



BioDelivery Sciences to Raise \$60 Million in Registered Direct Offering From Institutional Investors

February 10, 2014

Proceeds support BDSI's complete execution of anticipated 2014 commercial launch plans for BUNAVAIL™ and funding of Clonidine Topical Gel NDA program

RALEIGH, N.C., Feb. 10, 2014 /PRNewswire/ -- BioDelivery Sciences International, Inc. (Nasdaq:BDSI) announced that it has entered into a definitive securities purchase agreement with a select group of institutional investors led by Federated Kaufmann under which such investors have committed to purchase \$60 million of BDSI's common stock in a registered direct offering.

(Logo: <http://photos.prnewswire.com/prnh/20110217/CL49801LOGO>)

Under the terms of the securities purchase agreement, BDSI will sell an aggregate of 7,500,000 shares of its common stock at a price of \$8.00 per share. The offering is expected to be consummated on or before February 12, 2014, subject to customary closing conditions. The lead investor is Federated Kaufmann, a family of mutual funds, along with three current institutional holders.

Proceeds from this financing are expected to be used for:

- Execution of the sales, marketing and other commercialization and product supply chain activities to support the anticipated second half 2014 launch of BUNAVAIL™, BDSI's treatment for opioid dependence which is currently under review by the FDA with a June 7, 2014 PDUFA date, and that BDSI is actively preparing to commercialize on its own;
- for the initiation this quarter of the Phase III clinical program for Clonidine Topical Gel for the treatment of painful diabetic neuropathy, along with the overall clinical and regulatory advancement of this product;
- for support of BDSI's existing partnered products;
- for potential acquisition of clinical stage or marketed products in the therapeutic areas of central nervous system, addiction and pain medicine, to complement BDSI's current product pipeline; and
- for general working capital purposes.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy any securities nor shall there be any sale of such securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. A shelf registration statement (File No. 333-192618) relating to the common stock issued in the offering has been filed with the Securities and Exchange Commission (the "SEC") and was declared effective on December 18, 2013. A prospectus supplement relating to the offering will be filed by the company with the SEC. Copies of the prospectus supplement and accompanying prospectus may be obtained directly from the company.

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. 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.). BEMA Buprenorphine, which is licensed on a worldwide basis to Endo Pharmaceuticals, is currently in Phase III development for the treatment of moderate to severe chronic pain. Clonidine Topical Gel is expected to enter Phase III trials in the first quarter of 2014 for the treatment of painful diabetic neuropathy. BUNAVAIL™, a BEMA formulation of buprenorphine and naloxone, is currently under review by FDA for the maintenance treatment of opioid dependence and has a PDUFA date of June 7, 2104.

BDSI's headquarters is located in Raleigh, North Carolina. For more information, visit www.bdsi.com.

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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 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 Company's clinical, regulatory and commercialization activities described herein) 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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