# BioDelivery Sciences Provides an Update of Anticipated 2014 Milestones

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BEMA Buprenorphine Phase 3 opioid naive study database lock imminent; triggers $10M milestone payment from Endo Pharmaceuticals

BUNAVAIL PDUFA date June 7, 2014 - launch anticipated late third quarter

Clonidine Topical Gel Phase 3 program enrollment anticipated to begin first quarter

RALEIGH, N.C., Jan. 10, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced updates to the company's anticipated 2014 milestones for its product portfolio, including the imminent database lock for the Phase 3 clinical study of BEMA Buprenorphine for the treatment of moderate to severe chronic pain in opioid naive subjects, with topline data expected late January or early February.

(Logo: http://photos.prnewswire.com/prnh/20110217/CL49801LOGO)

The database for the BEMA Buprenorphine Phase 3 clinical study in opioid naive patients with chronic pain is expected to be locked shortly by BDSI's partner, Endo Pharmaceuticals. This event is expected to trigger a $10 million milestone payment from Endo per the licensing and development agreement signed in January 2012.

In addition, based on recruitment rates in a second Phase 3 clinical study of BEMA Buprenorphine in an opioid experienced patient group, the database for this trial is anticipated to be locked by mid-2014, with results following shortly thereafter.

BDSI also continues to develop the commercialization plans for the launch of BUNAVAIL for the maintenance treatment of opioid dependence. As previously reported, the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014 for BUNAVAIL, which if approved is anticipated to launch late third quarter 2014. BDSI estimates annual peak U.S. sales of BUNAVAIL of up to $250 million.

"This year will potentially provide two of the most significant value driving milestones that our company has ever experienced," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We look forward to the results of our two Phase 3 studies for BEMA Buprenorphine for the treatment of chronic pain, which could potentially lead to an NDA submission late this year. We are also extremely excited about the prospects of an NDA approval for BUNAVAIL this coming June with a launch shortly thereafter. Finally, initiating enrollment in our Phase 3 program for Clonidine Topical Gel for the treatment of painful diabetic neuropathy this quarter gives us our third exciting potential entry into the pain space."

Dr. Sirgo concluded, "Overall, this coming year will be an exceptionally exciting one for BDSI, and we look forward to the forthcoming milestones, which will be instrumental in enhancing the future value of the company."

**Anticipated 2014 Milestones**

BDSI expects to achieve the following key milestones in the upcoming year:

- *BEMA Buprenorphine Phase 3 data and additional milestone payments from Endo.* In addition to the aforementioned opioid naive study database lock and subsequent milestone payment, BDSI expects to receive additional milestone payments upon the database lock of the opioid experienced study and the NDA filing. BDSI anticipates the second database lock to occur in mid-year, and the potential filing of the NDA in late 2014.
- *Ongoing review and subsequent approval of the NDA for BUNAVAIL.* BDSI expects ongoing dialogue with the FDA in the review of the NDA for BUNAVAIL for the treatment of opioid dependence. The review of the BUNAVAIL NDA is expected to be completed by June 7, 2014.
- *Commercialization of BUNAVAIL in the U.S.* BDSI continues to evaluate its options for the commercialization of BUNAVAIL, including both partnering options as well as potentially leading efforts internally through the use of contract resources.
- *Initiation of Phase 3 study for Clonidine Topical Gel*. BDSI plans to initiate a Phase 3 study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy in the first quarter of 2014. This study could complete enrollment in late 2014.
- *Re-launch of ONSOLIS*. BDSI continues to work closely with its commercial partner, Meda Pharmaceuticals, on plans for the reintroduction of ONSOLIS into the U.S. market for the management of breakthrough pain in opioid tolerant patients with cancer. This is anticipated to take place in the second half of 2014.

**About BioDelivery Sciences International**

BioDelivery Sciences International (NASDAQ: BDSI) is a specialty pharmaceutical company that is leveraging its novel and proprietary patented drug delivery technologies to develop and commercialize, either on its own or in partnerships with third parties, new applications of proven therapeutics. BDSI is focusing on developing products to meet unmet patient needs in the areas of pain management and addiction.

BDSI's pain franchise currently consists of three products. ONSOLIS (fentanyl buccal soluble film) is approved in the U.S., Canada, and the E.U. (where it is marketed as BREAKYL), for the management of breakthrough pain in opioid tolerant, adult patients with cancer. The commercial rights are

licensed to Meda for all territories worldwide except for Taiwan(licensed to TTY Biopharm) and South Korea (licensed to Kunwha Pharmaceutical Co.). BEMA Buprenorphine, which is licensed on a worldwide basis to Endo Pharmaceuticals, is currently in Phase 3 development for the treatment of moderate to severe chronic pain. Clonidine Topical Gel is expected to enter Phase 3 trials in 2014 for the treatment of painful diabetic neuropathy.

BUNAVAIL, a BEMA formulation of buprenorphine and naloxone, is currently under review by FDA for the maintenance treatment of opioid dependence.

BDSI's headquarters is located in Raleigh, North Carolina. For more information, visit www.bdsi.com.



**Cautionary Note on Forward-Looking Statements**

This press release and any 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," "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 Company's 2014 initiatives described herein) 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 events or otherwise, except as required by applicable law.

Readers are cautioned that 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 estimates are accurate or that such sales levels will be achieved, if at all.

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