



**BioDelivery Sciences and Meda Announce
FDA Approval of ONSOLIS**

BDSI to Receive \$27 Million in Milestone Payments

Fourth Quarter Launch by Commercial Partner Meda is Anticipated

First Buccal Soluble Film Delivery System for the Treatment of Breakthrough Cancer Pain

RALEIGH, N.C., July 16, 2009 – [BioDelivery Sciences International, Inc.](#) (Nasdaq: BDSI) and [Meda AB](#) today announced approval from the U.S. Food and Drug Administration (FDA) to market ONSOLIS™ (fentanyl buccal soluble film), formerly referred to as BEMA™ Fentanyl, for the management of breakthrough pain (BTP) in patients with cancer, eighteen years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. ONSOLIS is the first product to utilize the company's proprietary BioErodible MucoAdhesive (BEMA) drug delivery technology, which consists of a small, dissolvable, polymer film for application to the buccal mucosa (inner lining of the cheek).

"The approval of ONSOLIS is a landmark and transformational event for BDSI and represents the culmination of an extraordinary and focused effort by a determined group of BDSI and Meda employees," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BioDelivery Sciences. "All of us at BDSI, along with our partner Meda, are very pleased to provide healthcare practitioners and their patients suffering from breakthrough cancer pain with a new treatment option for this serious and debilitating condition."

"Importantly, with the approval of ONSOLIS, we have validated the utility of the BEMA drug delivery technology and demonstrated our ability to move a product through clinical development and the regulatory requirements set by FDA," said Dr. Andrew Finn, Executive Vice President of Product Development. "We now look forward to replicating our performance and regulatory achievements as we progress our pipeline."

"Having worked on the clinical development of ONSOLIS, it is exciting to see it reach approval," said Dr. Richard L. Rauck, Executive Director of the Carolinas Pain Institute and for the Center for Clinical Research, a site that participated in the Phase 3 trials for ONSOLIS. "Many patients with cancer suffer from these sharp spikes in pain referred to as breakthrough pain. These patients can benefit from a product like ONSOLIS with its onset of action and oral tolerability profile. We look forward to having this important option available for our patients with cancer breakthrough pain."

ONSOLIS is anticipated to be available in the fourth quarter of 2009 and will be commercialized in the U.S. by Meda Pharmaceuticals, the U.S. subsidiary of Meda AB. Meda is the company's commercialization partner for the product worldwide, with the exception of Taiwan and South



Korea, the rights to which remain with BDSI. “We are very excited to launch ONSOLIS in the U.S. and make this product available to patients and healthcare providers,” said Anders Lonner, Chief Executive Officer of Meda AB. “The introduction of ONSOLIS has high priority for us, and we are well positioned to be successful.”

Under the terms of its commercialization agreement with Meda, BioDelivery Sciences will receive an aggregate of approximately \$27 million in milestone payments. The first is based upon FDA approval of ONSOLIS which is in the amount of approximately \$12 million. Meda had already advanced the company \$3 million in January 2009 against the \$15 million milestone payment. A second payment of \$15 million will be received following the manufacture of launch stocks of ONSOLIS, a target the company has also achieved. In addition, BDSI will receive a double-digit royalty on net sales as well as the potential for up to another \$30 million in milestone payments upon the achievement of certain sales thresholds.

“We are also announcing launch of the FOCUS™ (Full Ongoing Commitment to User Safety) Program for ONSOLIS, the first opioid Risk Management and Evaluation Strategy (REMS),” said Dr. David Wright, Director of Regulatory Affairs at BDSI. “The goal of the FOCUS Program for ONSOLIS is to mitigate the risk of ONSOLIS overdose, abuse, addiction, and serious complications due to medication errors. The program was created in accordance with the FDA’s requirements to help ensure that the benefits outweigh the risks of ONSOLIS. The program will facilitate appropriate use of ONSOLIS and provide healthcare practitioners, patients, and caregivers support through training and education.”

BDSI will hold a webcast to discuss the approval of ONSOLIS on Friday, July 17, 2009 at 10:00 a.m. Participants are invited to access the live webcast or obtain a dial-in number from the company’s website at www.biodeliverysciences.com.

About Breakthrough Pain

Breakthrough Pain (BTP) is a common, debilitating feature of chronic pain, particularly in patients with cancer. It is a transitory, severe, or excruciating pain flare-up that “breaks through” the relief provided by around-the-clock analgesics. Unlike persistent cancer pain, BTP is generally rapid in onset (within three minutes) and lasts up to two hours. Patients with cancer may experience between two and seven episodes of BTP a day. A large multicenter survey conducted by pain specialists in twenty-four countries found that 65% of 1,095 cancer patients had BTP¹. It is estimated that over a half-million people in the U.S. with cancer suffer from breakthrough pain, however, only about twenty thousand receive a treatment approved for the condition.

¹ Caraceni A, Martini C, Zecca E, et al. Breakthrough pain characteristics and syndromes in patients with cancer pain. An international survey. *Palliative Medicine*. 2004;18:177-183.



About ONSOLIS

ONSOLIS consists of a small, dissolvable, polymer film, formulated with the opioid narcotic fentanyl for application to the buccal mucosa (inner lining of the cheek). Fentanyl belongs to the group of medicines called narcotic analgesics, which are used to relieve pain. ONSOLIS was evaluated in over 300 patients with over 90,000 doses administered in clinical trials. ONSOLIS adheres to the buccal mucosa in seconds, starts to dissolve in minutes and delivers fentanyl across the mucosa for relief of BTP in opioid tolerant patients with cancer.

IMPORTANT SAFETY INFORMATION

ONSOLIS is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

ONSOLIS is contraindicated in opioid non-tolerant patients; acute or postoperative pain, including headache/migraine, dental pain, or use in the emergency room; and patients with intolerance or hypersensitivity to fentanyl, ONSOLIS, or its components. Life-threatening respiratory depression could occur in patients not taking chronic opiates.

ONSOLIS contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics.

Clinically significant respiratory and CNS depression can occur; patients should be monitored accordingly. ONSOLIS films contain medicine in an amount that can be fatal to a child. Keep out of the reach of children and dispose of unneeded films properly. Use with other CNS depressants or CYP3A4 inhibitors may increase depressant effects including hypoventilation (which may lead to potentially fatal respiratory depression), hypotension, and profound sedation; dosage adjustments may be warranted. ONSOLIS may impair ability for the performance of potentially dangerous tasks (e.g., driving a car or operating machinery). ONSOLIS should be titrated cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to hypoventilation. ONSOLIS should be administered with extreme caution in patients susceptible to intracranial effects of CO₂ retention.

Substantial differences exist in the pharmacokinetic profile of ONSOLIS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl. As a result of these differences, the substitution of ONSOLIS for any other fentanyl product may result in fatal overdose.

The most common adverse reactions (frequency $\geq 10\%$) seen in ONSOLIS clinical trials were: nausea, vomiting, dizziness, dehydration, dyspnea, and somnolence.



Safety and efficacy below age 18 years have not been established. ONSOLIS should be administered with caution to patients with renal or hepatic impairment.

ONSOLIS is available only through a restricted distribution program called the FOCUS Program and requires prescriber, pharmacy, and patient enrollment.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ:BDSI) is a specialty pharmaceutical company that is focused on developing innovative products to address growing market opportunities, including conditions such as pain. The company utilizes its owned and licensed patented drug delivery technologies to develop, partner, and commercialize new products using proven therapeutics. BDSI's pain franchise utilizes the Company's patented BEMA buccal soluble film technology and currently consists of: ONSOLIS (fentanyl buccal soluble film) a treatment for "breakthrough" pain in opioid tolerant patients with cancer, and BEMA Buprenorphine, a second analgesic in development with at least one potential target indication for the treatment of moderate to severe pain. The company is working with its BEMA and Bioral technologies on products targeted at conditions common to oncology and surgical patients such as pain and infections. The company headquarters is located in Raleigh, North Carolina, and its principal laboratory is located in Newark, New Jersey. For more information please visit www.biodeliverysciences.com.

About Meda AB

MEDA AB (publ) is a leading international specialty pharma company. The company specializes in marketing and pharmaceutical development in late clinical stage. Acquisitions and long-term partnerships drive the company's strategy. Meda is represented by its own organizations in about 40 countries. Meda's products are sold in 120 countries worldwide. The Meda share is listed under Large Cap on the Nasdaq OMX Nordic Stock Exchange in Stockholm. Find out more, visit www.meda.se.

Cautionary Note on Forward-Looking Statements

This press release and the statements of representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, 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, those relating to the timing for completion, and results of, scheduled or additional clinical trials and the FDA's or other regulatory review and/or approval and commercial launch and sales results (if any) of the Company's formulations and products and regulatory filings related to the same, and receipt by the Company of milestone payments, may differ significantly 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).

Contacts:

Investors:

Al Medwar
Vice President, Marketing & Corporate Development
BioDelivery Sciences International
amedwar@bdsinternational.com
Tel (919) 582-0198

Media:

Laura Colontrelle
Investors Relations Group
lcolontrelle@investorrelationsgroup.com
Tel (212) 825-3210