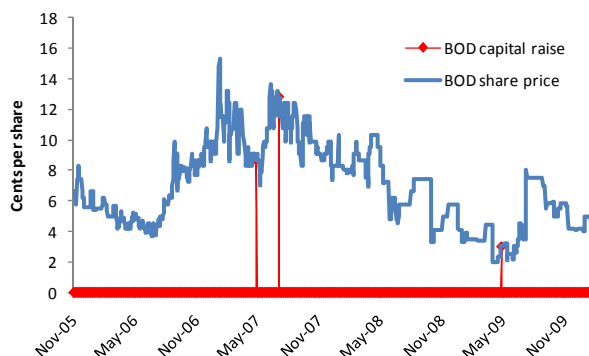
SOURCE: BOD, SOUTHERN CROSS EQUITIES. NOTE PIGGYBACK OPTIONS HAVE A TENTATIVE EARLY EXERCISE DATE OF 30/6/2010.

Figure 6 - BOD’s equity capital raising history

Date	Shares (million)	% of current shares on issue	Price	Amount raised (\$m)	Note
Mar-04	25.0	19.4%	\$0.20	5.0	IPO (as a retractable syringe technology developer)
May-07	10.5	8.2%	\$0.10	1.1	Share Purchase Plan
Jul-07	1.6	1.2%	\$0.20	0.3	1 for 10 issue to Aug '07 optionholders of 1 new share and 4 new Aug '10 options
May-09	42.9	33.3%	\$0.02	0.9	1 for 2 rights issue of shares
Total	80.0	62.1%	\$0.09	7.2	

SOURCE: BOD

Figure 7 – BOD has made three capital raisings worth only A\$7m since IPO



SOURCE: BOD, IRESS

Appendix II – The soft tissue repair marketplace

Some big companies play in soft tissue repair

Currently soft tissue repair is dominated by large American medical device companies:

- **C.R. Bard**²⁰ (2009 revenue US\$2.53bn), the world leader in soft tissue repair products through its Davol unit²¹, whose main product is various meshes for hernia repair;
- **J&J**²² (2009 revenue US\$61.9bn), whose Ethicon and Gynecare businesses are important players in hernia repair and pelvic floor reconstruction respectively;
- **Covidien**²³ (2009 revenue US\$10.7bn), which bought the UK's Tissue Science Laboratories for around US\$80m in early 2008, mainly to get hold of that company's Permacol surgical implant. Permacol is based on collagen derived from pig skins and is used in hernia repair;
- **W.L. Gore**²⁴ (annual sales around US\$2bn), whose Gore Medical Products business is big in hernia repair.

There are also various emerging companies playing in the space:

- **Kinetic Concepts**²⁵ (2009 revenue US\$527m), mainly known as a maker of advanced wound-care products, bought LifeCell²⁶ in 2008 for US\$1.7bn, primarily because of AlloDerm, which is technology to process human skin for use in hernia repair and breast reconstruction;
- **American Medical Systems**²⁷ (2009 revenue US\$519m), whose main focus is urological medical devices, is a big player in material for pelvic floor reconstruction;
- **RTI Biologics**²⁸ (2009 revenue US\$165m), whose business is the sterilisation of tissue for implantation purposes,
- **Synovis Life Technologies**²⁹ (2009 revenue US\$58m), a medical device company whose Synovis Surgical Innovations business makes soft tissue repair patches. Synovis bought Pegasus Biologics, a developer of collagen-based bioimplants for orthopaedic, spine, and neurosurgery applications, in mid-2009.

We see the potential for BOD to license ADAPT to one of these companies, or other companies in the medical device or biotech space looking to expand their tissue repair offering such as Boston Scientific, Genzyme, Medtronic, Stryker, St Jude Medical, Wright Medical and Zimmer.

²⁰ NYSE: BCR. Murray Hill, NJ. www.crbard.com.

²¹ A business run out of Warwick, RI. See www.davol.com.

²² NYSE: JNJ. New Brunswick, NJ. www.jnj.com.

²³ NYSE: COV. Mansfield, Ma. www.covidien.com.

²⁴ Privately held. Newark, De. www.gore.com. This is the company that brought you GORE-TEX, the famous waterproof and breathable fabric.

²⁵ NYSE: KCI. San Antonio, Tx. www.kci1.com.

²⁶ Branchburg, NJ. www.lifecell.com.

²⁷ Nasdaq: AMMD. Minnetonka, Mn. www.americanmedicalsyste.ms.com.

²⁸ Nasdaq: RTIX. Alachua, Fl. www.rtix.com.

²⁹ Nasdaq: SYNO. St Paul, Mn. www.synovislife.com.

Appendix III – A bioMD glossary

α -GAL epitope – A shape or marker on the surface of animal cells that triggers an immune response in people.

510(k) – Regulatory approval for a medical device in the US where the device has been found to be functionally equivalent to a device that was on the market before 1976. ADAPT will be able to apply for FDA approval through a 510(k) application.

Aortic root enlargement – An aneurysm (ie balloon-like deformity) in the wall of the aorta, which is the large artery that carries blood from the left ventricle of the heart to branch arteries. ADAPT has been used in surgery to treat aortic root enlargement.

ADAPT – bioMD's tissue fixing and sterilisation technology.

Atrial septal defect – See Septal defect.

Biocompatibility – The ability of a material to not be injurious or toxic to living tissue, as well as avoid generating an immunologic reaction.

Bovine – From cows. Bovine tissue is often used in soft tissue repair.

Calcification – The build-up of calcium in tissues, which reduces their flexibility and durability.

Cardiocel – bioMD's trademark for ADAPT when used for cardiovascular conditions.

Collagen – The fibrous protein that makes up connective tissue.

CE marking – The process of gaining European approval for a medical device. CE stands for *Conformité Européenne*.

Cross-links – Bonds that link one polymer chain to another.

Enzyme – A protein that catalyses a biological chemical reaction.

Expansion – The creation of more cells from a starting batch.

FDA – America's drug and medical device regulatory body.

Fibrosis – The abnormal formation of scar tissue, which generally limits the flexibility of the surrounding tissue.

Glutaraldehyde – A chemical used to stabilise the collagen structures in animal tissue when fixing them for surgical implantation in people.

Gynecel – bioMD's trademark for ADAPT when used for gynaecological conditions such as vaginal prolapse.

Hernia – A rupture of the wall or cavity containing an organ, so that the organ protrudes through it.

Histology – The study of tissue, done by examining thin slices of the material being examined.

Keratinocytes – The primary cell types found in the epidermis, the outer layer of skin.

Leaflet – The thin, triangle-shaped flap of a heart valve.

Matrix – The body substance in which tissue cells are embedded. Also called the 'extracellular matrix'.

Mesenchymal stem cells – Stem cells that give rise to a variety of cell types in the body such as fat, blood vessel and bone cells.

Mesh – The structure of most scaffolding material used in soft tissue repair.

Outflow tract reconstruction – Repair to the ventricular outflow tract through which blood from the ventricles of the heart pass before entering the large arteries. Right ventricular outflow tract reconstruction is most commonly done to prevent tachycardia, which is abnormally rapid heartbeat. ADAPT patches have been used in outflow tract reconstruction.

Pericardial – From the pericardium, that is, the membrane surrounding the heart. ADAPT is frequently used on bovine and kangaroo pericardial tissue.

Phase II – A clinical trial in humans to test efficacy in a small sample.

Phospholipids – Compounds composed of fatty acids and phosphoric acid with a nitrogenous base. Phospholipids are found in cell membranes, among other places.

Polymer - A large molecule composed of repeating structural units connected by chemical bonds.

Pre-clinical – Work such as animal testing that prepares a drug or medical device for clinical trials in humans.

Porcine – From pigs. Porcine tissue is often used in soft tissue repair.

Revascularisation – The formation of new blood vessels.

Septal defect– A defect in the walls that divide the chambers of the heart. A ventricular septal defect is a hole in the wall dividing the left and right ventricles (the lower chambers of the heart) while an atrial septal defect is a hole in the wall dividing the left and right atria (the upper chambers). ADAPT has been used to repair both kinds of septal defects.

Soft tissue - Tissues of the body that are not bone. ADAPT is useful in soft tissue repair.

Stem cells – Cells that can differentiate into many different cell types when subjected to the right biochemical signals.

Tissue – A group of specialised cells with a common structure and function, such as ‘muscle tissue’.

Tissue engineering – The process of creating tissue for use in repairing tissue defects in patients.

Vaginal prolapse – A female health condition in which the organs inside the pelvis protrude into the vaginal wall. Vaginal prolapse is treated via a pelvic floor reconstruction.

Ventricular septal defect – See Septal defect.

bioMD

COMPANY DESCRIPTION

The Perth-based bioMD (BOD) is an early stage biotechnology company commercialising a method of preparing animal tissue for use in soft tissue repair. bioMD's ADAPT technology significantly lowers the level of calcification in implanted tissue while retaining the desirable structural properties of the tissue. We see potential for ADAPT to be used in a variety of tissue repair situations such as hernias, heart valve replacement and pelvic floor reconstruction. Human trials are currently being undertaken in South Africa and Australia. We expect the first regulatory approval of ADAPT in 2011.

INVESTMENT STRATEGY

We see a payoff to shareholders arising from favourable clinical outcomes, followed by a licensing of the technology to large medical device companies involved in the soft tissue repair space. We also see BOD benefiting from improved sentiment towards Australian biotech stocks. The end of the Global Financial Crisis came at a time when many Australian biotech companies had reached late stage maturity. Consequently at 18/2/2010 the Southern Cross Equities Australian Biotechnology Index was up 349% on the level of 9/3/2009.

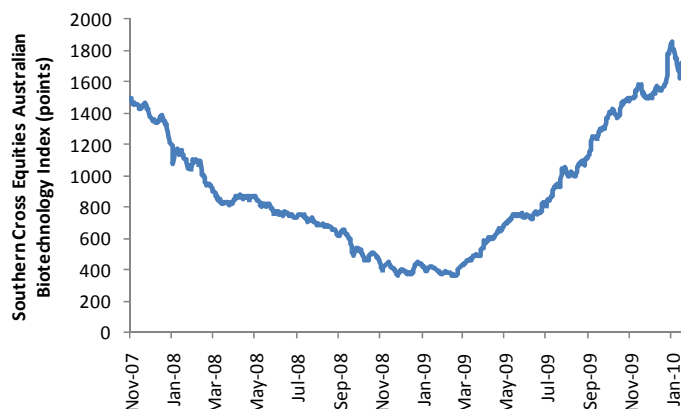
VALUATION

We value BOD at 18 cents base case and 42 cents optimistic case probability-weighted DCF valuation, which fully dilutes for the 2:3 piggyback options issue. We assume that BOD can be re-rated by the market as the near-term nature of ADAPT becomes apparent, helped by the further emergence of clinical and pre-clinical data.

RISKS

We see the main risk in BOD as being clinical risk – ie that products fail to perform in human trials. Another major risk facing the company is that prospective licensing partners may drive too hard a bargain for BOD shareholders to enjoy a strong return. A third significant risk is burn rate. At 31 December BOD had \$0.7m cash but has burned around \$100,000 per month since late 2005 when it first became involved in ADAPT. The company has raised \$7m in equity capital over the last five years. It may have to make further capital raisings to fund its burn rate until the clinical programmes yield licensable products.

Figure 8 – Sentiment toward Australian biotech stocks improved in 2009



SOURCE: IRESS, SOUTHERN CROSS EQUITIES

Recommendation structure

Spec Buy: Expect >30% total return on a 12 month view but carries significantly higher risk than its sector

Buy: Expect >15% total return on a 12 month view

Accumulate: Expect total return between 0% and +15% on a 12 month view

Reduce: Expect -15% and 0% total return on a 12 month view

Sell: Expect <-15% total return on a 12 month view

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Southern Cross Equities Ltd and its associates hold no shares in BOD as at the date of this report. This position is subject to change without notice.

Southern Cross will earn a fee of 2 million piggyback options for preparing this report.