



November 4, 2013

## **Johnson & Johnson and its Subsidiaries, Janssen Pharmaceuticals, Inc. and Scios Inc., Conclude Previously Disclosed Settlement Agreements with U.S. Department of Justice and 45 States**

NEW BRUNSWICK, N.J., Nov. 4, 2013 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) and its subsidiaries, Janssen Pharmaceuticals, Inc. and Scios Inc., today announced they have finalized previously disclosed settlement agreements with the U.S. Department of Justice (DOJ) and 45 states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL<sup>®</sup> from 1999 through 2005, and other matters. The resolution includes total settlement amounts of approximately \$2 billion to the federal government and state Medicaid programs, an amount previously accrued, and no additional charge to the company's earnings will be recorded in connection with this settlement.

As part of the resolution, Janssen will plead guilty to a single misdemeanor violation of the Food, Drug and Cosmetic Act for past promotional practices of RISPERDAL, subject to approval by the U.S. District Court. The agreement also resolves allegations related to the sales and marketing of INVEGA<sup>®</sup>, NATRECOR<sup>®</sup> by Scios Inc., and allegations related to Janssen's interactions with Omnicare, Inc. The Company has cooperated with the government since the separate investigations began nearly a decade ago, and today's agreements resolve all related federal criminal and federal civil liabilities on these matters. Janssen accepts accountability for the actions described in the misdemeanor plea. The settlement of the civil allegations is not an admission of any liability or wrongdoing, and the Company expressly denies the government's civil allegations.

The civil matters concerning RISPERDAL involved numerous discussions with the U.S. Food and Drug Administration (FDA) dating back to 1994. This resolution does not change the FDA's approval of RISPERDAL as safe and effective for its approved indications. RISPERDAL is supported by more than 20 years of extensive research and clinical studies and remains an important treatment option for people with serious mental illness. RISPERDAL continues to be appropriately reimbursed by Medicare and Medicaid.

"Today we reached closure on complex legal matters spanning almost a decade. This resolution allows us to move forward and continue to focus on delivering innovative solutions that improve and enhance the health and well-being of patients around the world," said Michael Ullmann, Vice President and General Counsel, Johnson & Johnson. "We remain committed to working with the U.S. Food and Drug Administration and others to ensure greater clarity around the guidance for pharmaceutical industry practices and standards."

The resolution also includes a five-year corporate integrity agreement (CIA) between the Office of Inspector General of the U.S. Department of Health and Human Services and Johnson & Johnson. Johnson & Johnson and its subsidiaries have robust compliance programs that have been continually strengthened and that will continue as part of this agreement. The CIA is largely consistent with existing compliance programs, and reflects the companies' commitment to ensuring integrity in the delivery of essential medicines to patients.

Under the criminal resolution, Janssen will pay \$400 million and plead guilty to a one-count misdemeanor misbranding charge. Under the civil settlement, Janssen and Scios will pay approximately \$1.6 billion to settle three pending civil False Claims Act cases in federal district courts related to RISPERDAL and INVEGA, NATRECOR, and Omnicare.

(This release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to, approval of Janssen's plea by the U.S. District Court; general industry conditions; economic factors, such as interest rate and currency exchange rate fluctuations; significant adverse litigation or government action; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; increased scrutiny of the health care industry by government agencies; and product efficacy or safety concerns resulting in product recalls or regulatory action. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.investor.jnj.com](http://www.investor.jnj.com) or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statements as a result of new information or

future events or developments.)

For more information, visit [www.janssen.com](http://www.janssen.com).

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