



## Alkermes Highlights Advancing Proprietary Product Portfolio at R&D Day

April 7, 2009

### Presents Positive Clinical Data for ALKS 33, An Oral Small Molecule Drug Candidate for Addiction and Other Nervous System Disorders

CAMBRIDGE, Mass., Apr 07, 2009 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today will present an overview of its proprietary pipeline at its Research and Development (R&D) Day meeting for analysts and investors in Cambridge, Massachusetts. For the first time, the company will detail its advancing portfolio of novel small molecules targeting opioid receptor pathways, which are implicated in a broad range of nervous system disorders. During the meeting, the company will also describe the scientific rationale and commercial opportunities for these product candidates and present positive topline data from a phase 1 study of ALKS 33, an opioid modulator with potential benefits in addiction and other nervous system disorders.

"We are pleased to report the progress we have made advancing our proprietary pipeline, a key driver for the company's long-term growth. The development of this proprietary portfolio is a natural evolution of our business, built on our strong foundation of two commercial products and proven science," commented David Broecker, president and CEO of Alkermes. "We are now well positioned to leverage our scientific and market insights to develop novel drug candidates in growing markets, such as addiction and pain."

"Our proprietary library of small molecule opioid modulators enables us to leverage new therapeutic understanding about opioid receptor pathways to develop novel medications for a broad range of diseases," stated Elliot Ehrich, chief medical officer at Alkermes. "The positive data presented today are encouraging and suggest that our biological and chemical insights can lead to the discovery and development of multiple new product candidates."

### R&D Highlights

Alkermes today will provide additional details on the following proprietary product programs:

- **Positive phase 1 data for ALKS 33 for the treatment of alcohol dependence and other reward disorders:** Alkermes will present topline data from a phase 1 study of ALKS 33, an oral opioid modulator for the treatment of alcohol dependence and other reward disorders. In the randomized, double-blind, placebo-controlled study involving 16 healthy volunteers, ALKS 33 demonstrated rapid oral absorption, high plasma concentrations and duration of action that supports once daily dosing. The study results are consistent with previous findings that ALKS 33 is not metabolized by the liver, a unique advantage over existing oral therapies for addiction. ALKS 33 was generally well tolerated during the study. Based on these preliminary results, Alkermes expects to initiate a phase 2 study of ALKS 33 in the second half of calendar 2009.
- **Positive pharmacokinetic data for ALKS 29 for the treatment of alcohol dependence:** Alkermes will present positive topline data from a clinical study of a proprietary, extended-release formulation of baclofen, a component of ALKS 29, an oral drug candidate for the treatment of alcohol dependence. ALKS 29 is a co-formulation of baclofen and ALKS 33. In the open-label, crossover study involving 16 healthy volunteers, Alkermes' baclofen-only formulation demonstrated a favorable pharmacokinetic profile compared to the currently marketed formulation and was generally well tolerated. Research suggests that baclofen, a FDA-approved muscle relaxant and antispasmodic therapeutic, may attenuate the compulsive component of alcohol dependence.<sup>1,2</sup> As a combination therapy that may address both the compulsive and impulsive components of alcoholism, ALKS 29 is designed to offer a new approach for the treatment of alcohol dependence.
- **Promising preclinical data for ALKS 36, a combination therapy for the treatment of pain:** Alkermes will present preclinical data for RDC-1036, a component of ALKS 36, an oral drug candidate for the treatment of pain. ALKS 36 is a co-formulation of an opioid analgesic and RDC-1036, an oral, peripherally-acting opioid antagonist. In preclinical studies, RDC-1036 demonstrated the potential to reverse opioid agonist effects on gastrointestinal motility. Preclinical data also showed that oral administration of RDC-1036 had significantly greater efficacy at a lower dose and for an extended period of time compared to an active comparator, methylnaltrexone. A pain medication that does not inhibit gastrointestinal motility, such as ALKS 36, may provide a unique advantage over current therapies. Alkermes expects to initiate a phase 1 study of RDC-1036 in the second half of calendar 2009.

### Webcast

A live webcast of the company's R&D Day will begin today at 8:30 a.m. EDT and will run until approximately 10:30 a.m. EDT. The webcast will be available on the investor relations section of the company's website at [www.alkermes.com](http://www.alkermes.com). To ensure a timely connection to the webcast, it is recommended that users register 15 minutes prior to the scheduled webcast. This webcast will be archived for 14 days.

### About Opioid Receptor Pathways

Opioid receptor pathways have biological activity throughout the body including the brain, gastrointestinal system, immune system and cardiovascular system. Consequently, opioid receptor pathways play a key role in a broad range of nervous system disorders such as pain, addiction, psychiatric disorders, gastrointestinal disorders and immune disorders. Opioid modulators can act as agonists, antagonists or partial agonists at opioid receptors throughout the body. Emerging biological research and new medicinal chemistry insights now allow for the development of novel opioid modulators with the potential to show enhanced activity at opioid receptor sites and could ultimately lead to improved therapeutic options.

## 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<sup>(R)</sup> for alcohol dependence and manufactures RISPERDAL<sup>(R)</sup> CONSTA<sup>(R)</sup> 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 the potential therapeutic value of Alkermes' proprietary molecules targeting opioid receptors and Alkermes' plans to continue development of such proprietary molecules. 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: whether the clinical trials discussed in this release will be completed on time or at all; potential changes in cost, scope and duration of the clinical trials; whether the company's product candidates will demonstrate sufficient efficacy and safety; and decisions by the FDA regarding such product candidates. 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<sup>(R)</sup> is a registered trademark of Alkermes, Inc. RISPERDAL<sup>(R)</sup> CONSTA<sup>(R)</sup> is a registered trademark of Janssen-Cilag group of companies.

<sup>1</sup> Addolorato G, Caputo F, Capristo E, Colombo G, Gessa GL, Gasbarrini G. 2000. Ability of baclofen in reducing alcohol craving and intake: II--Preliminary clinical evidence. *Alcohol Clin Exp Res* 24: 67-71.

<sup>2</sup> Addolorato G, Caputo F, Capristo E, Janiri L, Bernardi M, Agabio R, Colombo G, Gessa GL, Gasbarrini G. 2002. Rapid suppression of alcohol withdrawal syndrome by baclofen. *Am J Med* 112: 226-229.

SOURCE: Alkermes, Inc.

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