

In this edition...

The tactics used by generic drug companies in the US are not easy to understand, especially when more than one dose form of a drug exists. Warner Chilcott, for which Mayne Pharma manufactures the antibiotic Doryx, ran down stocks of its 150mg product, hoping to replace it in the market with a 200mg version, when the 150mg becomes open to generic competition next month. However, the FDA didn't approve the 200mg Doryx, which indirectly has put a dent in Mayne's earnings. While investors have been distracted by this issue, we suggest more attention should be placed on Mayne's antifungal product, the SUBACAP asset, which we have valued at \$97 million.

The Editors

Companies Covered: MYX, PVA, Sales and Profits Review

	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 - May '11)	45.4%
Year 11 now commenced	-21.3%
Cumulative Gain	231%
Av Annual Gain (10 yrs)	21.2%

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Bioshares

16 September 2011

Edition 425

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

Mayne Pharma Group – All Eyes on Doryx But SUBACAP Asset Being Missed

Mayne Pharma Group (MYX: 43.5 cents) presents an investment opportunity for investors. A temporary drop in sales of its lead product, Doryx, which is manufactured for **Warner Chilcott** in the US, has caused a lower than expected revenue and net profit result for FY2011. This combined with the company's SUBACAP drug in final stages of development, which is not being recognised by the market, makes Mayne Pharma an attractive investment at current prices.

Mayne is capitalised at \$70 million and is down 56% from its 12 month high. In FY2011, it generated total revenue of \$50.1 million, with a net profit of only \$1.7 million. (In FY2010, the company generated revenue of \$37 million with a net profit of \$3.3 million, however this only accounted for eight months of the pharmaceutical business operation, which was acquired during that year.) Doryx revenue fell 46% to \$21 million, now representing 42% of total revenue. And the appreciating Australian dollar, which was trading at US\$0.85 at 30 June last year, has had a negative \$3 million impact on the net result.

Temporary Doryx Issue

Doryx is a tetracycline class of antibiotic, used to treat a range infections and severe acne. It was developed by Mayne Pharma and was licensed to Warner Chilcott. In 2010 Warner Chilcott generated sales of US\$172 million, down from \$210 million in the previous year. This fall has been due to changes in Warner Chilcott's loyalty card program which has resulted in lower prescription volumes.

The Doryx product positioning can be difficult to understand, but here is the explanation. Warner Chilcott started selling Doryx as a 75mg and then a 100mg dose. It then introduced a 150mg dose, removing most of the lower doses from the market, with the higher dose having benefits over the smaller doses. This is the start of the generic drug game. The 150mg dose accounted for 95% of Doryx sales in 2010.

Generic competitors play catch up with the original or branded drug, in this case Doryx. The FDA has approved generic versions of smaller doses from Impax and Mylan in December last year. Warner Chilcott believes these products were launched 'at risk' in January this year. Warner Chilcott and Mayne have filed infringement lawsuits against two companies.

There is an outstanding Mayne patent over the Doryx product that extends out to 2022. With respect to the 150mg dose, the FDA has granted what's called a 30 month stay (ending 30 September 2011) for the disputing companies to settle the patent issue, after which the FDA can approve these generics. This stay was granted over the 150mg dose because Warner Chilcott had submitted Mayne's 2022 Doryx patent to be listed in the FDA's Orange book before the generics had filed their 150mg ANDAs (abbreviated new drug applications) with the FDA, but not before the smaller dose Doryx ANDAs were filed.

Cont'd over

Generic companies have a number of options: they can either launch their FDA approved 150mg generic Doryx product in what is called 'at risk', once approved, after 30 September; settle with Warner Chilcott to bring out their 150mg dose earlier than 2022 without risking a legal dispute and harsh penalties; or wait until 2022.

To date, two generics companies, Heritage Pharmaceuticals and Actavis, have settled with Warner Chilcott allowing them to market their generic 150mg doses from the end of 2016, five years earlier than the patent expiry. Other generic companies that may launch their product 'at risk' are Impax, Mylan and Sandoz.

But it becomes a poker game for these pharmaceutical companies. Warner Chilcott was hoping to get its 200mg dose approved by the FDA before 1 October (when the stay expires) but was unsuccessful. It can either argue the point with the FDA or conduct additional trials, which may take around six months. It's unclear which path it will take.

The issue for Warner Chilcott is that if it has not switched its customers from the 150mg dose to the 200mg dose by October 1, then Mylan and Impax can launch at risk in October. If the 200mg dose is approved prior to that date, then it makes it more difficult for the generic competitors to compete with their 150mg doses.

Mylan has received tentative approval from the FDA, and Impax has not, so Mylan should get a 180 day exclusivity as the only generic, if it launches at risk.

The issue with launching products at risk, which would likely result in a formal patent dispute, which is the case here, is that severe penalties apply for the infringing generic company if they lose. So many generics companies are not comfortable launching at risk.

Rather than have an oversupply of the 150mg dose, Warner Chilcott ran down supply levels assuming its 200mg dose would be approved. This contributed to the 46% drop in manufacturing orders to Mayne Pharma, together with a fall in sales due to loyalty card changes from Warner Chilcott and the unfavourable exchange rate movements for Mayne.

Warner Chilcott has now resumed ordering the 150mg doses of Doryx, which should see Doryx sales improve, if a generic competitor does not launch at risk, however profitability will continue to be affected by the high Australian dollar.

And There's More...

At the time of writing, it was announced that Warner Chilcott received approval from the FDA for a 'Dual-Scored' 150mg tablet. The generic competitors may need to have both a single and dual scored version available, so they may need to file a dual scored version for approval before their single scored versions can be approved. A second score means that the tablet can be broken into three parts, not two. However due to recent healthcare changes in the US, it's unclear how much this will delay competitors.

SUBACAP - Significant Value Has Been Created and Ready to be Realised

Mayne Pharma has developed what should be a valuable product in SUBACAP. SUBACAP is an improved version of the antifungal drug, itraconazole. SUBACAP delivers improved bioavailability, requiring only a half dose to the lead itraconazole product on the market, called Sporanox, and delivers a more consistent absorption profile across patients.

SUBACAP has been filed for approval in Europe by Mayne Pharma, as a half dose version with non-inferiority in safety and efficacy over incumbent products.

Mayne has spent around \$25 million developing SUBACAP, which should be a valuable asset. Over the last two years it has spent \$11 million on R&D. Its options are either to license the drug or sell it outright. The company is currently looking to find a group to market the drug, and this would likely deliver more value to Mayne once European approval has been granted.

According to Mayne management, there is substantial interest in this product. The global itraconazole market is valued around US\$550 million a year.

There is further potential upside for SUBACAP. Its lower effective dose and thereby implied better safety profile could see a future licensor take market share away from other antifungal markets. Sporanox has a black box warning from the FDA and this no doubt limits its sales. The FDA believes there is a 'small but real risk' of developing congestive heart failure from Sporanox use and it 'has been associated with serious liver problems resulting in liver failure and death', according to the FDA.

Sporanox has poor bioavailability and this is one of the core issues that SUBACAP addresses. That SUBACAP has been shown to be as effective at half the dose should see a place for it in the market with its implied better safety profile. That should translate to interest from potential licensors and also from regulators in allowing this drug onto the market.

The global annual antifungal market is worth US\$4.9 billion. One of the appeals of itraconazole (the active pharmaceutical ingredient in SUBACAP and Sporanox) is that it is one of the broadest acting antifungals on the market. This could see SUBACAP expand the itraconazole market share in the antifungal drug space.

In December last year Mayne filed SUBACAP for approval in Europe. The company is aiming for regulatory approval by mid 2012 with a licensing deal as well, which we would expect would follow approval. A Phase III study for SUBACAP in the US will be required, which could involve 600 patients, and take around 18 months to complete. It's unclear as to when this will start, with Mayne due to meet with the FDA by year's end for a Pre-Phase III meeting. We would not be surprised if a future licensing partner assumes responsibility for this trial. The trial is scheduled to be completed by the end of FY2013.

Cont'd over

Astrix and other business

Mayne sells two versions of a low dose 100mg aspirin, called Astrix. One is a more standard aspirin product, but the second is a high-tech aspirin. It is capsule with enteric coated pellets that delay absorption until the pellets reach the small intestine. With standard aspirin, there is a risk that long term use can cause gastric ulceration and bleeding, particularly if a large aspirin fragment adheres to the stomach lining. Mayne's is the only type of enteric coated pelletised aspirin on the market, and presumably is designed for safe chronic use to prevent clotting related illnesses such as stroke and heart attack.

The Astrix products are sold in Australia, Hong Kong, Sri Lanka, Mauritius and with the second largest market after Australia being South Korea. Astrix related revenue make up 16% of the company's revenue now, with sales increasing by 27% in FY2011. Mayne manufactures the Doryx (doxycycline), Astrix (aspirin), and Eryc/Erymax (erythromycin) products for licensors and it sells locally its own brand of these products. It also makes, under contract, the products Kadian, Magnoplasm and Urocard, and has capacity to increase its contract manufacturing services at its current facility.

Overall, Mayne's other businesses outside of Doryx manufacturing, delivered a very strong result, increasing by 18% in FY2011. Aside from the temporary drop in Doryx orders, the Mayne business looks to be in very good shape.

Valuation – \$1.04 per share

Using a probability adjusted discounted cash flow analysis, we estimate a fair value for the company's underlying business of 42 cents per share, excluding the value of the SUBACAP asset. We assign a current value to the SUBACAP asset of \$97 million. This assumes the drug is licensed to a third party, no upfront payments or milestones, sales starting in FY2013 at \$50 million, and peaking in 2017 at \$250 million. We arrive at an overall value of Mayne Pharma of \$162 million, or \$1.04 per share

Summary

Mayne Pharma is a diverse pharmaceutical business that generates annual revenue of around \$50 million a year. Whilst there is still a high reliance on a particular revenue stream, that of the Doryx product manufactured for Warner Chilcott, which makes up 42% of sales, the company is building its existing business, with an 18% growth in sales in the last financial year excluding Doryx.

There is much attention of the Doryx product and the circling of generic competitors. The shares are currently trading on the value of the underlying business, however assigning none of the considerable value the SUBACAP asset holds, which we value at \$97 million alone.

Bioshares recommendation: **Buy**

We have added Mayne Pharma to the Bioshares Model Portfolio.

Bioshares

How to turn your Nobel prizeworthy idea into a blockbuster medical product while keeping your investors happy and still finding time for golf.

Join other scientists at the MBA in a Day - Business basics for bioscientists **Ausbiotech BioPro** course in Adelaide on Sunday October 16 just before the Ausbiotech national conference.

OK, given it takes more than 7 years (world's best practice) and a hundred million plus to get there, you might not have much time for golf. But we've assembled 5 expert speakers to save you time, money and anguish along the yellow brick path to commercialising bioscience innovations.

[Are you a scientist who's spending less time in the lab and more time pondering how to turn IP into income?](#)

[Do you have staff who need a better grip on how to commercialise your organisation's inventions?](#)

[Do you want to understand how to build a business based on science?](#)

[Are you considering a career move from pure lab work into business development?](#)

Then this jam-packed day has been designed for you. It's like an MBA Executive Summary for life scientists.

In the morning these topics are covered:

- What is a company, how do you set one up and who controls it?
- How do you account for what happens to the money.
- Where do shareholders, directors, managers, inventors and customers fit in the pecking order?
- What are investors looking for - besides a return on their investment?
- How do you write an effective Business Plan?
- How do you protect your IP, value your innovations, raise money and negotiate deals with pharma that work?

In the afternoon, the theory is put into virtual practice with a Case Study that ties many of the points into a real example. Then participants are asked to put themselves in the shoes of the management and directors, by making critical choices and decisions at key turning points in the life of a company going through 4 stages of growth.

Speakers include Business **Professor Mike Vitale**, ex biotech CEOs **Tom Williams** and **Dr Ian Nisbet**, Corporate lawyer **Jason Watson** and Patent attorney **Stuart Boyer**. Produced by BioMentoring Australia for Ausbiotech.

Over 100 previous participants have found the day extremely worthwhile. Book via Ausbiotech at: <http://ausbiotech2011.com.au/ProfessionalDevelopment>

Results Summary June 30 Reporting Companies – FY2011

Company	Code	Cap (\$M)	Price 16/09/11	2010	2011	2010	2011	%ch.	2010	2011	%ch.	P	PE	P/S
				Revenues (\$M)	Revenues (\$M)	Sales (\$M)	Sales (\$M)		Profit/Loss (\$M)	Profit/Loss (\$M)				
Cochlear	COH	\$2,905	\$51.20	\$744.41	\$817.55	\$734.80	\$809.65	10%	\$155.15	\$180.11	16%	P	16	3.6
CSL	CSL	\$14,197	\$27.05	\$4,626.94	\$4,321.57	\$4,455.82	\$4,187.55	-6%	\$1,052.90	\$940.60	-11%	P	15	3.4
Resmed Inc.	RMD	\$4,327	\$2.83	\$1,112.63	\$1,279.93	\$1,092.36	\$1,243.15	14%	\$198.09	\$226.99	15%	P	19	3.5

Company	Code	Cap (\$M)	Price	2010	2011	2010	2011	%ch.	2010	2011	%ch.	P	PE	P/S
Atcor Medical	ACG	\$10	\$0.08	\$9.25	\$7.48	\$9.20	\$7.46	-19%	-\$1.22	-\$3.08				1.4
Alchemia	ACL	\$71	\$0.37	\$0.63	\$1.32	\$0.00	\$0.00		-\$8.80	-\$13.43				
AcruX	ACR	\$579	\$3.48	\$56.10	\$93.47	\$0.00	\$0.00		\$46.55	\$57.15	23%	P	10	
Acuvax	ACU	\$3	\$0.002	\$0.024	\$0.012	\$0.000	\$0.000		-\$1.841	-\$0.609				
Actinogen	ACW	\$2	\$0.03	\$0.09	\$0.09	\$0.05	\$0.06	21%	-\$0.74	-\$0.74				
Anteo Diagnostics	ADO	\$53	\$0.07	\$0.62	\$1.02	\$0.08	\$0.01	-86%	-\$2.26	-\$2.22				
Agenix	AGX	\$10	\$0.01	\$0.22	\$0.05	\$0.01	\$0.00		\$2.48	-\$2.71				
Allied Health Group	AHZ	\$24	\$0.04	\$4.16	\$6.77	\$4.15	\$6.75	63%	-\$0.04	-\$1.42				3.5
Analytica	ALT	\$9	\$0.02	\$0.29	\$0.28	\$0.00	\$0.00		-\$1.29	-\$0.20				
Advanced Surgical	AMT	\$5	\$0.15	\$7.47	\$7.37	\$6.03	\$7.20	19%	-\$0.90	-\$3.27				0.7
Antisense Therapeutics	ANP	\$9	\$0.01	\$0.10	\$0.09	\$0.00	\$0.00		-\$3.42	-\$1.81				
Leaf Energy	LER	\$3	\$0.10	\$0.00	\$0.09	\$0.00	\$0.00		\$0.91	-\$1.79				
Atos Wellness	ATW	\$3	\$0.02	\$0.01	\$0.35	\$0.00	\$0.00		-\$0.38	-\$1.04				
Avita Medical	AVH	\$24	\$0.10	\$3.88	\$4.54	\$2.69	\$3.12	16%	-\$5.89	-\$1.95				7.6
Aveva	AVX	\$39	\$0.05	\$1.70	\$1.66	\$0.00	\$0.00		-\$41.49	-\$5.05				
Austofix	AYX	\$4	\$0.29	\$2.81	\$1.84	\$2.65	\$1.60	-39%	-\$0.34	-\$0.53				2.4
Bluechiip	BCT	\$12	\$0.15	\$0.26	\$0.73	\$0.00	\$0.00		-\$3.13	-\$3.17				
Biodiem	BDM	\$10	\$0.10	\$0.00	\$0.20	\$0.00	\$0.00		-\$3.39	-\$2.62				
Biotron	BIT	\$16	\$0.11	\$0.00	\$0.45	\$0.00	\$0.00		-\$1.87	-\$1.91				
Blackmores	BKL	\$502	\$30.09	\$217.09	\$236.59	\$214.93	\$234.42	9%	\$24.30	\$27.31	12%	P	18	2.1
Benitec	BLT	\$21	\$0.02	\$0.18	\$0.35	\$0.00	\$0.00		-\$4.64	-\$3.54				
Bioniche	BNC	\$71	\$0.70	\$45.90	\$36.04	\$26.99	\$27.37	1%	-\$1.59	-\$15.34				2.6
Bone Medical	BNE	\$2	\$0.02	\$0.56	\$0.14	\$0.00	\$0.00		-\$3.95	-\$1.52				
Bionomics	BNO	\$159	\$0.46	\$3.88	\$4.14	\$1.63	\$1.56	-4%	-\$8.51	-\$8.43				
Brain Resource Corp	BRC	\$22	\$0.24	\$8.14	\$5.65	\$7.71	\$5.53	-28%	\$2.21	\$0.27	-88%	P	82	4.0
Biota	BTA	\$160	\$0.88	\$67.59	\$14.61	\$0.00	\$0.00		\$16.24	-\$28.09				
Cordlife	CBB	\$8	\$0.05	\$2.33	\$4.78	\$2.26	\$4.41	95%	\$2.35	-\$35.19				1.8
Cbio	CBZ	\$31	\$0.22	\$0.23	\$0.21	\$0.00	\$0.00		\$16.79	-\$13.68				
Cellmid	CDY	\$7	\$0.02	\$0.33	\$0.15	\$0.00	\$0.00		-\$1.34	-\$2.27				
Cogstate	CGS	\$11	\$0.16	\$9.59	\$8.25	\$9.48	\$8.13	-14%	\$1.64	-\$0.85				1.3
Circadian Technologies	CIR	\$24	\$0.52	\$2.25	\$1.83	\$0.00	\$0.00		-\$6.95	-\$10.26				
Compumedics	CMP	\$14	\$0.09	\$32.61	\$31.27	\$32.37	\$30.86	-5%	\$0.41	\$0.08	-80%	P	171	0.4
Cryosite	CTE	\$5	\$0.10	\$6.14	\$6.66	\$5.97	\$6.43	8%	\$0.005	\$0.33	7149%	P	14	0.7
Clinuvel Pharmaceuticals	CUV	\$49	\$1.62	\$1.85	\$2.28	\$0.00	\$0.00		-\$11.52	-\$11.41				
CathRx	CXD	\$21	\$0.15	\$0.76	\$0.78	\$0.48	\$0.02	-95%	-\$10.56	-\$8.95				
Calzada	CZD	\$19	\$0.06	\$0.63	\$0.91	\$0.00	\$0.00		-\$2.31	-\$2.94				
Ellex Medical Lasers	ELX	\$9	\$0.11	\$48.74	\$43.52	\$47.41	\$43.11	-9%	\$3.76	-\$0.70				0.2
Eastland Medical	EMS	\$8	\$0.02	\$4.02	\$3.14	\$3.93	\$3.00	-24%	-\$4.86	-\$4.51				2.7
Genera Biosystems	GBI	\$9	\$0.13	\$0.65	\$0.82	\$0.04	\$0.06	38%	-\$2.49	-\$2.94				
Genetic Technologies	GTG	\$79	\$0.20	\$8.66	\$18.28	\$4.92	\$4.59	-7%	-\$9.34	\$0.91		P	87	17.2
Helicon Group	HCG	\$12	\$0.02	\$0.00	\$0.00	\$0.00	\$0.00		-\$0.86	-\$1.14				
Holista Colltech	HCT	\$7	\$0.14	\$6.73	\$6.08	\$6.24	\$6.02	-3%	-\$1.57	-\$0.08				1.2
Mayne Pharma Group	MYX	\$66	\$0.44	\$36.71	\$50.10	\$34.37	\$45.70	33%	\$3.25	\$1.68	**	P	39	1.4
Healthlinx	HTX	\$3	\$0.02	\$0.05	\$0.05	\$0.01	\$0.01	8%	-\$1.86	-\$2.34				
IDT Australia	IDT	\$16	\$0.38	\$12.24	\$13.10	\$11.83	\$12.77	8%	-\$1.58	-\$0.24				1.3
Immuron	IMC	\$21	\$0.07	\$0.30	\$0.50	\$0.25	\$0.46	89%	-\$1.90	-\$2.60				
IM Medical	IMI	\$0	\$0.00	\$0.08	\$0.01	\$0.09	\$0.01	-94%	-\$1.69	-\$4.07				
Imugene	IMU	\$3	\$0.02	\$0.04	\$2.24	\$0.00	\$0.00		-\$1.54	\$0.42		P	7	
Impedimed	IPD	\$86	\$0.55	\$3.80	\$4.13	\$3.44	\$3.70	8%	-\$11.40	-\$14.82				23.2
ITL	ITD	\$12	\$0.09	\$41.35	\$41.12	\$40.86	\$40.71	0%	-\$12.86	\$0.94		P	13	0.3
KarmelSonix	KSX	\$19	\$0.02	\$0.53	\$0.49	\$0.35	\$0.33	-5%	-\$5.94	-\$6.68				
LBT Innovations	LBT	\$5	\$0.05	\$3.91	\$0.74	\$0.00	\$0.00		\$1.49	-\$1.16				
Living Cell Technologies	LCT	\$19	\$0.06	\$1.67	\$2.06	\$0.30	\$0.18	-41%	-\$5.67	-\$6.80				
Medigard	MGZ	\$2	\$0.03	\$0.29	\$0.17	\$0.00	\$0.00		-\$0.40	-\$0.64				
Medical Australia	MLA	\$9	\$0.02	\$7.30	\$8.78	\$7.30	\$8.78	20%	-\$1.34	-\$0.34				1.0
Mesoblast	MSB	\$2,263	\$8.09	\$0.76	\$120.92	\$0.00	\$0.00		-\$14.78	\$90.61		P	25	
Medical Developments	MVP	\$23	\$0.45	\$8.36	\$10.45	\$8.30	\$10.45	26%	\$0.88	\$1.74	98%	P	13	2.2
Nanosonics	NAN	\$131	\$0.57	\$1.71	\$3.30	\$0.76	\$2.25	194%	-\$8.17	-\$11.21				58.5
NeuroDiscovery	NDL	\$4	\$0.04	\$0.04	\$0.12	\$0.00	\$0.00		-\$1.71	-\$1.46				
Novogen	NRT	\$16	\$0.16	\$1.79	\$2.54	\$0.00	\$0.00		-\$15.25	-\$9.48				
NuSep Holdings	NSP	\$8	\$0.11	\$5.37	\$4.68	\$2.40	\$1.80	-25%	\$3.29	-\$6.56				4.5
OBJ	OBJ	\$22	\$0.02	\$0.96	\$0.89	\$0.00	\$0.00		-\$0.95	-\$0.90				
Optiscan Imaging	OIL	\$13	\$0.10	\$1.24	\$0.55	\$0.97	\$0.51	-47%	-\$1.65	\$0.01				25.6
OMI Holdings	OMI	\$2	\$0.00	\$1.64	\$0.10	\$0.79	\$0.00	-100%	-\$0.71	-\$0.60				
Patrys	PAB	\$16	\$0.07	\$1.53	\$1.07	\$0.00	\$0.00		-\$7.54	-\$7.42				

Legend: P - denotes Profitable, June 30, 2011; PE - Price/Earnings Ratio; P/S - Price/Sales Ratio [less than 100]

**Mayne Pharma results for FY2010 included only 8 months revenues, sales and earnings following a merger with Halcgyen Pharmaceuticals.

Cont'd over

Results Summary June 30 Reporting Companies – FY2011

Company	Code	Cap (\$M)	Price	2010		2011		%ch.	2010		2011		P	PE	P/S
				Revenues (\$M)	Revenues (\$M)	Sales (\$M)	Sales (\$M)		Profit/Loss (\$M)	Profit/Loss (\$M)	%ch.				
				16/09/11											
Probiotec	PBP	\$19	\$0.35		\$80.51	\$72.37	\$74.77	\$71.77	-4%	\$9.48	-\$10.34				0.3
Prana Biotechnology	PBT	\$41	\$0.17		\$0.22	\$0.16	\$0.00	\$0.00		-\$4.91	-\$6.43				
Probiomics	PCC	\$2	\$0.01		\$0.85	\$0.94	\$0.75	\$0.94	25%	\$0.08	\$0.00				1.9
Progen Pharmaceuticals	PGL	\$13	\$0.21		\$2.86	\$3.67	\$1.97	\$2.59	31%	-\$15.84	-\$6.10				4.9
Prima Biomed	PRR	\$206	\$0.21		\$0.52	\$1.07	\$0.00	\$0.00		-\$17.96	-\$21.08				
pSiVida	PVA	\$93	\$4.50	US\$	\$23.05	\$4.97	\$0.00	\$0.00		\$8.75	-\$8.63				
Pharmaxis	PXS	\$179	\$0.79		\$53.79	\$4.46	\$0.83	\$0.91	10%	-\$46.35	-\$45.76				
Phylogica	PYC	\$24	\$0.06		\$0.69	\$2.47	\$0.00	\$0.00		-\$4.57	-\$3.61				
QRXPharma	QRX	\$139	\$1.11		\$0.47	\$0.93	\$0.00	\$0.00		-\$27.47	-\$25.64				
Resonance Health	RHT	\$6	\$0.02		\$2.01	\$1.93	\$1.84	\$1.75	-5%	-\$0.10	-\$0.32				3.5
Southern Dental	SDI	\$18	\$0.15		\$54.04	\$54.98	\$53.09	\$54.85	3%	\$3.47	\$1.21	-65%	P	15	0.3
Sunshine Heart	SHC	\$47	\$0.05		\$0.47	\$0.53	\$0.00	\$0.00		-\$6.53	-\$11.48				
Solagran	SLA	\$30	\$0.09		\$2.06	\$1.21	\$1.22	\$1.02	-17%	-\$4.55	-\$7.63				29.0
Somnomed	SOM	\$47	\$1.16		\$10.71	\$12.34	\$10.71	\$12.34	15%	\$0.79	\$0.74	-6%	P	63	3.8
Starpharma Holdings	SPL	\$308	\$1.25		\$5.91	\$3.30	\$0.00	\$0.00		-\$6.38	-\$8.93				
Sirtex Medical	SRX	\$278	\$4.99		\$72.09	\$72.95	\$64.33	\$70.29	9%	\$16.08	\$11.48	-29%	P	24	4.0
Tyrian Diagnostics	TDX	\$2	\$0.00		\$2.05	\$1.20	\$0.45	\$0.07	-86%	-\$4.16	-\$4.37				
Tissue Therapies	TIS	\$64	\$0.47		\$0.38	\$0.43	\$0.00	\$0.00		-\$3.49	-\$5.34				
USCOM	UCM	\$8	\$0.16		\$1.02	\$0.88	\$0.84	\$0.84	0%	-\$1.02	-\$2.69				10.0
Unilife Corporation	UNS	\$264	\$0.71	US\$	\$11.42	\$6.65	\$2.54	\$2.77	9%	-\$29.75	-\$40.68				95.2
Virax Holdings	VHL	\$3	\$0.02		\$0.33	\$0.79	\$0.00	\$0.00		-\$1.86	-\$1.36				
Viralytics	VLA	\$32	\$0.54		\$0.06	\$1.66	\$0.00	\$0.00		-\$4.87	-\$4.36				

Legend: P - denotes Profitable, June 30, 2011; PE - Price/Earnings Ratio; P/S - Price/Sales Ratio [less than 100]

**Mayne Pharma results for FY2010 included only 8 months revenues, sales and earnings following a merger with Halcgen Pharmaceuticals.

Method

We have compiled revenue, sales and profit/loss results for 90 ASX listed life science companies that reported their full year results for the financial year ending June 30, 2011.

Companies not included were Reva Medical, Genesis R&D, Universal Biosystems, Phosphagenics, Cyclopham, Sigma Pharmaceuticals, API, Heartware International, Scigen, Neuren Pharmaceuticals, which have different reporting periods, and Clover Corp, which recently moved to a July 31 end of financial year reporting date.

At the time of this report the Asian Centre for Liver Diseases had not reported.

Revenues includes sales and all other income, including interest, grants, licence and royalty payments.

Sales comprises income from sale of products and services.

Analysis

Of 90 companies, 17 were profitable for the year ending June 30, 2011. Of profitable companies with sales, five companies posted an increase in net profit: Resmed (15%), Cochlear (16%), Medical Developments (98%), Blackmores (12%) and Cryosite (7200%).

Three companies with no history of sales reported profits for the year. They were Acrux, Mesoblast and Imugene.

The largest profit from companies with sales was recorded by CSL (\$941 million) followed by Resmed (US\$227 million), Cochlear (\$180 million) and Blackmores (\$27 million).

There were 26 companies which reported an increase in sales, 26 companies reported a decrease, with the balance of 38 companies reporting no sales.

There were 21 companies which reported sales of greater than \$1 million but less the \$10 million. Seven companies reported sales of greater than \$10 million but less than \$50 million. Three companies reported sales of greater than \$50 million but less than \$100 million – Sirtex Medical, Southern Dental and Probiotec.

Price/Sales Analysis

One financial ratio that can be used to analyse companies with sales but no or low profits is that of the price-to-sales ratio.

One rule of thumb is that high growth companies with sales but no profits can trade on multiple of 4 - 5 times sales.

For mature companies with low growth in sales, a sales multiple of 1 times is often considered as a benchmark measure of performance.

In the table above, five companies with sales of greater than \$30 million (Compumedics, Southern Dental, ITL, Probiotec and Ellex Medical Lasers) are trading on price/sales ratios of less than 0.5, indicating that these companies are expected to struggle to grow sales.

Several companies with very high price/sales ratios include Genetic technologies (17.2) and Impedimed (23.2), both of which operate in the field of diagnostics.

Bioshares Model Portfolio (16 September 2011)

Company	Price (current)	Price added to portfolio	Date added
Mayne Pharma Group	\$0.435	\$0.435	September 2011
Genetic Technologies	\$0.20	\$0.18	August 2011
Acrux	\$3.48	\$3.37	June 2011
Psivida	\$4.50	\$3.95	May 2011
Bioniche	\$0.70	\$1.35	March 2011
Somnomed	\$1.16	\$0.94	January 2011
Phylogica	\$0.058	\$0.053	September 2010
Sunshine Heart	\$0.046	\$0.036	June 2010
Biota Holdings	\$0.88	\$1.09	May 2010
Tissue Therapies	\$0.47	\$0.21	January 2010
Atcor Medical	\$0.08	\$0.10	October 2008
Impedimed	\$0.55	\$0.70	August 2008
Bionomics	\$0.46	\$0.42	December 2007
Cogstate	\$0.16	\$0.13	November 2007
Sirtex Medical	\$4.99	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$1.62	\$6.60	September 2007
Pharmaxis	\$0.79	\$3.15	August 2007
Universal Biosensors	\$1.00	\$1.23	June 2007
Alchemia	\$0.37	\$0.67	May 2004

Portfolio Changes – 16 September 2011**IN:**

Mayne Pharma Group has been added in at 43.5 cents. See analysis on page 1.

OUT:

No changes

Interesting Positioning for pSivida

pSivida (PVA: \$4.50) has announced that new trials for the treatment of posterior uveitis will commence. pSivida has already developed a treatment for this condition, called Retisert and now **sold by Bausch & Lomb**. What is interesting about this trial is that it will use the same delivery system and active pharmaceutical ingredient as its product Iluvien that has been partnered with **Alimera Sciences** and is currently under assessment with the FDA.

Iluvien has been filed for approval with the FDA for the treatment of diabetic macular edema. This is a market 30 times bigger than for the treatment of posterior uveitis. The Retisert product has a limited market because it has to be surgically implanted. Iluvien has shown to be effective for three years, being injected into the eye during a doctor's office visit.

The active pharmaceutical in Retisert, Iluvien, and in the planned new product for pSivida for posterior uveitis, is the corticosteroid fluocinalone acetonide.

An investigator-sponsored Phase I/II trial will be conducted with a smaller device using a smaller gauge needle to deliver the implant, which would have product advantages to Iluvien. If that trial is successful, pSivida will move on to a Phase III trial.

Issue for Alimera

The problem for pSivida's partner, Alimera Sciences, is that the data for Iluvien is co-owned by both companies. This means that Psivida can reference the NDA data for Iluvien for its own product in development for posterior uveitis which it owns outright, offering a faster and simpler path to market. pSivida has rights to a 20% profit share arrangement to Iluvien.

The issue for Alimera is that if pSivida introduces its own product that is identical to Iluvien for the treatment of posterior uveitis, there is the potential for some off-label use of the Psivida product, particularly if the Psivida product is sold at a significant discount.

It would appear that Alimera may need to better secure its lead product Iluvien, and this could lead to a re-negotiation of commercial rights to Iluvien, with potentially improved deal terms for pSivida.

Bioshares recommendation: Speculative Buy Class B

Bioshares

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, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec, Allied Healthcare Group

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