

# QRxPharma Limited

High quality drug development opportunity... potential  
~10x upside with better-than-average odds of success

- QRxPharma Limited is a specialty pharmaceutical company developing new drugs to treat moderate-to-severe pain.
- The company has patented the discovery that, in certain ratios, the combination of the opioid drugs morphine and oxycodone has an unexpected synergistic impact on pain relief. Phase II clinical trials showed the dual action of these drugs was able to deliver the same pain relief as morphine, but with approximately half the amount of opioid. This is expected to lead to reduced side-effects.
- The FDA has approved the company's most advanced clinical product, Q8003IR, to enter Phase III trials. The primary end point required for approval is pain relief relative to placebo. Given that Q8003IR is a combination of the existing pain-relief drugs morphine and oxycodone, we believe there is a high probability the primary end point will be met. A sustained-release version of this product, Q8011CR, is ready to enter Phase I clinical trials.
- If these two products are approved, and they show reduced side-effects, we expect the sales opportunity would be in the order of US\$300-500m p/a. Based on both a risk-adjusted DCF valuation, and comparables valuation, we believe the stock should trade at ~\$3.00 per share. As this is some ~75% higher than the current share price, we rate the stock an Overweight. We believe the wide discrepancy between our view and the share price is simply due to the stock being new to the market and its prospects unappreciated.

Initiation  
Overweight

**A\$1.70**

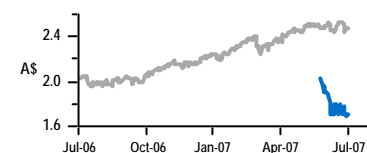
03 July 2007  
Price Target: A\$3.00

Healthcare

**Alexander Smith**<sup>AC</sup>  
(61-2) 9220 3201  
alexander.smith@jpmorgan.com

**Kylie Reynolds**  
(612) 9220 3194  
kylie.reynolds@jpmorgan.com

Price Performance



	YTD	-1M	-3M	-12M
Absolute	-16.3%	-10.5%	-16.3%	-16.3%
Relative	-26.3%	-9.4%	-21.7%	-38.2%

Source: RIMES, Reuters.

## QRxPharma Limited (Reuters: QRX.AX, Bloomberg: QRX AU)

Year-end Jun (A\$)	FY06A	FY07E	FY08E	FY09E
Total Revenue (A\$ mn)				
EBITDA (A\$ mn)		-5.0	-25.9	-26.9
Net profit after tax (A\$ mn)		-3.3	-16.9	-17.6
EPS (A\$)		-0.043	-0.225	-0.234
P/E (x)		NM	NM	NM
EV/EBITDA		NM	NM	NM
Dividend (A\$)		0.000	0.000	0.000
Net Yield (%)		0.0%	0.0%	0.0%
Normalised* EPS (A\$)		-0.040	-0.210	-0.218
EPS growth (%)				
Normalised* P/E (x)		NM	NM	NM
Relative P/E (%)				

Company Data	
52-week range (A\$)	2.10 - 1.69
Market capitalisation (A\$ bn)	0.09
Market capitalisation (\$ bn)	0.08
Fiscal Year End	Jun
Price (A\$)	1.70
Date Of Price	03 Jul 07
Avg daily t/over (12m) (A\$ mn)	
Shares outstanding (mn)	55.9
ASX100	5,070.4
ASX200-Ind	9,405.5
NTA/Sh <sup>^</sup> (A\$)	
Net Debt <sup>^</sup> (A\$ bn)	-0.05

Source: Company data, Reuters, JPMorgan estimates. ^ Next forecast FY. \* Normalisation excludes goodwill, P&L on FX movements, asset disposal and some non-operational items.

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## Executive Summary

QRxPharma Limited is a specialty pharmaceutical company developing new drugs to treat moderate-to-severe pain. The size of this market in the US for non-injectables is currently ~US\$5 billion p/a and it has been growing at ~8% p/a.

The drugs of choice in the moderate-to-severe pain market continue to be the opioids, e.g., morphine, hydromorphone, oxycodone, and fentanyl. Almost no therapeutically novel drugs have been developed in this area in the past 20 years, although some improvements have been made in the way these drugs are delivered, e.g. extended release tablets, transdermal patches. There continues to be a need for safer, more efficacious, drug therapies in this market.

QRxPharma has discovered that, in certain ratios, the combination of morphine and oxycodone has an unexpected synergistic impact on pain relief, and it has patented this invention. This forms the basis of its developmental drug products, Q8003IR (immediate release) and Q8011CR (controlled release).

In Phase II trials, the product demonstrated that it could achieve the same level of pain relief as morphine with approximately half the amount of opioid. It is anticipated that using a lower amount of opioid will result in a reduction in the side-effects common with opioid drugs such as respiratory depression, constipation, nausea, and vomiting. We believe that an opioid-based drug with a reduced side-effect profile would represent a significant advance in the moderate-to-severe pain market.

QRxPharma's most advanced compound, Q8003IR, has FDA approval to commence the first of two Phase III clinical trials required for marketing approval in the US. This trial requires enrolment of 660 patients and the primary endpoint is pain relief relative to placebo. We believe the clinical risk is therefore low because the drug contains opioids already known to deliver pain relief. The second Phase III trial design is currently being agreed with the FDA and enrolment is expected to begin in 2008. QRxPharma's other product, Q8011CR, is due to enter Phase I studies this year.

If successful in clinical trials, QRxPharma intends to establish its own sales force in the US market (and out-license in other markets). This is feasible because the US prescriber base is relatively concentrated and a small sales force can cover most of the high-volume prescribers. For example, ~1500 physicians write ~30% of the opioid prescriptions in the US market, and QRxPharma estimates that ~70 sales representatives could cover 2/3 of these physicians.

We believe this is a sensible strategy as it enables QRxPharma to control its own destiny (versus relying on a sales and marketing partner), and capture the full economic benefit (we believe gross margins in the order of 90% are possible). Furthermore, it does not preclude QRxPharma out-licensing, or selling, to an existing player if the terms are suitable and appropriate value can be realised early.

Based on other drugs in the market, we believe that if Q8003IR and Q8011CR are successful in clinical trials, and they exhibit a significantly improved side-effect profile, they could achieve sales of ~US\$300-500m p/a.

QRxPharma has a very high quality Board and management team with considerable relevant experience in pharmaceutical drug development and high-growth healthcare companies. The Chairman is Peter Farrell, founder of ResMed Inc, and the Managing Director and CEO is John Holaday, co-founder of EntreMed Inc and Medicis Pharmaceutical Corporation. The company has established a Scientific Advisory Board of internationally recognised leaders in pain therapy, including Solomon Snyder who discovered the opiate receptor.

The company is managing its regulatory risk by engaging as a consultant Cynthia McCormick, former medical reviewer in the Division of Neuropharmacological Drug Products at the US FDA. The company is also managing its sales force establishment risk by engaging as a consultant David Stack, former CEO and Director of The Medicines Company and CEO and founding partner of Stack Pharmaceuticals Inc, who has extensive experience building sales teams, including several targeting the pain relief market.

The company raised A\$50m at IPO in May 2007 and this should be sufficient to fund it through to FDA approval for Q8003IR. We expect the company will need to raise a further ~A\$50m if FDA approval is achieved to fund working capital associated with building a sales force.

We believe that if Q8003IR and Q8011CR are approved in clinical trials, and sales of US\$300-500m p/a are achieved as envisaged, the NPV of the free cash flows produced is ~A\$17.60 per share, or ~10x upside to the current share price. Although this NPV is large and represents ~US\$1.1 billion, it is supported by the US\$400-500m valuations for single opioid drugs implied by recent corporate transactions. Clearly, there could be significant upside if the company is successful.

We believe that the risks associated with the drug development program are relatively low and this is one of the key attractions of QRxPharma. FDA approval for Q8003IR only requires Phase III trials to demonstrate pain relief relative to placebo. Given that the drug components in Q8003IR (i.e. morphine and oxycodone) are already approved for pain-relief, it seems likely Q8003IR will clear this clinical hurdle. It remains to be seen what protocols are required for Q8011CR, but it would seem likely the FDA will apply a similar test as for Q8003IR.

If we adopted ~85% as the probability of Q8003IR reaching market (the average for a new active substance at the start of Phase III trials is ~65%), and ~20% for Q8011CR (this is conservative as it is only in-line with the average for a new active substance at the start of Phase I trials), we derive a risk-weighted valuation of ~A\$3.00 per share.

Interestingly, this is in-line with the A\$3.00-3.50 per share we would derive based on comparable companies, specifically US-listed Pain Therapeutics which has two opioid drugs in Phase III clinical trials and ASX-listed Avexa Limited which is not in the pain-relief area but has very similar characteristics to QRxPharma (i.e. recently raised funds for Phase III trials, better-than-average chances of clinical trials success in Phase III, similar market size and structure).

Accordingly, we believe that QRxPharma should trade at ~A\$3.00 per share. As this is some ~75% higher than the current share price, we rate the stock an Overweight. We believe the wide discrepancy between our view and the current share price is

simply that the stock is new to the market and its prospects unappreciated. Over time, we expect the market will adopt a view more in-line with our assessment of value.

We also highlight that the existing players in the pain therapeutics market are active acquirers (see, for example, pages 24-25), and it is entirely possible they will seek to license QRxPharma's products, or alternatively acquire the company. This in our view could provide some 'insurance' for investors if the market continues to price the stock well below its risk-adjusted value, i.e. we expect the existing players will seek to take advantage of this 'arbitrage'. We find the corporate activity in the pain-relief market another key attraction of the stock.

## Introduction

QRxPharma is a specialty pharmaceutical company engaged in developing and commercialising therapeutic treatments for disorders of the central nervous system, principally acute and chronic severe pain. The company's most advanced product, Q8003IR, has FDA approval to begin Phase III clinical trials in moderate-to-severe pain. An extended release version, Q8011CR, is expected to commence Phase I clinical trials this year.

The products originate from the work of Professor Maree Smith at the University of Queensland, Australia. The product rights were originally acquired by Sigma Pharmaceuticals Limited, which later sold the product rights to a private equity consortium led by Innovation Capital, Nanyang Ventures, SpringRidge Ventures, and UniSeed. The company listed on the ASX, raising A\$50m, on 25 May 2007. The company is headquartered in Sydney, Australia, but also has offices in the USA.

## Pain Therapeutics Market

### Definition

The pain management market is segmented according to the severity of the pain being treated.

- Mild pain (e.g. headache) is generally treated with over-the-counter drugs, such as aspirin.
- Moderate pain (e.g. arthritis) is often treated with weak opioids such as codeine or hydrocodone that require a prescription, generally from a general practitioner.
- Severe pain (e.g. cancer pain, chronic back pain) is treated with strong opioids such as morphine, oxycodone or fentanyl, which also require a prescription, often provided by a specialist.

Q8003IR and Q8011CR are targeting the moderate-to-severe pain segment.

### Market Size

The moderate-to-severe pain market is divided into two segments based on the delivery profile: immediate release, and controlled release.

In 2006 US sales for immediate release opioids, excluding injectables<sup>1</sup>, indicated for moderate-to-severe pain relief were US\$1.7 billion – see Table 1.

The drugs in this segment fall into 5 main categories:

- Oxycodone plus acetaminophen (US\$769m),
- Fentanyl (US\$651m),
- Oxycodone (US\$137m),
- Hydromorphone (US\$104m), and
- Oxycodone plus aspirin (US\$24m).

It is clear that there have been few therapeutic innovations in this market segment in the past 20 years. Much of the market is genericised and the main improvements have come from improved delivery technologies.

Q8003IR will compete directly against Percocet, Roxicodone, and Percodan.

In 2006 US sales for continuous release opioids, excluding injectables, indicated for moderate-to-severe pain relief were US\$3.3 billion – see Table 2.

The drugs in this segment fall into 3 main categories:

- Oxycodone (US\$1,412m),
- Fentanyl (US\$1,235m),
- Morphine (US\$601m),

As with the immediate release market, there have been few therapeutic innovations in this market segment in the past 20 years. Much of the market is genericised and the main improvements have come from improved delivery technologies.

OxyContin was the last major innovation in this market which launched in December 1995 (it was the first to provide 12 hour acting oxycodone in tablet form). The drug earned ~US\$1.5 billion in 2002, prior to the entry of generics. Purdue Pharma successfully sued the various companies selling unauthorised generic versions of OxyContin, and we understand these generic products will be removed from the market this year. This will make OxyContin an essentially brand-only market in the controlled release segment.

Q8011CR will compete directly against OxyContin, MS-Contin, Kadian, and Avinza. We believe that OxyContin highlights the sales potential for new innovative drugs in the controlled release pain segment.

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<sup>1</sup> we exclude these as they are not readily substitutable with tablet formulation – Q8003IR is a tablet

### Market Growth

The total opioid analgesics market (i.e. injectables, orals, and transdermal patches) in the US has shown an ~8% CAGR since 2002. Growth has slowed in recent years due to the increased use of generics in this market, for example, the 5 year CAGR in the US from 2001-2005 was ~12.6%. The global 5 year CAGR for all opioids, in all forms between 2001 and 2005 was ~13.8%.

Future growth is expected to be driven by an increasing incidence of chronic pain (e.g. cancer, arthritis), the introduction of new and reformulated branded products, the increased physician recognition for the need of effective pain treatment, and the ageing population.

### The Need For New Treatments

While opioids continue to remain the gold standard in pain relief, they have well recognised shortcomings:

- significant adverse side effects – e.g. respiratory depression, nausea, vomiting, dizziness, sedation, constipation;
- tolerance – chronic sufferers often develop a tolerance to opioids and require a stronger dose to achieve effective pain relief, concomitantly increasing the level of side effects;
- dependency – concerns about addiction may influence clinicians to prescribe less than adequate doses; and
- potential for abuse – recreational use

Most new products in the pain area have attempted to increase convenience rather than improving clinical benefits. For example, 12 hour tablet delivery of oxycodone is more convenient, but it does not enhance pain relief or reduce adverse side effects.

We believe that any new products that offer improved pain relief, and/or pain relief through a novel mechanism, and/or reduced side-effects, are likely to be well received in this field. For example, Phase III clinical trials are currently underway to develop products that offer some benefits in terms of side-effects:

- Pain Therapeutics and King Pharmaceuticals are developing Remoxy – an abuse-resistant version of long-acting oxycodone (a “sticky gel cap” which makes extraction of oxycodone into alcohol difficult, as well as grinding into a powder)
- Pain Therapeutics is developing Oxytrex – oxycodone and ultra low dose naltrexone which is anticipated to minimise the physical dependency side-effect
- Grünenthal GmbH and Johnson & Johnson are co-developing CG5503 (tapentadol) – a novel centrally acting analgesic expected to show improvement in gastro-intestinal tolerability (i.e. less incidence of nausea and vomiting).

QRxPharma’s products Q8003IR and Q8011CR are based on a therapeutic novel mechanism for achieving pain relief and offer the potential for an improved side-effect profile. The Q8011CR product will also incorporate anti-abuse technology. Therefore, we believe that if these products are successful in clinical trials, they will represent significant innovations in this marketplace.

Table 1: Immediate Release Oral and Transdermal Products Used in the US to Treat Moderate to Severe Pain (excluding injections)

Company	Brand (approval date)	Active Ingredient	Clinical Indication	Form	2006 US Sales (US\$m)
Endo Pharmaceuticals	Percocet (1976)	oxycodone hydrochloride & acetaminophen	Moderate to moderately severe pain	Tablets 2.5/325, 5/325, 7.5/325, 7.5/500, 10/325, 10/650mg	251.3
Endo Pharmaceuticals	Generic Percocet - Endocet (Dec-99)	oxycodone hydrochloride & acetaminophen	Moderate to moderately severe pain	Tablets 5/325, 7.5/325, 7.5/500, 10/325, 10/650mg	107.1
Watson Labs, Barr, Actavis, Tyco, Vintage, Roxane, Endo, Ortho McNeil, Mutual Pharma, Mikart	Generic Percocet (prior to Jan-82)	oxycodone hydrochloride & acetaminophen	Moderate to moderately severe pain	Tablets and Capsules 2.5/300, 2.5/400, 5/300, 5/325, 5/400, 5/500, 7.5/300, 7.5/325, 7.5/400, 7.5/500, 10/300, 10/325, 10/400, 10/500, 10/650mg	410.2
<b>oxycodone hydrochloride &amp; acetaminophen total</b>					<b>768.6</b>
Cephalon	Fentora (Sep-06)	fentanyl buccal	Management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain	Tablets 100, 200, 400, 600, 800mcg	25.4
Cephalon	Actiq (Nov-98)	fentanyl citrate	Management of breakthrough cancer pain in patients 16 and older with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain	Oral lozenge (lollipop) 200, 400, 600, 800, 1200, 1600mcg	625.5
<b>fentanyl combinations total</b>					<b>650.9</b>
Xanodyne Pharmaceuticals	Roxicodone (Aug-00)	oxycodone hydrochloride	Moderate to severe pain where the use of an opioid analgesic is appropriate.	Tablets 15, 30mg	13.6
Tyco, Actavis, KV Pharma, Vintage	Generic Roxicodone (Feb-04)	oxycodone hydrochloride	Moderate to severe pain where the use of an opioid analgesic is appropriate.	Tablets, 10, 15, 20, 30mg	123.2
<b>oxycodone hydrochloride total</b>					<b>136.8</b>
Abbott Laboratories	Dilaudid (Dec-92)	hydromorphone hydrochloride	Moderate to severe pain when an opioid analgesic is appropriate	Oral solution. Tablets 2, 4, 8mg. Suppositories 3mg.	22.9
Tyco, KV Pharma, Actavis, Roxane	Generic Dilaudid (Dec-04)	hydromorphone hydrochloride	Moderate to severe pain when an opioid analgesic is appropriate	Tablets 2, 4, 8mg	80.3
Roxane	Generic Dilaudid (Jul-98)	hydromorphone hydrochloride	Moderate to severe pain when an opioid analgesic is appropriate	Solution 5mg/5ml	0.4
<b>hydromorphone hydrochloride total</b>					<b>103.6</b>
Endo Pharmaceuticals	Percodan (1950)	oxycodone hydrochloride & aspirin	Moderate to moderately severe pain	Tablets 4.5mg	7.6
Endo, Mutual Pharm, Watson Labs	Generic Percodan (May-82)	oxycodone hydrochloride and aspirin	Moderate to moderately severe pain	Tablets 4.5mg	16.2
<b>oxycodone hydrochloride and aspirin total</b>					<b>23.8</b>
Endo Pharmaceuticals	Opana (Jun-06)	oxymorphone HCl	Moderate to severe acute pain where the use of an opioid is appropriate	Tablets 5, 10mg	3.4
<b>TOTAL</b>					<b>1,687.1</b>

Source: FDA Orange Book and Product Labels, IMS sales data for CY06. Note IMS sales data does not include sales through Wal-Mart stores, and may undervalue the level of generic sales.

Table 2: Controlled Release Oral and Transdermal Products Used in the US to Treat Moderate to Severe Pain (excluding injections)

Company	Brand (approval date)	Active Ingredient	Clinical Indication	Form	2006 US Sales (US\$m)
Purdue Pharma	OxyContin (Dec-95)	oxycodone hydrochloride	Moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time	Extended Release Tablets 10, 15, 20, 30, 40, 60, 80mg	763.8
Watson	Authorised Generic OxyContin (Oct-04)	oxycodone hydrochloride	Moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time	Controlled Release Tablets 10, 20, 40, 80mg	246.8
Teva, Endo	Generic OxyContin (Mar-04)	oxycodone hydrochloride	Moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time	Extended Release Tablets 10, 20, 40, 80mg	401.0
<b>oxycodone hydrochloride</b>					<b>1,411.6</b>
Johnson & Johnson	Duragesic (Aug-90)	fentanyl	Persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids	Transdermal patch 1.25, 2.5, 5, 7.5, 10mg	404.2
Mylan, Lavipharm Labs	Generic Duragesic (Jan-05)	fentanyl	Persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time, and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids	Transdermal patch 1.25, 2.5, 5, 7.5, 10mg	831.0
<b>fentanyl</b>					<b>1,235.2</b>
Xanodyne Pharma	Oramorph (Aug-91)	morphine sulfate	Relief of pain in patients who require opioid analgesics for more than a few days	Sustained Release Tablets 15, 30, 60, 100mg	6.5
King Pharma	Avinza (Mar-02)	morphine sulfate	Moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time	Extended Release Capsules 30, 60, 90, 120mg	174.2
Alpharma	Kadian (Jul-96)	morphine sulfate	Moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time	Extended Release Capsules 20, 30, 50, 60, 80, 100mg	190.2
Purdue Pharma	MS-Contin (May-87)	morphine sulfate	Moderate to severe pain when several days of continuous treatment is needed with a potent opioid analgesic	Controlled Release Tablets 15, 30, 60, 100, 200mg	25.0
Endo, KV Pharma, Tyco, Watson, AB Generics	Generic MS-Contin (Jul-98)	morphine sulfate	Moderate to severe pain when repeated dosing is needed with a potent opioid analgesic over a period of more than a few days	Extended Release Tablets 15, 30, 60, 100, 200mg	204.5
<b>morphine sulfate</b>					<b>600.5</b>
Endo Pharma	Opana ER (Jun-06)	oxymorphone HCl	Moderate to severe pain in patients requiring continuous, around-the-clock opioid therapy for an extended period of time	Extended Release Tablets 5, 10, 20, 40mg	12.0
<b>TOTAL</b>					<b>3,259.3</b>

Source: FDA Orange Book and Product Labels, IMS Sales data for CY06. Note IMS sales data does not include sales through Wal-Mart stores, and may undervalue the level of generic sales.

## QRxPharma Products

### Rationale

QRxPharma has discovered that, in certain ratios, the combination of morphine and oxycodone, has an unexpected synergistic impact on pain relief, and it has patented this invention. This forms the basis of its developmental drug products, Q8003IR (immediate release) and Q8011CR (controlled release).

In Phase II trials, the product demonstrated that it could achieve the same level of pain relief as morphine with approximately half the amount of opioid. It is anticipated that using a lower amount of opioid will result in a reduction in the side-effects common with opioid drugs such as respiratory depression, constipation, nausea, and vomiting.

### Q8003IR

Q8003IR is an immediate release, or short acting, tablet form of QRxPharma's proprietary combination of two opioids, morphine and oxycodone. The product is positioned in the moderate-to-severe pain market. Q8003IR will directly compete with other tablet forms of opioids, in particular Percocet, Roxicodone, Opana, Percodan, and their generic equivalents. Combined, these drugs had 2006 sales in the US of US\$932.7m.

We expect that the opportunity for Q8003IR, if it is successful in clinical trials, is in the order of US\$100-200m p/a in the US (we understand that QRxPharma will first launch in the US, and at a later time in Europe). This compares to Percocet which had US sales of US\$251.3m in CY06, even with generic competition.

If Q8003IR can indeed provide patients with significantly fewer side effects, then QRxPharma's share of the market could be higher.

### Q8011CR

Q8011CR is a controlled release, or long acting, version of the dual opioid product which is also in tablet form. It too therefore has the target of reducing the level of side-effects by using a reduced amount of opioids, yet still providing the same amount of pain relief, but over a longer time period than Q8003IR.

Q8011CR is at an earlier development stage than Q8003IR, with Phase I studies to begin in CY07. QRxPharma believe that if the NDA for Q8003IR is approved, a truncated NDA for Q8011CR could be filed 12 -18 months after this time.

Q8011CR will directly compete with other tablet forms of opioids (not readily substitutable with injectable forms), in particular OxyContin, which had US sales of ~US\$600m in the first year after its 1996 launch, and over ~US\$1.5b of sales in 2001.

While OxyContin is indicated as providing 12 hours of pain relief, it appears to be recognised amongst physicians that the drug gives only 8-10 hours of pain relief, necessitating additional opioids for breakthrough pain.

Furthermore, OxyContin is prone to abuse as it readily dissolves in alcohol and the full benefits of analgesia for the extended period can be absorbed immediately if it is crushed and snorted or injected. We note that false claims made by Purdue sales

representatives prior to 2001 about the difficulty of extracting oxycodone from the OxyContin tablet (amongst other things) led to a lengthy investigation by the FDA and subsequent criminal charges and civil liabilities worth more than US\$600m in a settlement on 10-May-07.

Q8011CR is believed to overcome these issues by providing 12 hour pain control with the pulsatile technology that delivers a drug release every 4 hours, and is abuse resistant (not dissolvable in alcohol, and a lower dose of opioids means it is less attractive to abusers) in addition to the expected reduction in the level of side effects whilst providing the same amount of analgesia.

As the market for controlled release non-injectable opioids is almost twice the size of the immediate release market, the opportunity for Q8011CR is twice that of Q8003IR. Hence, we expect that the opportunity for Q8011CR, if it is successful in clinical trials, is in the order of US\$200-300m p/a in the US (we understand that QRxPharma will firstly launch in the US, and a later time Europe). This compares to Avinza and Kadian which had sales of ~US\$180-190m in 2006, respectively, and OxyContin which had sales of ~US\$763m in 2006 and sales of ~US\$1.5b in 2002 prior to entry of generics.

#### **Existing Clinical Data**

Whilst oxycodone and morphine are structurally related, strong opioids, Professor Maree Smith of the University of Queensland discovered that both opioids do not act through the  $\mu$ -receptor, as was previously thought.<sup>2</sup>

Whilst morphine acts through the  $\mu$ -receptor to provide analgesia, oxycodone acts substantially through a subset of receptors pharmacologically distinct from the  $\mu$ -receptor, as a  $\kappa$ -opioid agonist, and it appears that oxycodone is the only known opioid that binds through this receptor.

Further research showed that sub-analgesic doses of oxycodone synergistically interacted with sub-analgesic doses of various  $\mu$ -receptor agonists to produce an analgesic result with fewer side effects in both animal<sup>2</sup> and human studies, for instance respiratory depression<sup>3</sup>, nausea and vomiting<sup>4</sup>.

QRxPharma has completed 6 clinical studies to date. A summary of the 6 clinical studies is provided below in Table 3. Note, that whilst injectable, capsule, and liquid delivery methods were used in these initial clinical studies, Q8003IR will be compounded into a tablet formulation for all further studies.

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<sup>2</sup> Ross FB, Wallis SC, Smith MT. Co-administration of sub-antinociceptive doses of oxycodone and morphine produces marked antinociceptive synergy with reduced CNS side-effects in rats. *Pain* 2000;84:421-428.

<sup>3</sup> Ladd LA, Kam PC, Williams DB, Wright AWE, Smith MT, Mather LE. Ventilatory responses of healthy subjects to intravenous combinations of morphine and oxycodone under imposed hypercapnic and hypoxemic conditions. *Br. J. Clin. Pharmacol* 2005;59:524-535.

<sup>4</sup> Lauretti GR, Oliveira GM, Pereire NL. Comparison of sustained release morphine with sustained release oxycodone in advanced cancer patients. *Br. J. Cancer* 2003;89:2027-2030.

Table 3: Summary of QRxPharma's Completed Clinical Studies of Morphine and Oxycodone

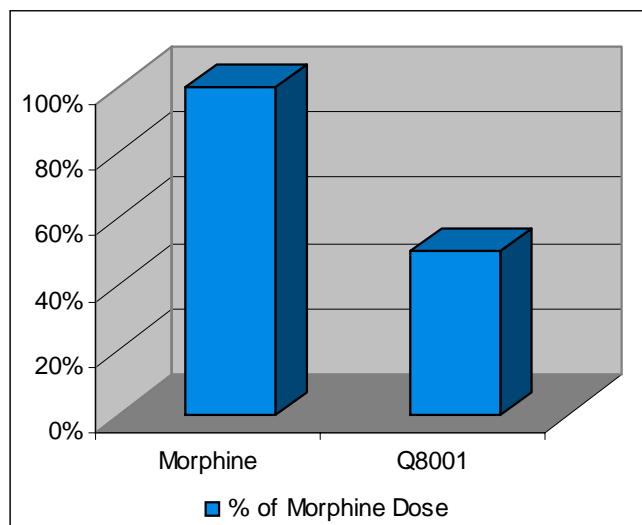
Study	Study Overview and Outcome
Preliminary	Pilot safety and efficacy study in 8 post-surgical patients comparing concomitant intravenous infusion of oxycodone and morphine at different doses and rates of infusion. The study indicated that concurrent administration of morphine and oxycodone was well tolerated and pain relief was observed.
1	Open-label study with 17 post-surgical patients tested with several different morphine and oxycodone combinations administered by intravenous infusion over 48 hours. The data showed all combinations were well tolerated and particular ratios were identified as optimal for achieving pain control.
2	Double-blind, placebo controlled, randomised crossover study on 10 healthy people to determine whether adverse ventilatory effects of co-administered morphine and oxycodone were synergistic. Results showed no disproportionate effects that could impede their use in pain management (Published - Ladd <i>et al</i> , BR J Clin. Pharmacol, 59(5), 524-535, 2005).
3	Double-blind crossover study on 21 patients with chronic non-cancer pain. A ratio combination of morphine and oxycodone in an oral liquid formulation was compared against morphine alone. Steady state pain control was achieved in all patients with both dose formulations, but 36% less morphine (49% on a drug weight basis) was needed when the combination drug was dosed compared to morphine alone (p=0.006).
4	Similar to study 3. Double-blind crossover study on 22 patients with chronic non-cancer pain. A formulation with a different fixed ratio to Study 3, of morphine to oxycodone was compared to morphine alone. Steady state pain control was achieved with both formulations, but 32% less morphine (49% on a drug weight basis), was needed when the combination drug was compared to morphine alone (p=0.003).
5	Single dose randomised 2-way crossover study under fasting and fed conditions on 16 healthy volunteers. The study compared the rate and extent of absorption of 8003 based on the fixed ratio of morphine to oxycodone used in study 3. No unexpected findings emerged.
6	Conducted on 17 healthy people in a 3-period randomised crossover design to determine safety, tolerance and dose proportionality. 8003 was evaluated after the single administration of 1, 2, or 3 capsules. Pharmacokinetic analysis showed that increasing blood levels of morphine and oxycodone were proportional to the increasing dose.

Source: QRxPharma reports.

The key finding of study 3 and study 4 was that the dual opioid, morphine and oxycodone, provided equivalent pain control to morphine at a 49% lower dose (on a drug weight basis) in patients with chronic non-cancer pain (Figure 1 and Figure 2).

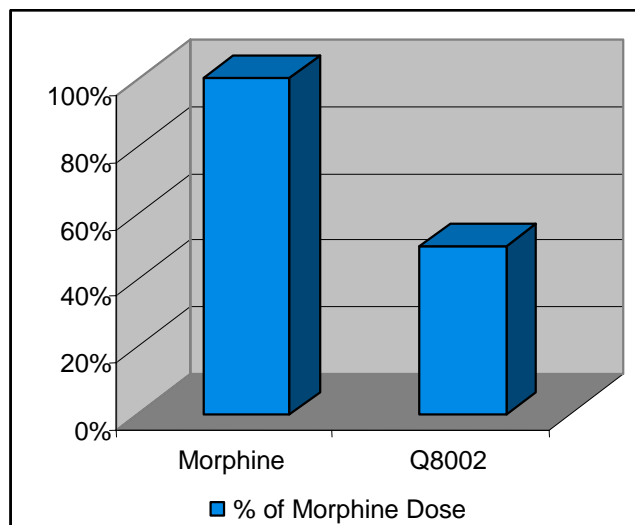
We note that oxycodone alone can give the same pain control as morphine at a ~33% lower dose (on a drug weight basis). Hence, the dual opioid should give the same pain relief as oxycodone or morphine using a lower dose, and it is anticipated that the side-effect profile will therefore be improved.

Figure 1: Dual Opioid Provided Equivalent Pain Control to Morphine at 49% Lower Dose - Study 3 statistical significance p<0.001



Source: Company reports.

Figure 2: Dual Opioid Provided Equivalent Pain Control to Morphine at 49% Lower Dose - Study 4 statistical significance p<0.002



Source: Company reports.

### **Q8003IR Phase III Clinical Trial Design**

The FDA has approved QRxPharma to proceed with a Phase III clinical trial for its Q8003IR product.

The FDA has advised QRxPharma that Q8003IR will be treated as a New Drug Application (NDA) and as such will require<sup>5</sup>:

- 2 double-blind (neither patients nor the investigators will know who will receive the treatment), randomised, well-controlled studies including placebo with at least 300 patients;
- A long-term safety plan with data on at least 50 patients over 12 months; and
- One study conducted according to the FDA's Fixed Combination Prescription Drug requirements (each component must make a contribution to the claimed effect and the dosage of each component must be safe and effective).

The FDA has not provided QRxPharma with any specific requirements for the trials to be conducted in a particular target group, e.g. cancer patients. Disease state appears to be irrelevant given that the method of action for the drug is the same regardless of the disease state. This is beneficial from the point of obtaining a broad label indication.

The Phase III trials will be largely outsourced. Approximately 40 high prescribing pain centres will be needed in each of the 2 Phase III trials to recruit the required number of patients. The sample size of the first of 2 Phase III trials is expected to be 660 patients suffering moderate-to-severe pain, most likely from a variety of disease states, e.g. osteoarthritis, cancer, chronic back pain.

The first study will have a 3-7 day titration period for pain control, followed by a 12 week steady state treatment phase, and then a 4 week treatment reduction period.

The primary endpoint of the first Phase III study is the responder rate of the Q8003IR group compared to placebo. Whilst it is difficult to measure pain levels, as there are no biochemical markers for pain, we expect that the comparison to placebo is a low hurdle relative to many other clinical drug programs. Furthermore, given that the Phase II studies have shown that the morphine and oxycodone combination is effective compared to morphine alone, this would suggest analgesia is highly likely to be shown in the dual opioid relative to the placebo.

Under FDA guidance, QRxPharma will use responder versus non-responder analysis for the interpretation of the trial results, to account for any subject drop-outs in the trial as a result of the placebo effect. The trials will be sufficiently powered (i.e. analyse a significantly large enough sample size) to account for a potential drop-out rate of 30% — calculated on the basis of other clinical trial observations.

The secondary endpoints of the first Phase III trial are:

- Drug requirements – average daily dose of the active treatments will be compared between groups at the end of the initial dose titration period, and at the end of the 12 week dose treatment period.

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<sup>5</sup> FDA protocol approval Q8003-CTP-06-03-v5 02 03 06 LBP final

- Evaluation of adverse effects – including nausea, vomiting, constipation, and dizziness will be measured according to severity and time of occurrence. Any other adverse effect will be monitored as part of the Safety Assessment.
- Amount of rescue medication consumed – in case of breakthrough pain. Rescue medication will be the same as the patient's treatment medication (or in the case of the placebo recipients, acetaminophen will be used), but labelled differently.
- Analgesic efficacy – patient self-assessment using a five point pain relief rating scale.

Although these secondary endpoints are being measured, we note that only success with the primary endpoint is required for FDA approval, i.e. pain relief versus placebo. Q8003IR will not make a label claim that it delivers a superior side-effect profile, as this is not its primary endpoint. However, if the product is approved, the preliminary market research by the company indicates that physicians will be willing to try the product based on the expectation the side-effects will be less because the dose of opioids used to achieve the same pain relief is less.

We understand that clinical trial costs in a pain indication typically cost ~US\$15,000 per patient. Hence, each Phase III trial is likely to cost ~US\$10m.

We expect that the first Phase III trials will be initiated mid-2007, with the first patient dosed by the end of CY07. QRxPharma intends on starting its second Phase III trial during 2008. Combined, both trials should be completed within ~2 years. If this is the case, the NDA filing should be ready for submission by late CY09.

Prior to commencing its second Phase III clinical trial, QRxPharma is planning to carry out a Special Protocol Assessment (SPA)<sup>6</sup> with the FDA to ensure that all the appropriate areas that the FDA is concerned with are addressed in the NDA, reducing the risk that there will be delays and changes in regulatory assessment.

QRxPharma expect the development timetable for Q8003IR is as follows:

2007:

- Prepare for commencement of clinical study – identify and contract CRO (Clinical Research Organisation)
- Plan FDA meetings – end of Phase II and SPA
- Prepare clinical trial materials. Detailed planning, preparation of first Phase III
- First Phase III patient to be dosed by late 2007
- Complete tablet development (current formulation is capsule), conduct comparative bioequivalence study

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<sup>6</sup> If a sponsor files an SPA with the FDA, the FDA must evaluate certain protocols and issues (e.g. clinical protocols for Phase III trials) within 45 days to assess whether they are adequate to meet scientific and regulatory requirements

2008:

- Complete first Phase III study
- Commence second Phase III study
- Commence open label safety study (extension of the Phase III studies)
- Complete manufacturing NDA batches and place on stability

2009:

- Complete second Phase III study
- Complete safety study (could still be ongoing when NDA is filed)
- Assemble data and reports and file NDA by late 2009

2010:

- NDA approval late 2010

Should the Q8003IR trials prove successful, it is quite likely that this success will be transferable to Q8011CR. If the Q8011CR Phase I studies can be completed by the end of CY07, with Phase II and III trials to follow, we expect that, at the earliest, a truncated NDA could be filed by the end of CY10.

We note that the Dr Warren Stern, the Senior VP for Drug Development at QRxPharma, will manage the clinical trials. Dr Stern is a psychopharmacologist, with over 25 years experience in developing CNS drugs. He has published ~90 papers on his research in Central Nervous System trials, holds 6 patents for his CNS product related inventions, and has successfully completed the NDA submissions for the depression treatments Wellbutrin and Celexa.

## Commercialisation

### Go-To-Market Strategy

There are two options open to QRxPharma to go-to-market:

- out-license to a specialty pharmaceutical company with a sales force in the pain market, or
- build its own sales force to distribute the product.

QRxPharma is intending on building its own sales force in the US, and out-licensing the rights to distribute the products in other countries.

QRxPharma believe this is feasible because the market in the US is very concentrated – ~10% of opioid prescriptions are written by 0.2% of the opioid prescribers, and approximately 1500 doctors write ~30% of the scripts. Based on the experience of company's management, 70 sales representatives should be sufficient to cover approximately 1000 of these doctors. This is likely to be sufficient to support initial sales for Q8003IR. We expect additional sales representatives would be required to support Q8011CR.

We provide a profile for sales achieved per sales representative for other pain therapeutic companies in Table 4. These estimates are approximate because precise data is not available for Xanodyne and Purdue which are private companies.

Nonetheless, it suggests that 70 sales representatives should be able to support sales in the order of ~US\$100-300m p/a.

Table 4: Approximate Sales Per Sales Force Representative

Company	Approx Sales	Approx Sales Reps	Sales per Reps
Xanodyne Pharmaceuticals	~US\$100m p/a	~65+	~US\$1.5m
Endo Pharmaceuticals	~US\$910m p/a	~590	~US\$1.5m
Purdue Pharmaceuticals	~US\$1,000m p/a	~250+	~US\$4.0m

Source: JPMorgan estimates, Company data.

We think it is a sensible strategy for QRxPharma to build its own sales force given the concentrated market makes it practically feasible, the potential returns available to QRxPharma should be sufficiently high to warrant the effort, third party manufacturers are available to supply the product, and it would enable QRxPharma to control its own destiny and not have to rely on a licensing partner.

The potential for high returns comes from the fact QRxPharma currently retains full ownership of its products and therefore does not have to pay royalties to third parties (although QRxPharma will have to pay Supernus a royalty to access their delivery technology for Q8011CR). Furthermore, gross margins are likely to be high on QRxPharma's products and we expect they are in the order of 90%.

Specialist clinicians in the pain market are generally receptive to trying new therapies, particularly given the lack of major new innovations that have occurred in this area. Therefore, we expect that if Q8003IR and Q8011CR are approved by the FDA, clinicians will try these products.

The degree of success of these products will then depend on their relative benefits (e.g. improved side-effect profile) and the skill of the QRxPharma sales force. We do not believe any of the competitors have sufficient market dominance in terms of therapeutic attributes, market share, the distribution channel, or product supply, to impede QRxPharma's access to the market, nor its take-up should clinicians want to preferentially prescribe the products.

## Intellectual Property

### Patents

We do not review in-depth the patent coverage for QRxPharma.

However, we note that the key patent family (see granted US patent 6,310,072) covers the invention that the "unexpected discovery that co-administration of sub-analgesic dosages of two strong opioids such as morphine and oxycodone results in potent analgesic synergy and a reduced propensity for causing... undesirable side effects".

The file date for the US patent is 29 Aug 1997. Given extensions possible under the Waxman-Hatch Act, patent coverage in the US to around 2020 is likely.

We also note that the continued release product, Q8011CR, requires access to intellectual property owned by Supernus associated with its delivery technology (see granted US patent 6,287,599). QRxPharma has negotiated rights to this intellectual property with Supernus and will pay them a royalty on future sales.

We understand that additional patents with additional claims are in the examination stage.

### **Generic Substitution Risk**

Given that both oxycodone and morphine are individually approved products which have become genericised, it is theoretically possible physicians could combine these drugs to achieve the synergistic effect of the QRxPharma products. Although this would infringe QRxPharma's patent rights, enforcing this would be impractical at the physician level.

However, there are various reasons why this is unlikely to occur, for example:

- Physicians would need to write two prescriptions to achieve synergy versus one for the QRx product. Any increased level of prescriptions is likely to attract scrutiny from the Drug Enforcement Administration (DEA) which tracks the dispensing habits of physicians prescribing controlled substances
- Patients' insurance would require double co-pays instead of single co-pay
- There is no financial incentive for the physician to substitute
- The fractional low doses of the individual API (Active Pharmaceutical Ingredient) components in Q8003IR are not available or approved in any branded or generic product. For example, the lowest dose morphine tablet or capsule sold is 15 mg compared to 5.4 mg in Q8003IR, and the lowest dose oxycodone tablet or capsule sold is 5 mg compared to 3.6 mg in Q8003IR. It is medical practice to dose to pain control and no further. Hence, it would not be sensible to dose to 15mg morphine and 10mg oxycodone to achieve same ratio as in Q8003IR as this is ~3x the dose required to achieve pain relief

### **Board And Management Team**

QRxPharma has a very experienced Board and management team. The following profiles have been sourced from the company.

#### **Dr Peter Farrell - Chairman of the Board (Non-Executive)**

Dr Peter Farrell is the Founder, Chairman, and CEO of ResMed Inc (RMD), a US\$3.8b market cap medical devices company. Dr Farrell has over 30 years of executive experience in medical devices, has received a number of awards and accolades, including US National Entrepreneur of the Year for Health Sciences in 2005.

#### **Dr John Holaday - Managing Director CEO**

Dr John Holaday co-founded pharmaceutical companies, EntreMed Inc and Medicis Pharmaceutical Corp which today have combined market capitalisations of over US\$2.2b. Dr Holaday has held key executive positions at various pharmaceutical companies, including CEO, Chairman, and Scientific Director. Additionally, Dr Holaday is an Associate Professor of Anaesthesiology and Critical Care Medicine and Senior Lecturer in Medicine at The John Hopkins University of Medicine. He has authored over 200 scientific articles and holds over 30 patents

#### **Dr Gary Pace - Director and Consultant**

Dr Gary Pace is a co-founder of QRxPharma and a distinguished entrepreneur having co-founded and built several early stage companies such as RTP Pharma (sold to

SkyePharma), Waratah Pharmaceuticals (merged with Transition Therapeutics), and CTour (sold to Statoil). Dr Pace is a director of ResMed Inc, Transition Therapeutics Inc, Celsion Corp, Resonance Health, and Peplin. Dr Pace is a Visiting Scientist at MIT, an Adjunct Professor at the University of Queensland, a Fellow of the Australian Academy of Technological Sciences and Engineering, and is co-author in over 50 research papers.

**Mr Peter Campbell - Non-Executive Director**

Mr Peter Campbell is a Board member and Chairman of the Audit Committee at Sonic Healthcare. He is also a Director of Silex Systems Ltd and Metlifecare Ltd.

**Mr Michael Quinn - Non-Executive Director**

Mr Michael Quinn is a co-founder and Chairman of venture fund Innovation Capital. Mr Quinn co-founded Memtec and was previously CEO of the manufacturer and distributor of healthcare and scientific products, Phoenix Scientific Industries. He is currently a Director of ResMed Inc.

**Mr Doug Saltel - COO**

Mr Doug Saltel has over 22 years of pharmaceutical experience. He founded and led Edgemont Pharmaceuticals, a specialty pharmaceutical company focused on commercialisation of products used to treat CNS diseases. He was VP of Sales & Marketing at JDS Pharmaceuticals, Head of Novartis' US Neuroscience business, VP of CNS for Parke-Davis in the US, and VP of Sales at Roche in Canada.

**Dr Warren Stern - Senior Vice President, Drug Development**

Dr Warren Stern is an experienced psychopharmacologist, with over 25 years experience in developing CNS drugs. He has published ~90 papers on his research in CNS trials, holds 6 patents for his CNS product related inventions, and has successfully completed the NDA submissions for the depression treatments Wellbutrin and Celexa. Dr Stern held senior Drug Development positions at Dov Pharmaceuticals and PAREXEL International Corporation – a major contract research organisation. Dr Stern has held a number of senior clinical research positions at Cato Research, and Forest Laboratories. He was previously the CEO of Pharmatec Inc, a CNS oriented drug delivery firm and founder of 2 drug delivery companies.

**Dr Gil Price - Vice President, Clinical Development**

Dr Gil Price is the founder of Congressional Pharmaceutical Corp (sold to HEPH) and Drug Safety Solutions - provider of investigational, clinical, and marketing services to leading biopharmaceutical companies. Dr Price was the Director of Medical Affairs at MedImmune and Glaxo. Dr Price is also active in the American Medical Association and the American Academy of Pharmaceutical Physicians.

**Dr Cynthia McCormick - FDA/Regulatory Consultant**

Dr Cynthia McCormick previously the Director of the Division of Anaesthetic, Critical Care and Addiction Drug Products at the US FDA, responsible for reviewing and approving pain treatments and initiating strategies to ensure a standardised approach to the development of pain drugs. Dr McCormick also served as medical reviewer in the Division of Neuropharmacological Drug Products at the US FDA for 5 years.

**Mr David Stack - Marketing and Sales Consultant**

Mr David Stack is currently the CEO and co-founder of Stack Pharmaceuticals, a commercialisation and marketing strategy firm for emerging healthcare companies. The principals of Stack Pharmaceuticals have built over 70 pharmaceutical and biotechnology sales forces, including the initial Endo Pharmaceuticals, Ligand, and Cephalon pain specialty representative teams. Previously, Mr Stack was CEO of The Medicines Company, and General Manager of Innovex Inc providing marketing, sales, and clinical development capabilities to pharmaceutical customers. He has held various senior positions at Roche Labs, and was initially a hospital and community pharmacist. In 2003 Mr Stack was recognised as Ernst & Young Entrepreneur of the Year.

**Dr Solomon Snyder - Chairman of the Scientific Advisory Board**

Dr Solomon Snyder is a co-founder of QRxPharma and a distinguished, world renowned scientist having discovered the opioid receptor that lead to the discovery of endorphins. Dr Snyder has published over 1,000 peer-reviewed scientific articles and is one of the 10 most cited biologists in the world. Currently, Dr Snyder is the Distinguished Professor of Psychiatry, Neurosciences, and Pharmacology at John Hopkins University School of Medicine and Senior Editor of the Proceedings of the National Academy of Sciences of the USA.

**Risk Mitigation**

We believe that management has attempted to mitigate many of the risks faced by QRxPharma. We outline some of these risks in Table 5.

Table 5: Risk Mitigation

Risk Factor	Mitigation
Clinical Trials	Only need to show pain relief versus placebo in first Phase III trial for Q8003IR. Side effect benefits are secondary end points but not required to achieve FDA approval. Risk of achieving FDA approval for Q8003IR may be minimised if the company achieves a Special Protocol Assessment (SPA) for its second Phase III trial. If Q8003IR is not successful in clinical trials, this would reduce the likelihood that Q8011CR would proceed to Phase III clinical trials.
FDA approval	Extensive discussions on agreed Phase III trial protocol. Likely to pursue SPA for Phase III. Former medical review of FDA pain unit is consulting to the company.
Manufacturing	3rd party API manufacturers are available and have sufficient capacity to supply product
Sales & Commercialisation	David Stack has developed the sales forces for many other companies, including several of those in the pain area. This will enable QRx to control its own destiny and not have to rely on an out-licensing partner (although this is still an option).
Market Penetration	This is a promotionally sensitive market and physicians are typically willing to try new products. There are also no major incumbent competitors that can hinder access.
Intellectual Property	Patent protection on combination of oxycodone and morphine. Patent protection on controlled release delivery technology.
Execution	Most of the key management has done this before – clinical trials, sales force development, commercialisation.

Source: JPMorgan.

## Valuation

### Approach

Given that QRxPharma is pre-revenue, and the outcomes are largely binary (i.e. FDA approval or rejection), valuation is non-trivial, and subject to a relatively high degree of judgment.

We examine several approaches:

- DCF valuation
- Risk-weighted DCF valuation
- Market prices for comparable publicly-listed drug development companies
- Relevant corporate transactions in the pain therapeutics area

### Forecasts

For the purposes of our valuation we adopt the following forecasts:

#### Revenue Assumptions

- Market grows at 7% p/a for immediate release and controlled release. We consider this a conservative assumption as the market has been growing historically at ~8% p/a. Immediate release market is currently ~US\$1.7 billion p/a and controlled release market is currently ~US\$3.3 billion p/a.
- Q8003IR Phase III data is submitted to the FDA 2H09 and approved in 2H10E. Sales begin in 1H11E and account for ~5% of total market sales after 2 years. This results in sales of ~US\$140m p/a at this time (equivalent to ~US\$85m p/a in today's market).
- Q8011CR Phase III data is submitted to the FDA in 2H11E and approved in 2H12E. Sales begin in 1H13E and account for ~5% of total market sales after 2 years. This results in sales of ~US\$290m p/a at this time (equivalent to ~US\$165m p/a in today's market). We consider this a conservative assumption. As previously indicated, at the earliest, a truncated NDA could be filed with the FDA by the end of CY10.
- We do not assume any sales outside the US market.
- We believe it is possible QRxPharma could achieve first sales earlier than we have assumed but we prefer to remain conservative for the purposes of valuation. Similarly, if the products work as envisaged, we expect the quantum of our sales assumed in our forecasts will prove conservative.
- We summarise our revenue forecasts in Table 6.

#### Cost Assumptions

- 90% gross margin on sales
- 100 sales representatives are required to sell Q8003IR and a further 50 for Q8011CR.
- The total cost per sales representative is US\$250k (as at today) and these costs escalate at 6% p/a.

- Clinical development and related costs are US\$40m for Q8003IR to reach FDA submission and US\$50m for Q8011CR to reach FDA submission. We also assume US\$20m is spent on other pipeline development projects.
- Once sales begin, ongoing R&D spend is 10% of sales.
- Royalty payments to Supernus at 5% of Q8011CR sales.
- Tax rate at 35%.
- A\$50m capital raising in 2H10 for working capital purposes associated with building a sales force for Q8003IR.

Table 6: Revenue Forecasts

Revenue Projections	FY07E	FY08E	FY09E	FY10E	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E
<b>Q8003 - Immediate Release</b>														
Total US Market Sales (US\$m)	1,729	1,850	1,980	2,118	2,267	2,425	2,595	2,777	2,971	3,179	3,402	3,640	3,895	4,167
growth (p/a)	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%
Market Share (%)	0.0%	0.0%	0.0%	0.0%	1.5%	3.5%	5.0%	5.0%	4.7%	4.3%	4.0%	4.0%	4.0%	4.0%
Revenue (US\$m)	0	0	0	0	34	85	130	139	140	137	136	146	156	167
<b>Q8011 - Controlled Release</b>														
Total US Market Sales (US\$m)	3,357	3,592	3,843	4,112	4,400	4,708	5,038	5,390	5,768	6,171	6,603	7,066	7,560	8,089
growth (p/a)	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%
Market Share (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%	3.5%	5.0%	5.0%	4.7%	4.3%	4.0%	4.0%
Revenue (US\$m)	0	0	0	0	0	0	76	189	288	309	310	304	302	324
<b>ROW Revenues</b>														
Revenue (US\$m)	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: JPMorgan estimates.

Table 7: Cost Projections

Cost Projections	FY07E	FY08E	FY09E	FY10E	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E
Gross Margin	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Raw Material Costs (\$USm)	0	0	0	0	(3)	(9)	(21)	(33)	(43)	(45)	(45)	(45)	(46)	(49)
Sales & Marketing Expense (\$USm)	0	0	0	(5)	(22)	(29)	(41)	(53)	(61)	(64)	(68)	(72)	(77)	(81)
R&D Expense (\$USm)	(2)	(20)	(20)	(30)	(20)	(20)	(21)	(33)	(43)	(45)	(45)	(45)	(46)	(49)
General & Administration Costs (\$USm)	(3)	(6)	(7)	(8)	(9)	(10)	(11)	(11)	(12)	(13)	(14)	(14)	(15)	(16)
Supernus Royalty (\$USm)	0	0	0	0	0	0	(4)	(9)	(14)	(15)	(16)	(15)	(15)	(16)

Source: JPMorgan estimates.

Table 8: Profit and Loss Summary

Profit and Loss (\$US million)	FY07E	FY08E	FY09E	FY10E	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E
Total Revenue	0	0	0	0	34	85	206	328	428	445	446	449	458
COGS	0	0	0	0	(3)	(9)	(21)	(33)	(43)	(45)	(45)	(45)	(46)
Gross Profit	0	0	0	0	31	77	185	295	385	401	402	404	412
SG&A	(3)	(6)	(7)	(13)	(31)	(39)	(52)	(65)	(73)	(77)	(82)	(87)	(92)
R&D	(2)	(20)	(20)	(30)	(20)	(20)	(21)	(33)	(43)	(45)	(45)	(45)	(46)
Royalty Payment	0	0	0	0	0	0	(4)	(9)	(14)	(15)	(16)	(15)	(15)
Total Expenses	(5)	(26)	(27)	(43)	(48)	(58)	(76)	(107)	(129)	(137)	(141)	(146)	(152)
EBIT	(5)	(26)	(27)	(43)	(17)	19	109	189	256	264	260	258	260
Net Interest Expense	0	0	0	0	0	0	0	0	0	0	0	0	0
Profit Before Tax	(5)	(26)	(27)	(43)	(17)	19	109	189	256	264	260	258	260
Tax	2	9	9	15	6	(7)	(38)	(66)	(90)	(92)	(91)	(90)	(91)
Net Profit After Tax	(3)	(17)	(18)	(28)	(11)	12	71	123	166	172	169	168	169
Depreciation	(0.1)	(0.1)	(0.1)	(0.2)	(0.6)	(1.0)	(1.4)	(1.8)	(2.2)	(2.6)	(3.0)	(3.4)	(3.8)
Amortisation	0	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation & Amortisation	(0.1)	(0.1)	(0.1)	(0.2)	(0.6)	(1.0)	(1.4)	(1.8)	(2.2)	(2.6)	(3.0)	(3.4)	(3.8)
EBITDA	(5)	(26)	(27)	(43)	(17)	20	111	190	258	267	263	262	264

Source: JPMorgan estimates.

### DCF Valuation

If QRxPharma were to achieve the forecasts outlined above, we estimate the NPV of the free cash flows discounted at the cost of equity is ~US\$1.1 billion, or ~A\$17.60 per share. This suggests if both drugs are approved, and the sales are achieved as envisaged by our forecasts, the upside from the current share price could be ~10x.

If QRxPharma were only successful in achieving approval with Q8003IR, we estimate the NPV of the free cash flows discounted at the cost of equity is ~US\$230 million, or ~A\$3.65 per share. This represents ~2x the current share price.

The significant difference between the two NPVs relates to the fact Q8011CR revenues are twice those of Q8003IR, and the incremental profits on these revenues are high because the company would not need to proportionally expand its sales force.

### Risk-Weighted DCF Valuation

Statistically, a new active substance at the start of Phase III clinical trials has ~65% chance of being launched in the market place, and at the start of Phase I clinical trials ~20% chance of being launched.

This would suggest that, on average, QRxPharma should have ~65% chance of having Q8003IR approved, and ~20% chance of having Q8011CR approved.

Based on these average 'probabilities', and our NPV calculated above, we estimate the risk-weighted value is ~US\$145m, or ~A\$2.30 per share. However, given that Q8003IR only needs to demonstrate pain relief relative to placebo, we expect it has a higher probability of being approved than the average. For example, if the probability of success is more like ~85% for Q8003IR, and ~20% for Q8011CR (we believe this is conservative as it is only in-line with the average probability), we estimate the risk-weighted value would be ~US\$190m, or ~A\$3.00 per share.

### US-Listed Comparables – Pain Therapeutics Inc

We believe that Pain Therapeutics Inc (PTIE), which is listed on NASDAQ, is the most direct comparable for QRxPharma.

Pain Therapeutics currently has no approved products but has two products in late stage clinical trials:

- Remoxy – an abuse-resistant version of long-acting oxycodone, positive Phase III trial results announced in September 2005, second Phase III trial commenced in February 2006.
- Oxytrex – a novel oral opioid painkiller for the treatment of severe chronic pain with less physical dependence, positive Phase III trial results announced in March 2005, second Phase III trial was initiated in December 2006.

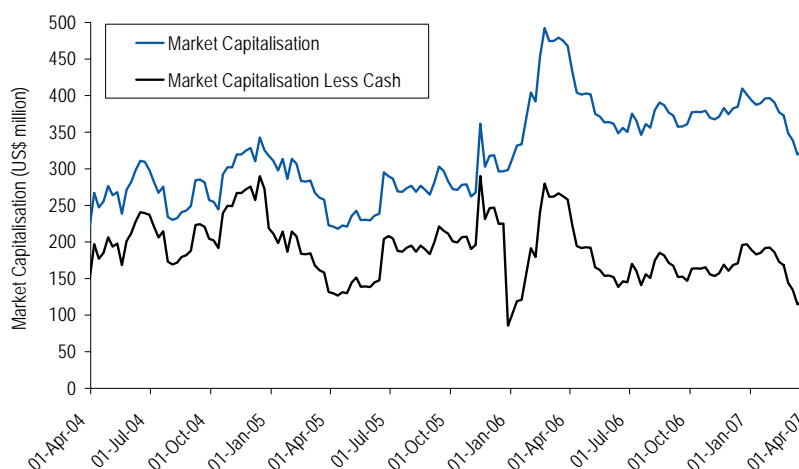
We present the market capitalisation for Pain Therapeutics over the past 3 years in Figure 3.

We note that in November 2006, Pain Therapeutics signed a licence agreement with King Pharmaceuticals for commercialisation of Remoxy and received an upfront US\$150m cash payment from King Pharmaceuticals (paid in January 2006). Prior to signing this agreement, the average market capitalisation of Pain Therapeutics was

US\$275m, or US\$200m excluding cash and cash equivalents. Post the milestone payment from King Pharmaceuticals, the average market capitalisation was US\$380m, or US\$170m excluding cash and cash equivalents.

If we adopt ~US\$185m market capitalisation excluding cash for QRxPharma, add A\$50m of cash raised at IPO, and discount for the fact Pain Therapeutics is approximately 12-24 months ahead of QRxPharma in terms of time-to-launch, we would derive a value for QRxPharma of A\$2.85-3.20 per share.

Figure 3: Pain Therapeutics Inc Market Capitalisation



Source: Datastream

**ASX-Listed Comparables – Avexa Limited**

Table 9 presents other late-stage drug development companies listed in Australia.

We believe that Avexa Limited (AVX) is the most relevant comparable to QRxPharma in the Australian market.

While Avexa is not developing a drug in the pain market, it is at a similar stage of clinical development with its NNRTi for the HIV market (i.e. entering Phase III trials), has a better-than-average chance of clinical success (i.e. every NNRTi successful in Phase II trials has been approved), and the market is of similar size and structure (~US\$5 billion p/a, a large number of approved drugs with varying degrees of novelty and a clear opportunity for more effective drugs).

The VWAP for Avexa since 1-May-07 (the date at which new shares were issued from its A\$70m capital raising to fund Phase III trials) is ~A\$0.65 per share, implying a market capitalisation of ~A\$260m. The equivalent share price for QRxPharma at this market capitalisation would be ~A\$3.45 per share.

We note that since 1-May-07, the Avexa share price has ranged between A\$0.55 and A\$0.74, implying a market capitalisation of A\$220-300m. The equivalent share price for QRxPharma at this market capitalisation would be ~A\$2.95-4.00 per share.

Table 9: Late-Stage Development Companies Listed On The ASX

Name	Market Cap (A\$m)	Net Cash (A\$m)	Phase	Therapeutic Area	Partner Status	JPMorgan Comments
Pharmaxis (PXS)	~\$565m	~\$100m	III	Chronic respiratory diseases	Distribution agreement with Trimedal	<ul style="list-style-type: none"> <li>▪ Bronchitol enhances mucus clearance, application in COPD (1m US emergency room visits per year), Cystic Fibrosis (Pulmozyme and Tobramycin sales ~US\$500m p/a), and bronchiectasis (110,000 diagnosed patients in the US)</li> <li>▪ Aridol – rapid and simple test to facilitate diagnosis of asthma. Launched in Australia, near launch in EU/US.</li> <li>▪ Peter Farrell is Non-Executive Director</li> </ul>
Clinuvel Pharma (CUV)	~\$265m	~\$30m	II/III	Actinic Keratosis, and Polymorphous Light Eruption.	N/A	
Progen (PGL)	~\$275m	~\$30m	III starts end CY07	Drug for liver cancer	None	<ul style="list-style-type: none"> <li>▪ US\$9b worldwide market.</li> <li>▪ Will need sales &amp; marketing partner</li> </ul>
Avexa (AVX)	~\$270m	~\$90m	III starts end CY07	New NNRTi for treating HIV	Licensing and manufacturing agreement with Shire.	<ul style="list-style-type: none"> <li>• Multiple competing products but need for new NNRTi's. ~US\$5b market, leading NNRTi, Tenofovir, has ~US\$1.2b sales.</li> <li>• High likelihood of clinical trial success (all drugs of this type have been approved once in Ph III trials).</li> <li>• Not developing own sales &amp; marketing</li> </ul>
Acrux (ACR)	~\$220m	~\$20m	III	Transdermal drug delivery	Licensing agreements with VIVUS, CSL, Eli Lilly	<ul style="list-style-type: none"> <li>▪ Delivery technology focus</li> <li>▪ Pain treatment (Fentanyl) in Ph I.</li> <li>▪ Not developing own sales / marketing capabilities but out-licensing</li> </ul>
ChemGenex (CXS)	~\$185m	~\$30m	II/III	Gleevec-resistant Chronic Myeloid Leukaemia	None	<ul style="list-style-type: none"> <li>▪ CML Market ~US\$400m.</li> <li>▪ Other early stage opportunities in trials.</li> </ul>
Alchemia (ACL)	~\$115m	~\$15m	III	Technology for large-scale production of carbohydrates	Licensing and manufacturing agreement with Dow Chemical Company	<ul style="list-style-type: none"> <li>▪ Targeting generic, synthetic heparin</li> <li>▪ Dow Chemicals to manufacture</li> <li>▪ Need to find new US marketing partner</li> <li>▪ Other pre-clinical pipeline opportunities</li> </ul>
Peplin (PEP)	~\$155m	~\$35m	II ongoing	Actinic (solar) Keratosis and Basal Cell Carcinoma	Co-development agreement with Medpharm in leukaemia	<ul style="list-style-type: none"> <li>▪ Market size currently ~US\$200m p/a (Aldara, 5 Fluorouracil, and Solaraze).</li> <li>▪ Gary Pace is Non-Executive Director</li> </ul>

Source: JPMorgan estimates, Company data, IRESS, \*approx market capitalisation as at 2 July 2007

### King Pharmaceuticals Acquisition Of Remoxy Product – Licensing Deal

In November 2005, and following the announcement of its first positive Phase III trial in September 2005, Pain Therapeutics entered into a strategic alliance with King Pharmaceuticals for commercialisation of Remoxy (an abuse-resistant version of long-acting oxycodone).

King Pharmaceuticals made an upfront payment of US\$150m, and will make additional milestone payments of up to US\$150m based on successful clinical and regulatory development of Remoxy and other abuse-resistant opioid products. King Pharmaceuticals is responsible for all R&D expenses related to the alliance, which could total US\$100m, including the second Phase III trial currently underway. Pain Therapeutics will receive a 20% royalty on sales of Remoxy, except the first US\$1 billion in cumulative net sales, where the royalty is set at 15%.

Therefore, King Pharmaceuticals essentially paid US\$400m for 80-85% of the future cash flows from this product, valuing 100% of the product at US\$470-500m at the time of approval.

Q8003IR should reach the same stage of development as when Remoxy was licensed in early-to-mid 2008.

#### **King Pharmaceuticals Acquisition Of Avinza Product – Licensing Deal**

In February 2007, King Pharmaceuticals acquired the Avinza product from Ligand Pharmaceuticals. Avinza is indicated for once-daily morphine treatment for chronic moderate-to-severe pain in patients who require continuous, around-the-clock opioid therapy for an extended period of time. 2006 sales of Avinza were ~US\$178m. The product has formulation patent coverage through to 2017.

King Pharmaceuticals paid US\$265m for the US and Canadian rights, assumed US\$48m of payments due to a third party, and assumed royalty obligations to various parties which we estimate at ~22% of net sales. Therefore, King Pharmaceuticals essentially valued the product at ~US\$400m.

#### **Conclusion**

If both Q8003IR and Q8011CR are successful in clinical trials, and deliver as per the forecasts outlined above, we derive an NPV for the free cash flows of ~US\$1.1 billion, or A\$17.60 per share. This would imply upside of ~10x from the current share price.

Although this is clearly a large valuation, we believe it is supported by the recent corporate transactions in the opioid drug market. For example, King Pharmaceuticals effectively valued Remoxy (in Phase III trials) at ~US\$470-500m and Avinza (on-market) at ~US\$400m. Therefore, if both QRxPharma's opioid drugs succeed, the precedent transaction suggest a value of ~US\$1 billion.

If we risk-weight our valuation using the average probability of success in clinical trials, we would derive a risk-weighted value for QRxPharma of ~A\$2.30 per share. However, we believe that QRxPharma has a better-than-average chance of succeeding in clinical trials, particularly for Q8003IR which only has to show pain relief relative to placebo. If we assume a better-than-average chance of success for Q8003IR, but only an average chance of success for Q8011CR (a conservative stance in our view), our risk-weighted valuation increases to ~A\$3.00 per share.

The most appropriate comparable is Pain Therapeutics in the US. Based on the market capitalisation of Pain Therapeutics, and adjusting for the fact its products are 12-24 months closer to market-launch, we would price QRxPharma at ~A\$3.00 per share. The most appropriate comparable in the Australian market is Avexa. Based on the market capitalisation of Avexa post its recent fund raising (for Phase III trials), we would price QRxPharma at A\$3.00-3.50 per share.

Based on the analysis above, we believe that QRxPharma should trade at ~A\$3.00 per share, which represents ~75% upside from the current share price.

## Share Price Target

We set our Jun 08 share price target at A\$3.00, equal to our risk-weighted valuation for QRxPharma, assuming a better-than-average chance of success for Q8003IR, but only an average chance of success for Q8011CR. Risks to our share price target could come from failure to achieve clinical trial success in-line with our forecasts, delays in gaining FDA approval, cost over-runs, or corporate activity.



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## JPMorgan Australasia Research Responsibilities

Paul Brunker, Head of Research (61-2) 9220 1638

[paul.m.brunker@jpmorgan.com](mailto:paul.m.brunker@jpmorgan.com)

### Banks

Brian Johnson (61-2) 9220 1605  
Scott Manning (61-2) 9220 1803

[brian.d.johnson@jpmorgan.com](mailto:brian.d.johnson@jpmorgan.com)  
[scott.r.manning@jpmorgan.com](mailto:scott.r.manning@jpmorgan.com)

### Infrastructure

Kirsty Mackay-Fisher (61-2) 9220 1609

[kirsty.a.mackay-fisher@jpmorgan.com](mailto:kirsty.a.mackay-fisher@jpmorgan.com)

### Insurance & Diversified Financials

Shane Fitzgerald (61-2) 9220 1596  
Liam McCarthy (61-2) 9220 1598

[shane.g.fitzgerald@jpmorgan.com](mailto:shane.g.fitzgerald@jpmorgan.com)  
[liam.x.mccarthy@jpmorgan.com](mailto:liam.x.mccarthy@jpmorgan.com)

### Property Trusts

Rob Stanton (61-2) 9220 1923  
Adam Fairfax (61-2) 9220 3134  
Robyn Nguyen (61-2) 9220 1640  
Michael Scott (61-2) 9220 1570

[rob.a.stanton@jpmorgan.com](mailto:rob.a.stanton@jpmorgan.com)  
[adam.c.fairfax@jpmorgan.com](mailto:adam.c.fairfax@jpmorgan.com)  
[robyn.h.nguyen@jpmorgan.com](mailto:robyn.h.nguyen@jpmorgan.com)  
[micheal.x.scott@jpmorgan.com](mailto:micheal.x.scott@jpmorgan.com)

### Telecommunications

Laurent Horrut (61-2) 9220 1593  
Dee Senaratne (61-2) 9220 1408

[laurent.j.horrut@jpmorgan.com](mailto:laurent.j.horrut@jpmorgan.com)  
[dee.c.senaratne@jpmorgan.com](mailto:dee.c.senaratne@jpmorgan.com)

### Emerging Companies

Alex Mees (61-2) 9220 1939  
Richard Amland (61-2) 9220 1589

[alexander.c.mees@jpmorgan.com](mailto:alexander.c.mees@jpmorgan.com)  
[richard.p.amland@jpmorgan.com](mailto:richard.p.amland@jpmorgan.com)

### Transport

Matthew Crowe (61-2) 9220 1607  
Russell Crichton-Browne (61-2) 9220 15866

[matthew.j.crowe@jpmorgan.com](mailto:matthew.j.crowe@jpmorgan.com)  
[russell.j.crichton-browne@jpmorgan.com](mailto:russell.j.crichton-browne@jpmorgan.com)

### Resources

David George (61-3) 9608 4002  
  
Mark Greenwood (61-2) 9220 1563  
Matthew Whittall (61-3) 9608 4038  
Benjamin Wilson (61-2) 9220 1384  
Dale Koenders (61-3) 9608 4053  
Lun Zhang (61-3) 9608 4053

[david.b.george@jpmorgan.com](mailto:david.b.george@jpmorgan.com)  
  
[mark.j.greenwood@jpmorgan.com](mailto:mark.j.greenwood@jpmorgan.com)  
[matthew.whittall@jpmorgan.com](mailto:matthew.whittall@jpmorgan.com)  
[ben.x.wilson@jpmorgan.com](mailto:ben.x.wilson@jpmorgan.com)  
[lun.x.zhang@jpmorgan.com](mailto:lun.x.zhang@jpmorgan.com)  
[lun.x.zhang@jpmorgan.com](mailto:lun.x.zhang@jpmorgan.com)

### Media & Gaming

Rebecca Michele (61-2) 9220 7961  
Matt Ryan (61-2) 9220 1533

[rebecca.a.michele@jpmorgan.com](mailto:rebecca.a.michele@jpmorgan.com)  
[matthew.h.ryan@jpmorgan.com](mailto:matthew.h.ryan@jpmorgan.com)

### Beverages & Food, Retail

Stuart Jackson (61-2) 9220 1601  
Shaun Cousins (61-2) 9220 1524  
Russell Gill (61-2) 9220 1525

[stuart.a.jackson@jpmorgan.com](mailto:stuart.a.jackson@jpmorgan.com)  
[shaun.r.cousins@jpmorgan.com](mailto:shaun.r.cousins@jpmorgan.com)  
[russell.j.gill@jpmorgan.com](mailto:russell.j.gill@jpmorgan.com)

### Strategy

Martin Duncan (61-2) 9220 7841  
Charles Jones (61-2) 9220 1528

[martin.j.duncan@jpmorgan.com](mailto:martin.j.duncan@jpmorgan.com)  
[charles.e.jones@jpmorgan.com](mailto:charles.e.jones@jpmorgan.com)

### Healthcare

Alex Smith (61-2) 9220 3201  
Kylie Reynolds (61-2) 9220 3194

[alexander.smith@jpmorgan.com](mailto:alexander.smith@jpmorgan.com)  
[kylie.reynolds@jpmorgan.com](mailto:kylie.reynolds@jpmorgan.com)

### Economics

Stephen Walters (61-2) 9220 1599  
Jarrod Kerr (61-2) 9220 1669  
Helen Kevans (61-2) 9220 3250

[stephen.b.walters@jpmorgan.com](mailto:stephen.b.walters@jpmorgan.com)  
[jarrod.w.kerr@jpmorgan.com](mailto:jarrod.w.kerr@jpmorgan.com)  
[helen.e.kevans@jpmorgan.com](mailto:helen.e.kevans@jpmorgan.com)

### Basic Materials, Property Developers, Conglomerates

Andrew Scott (61-2) 9220 7894  
Alistair Reid (61-2) 9220 1538

[andrew.ge.scott@jpmorgan.com](mailto:andrew.ge.scott@jpmorgan.com)  
[alistair.g.reid@jpmorgan.com](mailto:alistair.g.reid@jpmorgan.com)

### Quantitative

Steve Malin (61 2) 9220 1862  
Thomas Reif (61 2) 9220 1473  
Berowne Hlavaty (61-2) 9220 1591  
Matthew Hook (61-2) 9220 1580  
Tim Moroney (61-2) 9220 1919

[steven.j.malin@jpmorgan.com](mailto:steven.j.malin@jpmorgan.com)  
[thomas.w.reif@jpmorgan.com](mailto:thomas.w.reif@jpmorgan.com)  
[berowne.d.hlavaty@jpmorgan.com](mailto:berowne.d.hlavaty@jpmorgan.com)  
[matthew.s.hook@jpmorgan.com](mailto:matthew.s.hook@jpmorgan.com)  
[tim.j.moroney@jpmorgan.com](mailto:tim.j.moroney@jpmorgan.com)

### Utilities

Grace Chan (61-2) 9220 1437  
Raoul Bostrom (61-2) 9220 1606

[grace.ky.chan@jpmorgan.com](mailto:grace.ky.chan@jpmorgan.com)  
[raoul.v.bostrom@jpmorgan.com](mailto:raoul.v.bostrom@jpmorgan.com)