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In this edition...
Drug development of combination drugs has its own challenges. It is not enough to show that the drug is better, but a sponsor has to show that the combination drug is better than its components. So QRxPharma has conducted a dozen studies in developing MoxDuo IR, including safety, compliance and marketing studies. An NDA filing is anticipated this year.
Half year reports have now been filed. Some previously profitable companies reported losses, and results were generally weak overall. IDT posted a profit, following two consecutive loss making halves, Probiotec's profit slumped, while Cryosite and Brain Resource results were essentially flat. Although modest, Somnomed's profit results were supported by strong volume growth, which is expected to continue.
The Editors
Companies Covered: BRC, CTE, CGS, IDT, PBP, QRX, SOM

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	30.6%
Cumulative Gain	**278%**
Av Annual Gain (9 yrs)	**18.5%**

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

QRxPharma – NDA Filing Expected in Coming Months

Terminology
- *12/8 MoxDuo IR: 12mg of morphine plus 8mg of oxycodone, in an immediate release tablet form*
- *Equal analgesic dose: same level of a pain drug to achieve the same therapeutic effect*
- *Equal opioid dose: It is considered that 12/8 MoxDuo is the same level of opioid dosage as either 24mg of morphine or 16mg of oxycodone*

With 12 clinical studies completed and a final Phase III study now underway, QRxPharma is nearing the end of the clinical development required for its lead drug candidate MoxDuo IR to reach the market. Its final clinical study is expected to be completed in April and by mid year the company should have filed its NDA (new drug application) with the FDA.

MoxDuo is a combination of two opioid drugs, morphine and oxycodone. The company's theory is that using a combination of these opioids delivers a more favourable pain treatment to the patient rather than using either of the opioid drugs alone. It is believed that combining the drugs delivers synergistic pain control, where pain blocking mechanisms in the body are heightened through cross interactions of pain channel pathways. Or put more simply, one plus one equals three rather than two.

To get a pain drug to market requires some peculiar studies. These start with fairly standard safety studies, early proof of concept, and dose ranging Phase II studies. However, the FDA requires a company must demonstrate that taking, for example, 12 mg of morphine with 8 mg of oxycodone combined does not deliver inferior pain control to taking 12 mg of morphine or 8 mg of oxycodone. A drug sponsor needs to show that if you deliver more of the opioid combination you achieve better pain control than when you deliver less, and you need to show that your opioid combination is better than a placebo.

From the FDA's perspective, perhaps the regulator wants to know they are approving a product that will not deliver inferior pain control and that the safety aspect of taking these opioids is not compromised.

In the table on the next page, we list all of the 13 trials conducted with MoxDuo IR (note the first trial was really with an intravenous version not an IR or immediate release version). The trials can be segregated as safety and what we have termed compliance trials, and proof-of-concept/marketing studies (highlighted in grey), with the latter showing the real benefit of using the opioid combination that QRxPharma is commercialising.

Safety/compliance Studies

QRxPharma has now completed most of its safety studies and its two Phase III compliance studies that will allow it to file its drug for approval with the FDA. We expect the NDA to be filed by mid year.

– Cont'd over

Additional Safety Study

QRxPharma recently started an additional Phase III trial (study 022) in 375 patients who will undergo a bunionectomy procedure, which is a common study group for pain drug developers. This study primarily will look at the side effect profile of taking a 12mg/8mg MoxDuo combination versus what is considered equal opioid doses of morphine (24 mg) or oxycodone (16mg). This study is expected to be completed in April.

The study will be included with the company's European submission by year's end, and the company will likely include data from this trial with its US submission, with the company allowed to submit additional safety data at 120 days after it has filed its NDA with the FDA.

But this study will be more than just a safety study effectively, providing information on the core benefit of using MoxDuo versus equal analgesic quantities of morphine or oxycodone.

Completed Proof-of-Concept/Marketing Studies

Prior to listing in 2007, QRxPharma had completed two core proof-of-concept studies. These studies supported the development of MoxDuo, showing that in one study the same therapeutic effect in patients could be achieved using 40% less opioid equivalent drug compared to morphine (Study 003) using a combination of morphine and oxycodone. In the second trial (Study 004) a 34% reduction in opioid equivalent was achieved using a different combination of morphine and oxycodone versus morphine alone.

The next proof of efficacy (Study 021) came in April 2009, when the company compared a 6mg/4mg dose of MoxDuo against equal opioid doses of morphine (12mg) and against oxycodone (8mg). There were big reductions (50%-75%) in vomiting, nausea and dizziness experienced by patients in the MoxDuo arm over the morphine and oxycodone arms whilst achieving the same pain control. There was an increase in the number of patients reporting headaches in the MoxDuo arm (9% compared to 3% in the morphine arm and no patients in the oxycodone arm).

In August 2009, the company released results from a trial (study 020) that compared equal analgesic doses of MoxDuo with Percocet (oxycodone and paracetamol). That study also showed that side effects such as nausea and also constipation were clearly lower with MoxDuo than with patients taking Percocet whilst achieving the same pain control.

The safety trial underway (study 022) should also deliver some important efficacy data highlighting the benefit of the MoxDuo concept.

Summary

By mid year QRxPharma should have filed its NDA in the US and it should also have received data from its largest trial showing the benefits of the MoxDuo IR combination opioid treatment. By years end its European drug application should be submitted and in the process we expect partnering talks will accelerate. QRxPharma has several major milestones to look out for over the next 12-15 months. The company is capitalised at $182 million with $21 million in cash.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

QRxPharma Clinical Trials Summary for MoxDuo IR - Completed and Underway

Trial	Patients	Progress/results	Length of trial	Design	Indication	Type of study
Study 022, Phase III	375	Started Jan 2011, to be completed April 2011	2 days	12/8 MoxDuo IR vs 24 morphine vs 16 oxycodone	Post bunionectomy surgery	Marketing/safety study
Study 009, Phase III	141	Completed February 2011	2 days	Flexible dose MoxDuo IP vs low doses MoxDuo IR	Post knee replacement surgery	Compliance study
Study 008, Phase III	522	Completed April 2010	2 days	12/8 MoxDuo IR vs 12mg morphine vs 8mg oxycodone	Post bunionectomy surgery	Compliance study
Study 0021, Phase II	197	Completed April 2009	2 days	6/4 MoxDuo vs 12mg morphine vs 8mg oxycodone (and others)	Post bunionectomy surgery	Marketing study
Study 020, Phase II	44	Completed August 2009	2 days	MoxDuo vs Percocet	Post knee replacement surgery	Marketing study
Study 007, Phase III	256	Completed May 2008	2 days	4 doses of MoxDuo vs placebo	Post bunionectomy surgery	Compliance study
Safety study	16	Finshed March 2008	4 weeks	Up to 36mg/24mg MoxDuo IR	Post bunionectomy surgery	Safety study
Study 006, Phase I	17	Completed pre listing in 2007	Single administration	Three doses, PK study	Healthy volunteers	Safety study
Study 005, Phase I	16	Completed pre listing in 2007	Single administration	Single dose, PK study	Healthy volunteers	Safety study
Study 004, Phase II	23	Completed pre listing in 2007	Equal analgesic dose	MoxDuo vs morphine (different dose to study 003)	Chronic pain patients	Proof of concept
Study 003, Phase II	21	Completed pre listing in 2007	Equal analgesic dose	MoxDuo vs morphine	Chronic pain patients	Proof of concept
Study 002, Phase I	10	Completed pre listing in 2007	n/a	Low dose MoxDuo combinations	Healthy volunteers	Safety study
Study 001, Phase II	17	Completed pre listing in 2007	2 days	IV dose of MoxDou	Post surgery patients	Safety

2010 A Difficult Year For Cogstate

Cogstate (CGS: $0.21) markets a proprietary software cognition test that is used by pharmaceutical companies in clinical trials, particularly in drugs being developed for the treatment of Alzheimer's disease.

For Cogstate, 2010 was a difficult year. Earnings were hit by an appreciating Australian dollar and a drop off in the number of clinical trials being conducted in the schizophrenia market, with two major pharmaceutical companies reducing their focus in this area because of development failures and the perceived difficulty in the therapeutic class.

Revenue recorded for calendar year 2010 was $8.3 million, down from $9.6 million in calendar year 2009. At around $8 million of revenue, the company is only operating close to breakeven, largely due to the continued investment it is making in seeking to grow the business. The challenge for the company is to expand its revenue base to the next level, to achieve consistent revenues in the order of $13-$15 million a year. At these levels it should be well positioned profits-wise, regardless of currency movements and any unevenness in its contract revenue.

Over the five years from financial year 2005 to 2010, the company gained a solid footing in providing cognition monitoring services in the clinical trial space, increasing revenue from $1.0 million in 2009 to $9.5 million in 2010. Calendar year 2010 was the first time over that period that sales have started to decline. Some of this was due to currency movements, but some was also due to a drop in the market for cognition testing in clinical trials. No doubt that market will continue to fluctuate somewhat each year depending on progress with individual clinical programs.

After six years of operating in the clinical trials business, the company has likely captured the majority of its potential slice of the market with its current product offering, if the leveling out of sales over the last 18 months is an accurate indicator.

Next Growth Area – Axon Sports

In August last year the company expanded the use of its product into concussion testing through a 50/50 joint venture which has been called Axon Sports (see www.axonsports.com). That market has a strong growth potential, however the market needs to be created and that will likely take at least two to three years before good traction can be seen.

Axon Sports combines the cognition testing expertise and software development skills of Cogstate with a proven and successful sports marketing team. The co-founder of Axon Sports is Rudy Chapa, who was formerly the Global Director for Sports Marketing at Nike. The current focus for Axon Sports is preparation for the start of the new school year in the USA in August. Concussion injuries and management of concussion in sport in the USA continues to be a major issue. Axon Sports is offering a baseline cognitive test that can be retaken following a concussion to ensure the player is fit to resume competitive activity. This test can be conducted accurately on any computer via the internet at a sale price of $7.50 per test.

Cogstate recorded a $400,000 loss against its investment in Axon Sports in the first half of this financial year. The company has not released information of the level of product sales.

Dementia Screening – A Future Market at the Right Time

Another potential future application for the Cogstate test is in dementia screening, particularly in the area of Alzheimer's disease. However for that market to be tackled, an effective drug that alters the course of the disease would need to be available.

Summary

Following a difficult year in 2010, an improvement is expected this year, with increased interest starting to emerge in the cognitive testing market in clinical trials according to CEO Brad O'Connor. Cogstate finished the calendar year with $2.4 million in cash and is capitalised at $14 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Half Yearly Results: Selected Profit Reporting Companies

Brain Resource Company (BRC)

CMP	$0.35
Capitalisation ($M)	$32
PE (Annualised)	28

Period	H1 2009	H2 2009	H1 2010	H2 2010	H1 2011
Revenue ($M)	$3.1	$4.3	$4.0	$4.1	$3.8
% ch, prev. period	*130%*	*37%*	*-5%*	*-44%*	*-7%*
EBITDA ($M)	$3.4	$0.0	$0.7	$1.8	$0.5
% ch, prev. period	*N.A*	*-99%*	*1947%*	*-48%*	*-70%*
Depreciation	-$0.1	-$0.1	-$0.1	-$0.1	-$0.1
EBIT ($M)	$3.3	$0.0	$0.7	$1.7	$0.4
% ch, prev. period	*N.A*	*-101%*	*N.A*	*-49%*	*-74%*
Interest ($M)	$0.5	$0.4	$0.1	$0.2	$0.1
Tax ($M)	$0.1	$0.0	$0.0	-$0.4	$0.0
NPAT ($M)	$3.8	$0.4	$0.8	$1.4	$0.6
% ch, prev. period	*N.A*	*-91%*	*125%*	*-66%*	*-60%*

Brain Resource Company

The Brain Resource Company sells a brain health product to clinicians to assess brain characteristics as well as a brain training product, sold as a health and productivity tool to employers in other industries.

Sales dipped in the last half year, falling 7% to $3.8 million from the previous period. However, NPAT of $0.6 million was down 60% from the previous period and down 30% from the previous corresponding period.

BRC is developing a product to be used in the management of depression – iSPOT. An FDA pre- IDE meeting is sheduled for 2011 Q2 with a regulatory filing to follow soon after.

Bioshares recommendation: **Not formally covered**

Cyrosite (CTE)

CMP	$0.11
Capitalisation ($M)	$5
PE (Annualised)	16

Period	H1 2009	H2 2009	H1 2010	H2 2010	H1 2011
Sales ($M)	$3.2	$3.0	$3.1	$2.9	$3.3
% ch, prev. period	*16%*	*-8%*	*3%*	*-5%*	*14%*
EBITDA ($M)	$0.29	-$0.3	$0.03	-$0.1	$0.29
% ch, prev. period	*-10511%*	*-215%*	*N.A*	*-396%*	*-381%*
Depreciation	-$0.2	$0.0	-$0.1	$0.1	-$0.2
EBIT ($M)	$0.1	-$0.4	-$0.1	$0.0	$0.0
% ch, prev. period	*-1465%*	*-371%*	*-83%*	*-91%*	*-754%*
Interest ($M)	$0.09	$0.1	$0.08	$0.1	$0.12
Tax ($M)	$0.0	$0.2	$0.0	$0.0	$0.0
NPAT ($M)	$0.225	-$0.2	$0.021	-$0.02	$0.163
% ch, prev. period	*1140%*	*-168%*	*-114%*	*-178%*	*-1075%*

Cryosite

Crysosite supplies storage, warehousing and distribution services of biological materials to a select number of life science companies, including companies conducting clinical trials and cord blood collection companies.

The company posted sales of $3.3 million in the half year ending december 31, 2010, an increase of 14% from the previous period. NPAT for the period was $163,000, compared to a loss of $20,000 in the previous period and a profit of $21,000 in the PCP.

Bioshares recommendation: **Not formally covered**

IDT Australia

CMP	$0.52
Capitalisation ($M)	$22
PE (Annualised)	13

Period	H1 2009	H2 2009	H1 2010	H2 2010	H1 2011
Revenue ($M)	$13.7	$13.0	$6.3	$5.9	$8.3
% ch, prev. period	*-20%*	*-6%*	*-51%*	*-7%*	*40%*
EBITDA ($M)	$5.6	$5.7	$0.3	$1.7	$2.4
% ch, prev. period	*-21%*	*2%*	*-94%*	*414%*	*37%*
Depreciation	-$1.2	-$1.1	-$1.3	-$1.3	-$1.3
EBIT ($M)	$4.4	$4.6	-$1.0	$0.4	$1.1
% ch, prev. period	*-27%*	*4%*	*-121%*	*-145%*	*145%*
Tax ($M)	-$1.4	-$1.2	$0.3	-$1.4	-$0.2
NPAT ($M)	$3.1	$3.3	-$0.6	-$0.9	$0.8
	-28%	*9%*	*-119%*	*47%*	*-189%*

IDT Australia

Following two dismal, consecutive loss making half years, contract pharmaceutical manufacturer and clinical services provider IDT Australia posted a modest profit of $0.8 million from sales of $8.3 million. Sales increased 40% from the previous period. However, annualised sales remain at half of FY2008 levels (~$31 million.

The company's revenues in the past few years have suffered as a consequence of weak economic and financial market conditions impacting on its local and international customer base.

The company is exanding its business to include the development of generic pharmaceuticals, including a hormone and anti-cancer drug, and veterinary drugs. We have concerns as to how well generic drug development and sponsorship fits within the capabilities of IDT Australia.

Bioshares recommendation: **Hold**

Probiotec (CMP)	
CMP	$0.60
Capitalisation ($M)	$32
PE (Annualised)	16

Period	**H1 2009**	**H2 2009**	**H1 2010**	**H2 2010**	**H1 2011**
Revenue ($M)	$46.5	$40.7	$39.8	$39.1	$36.1
% ch, prev. period	*40%*	*-12%*	*-2%*	*-2%*	*-8%*
EBITDA ($M)	$8.2	$8.7	$9.6	$8.7	$3.9
% ch, prev. period	*16%*	*6%*	*10%*	*-9%*	*-55%*
Depreciation	-$1.1	-$2.7	-$1.6	-$6.0	-$1.6
EBIT ($M)	$7.1	$6.0	$8.0	$2.8	$2.2
% ch, prev. period	*16%*	*-15%*	*33%*	*-65%*	*-20%*
Interest ($M)	-$1.1	-$0.9	-$0.7	-$1.0	-$1.1
Tax ($M)	-$1.7	-$1.4	-$1.1	$0.4	-$0.1
NPAT ($M)	$4.3	$4.6	$6.2	$3.2	$1.0
% ch, prev. period	*11%*	*9%*	*35%*	*-49%*	*-68%*

Probiotec

Probiotec manufactures and sells pharmaceutical and OTC products and also provides contract manufacturing services.

Earnings slumped in the half year ending December 31, 2010. NPAT of $1 million fell 68% from the previous period and 84% from previous corresponding period (PCP). Revenues of $36.1 million fell 8% from the previous period and 9% PCP.

Hardest hit were contract manufacturing revenues of $5.9 million, which decreased by 29% over the PCP, with export sales of $5.6 million recording an 11% decrease over the PCP. Pharmaceutical and consumer health product sales of $21 million declined by 2.5% over the PCP, impacted by a decline in a meal replacement range of products.

The company has set guidance of sales for FY2011 of $83.8 million, or $47.7 million for the second half of the current financial year. Profit guidance is for NPAT of $5.2 million.

The company's gearing ratio at Dec. 31 was 41.6%.

Bioshares recommendation: **Buy**

Somnomed (SOM)	
CMP	$1.01
Capitalisation ($M)	$41
PE (Annualised)	69

Period	**H1 2009**	**H2 2009**	**H1 2010**	**H2 2010**	**H1 2011**
Revenue ($M)	$3.2	$4.6	$5.0	$5.7	$6.0
% ch, prev. period	*47%*	*43%*	*9%*	*15%*	*4%*
EBITDA ($M)	-$1.3	-$0.4	$0.2	$0.0	$0.4
% ch, prev. period	*-1%*	*-69%*	*N.A*	*-110%*	*-1885%*
Depreciation	-$0.1	-$0.2	-$0.1	-$0.1	-$0.1
EBIT ($M)	-$1.4	-$0.6	$0.1	-$0.1	$0.3
% ch, prev. period	*-6%*	*-57%*	*N.A*	*-182%*	*-330%*
Interest ($M)	$0.2	$0.1	$0.0	$0.0	$0.0
Tax ($M)	$0.0	$0.0	$0.4	$0.2	$0.0
NPAT ($M)	-$1.2	-$0.6	$0.6	$0.2	$0.3
% ch, prev. period	*0%*	*-53%*	*N.A*	*-71%*	*67%*

Units	5,475	6,779	9,140	10,403	11,462
% ch, prev. period	*32%*	*24%*	*35%*	*14%*	*10%*

Somnomed

Somnomed markets the Somnodent dental appliance, a device used to manage obstructive sleep apnea.

For the last half year period, the company registered sales of $6 million, an increase of 4% from the previous period and a 20% increase from the pevious corresponing period. Somnomed posted a modest profit of $295,418.

The company sold 11,462 units in the latest period, an increase of 10% from 10,403 units sold in the previous half year period.

Somnomed's growth prospects look set to benefit from changes recently made to US Medicare DME policy. The policy will see only customised dental appliances covered by Medicare, removing benefits for 'boil and bite' devices. Medicare also approved coverage for dental appliances when used as a first-line treatment for mild-to-moderate sleep apnea, instead of as a second line following failure with a CPAP machine

The expectation is that these coverage decisions that affect about 15% of the US population will be taken up by the private health insurers which cover about 200 million people.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (4 March 2011)

Company	Price (current)	Price added to portfolio	Date added
Somnomed	$1.01	$0.94	January 2011
Phylogica	$0.070	$0.053	September 2010
Sunshine Heart	$0.036	$0.036	June 2010
Biota Holdings	$1.08	$1.09	May 2010
Tissue Therapies	$0.71	$0.21	January 2010
QRxPharma	$1.47	$0.25	December 2008
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.78	$0.70	August 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.43	$0.42	December 2007
Cogstate	$0.21	$0.13	November 2007
Sirtex Medical	$5.58	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.03	$6.60	September 2007
Starpharma Holdings	$1.12	$0.37	August 2007
Pharmaxis	$2.50	$3.15	August 2007
Universal Biosensors	$1.37	$1.23	June 2007
Acrux	$3.44	$0.83	November 2004
Alchemia	$0.72	$0.67	May 2004

Portfolio Changes – 4 March 2011

IN:
No changes

OUT:
No changes

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip

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