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Exhibit 99.1

BioDelivery Sciences Announces NDA Submission for BUNAVAIL on Track Following Positive Pre-NDA Meeting with FDA

BUNAVAIL NDA submission continues on target for mid-summer 2013

RALEIGH, N.C. – June 10, 2013 - BioDelivery Sciences International, Inc. (Nasdaq: BDSI) announced today that it engaged in a positive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding BUNAVAIL for the maintenance treatment of opioid dependence.

The positive outcome of the pre-NDA meeting allows BDSI to maintain its expectation of an NDA filing with FDA for BUNAVAIL in mid-summer 2013 as planned.

This scheduled meeting with FDA regarding the NDA submission of BUNAVAIL was undertaken to review the key data elements for the NDA, which includes data from a positive pivotal bioequivalence study versus Suboxone, an open-label safety study in patients switched from Suboxone film or tablets to BUNAVAIL, and product stability information. As a result of the feedback obtained, BDSI will continue forward with its NDA submission as planned.

“We are pleased with the outcome of our pre-NDA meeting where we reviewed the key elements of our NDA with the Agency,” said Dr. Andrew Finn, Executive Vice President of Product Development for BDSI. “This outcome is allowing us to move confidently forward in finalizing and submitting our NDA.”

BUNAVAIL utilizes BDSI’s proprietary BioErodible MucoAdhesive (BEMA) technology to deliver buprenorphine for the maintenance treatment of opioid dependence, along with the opioid antagonist naloxone, which is intended to serve as an abuse deterrent. BDSI believes BUNAVAIL may offer meaningful advantages over existing treatments and could provide an alternative to the over 2 million people in the U.S. with opioid dependence. Currently, Suboxone is the only available film formulation of buprenorphine and naloxone, with the film formulation generating in excess of one billion dollars in sales in 2012. BUNAVAIL is positioned to be the next film formulation to enter the market. BDSI believes BUNAVAIL has the potential to generate peak sales in excess of $250 million.

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, two of which utilize the patented BioErodible MucoAdhesive (BEMA) drug delivery technology. 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.).

BDSI’s second pain product using the BEMA technology, BEMA Buprenorphine, is being developed for the treatment of moderate to severe chronic pain and is licensed on a worldwide basis to Endo Health Solutions. BDSI’s third pain product in development is Clonidine Topical Gel for the treatment of painful diabetic neuropathy, which was recently licensed from Arcion Therapeutics.

Additionally, BDSI is developing BUNAVAIL, a high dose formulation of buprenorphine in combination with naloxone for the treatment of opioid dependence. Both BEMA Buprenorphine and BUNAVAIL are in Phase 3 clinical development, and Clonodine Topical Gel is in Phase 2 clinical development.

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) 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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