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In this edition...
Our attention this week and next is on a group of companies which are set to experience pivotal events in 2013. Our goal it gauge the degree of impact a positive or negative outcome will have on a company's share price. QRxPharma's MoxDuo IR will be re-considered by the FDA; Mesoblast has two Phase II trials set deliver interim but vital readouts during the year; Clinuvel's Scenesse is before the European drug agency; Pharmaxis is facing an almost certain rejection by the FDA for Bronchitol for use with CF patients this month, however, a Phase III trial in bronchiectasis patients may yet deliver a positive result. Mayne Pharma is now a better structured and more diversified business following its Metrics acquisition in 2012, however, the stock is now expensive.
Companies Covered: CUV, MSB, MYX, PXS, QRX, Myostin Therapeutics

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	0.0%
Cumulative Gain	**245%**
Av. annual gain (11 yrs)	**17.8%**

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Companies With Pivotal Events Ahead – Part 1

In this week's and next week's editions of *Bioshares*, we will focus on companies with pivotal events approaching, whether they be key registration hurdles or results from clinical studies. We will look at what impact passing those hurdles should have on company share prices, and what are the likely chances of success.

QRxPharma's Second Run at the FDA

QRxPharma's (QRX: $1.00) NDA for its dual opioid combination therapy, MoxDuo IR, was knocked back by the FDA in June last year. This event surprised most investors. This week the company announced it had refiled its drug for approval.

This stock is high risk. A negative result will likely mean the company will need to conduct additional clinical trials. This will mean a lot of stock dilution with funds that would need to be raised at a much lower share price. A negative FDA decision will see the share price savaged once again.

On the flip side, approval from the FDA could see the stock surge by over 60-80%. So what is the likelihood of a positive outcome? The company has been in close dialogue with the regulator. The FDA has requested that an advisory panel review the company's application.

Core Issue – Oxygen Desaturation Levels

The core issue is over oxygen desaturation levels in patients when taking opioid drugs. This is the reason for respiratory depression, which is the cause of fatalities from drug overdose. This week the company released some very useful data. In the company's presentation (Slide 22), a chart shows the probability of having a severe oxygen desaturation event. We suspect this data is what the FDA will pay the most attention to.

The chart shows that MoxDuo clearly outperforms oxycodone at each time interval. Against equal analgesic doses of morphine, the chart shows that MoxDuo starts out better than morphine, then between hours 6-16, morphine exhibits a lower probability of severe oxygen desaturation, and after 16 hours MoxDuo is clearly better than morphine on this measure. This chart may be enough to get QRxPharma across the line.

What is also important is that during that 6-16 hour period, when there is a small advantage for morphine over oxycodone, that patients would generally still be in hospital. The new data also shows that in patients over 60 years of age, MoxDuo is clearly better than equal analgesic doses of morphine or oxycodone on the measure of serious oxygen desaturations (Slide 23). For patients younger than 60, Moxduo was equal with morphine but still much better than oxycodone on the same measure.

MoxDuo also has advantages over equal analgesic doses of morphine or oxycodone in nausea, vomiting, dizziness, headaches and in lowering the level of sedation. To date the

Cont'd over

company has conducted clinical trials involving around 1,600 patients.

QRxPharma has a much stronger chance of approval now it has re-articulated around oxygen desaturation to more effectively address the FDA's concerns.

QRxPharma expects an FDA decision on its re-filed NDA in the third quarter of this year. In the meantime, the company will file marketing applications for the drug in Europe, Australia and Canada.

Possible Launch in Second Half

If QRxPharma receives approval in the US, the company expects to launch its product, through its partner Actavis, in the second half of 2013. QRxPharma will receive a 50% royalty on the first $150 million of sales (delivering QRxPharma $75 million, which roughly equates to the development costs to date for MoxDuo).

In Canada, MoxDuo is licensed to Paladin Labs, whereby QRxPharma will receive double digit royalties from sales and up to US$25 million in milestone payments.

The market for acute pain drugs is valued at $2.5 billion a year. In January this year the FDA Advisory Committee voted in favour of placing stricter controls on Schedule 2 pain drugs such as Vicodin. This will allow QRxPharma to compete on a level playing field with Vicodin for 130 million prescriptions a year. The timing cold be perfect for QRxPharma, if it gets approval from the FDA this year.

QRxPharma is capitalised at $144 million. The company held $16.6 million in cash at the end of last year.

Bioshares recommendation: **Speculative Hold Class A**

Clinuvel Pharmaceuticals – Scenesse's EU EPP Approval Expected 2013 H1

In February 2012, Clinuvel Pharmaceuticals (CUV: $2.46) filed its drug candidate, Scenesse, for approval with European regulators. The application is for the treatment of EPP, which is a condition characterised by a severe intolerance to light.

EPP affects around 4,000 people in Europe and the same number in the US. It has been evaluated in 349 patients, and 172 patients have taken the drug under compassionate use in Italy and Switzerland, where it has been sold under special reimbursement programs.

EPP is an orphan market opportunity, which the company has estimated the commercial opportunity to be between US$50-$100 million a year. Clinuvel is also completing a Phase III trial in the US, with results due in the first half of 2013.

The larger market for Clinuvel is in the treatment of vitiligo, which is a skin discoloration. Scenesse is a depot injection lasting two months, which increases the pigment density in the skin. The company sees the addressable market in vitiligo at over $500 million a year. Positive Phase II results have already been achieved.

Clinuvel is expecting a decision from the European regulator, the EMA, in the first half of 2013. This will be a major milestone for the company. A positive result should see a moderate increase in the company's share price. A negative result can be expected to see a sharp sell off in the stock.

Question of Sufficient Benefit?

The efficacy and safety of the therapy appears to be very good. The company has also worked well to build awareness and support of the technology amongst clinicians and patients. The question with regulators is not whether the drug works, or whether it is safe, but rather whether there is sufficient benefit to patients to warrant approval; patients can stay out of the sun to avoid the severe intolerance to sunlight.

That the drug is already available in Italy and Switzerland through special access programs is a strong positive for the company, as is the support the company has built up from specialists in the field.

The company has to date generated $2.2 million in sales from the product.

Pediatric Use

A issue that regulators will likelyfocus on is the use of the drug with children, where quality of life without an effective treatment is severely compromised. The EMA has previously asked the company to consider conducting trials in children. This issue has the potential to contribute to a positive regulatory outcome for Scenesse.

Clinuvel is considering whether to market the product directly in Europe or to find a marketing partner. Given the concentrated distribution channels for this orphan disease, the company could sell the product in Europe with a very small sales force of less than 10 people.

Clinuvel is moving through a high risk stage of development as it faces a decision from the EMA. We give the company a moderate-to-high chance of regulatory success.

Clinuvel is capitalised at $86 million. It had $10.1 million in cash at the end of last year.

Bioshares recommendation: **Speculative Hold Class A**

Pharmaxis – FDA CF Decision for Bronchitol and Bronchiectasis Phase III Results

Pharmaxis (PXS: $0.51) has two major events approaching. The first is the decision from the FDA on its new drug application for Bronchitol for the treatment of cystic fibrosis.

The FDA is expected to vote on the company's NDA on or around 18 March. Following the negative opinion from the FDA Advisory Panel, it is not expected that the drug will get through, with a negative response factored into the company's share price.

What will be of particular interest is any guidance the company may receive about what will be required to resubmit the applica-

tion if approval is not received. However better detail is generally obtained in the months after the initial FDA response.

We expect Pharmaxis' NDA to be declined by the FDA which should result in a small fall in the company's share price, if any.

Pharmaxis will report data from a second Phase III trial in patients with bronchiectasis in the second quarter of this year. That trial enrolled 485 patients who received Bronchitol therapy for one year. There is a reasonable chance that the trial will deliver some positive signs, although whether it will reach statistical significance on any of the endpoints is a greater unknown.

We would expect that positive data emerging from this trial result is likely to have a moderate impact on the company's share price. The current share price is largely not factoring in any positive outcome. We view the likelihood of some positive data as moderate. A negative overall result can be expected to have a small negative impact on the share price.

Pharmaxis is capitalised at $157 million.

Bioshares recommendation: **Speculative Hold Class B**

Mesoblast – 2 X Phase II Trial Results

The year ahead for Mesoblast (MSB: $6.44) is expected to include the announcement of results from two Phase II trials, one for the use of Mesoblast's mesenchymal precursor stem cells (MPCs) for early stage invertebral disc repair, the other for the treatment of Type II diabetes.

Invertebral Disc Repair for Lower Back Pain (Trial Code DR001)

Mesoblast has completed enrollment in a 100 patient Phase II trial in patients suffering early intervertebral disc degeneration. The trial is randomised and double blinded. Two doses of MPCs are being evaluated.

This study is primarily evaluating safety. However, secondary endpoints include the effect of the MPC therapy (known as Neofuse in orthopedic disease indications) on pain levels and on quality of life. These metrics will be evaluated at 1, 3, 6, 12, 24 and 36 months after injection. The six month mark is the key point in time for which Mesoblast will reveal progress with the trial and effectiveness and safety of the therapy.

Also at six months, Magnetic Resonance Imaging (MRI) will be used to study the change of treated lumbar intervertebral discs.

(Early stage) disc repair is a worthwhile therapeutic indication for Mesoblast to tackle because of a lack of surgical options.

A related Phase II trial of Neofuse in 24 patients requiring lumbar spinal fusion delivered mixed results, with one dose performing better than the standard of care and another dose performing below the standard of care. However, no safety issues emerged from the trial, a fact which indicates a similar outcome is likely for the DR001 trial.

In our view, positive trial results are less likely to stimulate a gain in Mesoblast's share price, with its share price currently factoring in positive results from many of the company's clinical programs.

What remains to be seen is what impact positive data from the trial will have on Mesoblast's partnering plans for Neofuse.

Type II Diabetes Study

The Type II diabetes trial is primarily a safety study. However, the trial will recruit 60 subjects diagnosed with Type II diabetes. These patients will have above normal levels of HbA1c (glycosylated hemoglobin or blood glucose) (> than 7%). They will also have been receiving therapuetics doses of metformin.

Three different doses of MPCs will be evaluated. However, perhaps somewhat controversially for a diabetes treatment, the stem cells will be administered with a single IV injection.

The inherent limitation of the trial is that it is a single arm study and will not yield data that could, as with a properly powered, fully blinded, comparator drug, randomised, Phase III study, definitively illustrate the superiority or inferiority of MPCs.

However, the ubiquity, or wide acceptance of Hb1Ac as a diabetes marker means that the any therapy that can not only lower levels of Hb1Ac but maintain them in a normal range means that comparable effectiveness can be inferred on reasonable grounds.

Mesoblast's earlier single injection pre-clinical study in 17 non-human primates demonstrated a dose response effect over eight, 12 and 26 weeks on mean fasting blood glucose. Mesoblast will initially release safety data relating to 12 weeks of dosing from its Phase II trial. The trial will ultimately produce results covering 116 weeks, and is hence, timed for full completion in 2015.

This Phase II study has the potential to consolidate a new indication frontier for Mesoblast because diabetes and its related disease conditions represents opportunity to treat Type 2 diabetes patients with complicated health problems. The point of difference for MPCs is the chance to offer a single therapeutic dose that can also potentially treat renal complications and cardiovascular problems that relate to Type 2 diabetes. A specific trial focusing on the renal complications of diabetes is being considered.

With significant upside currently factored into the Mesoblast share price, a positive diabetes trial result is unlikely to cause a price gain. Going foward, the release of positive clinical trial data is more likely to contribute to a stabilising of Mesoblast's share price.

Mesoblast is capitalised at $1.85 billion.

Bioshares recommendation: **Take Profits / Reduce Exposure**

Bioshares Model Portfolio (1 March 2013)

Company	Price (current)	Price added to portfolio	Date added
Allied Healthcare	$0.030	$0.026	February 2013
Psivida	$2.00	$1.550	November 2012
Benitec	$0.013	$0.016	November 2012
Nanosonics	$0.500	$0.495	June 2012
Osprey Medical	$0.52	$0.40	April 2012
QRxPharma	$1.00	$1.66	October 2011
Somnomed	$1.06	$0.94	January 2011
Cogstate	$0.360	$0.13	November 2007
Clinuvel Pharmaceuticals	$2.50	$6.60	September 2007
Universal Biosensors	$0.81	$1.23	June 2007

Portfolio Changes – 1 March 2013

IN:
No changes

OUT:
No changes

Mayne Pharma Group First Half Results

Generic drugs manufacturer Mayne Pharma Group (MYX: $0.415) posted a loss for the half year ending December 31, 2012 of $2.5 million. Group sales for the half year were $27 million.

The company's accounts for the period include approximately *six weeks* of financial data that relate to the acquisition of Metrics Inc.

Mayne Pharma acquired the privately-held US generics business Metrics in November 2012, for a total cost of $113 million. A potential future earn-out of $10 million stands in relation to the deal.

NPAT, when adjusted for transaction costs relating to the acquisition of Metrics ($-3.9 million) and the revaluation of certain directors options ($-0.2 million) was $2.9 million. This adjusted profit figure was above guidanance announced at the time of the Metrics acquistion of $2.0-$2.7 million.

Mayne Pharma Group now has four reporting units – Metrics Products, Metrics Services, Mayne Pharma Global and Mayne Pharma Australia.

Although *only six week*s worth Metrics figures were included, it is worth noting that for the six months ending December 31, sales from Metrics Products were US$19.8 million, 50% higher than the previous corresponding period (pcp). Similarly, sales for Metrics Contract Services were US$12.4 million, up 6.8% from the pcp.

Sales from Mayne Pharma Australia of $4.8 million for the half year decreased slightly (-1.3%) from the pcp. (Note, Mayne has now recommenced manufacture of Doryx and expects supply to 'normalise to more closely match the underlying prescription demand.')

Sales from Mayne Pharma Group fell 35.9% to $14.1 million. The steep fall was due to the launch of a generic competitor to Doryx, which is marketed in the US by Warner Chilcott.

Products in Development and in Registration

The enlarged Mayne Pharma Group has a suite of products in development or planned for lodgement in Australia and elsewhere.

Mayne intends to lodge eleven submissions with the TGA this year, covering eleven injectable drugs which relate to current annual market sales of approximately $70 million.

Folowing the Metrics acquisition, Mayne now has 17 products under development. Four of those products have been filed wth the FDA. The company expects to file five ANDAs with the FDA this year and expects three drugs to be approved and launched during CY2013.

SUBACAP Update

Mayne's antifungal drug SUBACAP (itraconazole) received marketing authorisation in the UK in January, with authorisations expected to follow later this year in Germany, Spain and Sweden. It will separately use the 'repeat use procedure' to access marketing approval in Italy. Sales of itraconazole in these five countries are currently running at $90 million a year.

Mayne is seeking a European marketing partner for SUBACAP, preferably a company with a track record in the antifungals segment.

Following discussions with the FDA, Mayne Pharma will now be required to complete two (replicate) pharmacokinetic trials of SUBACAP, each enrolling between a 36 and 72 subjects.

Summary

We estimate Mayne is currently trading on a prospective full year PE ratio of 26, using an adjusted NPAT forecast and annualised half year sales figures and static profit margins. It does not take into account the company's acquisition of the Australian rights of Kapanol from GlaxoSmithKline, a drug the Mayne believes has potential if marketed with increased effort.

Two revenue questions ahead for Mayne investors include the rate of sales growth in the Metrics Product business, with Mayne Pharma CEO Scott Richards warning investors to not expect the recent half year period's rate of growth to be sustained. Second, with Doryx manufacture recommencing, following a pause, the question is how durable demand will be for that product, based on Warner Chilcott's retention of market share.

Mayne Pharma is capitalised at $233 million.

Bioshares recommendation: **Sell**

Private Company Profile – Myostin Therapeutics

Biotech entrepreneur Kevin Healey is back with his latest venture, private company Myostin Therapeutics. Myostin is developing a treatment for muscular dystrophy, a genetic disorder for which there is no current therapy.

Healey's reputation for launching promising early stage ventures was confirmed recently when Gilead Sciences purchased YM Biosciences for US$510 million. The main asset YM had was CYT387 for the treatment of myelofibrosis. CYT387 was pioneered by Healey and scientist Andrew Wilks in Melbourne-based company Cytopia, which YM picked up at a bargain basement price of $14 million during the GFC. However, this occurred after Healey had resigned as CEO but continued as a director of Cytopia. It is a moot point that Cytopia could have been sold for a higher figure.

Muscular Dystrophy

Muscular dystrophy (MD) affects about one in 3,500 males (boys). There are about 40,000 boys in the US and Europe afflicted with this genetic disorder. There are about nine different types of MD.

The most common form, Duchenne Muscular Dystrophy (DMD), is caused by one or more mutations in the gene that produces the protein dystrophin, which is a critical protein involved in muscle development. MD is disease in which progressive loss of muscle function and weakness occurs.

Myostin's Approach

Myostin is developing peptides as drug candidates which are antagonists to a protein called myostatin. Myostatin's role is to act as a natural limit to muscle growth.

The idea of controlling myostatin in MD is based on the observation that genetic mutations have been observed in humans, cattle, mice and dogs which cause a lack of functional myostatin. These mutations result in excessive muscle growth. However, Myostin's approach is to use a peptide to inhibit myostatin, thereby accelerating muscle growth in muscular dystrophy sufferers whose muscles are in a state of waste.

Technology History

The Myostin technology originated at AgResearch in New Zealand in 2002, where researchers were seeking to improve muscle growth in farm animals. That group discovered a number of peptides that inhibit myostatin. For five years AgResearch's spinout company worked on developing a therapeutic for DMD.

In 2010, Myostin acquired the intellectual property from AgRresearch and its related entities. To date an estimated $20 million has been invested in this research for human and animal applications in NZ.

Deal with DART Pharmaceuticals

Pending final due diligence, DART Pharmaceuticals in the US plans to write a licensing option with Myostin. DART will fund the final stages of lead optimisation and will have the option to license global rights at the end of the lead optimisation stage.

DART was formed in 2010 to develop therapies for DMD. One of the company's founders is Gene Williams, who was previously Senior Vice President of Genzyme, which focused on developing therapies for orphan diseases. DMD is an orphan disease.

Pre-Cinical Results

Pre-clinical tests have been conducted in a well accepted mouse model for this disease. In discussion with *Bioshares*, Healey said the results were outstanding. The results clearly showed larger and stronger muscle fibres over the control, and increased muscle strength.

Other Applications

Myostin's broader plan is to become a world leader in developing therapies for muscle wasting disorders. The deal with DART will only be for DMD. Myostin will be free to develop therapies against other muscle wasting disorders, including sarcopenia in the elderly and cachexia in patients with cancer.

Other Approaches to treating DMD

Myostin is not seeking to treat the underlying disease by correcting the genetic flaws responsible for this disease. Rather it is seeking to treat the symptoms associated, specifically the muscle wasting, which sees boys die in the late teens and early 20's, with onset starting between the ages of two and six.

Other approaches seek to correct the genetic flaw so that the correct dystrophin protein can be produced. This is called exon skipping, where the aim is to skip over the damaged gene. Companies following this or a similar approach to correct the underlying genetic fault include AVI/Biopharma/Sarepta, PTC Therapeutics and GlaxoSmithKline/Prosensa.

AVI Biopharma/Sarepta reported some positive Phase II clinical results in October last year and is conducting a 180 patient Phase III study. It is meeting with the FDA to discuss accelerated approval of its DMD drug candidate. This is the clear leader in the field at the moment.

PTC Therapeutics is seeking conditional approval in Europe, even though its Phase II studies did not demonstrate strong efficacy. It will also be conducting a confirmatory Phase III trial.

GlaxoSmithKline ran into problems this week with its antisense approach. Patients were hospitalised due to kidney toxicity associated with its drug in the company's Phase II and Phase III ongoing studies. The issue with GSK's drug is that it has a narrow therapeutic index, whereas Sarepta's drug has a wide therapeutic window.

It is expected that exon skipping will potentially treat around 40% of people with DMD. The difficulty is where there are multiple genetic mutations. Drugs to treat the muscle wasting may still need to be taken with these exon skipping approaches.

Breakthrough Therapies – FDA Pathway

A development going in Myostin's favour is a move by the FDA to bring therapeutics to market sooner for serious or life threaten-

Cont'd over

ing diseases under a new Breakthrough Therapy classification. This could see drugs approved where there is only 'preliminary clinical evidence' according to FDA Director Janet Woodcock. The new law, passed only last year, is called the "Food and Drug Administration Safety and Innovation Act".

Patents

Myostin has patents already granted in the US around its myostatin antagonists and myostatin isoforms. The company has received patent advice that it has freedom to operate in the myostatin area.

Executive Expertise

One of Healey's areas or expertise is peptide chemistry. He was a founder and non-executive director of Xenome, which was developing pain therapeutics from peptides derived from marine cone snails. Myostin has also employed a program director, Dr Patricio Sepulveda, who has expertise in muscle biology and cell signalling.

Pharma Interest

Healey understands most of the large pharmaceutical companies have muscle regeneration programs. He is already receiving interest from some of the major companies he has dealth with previously and believes once toxicology studies are complete, that pharmaceutical companies will want engage in deeper discussions.

Timing and Investment Return

Myostin's aim is to get its DMD program ready to move into the clinic in 2014. It is expected that DART will fund all development costs, with Myostin seeking funding now for operational costs and to examine other therapeutic indications. The company believes that potentially a very large return can be achieved once final toxicology results are completed and a Phase I study is done.

By way of examples in other deals in this field, in 2010 Shire Pharmaceuticals paid Acceleron Pharma a US$45 million up front payment in a deal worth up to US$498 million. That program had only completed Phase I studies. Acceleron is using an antibody approach to inhibit the myostatin receptor.

Myostin could be two years away from doing such a deal with its expected partner DART or jointly with a pharmaceutical company.

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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