Cadence Makes Big Addition to Pain-Relief Arsenal

San Diego Business Journal

CADENCE PHARMACEUTICALS INC.

CEO: Ted Schroeder.

Revenue: Not disclosed.

Net loss: $45.4 million in 2009; $57.1 million in 2008.

N**o. of local employees:** 247.

Headquarters: Carmel Valley.

Year founded: 2004.

Stock symbol and exchange: CADX on the Nasdaq.

Company description: Biotech focused on in-licensing, developing and commercializing proprietary therapeutics principally for use in a hospital setting.

Befitting the companys name, San Diego-based Cadence Pharmaceuticals Inc.s sales staffers are marching to appointments to get a share of the pain-relief business at the nations hospitals.

The companys distribution centers are fully stocked and accepting orders for Ofirmev, the injectable therapeutic now being marketed by Cadence.

After an expensive seven-year process to bring the drug to market, the companys top executive said Cadence is looking to meet a huge unmet need at the nations hospitals with its intravenous pain reliever for patients who are unable to swallow pain pills.

Helping fund the companys various efforts was a November 2010 financing where Cadence raised $86.2 million in common stock. A similar amount was raised in February 2009. Cadence is well-capitalized to focus on this launch.

"Thanks to our investors, were building a company with the purpose of improving the lives of hospitalized adults and children," said Ted Schroeder, the companys founder, president and chief executive officer, referring to the first and only IV formulation of acetaminophen to be approved in the U.S.

In February 2010, the U.S. Food and Drug Administration had held off approval of Ofirmev because of concerns at a contract manufacturing plant, which were later resolved. Cadence resubmitted its application for the drug in May.

FDA Grants Marketing Approval

Cadence was granted marketing approval by the FDA for its injectable pain and fever relief drug in November 2010.

Cadence entered into a licensing agreement with a European subsidiary of Bristol-Myers Squibb. Cadence will make a $15 million payment - tied to U.S. approval of the drug. - to the subsidiary.

Schroeder said the national launch is being supported by 150 sales personnel and 13 field medical-science liaisons.

"With roughly 50 million surgeries performed in the U.S. each year, the potential market is significant," said Schroeder, who declined to make revenue estimates for this year.

One analyst places the current market for intravenous painkillers in the U.S. at around $500 million. Charles Duncan of JMP Securities LLC said Cadence, which has no competition for injectable acetaminophen, is making good progress as evidenced by the news that 10 hospitals have begun stocking Ofirmev. Pricing has been set at $10.75 per vial, but Duncan expects the company will discount the price for large purchasers.

"Their launch plan is focused on 900 key institutions, which represent about 50 percent of the market opportunity," said Duncan, whose San Francisco-based company provides equity research, institutional brokerage and investment banking services to public and private growth companies and their investors.

Drumming Up Business

The Cadence sales calls will be to surgeons, anesthesiologists and hospital pharmacy executives in order to build business at the nations hospitals, according to Schroeder.

Another factor that could possibly boost sales of the drug is news from the FDA that its recently announced restrictions on acetaminophen, including a black box warning, will not apply to Ofirmev, said Duncan.

The only nonopioid IV analgesics currently available in the U.S. are the nonsteroidal anti-inflammatory drug Toradol, a generic form of which is also available in the nation from a number of manufacturers, and Caldolor (ibuprofen), which was approved by the FDA in 2009.

Severe pain management in hospitals utilizes various approaches, the most common being the use of morphine, which "has a long laundry list" of side effects

such as nausea, diarrhea and respiratory depression, said Schroeder. Injectable ibuprofen is particularly good for inflammation due to sprains and muscle tears, said Schroeder.

"Our therapeutic is addressing incisional pain following surgery," said Schroeder. "When combined with a stronger drug, it allows for much better pain relief."

Reduced Reliance on Morphine

According to Schroeder, Cadences medical advisers say that with the use of Ofirmev, hospitals can cut back morphine use on adult and pediatric patients from one-third to three-fourths of a dosage.

He said the safety and efficacy of IV acetaminophen has been well established in numerous clinical trials and it has become the standard of IV pain management since being introduced in 2002 in Europe.

Despite major improvements in surgical techniques and the introduction of various drugs, the overall treatment of postoperative pain has not substantially improved over the past 20 years, said Schroeder.

According to the industry research group Datamonitor, a provider of global business information, up to 75 percent of patients report inadequate pain relief following surgery.

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