



Alkermes Regains Full Commercialization Rights to VIVITROL(R) in US

December 1, 2008

- Will Continue to Market VIVITROL in US and Focus on Clinical Development for Opioid Dependence -

- Updates Financial Expectations to Reflect Independent Commercialization of VIVITROL -

CAMBRIDGE, Mass., Dec 01, 2008 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced that it has regained from Cephalon, Inc. full commercialization rights to VIVITROL(R) (naltrexone for extended-release injectable suspension) in the U.S. following a portfolio review by Cephalon. The collaboration between the two companies will terminate effective December 1, 2008. VIVITROL, the first and only long-acting injectable medication commercially available for the treatment of alcohol dependence, is also being developed by Alkermes as a potential treatment for opioid dependence.

Cephalon will pay Alkermes \$11 million to cover its share of the estimated losses on VIVITROL for the next 12 months and Alkermes will pay Cephalon \$16 million to purchase manufacturing equipment for the product. Alkermes will recognize remaining milestone revenue and deferred revenue of approximately \$120 million related to its previous agreements with Cephalon as net collaborative profit in the third quarter of fiscal 2009. Further terms of the agreement were not disclosed.

"We continue to believe in the potential for VIVITROL to help patients struggling with alcohol dependence and are working to increase sales through a focus on high-impact activities with patients and physicians. We will, however, carefully manage our investments in VIVITROL to align with the sales trajectory for the product," stated David Broecker, CEO of Alkermes. "Overall, we are very pleased to have worked with Cephalon. The collaboration funded key market development initiatives for VIVITROL. In addition, over the next 12 months, Cephalon will partially fund our commercial activities, enabling Alkermes to dedicate resources we believe will result in increased VIVITROL sales."

"We have a lot of opportunities on our plate and cannot give VIVITROL the focus it deserves," said Frank Baldino, Jr., Ph.D., chairman and CEO of Cephalon. "Alkermes will be able to provide the necessary attention to this important product and we will work closely with them during this transition period to ensure that patients and physicians continue to have access to this important medication."

Following the termination of the collaboration, Alkermes will continue to market VIVITROL in the U.S. with a commercial team of approximately 70 individuals. The team will be fully staffed to manage sales, field and reimbursement support for VIVITROL. Commercial efforts for VIVITROL over the next 12 months will focus on improving three key areas, which include: increasing utilization among physicians currently prescribing VIVITROL; streamlining product access and reimbursement; and enhancing continuity of care for patients transitioning between treatment settings.

During a transition period ending May 31, 2009, Cephalon will continue to work with Alkermes to ensure that patients and physicians have access to VIVITROL and that commercial activities are smoothly transitioned between the two companies.

Updated Financial Expectations for Fiscal 2009

Alkermes today updated its financial expectations for the fiscal year ending March 31, 2009, to reflect revenues and expenses related to the independent commercialization of VIVITROL in the U.S. These financial expectations include the impact of share-based compensation expense. Certain statements set forth below constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For information with respect to factors that could cause Alkermes' actual results to differ materially from its expectations, please see the risk factors provided at the end of this press release and in Alkermes' Form 10-K for the fiscal year ended March 31, 2008, as filed with the U.S. Securities and Exchange Commission.

- **Product Sales:** Effective December 1, 2008, Alkermes will record product sales related to VIVITROL. The company expects gross sales of VIVITROL to remain in the range of \$19 to \$24 million. For fiscal 2009, Alkermes expects to record net sales from VIVITROL effective December 1, 2008, in the range of \$5 to \$8 million.
- **Manufacturing Revenues:** The company is adjusting its expectation for manufacturing revenues to a range of \$111 to \$122 million, revised from an expectation of \$116 to \$129 million. The company expects manufacturing revenues related to RISPERDAL(R) CONSTA(R) to remain in the range of \$109 to \$118 million. For fiscal 2009, the company expects manufacturing revenues related to VIVITROL to range from \$2 to \$4 million, revised from an expectation of \$7 to \$11 million. As of December 1, 2008, the company will no longer sell VIVITROL to Cephalon.
- **Royalty Revenues:** The company expects royalty revenues from RISPERDAL CONSTA to remain in the range of \$34 to \$36 million.
- **Research and Development (R&D) Revenues:** The company expects R&D revenues to remain in the range of \$45 to \$50 million.
- **Net Collaborative Profit:** The company is adjusting its expectation for net collaborative profit to a range of \$125 to \$130 million, revised from an expectation of \$5 to \$10 million. This revised expectation includes the recognition of approximately \$3 to \$5 million of the \$11 million of deferred revenue received from Cephalon to cover its share of the expected net losses on VIVITROL over the next 12 months.
- **Total Revenues:** The company is adjusting its expectation for total revenues for fiscal 2009 to a range of \$320 to \$346 million.

million, revised from an expectation of \$200 to \$225 million.

- Cost of Goods Manufactured: The company is adjusting its expectation for cost of goods manufactured to a range of \$40 to \$45 million, revised from an expectation of \$40 to \$50 million.
- R&D Expenses: The company expects R&D expenses to remain in the range of \$92 to \$97 million.
- Selling, General and Administrative Expenses (SG&A): The company is adjusting its expectation for SG&A expenses to a range of \$53 to \$58 million, revised from an expectation of \$48 to \$53 million.
- Operating Income: The company is adjusting its expectation for operating income to a range of \$135 to \$146 million, revised from an expectation of \$20 to \$25 million.
- Net Interest Income/Expense: The company expects net interest income/expense to remain unchanged at \$0.
- Income Taxes: The company continues to expect income taxes of \$1 million.
- GAAP Net Income: The company is adjusting its expectation for GAAP net income to a range of \$134 to \$145 million or a basic earnings per share in the range of \$1.41 to \$1.53, revised from an expectation of \$19 to \$24 million or a basic earnings per share in the range of \$0.20 to \$0.25. These per share calculations are based on the current share count of 95 million shares outstanding.
- Cash Flow from Operations: The company expects cash flow from operations to remain in the range of \$50 to \$55 million.
- SFAS 123R: The company expects share-based compensation expense to remain in the range of \$15 to \$20 million.

About Alcohol and Opioid Dependence

Alcohol dependence is a chronic disease with underlying neurological and genetic factors.(1) Approximately 18 million people in the U.S. are dependent on or abuse alcohol; half are considered to be alcohol dependent.(2) Worldwide, approximately 76 million people have diagnosable alcohol use disorders.(3) Psychosocial support, such as counseling or group therapy, is the traditional approach for treating alcohol dependence; however, experts in the field increasingly recommend and support a treatment approach that includes a combination of medication and psychosocial support.(4,5) Alcohol abuse and dependency are an economic burden to society that costs approximately \$185 billion annually in the U.S.(6)

In addition to the use of heroin, an illegal opioid, opioid abuse and addiction includes the non-medical use of approved opioid analgesics, including prescription pain relievers, and represents a growing public health problem in the U.S. According to the 2006 U.S. National Survey on Drug Use and Health, an estimated 1.9 million people aged 12 or older were dependent on or abused pain relievers or heroin.(7) In 2005, the European Monitoring Centre for Drugs and Drug Addiction estimated the prevalence of problem opioid use in Europe to be in the range of 1.3 to 1.7 million people.(8) Researchers have found that the cost of prescription opioid abuse in the U.S. in 2001 was \$9.2 billion.(9)

About VIVITROL

VIVITROL is the first and only once-monthly, extended-release injectable medication for the treatment of alcohol dependence and was approved by the U.S. Food and Drug Administration in April 2006. The proprietary Medisorb(R) drug delivery technology in VIVITROL enables the medication to be gradually released into the body at a controlled rate over a one-month time period.

Important Safety Information

Naltrexone has the capacity to cause hepatocellular injury when given in excessive doses. Naltrexone is contraindicated in acute hepatitis or liver failure, and its use in patients with active liver disease must be carefully considered in light of its hepatotoxic effects. The margin of separation between the apparently safe dose of naltrexone and the dose causing hepatic injury appears to be only five-fold or less. VIVITROL does not appear to be a hepatotoxin at the recommended doses. Patients should be warned of the risk of hepatic injury and advised to seek medical attention if they experience symptoms of acute hepatitis. Use of VIVITROL should be discontinued in the event of symptoms and/or signs of acute hepatitis.

VIVITROL is contraindicated in patients receiving or dependent on opioids, in acute opioid withdrawal, and in those who have failed the naloxone challenge test or have a positive urine screen for opioids; and in those with previous hypersensitivity to naltrexone, PLG, carboxymethylcellulose, or any other components of the diluent.

Patients must be opioid free for a minimum of 7-10 days before treatment. Attempts to overcome opioid blockade due to VIVITROL may result in fatal overdose. In prior opioid users, use of opioids after discontinuing VIVITROL may result in fatal overdose because patients may be more sensitive to lower doses of opioids. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by appropriately trained personnel in a setting equipped for cardiopulmonary resuscitation.

Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia. Injection site reactions not improving may require prompt medical attention. Alcohol-dependent patients, including those taking VIVITROL, should be monitored for the development of depression or suicidal thinking. Caution is recommended in administering VIVITROL to patients with moderate to severe renal impairment.

The most common adverse events associated with VIVITROL in clinical trials were nausea, vomiting, headache, dizziness, asthenic conditions and injection site reactions. For full prescribing information, please visit www.vivitrol.com or call 1-800-896-5855.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL(R) for alcohol dependence and manufactures RISPERDAL(R) CONSTA(R) for schizophrenia. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to: statements concerning future business and operating results and profitability; the therapeutic value of the company's products to patients; and the successful continuation of development activities for proprietary and partnered programs. Although the

company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and the company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: we may be unable to develop the selling and marketing capabilities, and/or infrastructure, necessary to successfully commercialize VIVITROL; the outcome of clinical and preclinical work the company is pursuing, both on its own and with partners; decisions by the FDA or foreign regulatory authorities regarding the company's products; potential changes in cost, scope and duration of clinical trials; and the occurrence of unintended side effects, adverse reactions or incidents of misuse related to the company's products and product candidates that could cause the FDA or other foreign regulatory authorities to require post approval studies, new labeling, or removal of such products from the market. For further information with respect to factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports the company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and the company disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

VIVITROL(R) is a registered trademark of Cephalon, Inc. RISPERDAL(R) CONSTA(R) is a registered trademark of Janssen-Cilag group of companies.

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