BioDelivery Sciences Provides Business Review and Update in Conjunction with Filing of First Quarter 2014 Financials

May 8, 2014

BUNAVAIL PDUFA date June 7, 2014; Pre-launch activities underway to support an anticipated late Q3 2014 launch

BEMA Buprenorphine Phase 3 clinical trial results in opioid experienced patients with chronic pain expected early July 2014

Clonidine Topical Gel for Painful Diabetic Neuropathy - first Phase 3 study 50% enrolled; Interim analysis expected in Q3 2014

$60 Million equity financing led by Federated Kaufmann in February solidified balance sheet

Endo second data base lock $10 million milestone payment anticipated in June

RALEIGH, N.C., May 8, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 with the U.S. Securities and Exchange Commission and, in connection therewith, is providing a review of BDSI's recent achievements and an update on business operations and upcoming milestones for 2014.

BDSI is expecting to hear from the U.S. Food and Drug Administration (FDA) on its New Drug Application (NDA) for BUNAVAIL (buprenorphine and naloxone buccal film) on or about June 7, 2014. Assuming BUNAVAIL is approved, BDSI intends to launch BUNAVAIL, a proposed maintenance treatment for opioid dependence, in the latter part of the third quarter of 2014. In March, BDSI announced that it entered into an agreement with Quintiles to provide a range of services to support the anticipated launch including the establishment of a sales team. Separately, BDSI entered into an agreement with Ashfield Market Access, led by former GSK veteran Steve Stefano, to provide managed markets and trade support for BUNAVAIL.

As recently reported, data from clinical studies of BUNAVAIL were presented at the American Society of Addiction Medicine (ASAM) 45th Annual Medical-Scientific Conference, April 10-13, 2014 in Orlando, Florida. Four posters were presented highlighting data from the clinical development program, which included the pivotal bioequivalence study of BUNAVAIL compared to Suboxone tablets. Also highlighted was a safety study conducted in 249 subjects undergoing maintenance treatment for opioid dependence with Suboxone film or tablets who were converted to BUNAVAIL for 12 weeks. The posters are accessible at www.bdsi.com.

On January 23, 2014, Endo Pharmaceuticals and BDSI announced positive top-line results from its pivotal Phase 3 efficacy study of BEMA Buprenorphine in opioid "naïve" subjects, and in conjunction with database lock, BDSI received a milestone payment from Endo in the amount of $10 million. BEMA Buprenorphine is being developed for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy for an extended period of time. Results of the second Phase 3 study, which was conducted in opioid "experienced" patients, are anticipated in early July. If successful, an NDA for an indication of the treatment of moderate to severe chronic pain would be anticipated to be submitted in late 2014 or early 2015.

On April 3, 2014, BDSI announced the enrollment of the first patient in the RHAPSODY Study, a Phase 3 clinical trial of Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN). The Phase 3 trial is a multicenter, randomized, double-blind, placebo-controlled study in 140 subjects to determine the efficacy and safety of Clonidine Topical Gel in the treatment of pain associated with PDN. As of the beginning of May, over 50% of subjects had been randomized in this trial with the interim analysis anticipated to occur in the third quarter of 2014. The purpose of the interim analysis is to confirm the assumptions regarding the study sample size and allow for an adjustment in size if needed. Clonidine Topical Gel has the opportunity to be the first topical product approved by FDA for the treatment of PDN. As such, BDSI currently estimates annual peak sales potential for this product in excess of $300 million.

In February 2014, BDSI closed a $60 million registered common stock financing with a select group of institutional investors led by Federated Kaufmann. This financing strengthened BDSI's balance sheet in front of its anticipated 2014-2015 activities, and at March 31, 2014, BDSI had $88.2 million in cash compared to $23.2 million at December 31, 2013.

Research and development costs were $14.6 million in the first quarter of 2014, compared to a corresponding $12.0 million in the first quarter of 2013. The current quarter increase in research and development expense was due primarily to additional research and development costs associated with the BEMA Buprenorphine for chronic pain late stage development program and the initiation of the Clonidine Topical Gel Phase 3 program. Overall R&D costs for 2014 will fall below 2013 levels.

"There has never been a more exciting time at BDSI as we move closer to the PDUFA date of June 7th and potential launch of BUNAVAIL this year, as well as the data read out of our second pivotal trial for BEMA Buprenorphine for chronic pain in early July," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "As it relates to BUNAVAIL, opioid dependence has unfortunately become a national epidemic and a clear need exists for new treatment options. To help address this need, we are currently readying launch plans for BUNAVAIL and have entered into agreements with Quintiles and Ashfield Market Access to provide the services and infrastructure needed to support our planned sales and managed markets activities. Additionally, we are working aggressively with our commercial partner Endo to complete the Phase 3 program and believe the market opportunity for BEMA Buprenorphine for chronic pain continues to expand for a differentiated Schedule 3 opioid. Furthermore, we are excited to have expanded our late-stage product pipeline with the initiation of the Phase 3 clinical trial of Clonidine Topical Gel for the treatment of painful diabetic neuropathy."

"With a strengthened balance sheet, BUNAVAIL approaching its PDUFA date, the final pivotal study for BEMA Buprenorphine for chronic pain

reporting out mid-year and Clonidine Topical Gel in Phase 3, we believe BDSI has the strongest potential in it's history to generate sustainable value for our shareholders," concluded Dr. Sirgo.

Anticipated 2014 Milestones

BDSI is focusing its resources on achievement of the following key milestones:

- *BUNAVAIL for Opioid Dependence.* Given the PDUFA date of June 7, 2014, BDSI is currently working on the execution of the sales, marketing and other commercialization and product supply chain activities to support the anticipated late third quarter 2014 launch of BUNAVAIL.
- *BEMA Buprenorphine for Chronic Pain.* BDSI anticipates the second database lock from the Phase 3 trial for opioid experienced patients and subsequent $10 million milestone payment from Endo to occur in mid-year 2014. Assuming positive results, the potential filing of the NDA would be expected to take place in late 2014 or early 2015.
- *Clonidine Topical Gel for Painful Diabetic Neuropathy.* A Phase 3 study was initiated earlier in 2014 with the potential for the planned interim analysis during third quarter of this year.

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 consists of three products, two of which utilize the patented BioErodible MucoAdhesive (BEMA) drug delivery technology. ONSOLIS (fentanyl buccal soluble film) is approved in the U.S., Canada, E.U. (where it is marketed as BREAKYL) and Taiwan (where it will be marketed as PAINKYL), 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 is in Phase 3 clinical trials for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Pharmaceuticals. Clonidine Topical Gel for the treatment of painful diabetic neuropathy is currently in Phase 3 development.

An NDA for BUNAVAIL, a BEMA formulation of buprenorphine in combination with naloxone, is currently under review for the maintenance treatment of opioid dependence and has a PDUFA date of June 7, 2014.

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 (including, without limitation, at the presentations described herein) 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 FDA's review of BUNAVAIL, the results of the Company's commercial efforts for BUNAVAIL, and the results of the Company's clinical trials for BEMA Buprenorphine and Clonidine Topical Gel) 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.

SOURCE BioDelivery Sciences International, Inc.

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