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In this edition...
We published our first Clinical Trials Survey in 2003 and have followed through with the survey each year, although no survey was conducted in 2010.
This year's survey of current and planned trials covers 22 companies and 54 trials. Surveys, being surveys, are never complete for a multitude of reasons. However, our clinical trials survey is of benefit to shareholders looking to time their investments in companies as they progress the development of their therapeutic products through key stages of clinical development.
QRxPharma has now completed an additional trial of Mox Duo IR, with the next steps for the company to submit its NDA to the FDA in mid-year and secure a partner for the product.
The Editors
Companies Covered: QRX, 2011 Clinical Trials Survey

	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	-11.1%
Cumulative Gain	**274%**
Av Annual Gain (10 yrs)	**21.2%**

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Bioshares

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Edition 412

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

Clinical Trials Survey 2011

Cancer therapy trials dominate the current and prospective trial activities of ASX listed life science firms according to the survey we have conducted for 2011. Cancer therapies accounted for almost 40% of trials, or 21 out of 54 trials included in the survey.

Infectious diseases and the conditions they cause were the next group of any significance, accounting for five out of 54 trials and CNS conditions accounting for six.

The *Bioshares* 2011 Survey of Clinical Trials Underway or Planned includes data from 22 companies and is biased towards therapeutic product companies. It is not a complete survey, with not every ASX-listed life science company surveyed and also with a number of companies not included due to non-response. Some of the data is supplemented with information taken from the National Institutes of Health's clinical trials database at www.clinicaltrials.gov. The survey excludes large companies such as CSL, Resmed and Cochlear. Investors should note that a number of the trials are planned and their execution is contingent on gaining funding or partners or approvals from regulatory authorities.

The survey collects information on trial status and design and a summarised version of the survey can be found in Appendix A. An expanded version is available to subscribers by request.

Reporting Dates

One of the goals of the survey is to ascertain the reporting dates of selected clinical trials. Such information is helpful to investors looking to time their investments in specific stocks.

The results, including interim results in some cases, of ten trials should available by the end of 2011, with 15 falling due in 2012, 10 in 2013, three in 2014 and 2015 and two in 2016 (see table next page). The reporting (or trial conclusion) dates were not available or disclosed for nine trials.

From Q3 2012 to Q4 2013, 15 Phase I/II and Phase II trials are expected to deliver results, suggesting that the period could be of more heightened interest to investors.

The second half of 2012 is expected to be an intense period with seven Phase II and two Phase III trials reporting.

A spate of Phase III trials are scheduled to report in 2014 and 2015, with five trials expected to be completed. Sirtex Medical will report on its SIRFLOX and SIRVENIB trials, Prima Biomed is planning to report on its CVac CAN-005 trial, Agenix on a planned trial of its Thromboview diagnostic (subject to divestment and other factors) and Bioniche (through its partner Endo Pharmaceuticals) intends to report on its Phase III EN3348-303 trial of Urocidin, an agent for the treatment of bladder cancer.

QRxPharma Completes Final Study of MoxDuo IR

QRxPharma (QRX: $1.60) has completed a 375 patient safety study with its opioid pain medicine combination, MoxDuo IR.

The trial compared what is considered equal analgesic levels of the company's morphine (12mg) and oxycodone (8mg) against twice the level of morphine oxycodone used alone (24mg, which is considered the same analgesic opioid dose as the 12mg/8mg MoxDuo combination), and similarly against 16mg of oxycodone alone, also an equal analgesic opioid dosage.

The primary endpoint was differences in respiratory depression, measured as changes in oxygen levels in the blood to less than 90%. The fatal outcomes from an opioid overdose is in fact a direct result of blood oxygen levels dropping to less than 80%. When these levels drop below 90% is when doctors become concerned for any patient and this was the primary marker in this trial.

Results

Compared against 24mg of oxycodone, ModDuo IR was shown to deliver a statistically significant improved outcome ($p<0.02$). However a disappointing outcome was that statistical significance was not met when compared against the 16mg of morphine arm. There was a beneficial trend towards MoxDuo IR over morphine. QRxPharma CFO, Chris Campbell, said the study was not powered for significance and that achieving a statistically significant outcome against morphine was very close.

The study also showed a statistically significant reduction in severe vomiting when compared against oxycodone, with 32% of patients on MoxDuo experiencing severe vomiting versus 42% in the oxycodone arm. Compared to morphine, the moderate to severe vomiting rates were similar to the MoxDuo arm.

– Cont'd over

Clinical Trials Survey 2011:
Summary of Clinical Trials by Reporting Quarter

	Class III Device	Pilot	Phase I	Phase I/II	Phase II	Phase II/III	Phase III	Total
2010 Q3 (Ongoing)				1				1
2011 Q1 (Interim)						1		1
2011 Q3				1				1
2011 Q3	1		1		1			3
2011 Q3 (Interim)				1	1			2
2011 Q4				1	2		1	4
2012 Q1				2				2
2012 Q1			2					2
2012 Q2			1		1			2
2012 Q3					3			3
2012 Q4				2				2
2012 Q4					2		2	4
2013 Q1				1				1
2013 Q1					1		1	2
2013 Q1 /2014 Q2					1			1
2013 Q2					1			1
2013 Q2				1	1			2
2013 Q3					1			1
2013 Q4				1				1
2013 Q4		1						1
2014 Q1							1	1
2014 Q4					1		1	2
2015 Q1							1	1
2015 Q1*							1	1
2015 Q4							1	1
2016 Q2							2	2
NA			5		1		1	7
ND			1	1				2
Total	1	1	10	12	17	1	12	54

NA - Not Available, ND - Not Disclosed

Summary of Trials by Disease/Condition

Diseases/Conditions	Num.
Alzheimer's Disease	1
Apathy Syndrome	1
Asthma	1
Bacterial Vaginosis	2
Bronchiectasis	1
Cancer	21
Chronic pain	2
Congestive Heart Failure	2
Coronary Artery Disease	1
Degenerative Disc Disease	4
Diabetic Retinopathy	1
Hepatitis	1
HCV infection	1
HIV infection	1
Human rhinovirus infection	1
Huntington's Disease	1
Influenza infection	2
NASH/ Metabolic Syndrome	1
Osteoarthritis	1
Pulmonary Embolism	1
Rheumatoid Arthritis	1
Traumatic Brain Injury (TBI)	3
Type I Diabetes Mellitus	2
Venous Leg Ulcers	1
Total	**54**

Bioshares Model Portfolio (17 June 2011)

Company	Price (current)	Price added to portfolio	Date added
Psivida	$3.90	$3.95	May 2011
Bioniche	$0.96	$1.35	March 2011
Somnomed	$1.30	$0.94	January 2011
Phylogica	$0.071	$0.053	September 2010
Sunshine Heart	$0.056	$0.036	June 2010
Biota Holdings	$1.03	$1.09	May 2010
Tissue Therapies	$0.50	$0.21	January 2010
Atcor Medical	$0.13	$0.10	October 2008
Impedimed	$0.56	$0.70	August 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.56	$0.42	December 2007
Cogstate	$0.19	$0.13	November 2007
Sirtex Medical	$4.95	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.80	$6.60	September 2007
Starpharma Holdings	$1.30	$0.37	August 2007
Pharmaxis	$1.07	$3.15	August 2007
Universal Biosensors	$0.99	$1.23	June 2007
Alchemia	$0.62	$0.67	May 2004

Portfolio Changes – 17 June 2011

IN:
No changes.

OUT:
Hexima has been removed from the portfolio at 31 cents due to its delisting from the ASX.

Filing of NDA Expected Soon

QRxPharma has now completed all of its studies for its NDA (new drug application) to be filed with the FDA. That submission is now underway, taking five to six months to complete from beginning to end. The NDA is expected to be submitted in August, and the company has 120 days after that to submit the additional safety study from this 375 patient study.

It's a long and complicated path to have a new opioid product approved by regulators. The regulatory pathway does not appear to be clear at all times and certainty can not always be assured. QRxPharma has now reached the finish line, in terms of conducting the clinical trials necessary to have its first product approved in the major US market.

Campbell said the company has now built up a lot of information that may be used to assess the labelling claims for its MoxDuo product and the benefits that this opioid combination therapy delivers over use of oxycodone or morphine alone.

MoxDuo IR has also shown benefits against other pain products such as Percocet (paracetamol and oxycodone). Thehe new regulations governing high dose forms of drugs such as Percocet and Vicodin (see *Bioshares* 409) should work to open the door for a new pain therapeutic product such as MoxDuo IR.

More Marketing and Phase IV Studies Ahead

Campbell said the company has done the heavy lifting in terms of clinical studies and the company is not funded to continue with further marketing studies of MoxDuo IR. More marketing studies will likely be conducted in the future, however these will be undertaken by a future partner. Other marketing (Phase IV) studies could include a larger head-to-head study against Percocet. The company believes it has sufficient data to register the product for use.

The focus for the next 12 months for the company is to gain approval for MoxDuo IR and to negotiate a strategic partnership in 2011.

QRxPharma is capitalised at $201 million and held cash of $14.9 million at March 31, 2011.

Bioshares recommendation: **Speculative Hold Class A**

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

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