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PharmaCore Opens New GMP Pilot Plant

February 12, 2009 (High Point, NC)—In response to customer demand for larger quantities of cGMP APIs, PharmaCore, Inc. has added a new 16,000 square foot pilot plant to its existing facility. Lab and kilo-scale cGMP capacity are augmented with the addition of several new synthesis suites with reactor sizes up to 2000 liters.

This project represents PharmaCore's continued emphasis on cGMP manufacturing. Company president, Rob Maddox says, "Customers expect high standards from us and they rely on PharmaCore not only for custom synthesis but also for contract research to support their chemistry programs. We have developed partnerships with many companies and our talented chemistry group coupled with great customer service sets us apart. One area of focus is to continue to increase our presence in cGMP synthesis so that we are better able to meet the needs of our customers. PharmaCore has been successful in taking projects from the early R&D stage and then scaling them up to provide material for clinical trials. Some of these materials are now in Phase I and Phase II studies."

PharmaCore currently has eight cGMP suites with the addition of the five new suites in the new facility. Two of the new suites support kilo-scale processing in 100 liter glass reactor systems. The other three are pilot-scale rooms equipped, respectively, with a 200 liter hydrogenator, a pair of 800 liter glass-lined steel reactors, and a 1200/2000 liter glass-lined steel reactor pair. The pilot-scale reactors are capable of running chemistries from -70 to +160 °C. Supporting equipment includes pressure filters, vacuum dryers, and process-

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scale chromatography. Utilities are supplied by state-of-the-art temperature control modules, dry running vacuum systems, and process automation and control.

Vice president of GMP manufacturing, Brian Swierenga was hired in late 2007 to complete the facility design and construction and to run the new facility. Most recently, Brian built and managed a Pfizer API manufacturing facility in Ann Arbor, Michigan.

Part of the new facility is dedicated to analytical support. Testing of raw materials, intermediates, and final products will be carried out in house. An independent Quality Assurance department ensures that materials are manufactured in accordance with cGMP requirements and that established Standard Operating Procedures are followed.

"The new facility is only one piece of our broadened services," Maddox said. "We have hired top-notch staff with extensive problem-solving experience. I am confident in their ability to work with our customers to achieve the best results possible for every project."

PharmaCore®, Inc., headquartered in High Point, NC, is a leader in small molecule chemistry for drug discovery. The company develops and manufactures novel chemical building blocks and scaffolds for drug-like molecules, provides custom synthesis services (including GMP scale-up) of pharmaceutical intermediates and API's, and performs contract research to support drug discovery efforts at major pharmaceutical and biotechnology companies. Additional information is available at www.pharmacore.com.

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