



News Release

BDSI Anticipates Announcing Phase III BEMA Fentanyl Efficacy Data in April Treatment for Breakthrough Cancer pain

MORRISVILLE, N.C.--(BUSINESS WIRE)—February 8, 2007—BioDelivery Sciences International, Inc. (Nasdaq:BDSI) plans to report Phase III data in April, regarding the efficacy of BEMA Fentanyl in the treatment of breakthrough pain in cancer patients.

“We are finishing patient recruitment for this pivotal trial,” said Dr. Andrew Finn, BDSI’s Executive Director of Clinical Development and Regulatory Affairs. He added “Recruitment has been challenging given the terminal nature of most of these patients and the limited number that ultimately meet all of the entry criteria for our study design. We look forward to completing enrollment over the next several weeks, analyzing the data and reporting our efficacy results in April.”

“We are encouraged with the progress we are making in our Phase III BEMA Fentanyl program for breakthrough cancer pain. We plan to give additional guidance on the timing of our NDA submission when we have our results from this efficacy trial,” said BDSI’s President and CEO, Dr. Mark Sirgo.. We continue to focus the use of our financial and other resources into moving this program forward as we envision our BEMA Fentanyl product taking its place as the next available product in the fast-dissolving fentanyl breakthrough cancer pain market place, following Cephalon’s newly launched Fentora. We are taking every step to assure the quality of this program. Our estimated minimum peak sales for BEMA Fentanyl for the indication of breakthrough cancer pain are \$250 million.”

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. is a specialty pharmaceutical company that is focused on developing innovative products to treat acute conditions such as pain. The company utilizes its owned and licensed patented drug delivery technologies to develop, partner and commercialize, clinically-significant new products using proven therapeutics. BDSI’s pain franchise currently consists of two products in development utilizing the company’s patented BEMA™ oral adhesive disc technology: BEMA™ Fentanyl, a treatment for “breakthrough” cancer pain, and BEMA™ LA, a second analgesic with a target indication of the treatment of moderate to severe pain. The company is also working with both its BEMA™ technology and its patented Bioral® nanocochleate technology on products targeted at other acute treatment opportunities such as insomnia, nausea and vomiting, and infections. The company’s headquarters are located in Morrisville, North Carolina and its principal laboratory is located in Newark, New Jersey. For more information please visit www.bdsinternational.com.

Forward-Looking Statements

Note: Except for the historical information contained herein, this press release contains, among other things, certain forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Such statement may include, without limitation,



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statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results, including, without limitation, actual sales results, if any, the application of funds, or the timing for completion and results of scheduled or additional clinical trials and FDA review of the Company's formulations and products, may differ from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). Peak sales and market size estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such sales levels will be achieved, if at all.

Contact:

Investor Relations Group

Investor Relations:

James Carbonara 212-825-3210

or

Public Relations:

Janet Vasquez or Bill Douglass, 212-825-3210