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

November 5, 2014

BUNAVAIL™ (buprenorphine and naloxone) buccal film now available by prescription for the maintenance treatment of opioid dependence

Positive top-line results from second Phase 3 BEMA Buprenorphine clinical trial in chronic pain; recent pre-NDA meeting confirmed NDA submission on track for year-end or early 2015

Positive interim analysis completed in Phase 3 trial of Clonidine Topical Gel for painful diabetic neuropathy; Top-line results anticipated by end of first quarter 2015

Agreement signed to develop and commercialize long-acting, injectable, microparticle formulation of buprenorphine for opioid dependence and pain to compliment current portfolio

RALEIGH, N.C., Nov. 5, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has filed its Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Earlier this week, BDSI announced the availability of BUNAVAIL™ (buprenorphine and naloxone) buccal film (CIII) in the U.S., which will be supported by a dedicated sales force of approximately 60 representatives. BUNAVAIL is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. BUNAVAIL is the first and only buccal film formulation of buprenorphine and naloxone approved by the U.S. Food and Drug Administration (FDA) and will compete in the $1.7 billion, and growing, U.S. opioid dependence market.

In July, Endo Pharmaceuticals and BDSI announced positive top-line results from its second pivotal Phase 3 efficacy study of BEMA Buprenorphine in opioid-experienced patients for the treatment of chronic pain. The trial successfully met its primary efficacy endpoint demonstrating that BEMA Buprenorphine resulted in significantly improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BEMA Buprenorphine compared to placebo. The locking of the database for the opioid-experienced study also triggered a $10 million milestone payable from Endo to BDSI that was collected in July. Endo and BDSI engaged in a positive pre-NDA meeting on July 15, 2014, and maintain expectations to submit a New Drug Application (NDA) to FDA by year-end or early 2015.

Earlier in the quarter, BDSI also announced that it has completed a pre-specified interim analysis of the ongoing initial pivotal Phase 3 trial for Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN). BDSI expects to announce top-line results near the end of the first quarter of 2015. The FDA has granted Fast Track designation for the program, which recognizes the need for developing new therapies for this serious condition.

At the end of the third quarter of 2014, BDSI had $85.8 million in cash, compared to $23.2 million on December 31, 2013. Included in the cash balance is $10 million from the database lock from the Phase 3 study from Endo, the sale of 529,010 shares of common stock through the "at-the-market" offering program during September, 2014, which totaled $8.7 million dollars, and the exercise of 300,141 warrants which totaled $ 0.9 million

BDSI's research and development costs were $6.8 million compared to a corresponding $16.4 million in the third quarter of 2013. Through the nine months ended September 30, 2014, research and development costs were $29.4 million, compared to $41.2 million in the comparable period of 2013. The decrease in research and development expense was primarily due to the wind down of the BEMA Buprenorphine Phase 3 trials, partly offset by the increase in spending on the Phase 3 program for Clonidine Topical Gel.

SG&A expenses for the third quarter of 2014 were $13.6 million versus $3.0 million during the comparable period of 2013. Of the third quarter SG&A expense, $7.4 million represent expenses attributable to hiring, training, and deploying our sales force as well as marketing efforts in support of the Bunavail Launch versus 2013 where there were no commercial expenses. Year to date through September 30, 2014, SG&A expenses were $25.5 millionversus $9.1 million for the comparable period of 2013. Of the year to date SG&A expenses, $11.4 million can be attributed to commercialization of Bunavail.

"The recent launch of BUNAVAIL for opioid dependence has completed BDSI's evolution into a fully integrated specialty pharmaceutical company with a dedicated U.S. commercial sales-force," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We are confident that we have built what will be a successful commercial organization and now have the ability to take control of our own destiny. Importantly, we have recently entered into an agreement with Evonik to develop a long-acting, injectable formulation of buprenorphine, which will potentially enable us to further leverage our current addiction salesforce in the future. Additionally, we now have positive data from two Phase 3 trials with BEMA Buprenorphine for chronic pain, partnered with Endo. Our recent pre-NDA meeting confirmed timelines for an NDA filing later this year or early 2015. Finally, we were encouraged by the interim analysis of the Clonidine Phase 3 study and look forward to the results near the end of the first quarter of 2015."

Dr. Sirgo continued, "In summary, this has been a truly remarkable quarter for BDSI as we have successfully transformed into a commercial organization, have worked with our partner Endo to move BEMA Buprenorphine toward an NDA submission, and have made an important move toward expanding our development portfolio. We look forward to the next several months as we continue the introduction of BUNAVAIL and provide those with opioid dependence and their healthcare providers an important new treatment option."

In October, following the end of the quarter, BDSI announced that J. Chris Prue, RPh, MBA joined BDSI as Vice President of Regulatory Affairs and Quality Assurance. Mr. Prue brings more than 30 years of pharmaceutical industry experience in regulatory affairs and quality assurance to BDSI. As a further organizational development, BDSI announced in October that the Research and Development group will be reorganized and that both Regulatory Affairs and Quality Assurance will report to him.

In October, BDSI also announced an exclusive agreement with Evonik Corporation to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection. While BDSI plans to pursue an indication for the maintenance treatment of opioid dependence, the company has also secured the rights and plans to develop a product for the treatment of chronic pain in patients requiring continuous opioid therapy. This product will compliment BUNAVAIL and plans would be for it to be sold by the company's current sales force.

Anticipated 2014/2015 Milestones

In addition to the BUNAVAIL launch, BDSI is currently focused on the achievement of the following key milestones:

- *BEMA Buprenorphine for Chronic Pain.* Endo and BDSI are working on the filing of an NDA, expected to take place in late 2014 or early 2015.
- *Clonidine Topical Gel for Painful Diabetic Neuropathy.* Top-line study results are anticipated near the end of first quarter of 2015 and a second Phase 3 study is planned to begin in early 2015.
- *Depot Buprenorphine*. Development program with Evonik on a long-acting, injectable formulation of buprenorphine to begin with plans to file an Investigational New Drug Application (IND) by the end of 2015.

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) and Twitter (Twitter.com/BioDeliverySI)

About BUNAVAIL

INDICATION

BUNAVAIL (buprenorphine and naloxone) Buccal Film (CIII) is a prescription medicine indicated for the maintenance treatment of opioid dependence. BUNAVAIL should be used as part of a complete treatment plan to include counseling and psychosocial support.

Prescription use of this product is limited under the Drug Addiction Treatment Act (DATA).

IMPORTANT SAFETY INFORMATION

Keep BUNAVAIL (buprenorphine and naloxone) Buccal Film (CIII) out of the sight and reach of children. Ingestion of BUNAVAIL by a child may cause severe breathing problems and death. If a child takes BUNAVAIL, get emergency help right away.

Do not take BUNAVAIL if you are allergic to buprenorphine or naloxone, as serious negative effects including anaphylactic shock, have been reported.

Do not take BUNAVAIL before the effects of other opioids (e.g., heroin, methadone, oxycodone, morphine) have lessened as you may experience withdrawal symptoms.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how BUNAVAIL affects you.

BUNAVAIL contains buprenorphine, an opioid that can cause physical dependence. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking BUNAVAIL without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

Do not switch from BUNAVAIL to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose

of BUNAVAIL is not the same as the amount of buprenorphine in other medicines. Your doctor will prescribe a dose of BUNAVAIL that may be different than other buprenorphine-containing medicines you may have been taking.

BUNAVAIL can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines, sedatives, tranquilizers or alcohol. You should not drink alcohol while taking BUNAVAIL, as this can lead to loss of consciousness or even death.

Like other opioids (e.g., heroin, methadone, oxycodone, morphine), BUNAVAIL may produce orthostatic hypotension ('dizzy spells') in ambulatory individuals.

Common side effects of BUNAVAIL include headache, drug withdrawal syndrome, lethargy (lack of energy), sweating, constipation, decrease in sleep (insomnia), fatigue and sleepiness.

Because BUNAVAIL contains naloxone, injecting BUNAVAIL may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

BUNAVAIL can be abused in a manner similar to other opioids, legal or illicit. Keep BUNAVAIL in a safe place. Do not give your BUNAVAIL to other people, it can cause them harm or even death. Selling or giving away this medicine is against the law.

BUNAVAIL is not recommended in patients with severe hepatic impairment. BUNAVAIL may be used with caution for maintenance treatment in patients with moderate hepatic impairment.

Before taking BUNAVAIL, tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking BUNAVAIL, tell your doctor immediately as there may be significant risks to you and your baby; your baby may have symptoms of withdrawal at birth.

Before taking BUNAVAIL, talk to your doctor if you are breast-feeding or plan to breast-feed your baby. BUNAVAIL can pass into your breast milk and may harm your baby. Monitor your baby for increased sleepiness and breathing problems. Your doctor should tell you about the best way to feed your baby if you are taking BUNAVAIL.

This is not a complete list of potential adverse events associated with BUNAVAIL Buccal Film. Please see full Prescribing Information for a complete list.

To report negative side effects associated with taking BUNAVAIL Buccal Film, please call 1-800-469-0261. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see full Prescribing Information and Medication Guide for BUNAVAIL™ Buccal Film (CIII)

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 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 events or otherwise, except as required by applicable law.

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