



BioDelivery Sciences to Receive \$10 Million Milestone Payment from Endo Pharmaceuticals Inc. in Conjunction with Acceptance of NDA for BELBUCA™ (buprenorphine HCl) Buccal Film for Chronic Pain

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RALEIGH, N.C., Feb. 23, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) and Endo Pharmaceuticals Inc., a subsidiary of Endo International plc (NASDAQ: ENDP) (TSX: ENL) announced that the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for BELBUCA™ (buprenorphine HCl) buccal film under development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate.

Acceptance of the NDA for BELBUCA has also triggered a \$10 million milestone payment to BDSI from Endo Pharmaceuticals per the licensing agreement. BDSI will be eligible for an additional milestone payment of up to \$50 million upon approval of the NDA. FDA has indicated a standard review designation for the NDA, and therefore, the action date is expected 10 months from the NDA submission (October 2015), which is standard for a 505(b)(2) application.

Additionally, the FDA recently accepted BELBUCA as the proprietary name for buprenorphine HCl buccal film.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ:BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs.

BDSI's development strategy focuses on utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's particular area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence.

BDSI's headquarters is located in Raleigh, North Carolina.

For more information visit www.bdsi.com.

BDSI can now be followed on Facebook ([Facebook.com/BioDeliverySI](https://www.facebook.com/BioDeliverySI)) and Twitter ([Twitter.com/BioDeliverySI](https://twitter.com/BioDeliverySI))

Cautionary Note on Forward-Looking Statements

This press release, the presentation described herein, and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, the results of the FDA's review of BELBUCA) 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," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" 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, the results of the commercial launch of BUNAVAIL and the Company's clinical trials for, and FDA review of, the Company's products in development) 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). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

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