



ASX RELEASE
26 June 2013

QRXPHARMA UPDATES MOXDUO[®] NDA REVIEW

New Information to Delay Planned FDA Advisory Committee Meeting and PDUFA date

Sydney, Australia and Bedminster, New Jersey – QRxPharma Limited (ASX: QRX and OTCQX: QRXPY) announced today the planned 17 July 2013 US Food and Drug Administration (FDA) Advisory Committee meeting to consider the MOXDUO combination opioid analgesic New Drug Application (NDA) will be delayed in order to allow the Company and the FDA time to fully consider results of recent findings for Study 022. The NDA was re-filed in late February 2013, with the original Advisory Committee meeting scheduled for 17 July 2013 and the Prescription Drug User Fee Act (PDUFA) date was 26 August 2013.

While reviewing data from Study 022 in preparation for its Advisory Committee meeting, QRxPharma found that for 17% of the 375 patients, the timing of electronically collected oxygen desaturation information at one trial site did not accurately reflect the local time zone or changes relating to daylight savings time. For these patients, this resulted in a displacement of electronic oxygen desaturation data relative to nurse-reported events by 1 or 2 hours out of the 48-hour study. The Company's initial analysis shows that adjustments for timing should have no significant effect on the conclusion that MOXDUO demonstrated a respiratory safety advantage over equi-analgesic doses of morphine or oxycodone.

The Company promptly notified the FDA of these recent findings and is undertaking further analysis to confirm: 1) the integrity of the data set and 2) that the safety conclusions from Study 022, submitted as part of the re-filed NDA in late February 2013, remain unchanged. Once the Company's analysis is complete, a data amendment for Study 022 will be formally submitted to the revised NDA, and the FDA will require additional time to evaluate this information.

Investor Conference Call

An investor conference call will be held on Thursday 27 June 2013 at 9.00am Australian Eastern Standard Time (United States: Wednesday 26 June 2013 at 7.00pm EST / 4.00pm PST) with Dr. John Holaday, Managing Director and CEO QRxPharma and Dr. Edward Rudnic COO.



Conference participant ID 11435626

Australia	1800 123 296
Hong Kong	800 908 865
New Zealand	0800 452 782
Singapore	800 616 2288
United Kingdom	0808 234 0757
United States	1855 293 1544
Canada	1855 5616 766

All other international locations call + 61 2 8314 8370.

“We will continue to work closely with the FDA to ensure that our plans are acceptable and to minimise any further delays on the overall timing of the MOXDUO NDA review” said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. “We are pleased with the spirit of cooperation that the FDA put forth in our recent conversation regarding these matters”.

The FDA previously confirmed that the Company’s Combination Rule Trial (Study 008) satisfied efficacy requirements, and that there were no safety issues in any of the studies submitted as part of the original NDA. As agreed with the FDA, a further analysis of the respiratory effects of MOXDUO from Study 022 was conducted to demonstrate its potential safety benefit.

These ongoing activities have not changed QRxPharma’s belief that the totality of evidence confirms that MOXDUO’s primary safety advantage over its components is a reduction in respiratory risks. Additionally, the Company believes that MOXDUO provides a safer starting dose and finer dose titration than either of its components, thus giving greater flexibility to physicians and patients in managing acute pain.

The Company expects to complete and submit its revised analysis of oxygen desaturation data from Study 022 in July, and the FDA will then confirm a new date for the Advisory Committee meeting and the new PDUFA date.

“We will keep our shareholders promptly informed as we continue to engage with the FDA and progress through the approval process,” concluded Holaday.

###

Media Contact information:

Lisa Fels
Brightline Strategies
Tel: +1 703 739 2424 x110
Email: lfels@brightlinestrategies.com

Kyahn Williamson
Buchan Consulting
Tel: +61 401 018 828
Email: kwilliamson@buchanwe.com.au



About QRxPharma

QRxPharma Limited is an Australian based, commercial-stage specialty pharmaceutical company focused on the development and commercialisation of new treatments for pain management. The Company's product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, and improved patient outcomes. The Company's lead product candidate, immediate release MOXDUO[®] for the treatment of acute pain, is presently under review at the US Food and Drug Administration. QRxPharma entered into strategic collaborations with Actavis Inc. in December 2011 and Paladin Labs Inc. in October 2012 for the commercialisation of immediate release MOXDUO[®] in the US and Canadian acute pain markets respectively. Additionally, the Company's clinical pipeline includes an intravenous (IV) and continuous release (CR) formulation of MOXDUO. For more information, visit www.qrxpharma.com.

Forward Looking Statements

This release contains forward-looking statements. Forward-looking statements are statements that are not historical facts; they include statements about our beliefs and expectations. Any statement in this release that states our intentions, beliefs, expectations or predictions (and the assumptions underlying them) is a forward-looking statement. These statements are based on plans, estimates and projections as they are currently available to the management of QRxPharma. Forward-looking statements therefore speak only as of the date they are made, and we undertake no obligation to update publicly any of them in light of new information or future events. By their very nature, forward-looking statements involve risks and uncertainties. A number of important factors could therefore cause actual results to differ materially from those contained in any forward-looking statement. Such factors include risks relating to the stage of products under development; uncertainties relating to clinical trials; dependence on third parties; future capital needs; and risks relating to the commercialisation of the Company's proposed products.