BioDelivery Sciences Provides Business Review and Update in Conjunction with Filing of its 2013 Annual Report

March 14, 2014

BUNAVAIL PDUFA date June 7, 2014; Plans underway for potential Q3 2014 launch

Positive results announced for Phase 3 clinical trial of BEMA Buprenorphine in opioid naive patients; results in opioid experienced patients expected mid-2014

Clonidine Topical Gel Phase 3 program initiated; study completion expected by year-end 2014

$60 million equity financing in February solidified balance sheet

RALEIGH, N.C., March 14, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that it has filed its Annual Report on Form 10-K for the year ended December 31, 2013 with the U.S. Securities and Exchange Commission and, in connection therewith, is providing a review of BDSI's 2013 financials and achievements as well as an update on business operations and upcoming milestones for 2014.

In 2013, BDSI made important progress in significantly advancing and building its product portfolio in pain and addiction treatment and made meaningful strides in its continuing evolution from a development stage entity to a commercial enterprise. This included significant progress in the development of BDSI's two buprenorphine-containing products, BUNAVAIL for the maintenance treatment of opioid dependence and BEMA Buprenorphine, in partnership with Endo Pharmaceuticals, for the treatment of moderate to severe chronic pain.

A New Drug Application (NDA) for BUNAVAIL was submitted to the U.S. Food and Drug Administration (FDA) in mid-2013 and has a Prescription Drug User Fee Act (PDUFA) date of June 7, 2014. In January 2014, BDSI and Endo announced positive top-line results from the Phase 3 clinical trial of BEMA Buprenorphine in opioid naive patients. The trial successfully met its primary efficacy endpoint in demonstrating that BEMA Buprenorphine resulted in significantly ($p<0.005$) improved pain relief compared to placebo. Additional secondary endpoints supported the efficacy of BEMA Buprenorphine while the most commonly reported adverse events in patients treated with BEMA Buprenorphine compared to placebo in the double blind phase of the study were nausea (10% vs. 8%), vomiting (4% vs. 2%) and constipation (4% vs. 2%). A second Phase 3 pivotal study for BEMA Buprenorphine, which is ongoing and being conducted in opioid experienced patients, is expected to report top-line results in mid-2014.

In addition to the progress on its two buprenorphine containing products, BDSI expanded its product portfolio in 2013 by in-licensing Clonidine Topical Gel, a proposed treatment for painful diabetic neuropathy. Following a positive end of Phase 2 meeting with FDA in November, BDSI will begin this quarter enrolling patients in the first of two Phase 3 studies.

BDSI's financials reflect the company's investment in these late-stage clinical programs during 2013. The concurrent execution of Phase 3 studies for both BUNAVAIL and BEMA Buprenorphine increased BDSI's research and development expenditures from $35.4 millionin 2012 to $53.3 million in 2013. The majority of the research and development expense was incurred in the BEMA Buprenorphine chronic pain program ($41.8 million) and the remainder was incurred primarily from BUNAVAIL-related activities ($7.1 million). In 2013, BDSI recognized $11.4 million in revenue, including $9.1 million from Endo, $6.3 of which was recognition of previously deferred revenue associated with a 2012 signing milestone and $2.8 million was for reimbursements of certain contractual research and development expenses.

BDSI reported a net loss of ($57.4) million or ($1.51) per share for the twelve months ending December 31, 2013. That compares to net income of $1.7 million, or $0.05 per share in 2012. This difference came from the increase in research and development spending in 2013, as previously noted. In addition, 2012 revenue included $53.4 million from one-time sources, including $35.8 million from two Endo milestones (upon signing and patent approval) and $17.5 million of deferred revenue recognized upon launch of BREAKYL (BEMA Fentanyl) in Europe. This deferred revenue was originally generated from various contractual milestones from Meda, BDSI's commercial partner for its approved product ONSOLIS.

At the end of 2013, BDSI had $23.2 million in cash compared to $63.2 million at December 31, 2012. BDSI's cash balance was increased significantly in several early 2014 transactions, including proceeds from the $60 million registered direct financing which closed in February 2014, a database lock milestone payment from Endo for $10 million related to the BEMA Buprenorphine opioid naive study, the sale of 658,459 shares of common stock through the "at-the-market" offering program during January 2014, which totaled $3.9 million dollars, and the exercise of certain outstanding warrants totaling another $2.6 million. As a result of the foregoing, BDSI's February 28, 2014 cash balance was approximately $89.8 million, which it plans to utilize toward the execution of its corporate goals in 2014 and beyond.

"I am exceptionally pleased by the progress made by BDSI in the past year and excited about the prospects for 2014," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "In 2013, we significantly progressed our product portfolio while adding to it with the licensing of Clonidine Topical Gel. In addition, we have strengthened our management team with several key additions in research and development, finance and commercial organization. Also, with the completion of our $60 million dollar offering in February of this year, we solidified our balance sheet while strengthening our shareholder base."

"From a research and development perspective, we now have two programs in Phase 3 and a third awaiting FDA approval," continued Dr. Sirgo. "The accomplishment of BDSI's key business objectives during the past year is a tribute to the focus and dedication of our employees. In 2014, we are looking forward to an extremely exciting year as we make plans to transition from a development focused organization to a commercial enterprise following our potential approval and subsequent launch of BUNAVAIL. As it relates to the potential launch of BUNAVAIL, we will be providing more

details on our launch plan as we approach our June 7 PDUFA date. Overall, this will be a very busy year for BDSI and one that has the potential to continue to create substantial value for our shareholders."

Corporate Update and Recent Accomplishments

BDSI had multiple clinical, regulatory, business development and corporate accomplishments over the past 15 months, including:

- *BEMA Buprenorphine for Chronic Pain.* In conjunction with partner Endo, BDSI recently announced positive top-line results from its pivotal Phase 3 efficacy study of BEMA Buprenorphine in opioid "naive" subjects.
- *BUNAVAIL for Opioid Dependence.* Clinical development work was completed and the NDA was submitted to the FDA and subsequently assigned a PDUFA date of June 7, 2014.
- *Clonidine Topical Gel – Painful Diabetic Neuropathy.* Clonidine Topical Gel was in-licensed from Arcion Therapeutics for $2.5 million in BDSI stock, and BDSI confirmed with FDA the Phase 3 regulatory pathway. The first of two Phase 3 studies for the treatment of painful diabetic neuropathy is anticipated to begin shortly.
- *$60 Million Registered Financing.* In February 2014, BDSI closed a non-brokered registered direct financing (near market price and no warrants) which yielded gross proceeds of $60 million. The lead investor was Federated Kaufmann, along with three current institutional investors.
- *Strengthened Management Team.* BDSI improved the depth and breadth of its management as the company moves toward commercialization of BUNAVAIL as well as further business development opportunities. Appointed were Ernest R. De Paolantonio as Chief Financial Officer, Adrian Hepner, MD, as Vice President of Clinical Research and Regulatory Affairs, and David Acheson as Vice President of Sales and Managed Markets.

Anticipated 2014 Milestones

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

- *BUNAVAIL for Opioid Dependence.* Given the FDA action 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 third quarter 2014 launch of BUNAVAIL. Additionally, data from clinical studies of BUNAVAIL will be presented at the American Society of Addiction Medicine (ASAM) 45th Annual Medical-Scientific Conference, April 10-13, 2014 in Orlando, Florida.
- *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, and the potential filing of the NDA in late 2014 or early 2015.
- *Clonidine Topical Gel for Painful Diabetic Neuropathy.* A Phase 3 study will be initiated by the end of first quarter 2014 with the potential for interim data by year-end.

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 is 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. 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 used 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, the presentation referred to herein, 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 and those that relate to the Company's ability to leverage the expertise of employees and partners to assist the Company in the execution of its strategy. Actual results (including, without limitation, the timing for and results of the clinical trials and proposed NDA submissions for, and FDA review of, the Company's products in development, as well as the outcomes of the Company's commercial plans) 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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