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

August 7, 2014

BUNAVAIL™ (buprenorphine and naloxone) buccal film (CIII) approved by FDA for the maintenance treatment of opioid dependence; US launch planned for late Q3

2nd Positive Phase 3 BEMA Buprenorphine clinical trial in chronic pain leads to NDA submission targeted for year-end or early 2015

Enrollment for Clonidine Topical Gel for Painful Diabetic Neuropathy Phase 3 trial expected to complete by year-end; Top-line results anticipated by end of 1Q15

Company earns $10 million milestone from Endo on BEMA Buprenorphine Phase 3 data lock and had $88 million in cash as of July 7

BDSI will host an investor and analyst luncheon on September 5 in New York City

RALEIGH, N.C., Aug. 7, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has filed its Quarterly Report on Form 10-Q for the quarter ended June 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.

In June, BDSI received approval of the New Drug Application (NDA) for BUNAVAIL™ (buprenorphine and naloxone) buccal film from the U.S. Food and Drug Administration (FDA). 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 FDA-approved buccal film formulation of buprenorphine and naloxone and will compete in the $1.7 billion and growing U.S. opioid dependence market. BDSI expects to launch BUNAVAIL late in the third quarter of 2014 with a dedicated U.S. sales force. BDSI plans to share additional details on its launch plans at its Investor and Analyst Luncheon on September 5, 2014 in New York City.

On July 7, Endo Pharmaceuticals and BDSI announced positive top-line results from its second pivotal Phase 3 efficacy study of BEMA Buprenorphine in opioid-experienced patients. The trial successfully met its primary efficacy endpoint in 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. Endo and BDSI plan to submit an NDA to FDA by year-end or early 2015.

Earlier in the week, BDSI 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). The encouraging outcome reported in this interim analysis was performed on data from the first 50% of patients who completed the study. The purpose of the interim analysis was to allow for a sample size adjustment if necessary to maintain appropriate statistical power to detect a treatment effect between Clonidine Topical Gel and placebo. As a result of the interim analysis, a total of approximately 80 additional patients will be added to the ongoing trial in an effort to maintain 90% power to detect a statistically significant difference between Clonidine Topical Gel and placebo. This will extend patient enrollment until year-end with top-line results expected by the end of the first quarter of 2015. This is the first of two pivotal trials that would be required for submission of an NDA to the FDA. 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 second quarter of 2014, BDSI had $88.4 million in cash, which includes the $10 million milestone payment from Endo which was collected in early July, compared to $37.4 million at June 30, 2013. BDSI's research and development costs were $8.0 millioncompared to a corresponding $12.8 million in the second quarter of 2013. Year to date through June 30, 2014, research and development expenses were $22.6 million versus $24.8 million for the comparable six month period of 2013. The decrease in research and development expense was due primarily to the conclusion of the BEMA Buprenorphine Phase 3 trial in opioid naïve patients and the winding down of the opioid experienced study.

SG&A expenses for the second quarter of 2014 were $7.2 million versus $3.1 million during the comparable period of 2013. Year to date through June 30, 2014, SG&A expenses were $11.9 million versus $6.0 million for the comparable period of 2013. The increase reflects the ramp-up of marketing and sales activity to support the launch of BUNAVAIL.

"It has been ten years in the making, but the recent FDA approval 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 and, as a result, allows the company to take more control over its destiny," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "We are in the final steps of hiring the sales representatives that will sell this product as we prepare for this historic launch later this quarter. At the same time, our Endo partnership around BEMA Buprenorphine for chronic pain continues to flourish with the recent reporting of the positive outcome in the second Phase 3 pivotal trial which could lead to an NDA submission as early as year-end. Finally, the result of our recent interim analysis of the first Phase 3 study of Clonidine Topical Gel for the treatment of painful diabetic neuropathy is very encouraging and will lead to top-line efficacy data by the end of the first quarter of 2015," Dr. Sirgo concluded.

In July, following the end of the quarter, BDSI announced that Charles J. (Chuck) Bramlageand Dr. Barry I. Feinberg were appointed as members of BDSI's Board of Directors. Mr. Bramlage is a veteran pharmaceutical industry executive with extensive experience in marketing, sales and other commercial functions. He is currently the Chief Executive Officer of Pearl Therapeutics. Dr. Feinberg is a noted specialist in the area of pain management, where he is board certified. Since 2008, he has served as a member of the Board of Directors and Medical Executive Committee of the

Frontenac Surgery and Spine Care Center in St. Louis, Missouri. BDSI expects these new directors to added valuable and timely expertise to its Board of Directors.

Anticipated 2014 Milestones

BDSI is currently focused on the achievement of the following key milestones:

- *BUNAVAIL for Opioid Dependence.* Following FDA approval in June, 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. The company will host an analyst and investor day in New York City on September 5th to discuss the commercialization plan for BUNAVAIL in more detail.
- *BEMA Buprenorphine for Chronic Pain.* With the second of two positive Phase 3 trials now completed, Endo and BDSI are working on the filing of an NDA for this product, 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, and following the recent interim analysis, it was determined that enrollment will continue until the end of the year. Topline study results are anticipated by the end of first quarter 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, the interview described and presented herein, 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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