RxPharma announced that a number of patients have been treated in the first of several clinical studies to be conducted as part of the Phase III development program for its lead product candidate Q8003IR, an immediate release dual opioid pain therapy.

The initial clinical trial is a double-blind, placebo-controlled study designed to compare the efficacy and safety of four different dosage strengths of Q8003IR vs. placebo in a post-surgery, acute pain setting. The study is being conducted at eight US clinical research sites and is targeted to enroll 250 patients experiencing moderate to severe pain following a scheduled surgical procedure (bunionectomy).

“Initiation of this Phase III clinical trial program not only demonstrates the Company’s ability to deliver on its development milestones for Q8003IR in terms of budget and timeline projections, but also represents a significant step forward towards our goal of commercializing our first dual-opioid pain therapy in 2010,” said Dr John Holaday, Managing Director and Chief Executive Officer of QRxPharma.

The primary clinical endpoints for this acute, post-surgery pain study focus on pain relief and pain intensity scores vs. placebo over the first 48 hours post-surgery. Secondary endpoints include: (1) efficacy relating to the time to onset of analgesia and the duration of effect from a single oral dose; and (2) safety as measured by the incidence and intensity of opioid-related adverse events. A safety extension trial will immediately follow patient enrollment in this first trial to begin capturing longer-term patient safety data in support of our planned future New Drug Application (NDA) data submission package for Q8003IR.

Q8003IR is a patent-protected, immediate release dual-opioid product that synergistically combines sub-analgesic doses of oxycodone and morphine. Several clinical trials to date have shown that this unique, dual-opioid combination can achieve equal or better analgesic pain relief at materially lower doses than the active opioid comparator while simultaneously reducing side effects (e.g. less nausea, vomiting, respiratory depression, constipation and sedation).

About QRxPharma
QRxPharma is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of new treatments for pain management and central nervous system disorders. Based on a development strategy which focuses on enhancing and expanding the clinical utility of currently marketed compounds, the company’s product portfolio includes both late and early stage clinical drug candidates with the potential for reduced risk, abbreviated development paths, improved safety and patient outcomes, and greater market value for direct commercialization in the US as well as potential for strategic partnerships abroad.