BioDelivery Sciences Provides Corporate Update and Reports Fourth Quarter and Year-End 2014 Financial Results

March 16, 2015

2014 - A Year of Many Significant Milestones, with More Expected for 2015, as BDSI Continues its Growth as an Integrated Specialty Pharmaceutical Company

Strong Year-End Cash Position of $70.5 Million to Support Existing Programs and Growth

BUNAVAIL® (buprenorphine and naloxone) Buccal Film Approved and Launched in U.S. for Opioid Dependence

NDA Submitted and Accepted for BELBUCA™ (buprenorphine HCl) Buccal Film for Chronic Pain

Encouraging Interim Analysis Completed in Phase 3 trial of Clonidine Topical Gel for Painful Diabetic Neuropathy

30-Day Injectable Buprenorphine In-licensed for Development for Treatment of Opioid Dependence and Pain

Company Receives $20 Million in Milestone Payments in 2014 from Endo for Further Development of BEMA Buprenorphine for Chronic Pain

Company to Host Conference Call Today at 5:00 PM ET

RALEIGH, N.C., March 16, 2015 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) today reported financial results for the fourth quarter and fiscal year ended December 31, 2014, and reviewed its significant 2014 accomplishments and anticipated milestones for 2015.

Corporate Update and Recent Accomplishments

- *BUNAVAIL (buprenorphine and naloxone) buccal film*: Approved and launched in the U.S. for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support. BUNAVAIL is BDSI's second FDA approved product and the first that it is self-commercializing.
  - BUNAVAIL launched by BDSI with a 60 person contract sales force in early November 2014
  - To date, over 10,000 prescriptions dispensed for BUNAVAIL (according to data from Symphony Health)
  - BUNAVAIL available with unrestricted managed care access in approximately 165 to 175 million lives
- *BELBUCA (buprenorphine HCl) buccal film* (formerly referred to as BEMA Buprenorphine): Positive results reported from two Phase 3 trials, one in opioid naive and one in opioid experienced patients. BELBUCA is partnered with Endo Pharmaceuticals, an affiliate of Endo International plc (NASDAQ: ENDP).
  - New Drug Application (NDA) for BELBUCA submitted to FDA on December 23, 2014, and subsequent acceptance of filing for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate; a PDUFA date is set for October 23rd of this year.
  - BDSI received a total of $30 million in milestone payments from Endo in conjunction with completion of each Phase 3 study and acceptance of the NDA filing
- *Clonidine Topical Gel*: Completed encouraging interim analysis in Phase 3 trial for painful diabetic neuropathy
  - As a result of interim analysis, approximately 80 additional patients were added to ongoing trial to maintain 90% percent power to detect a statistically significant difference between Clonidine Topical Gel and placebo
  - Phase 3 results available by end of 1Q15
- *ONSOLIS® (fentanyl buccal soluble film)*: Re-acquired North American marketing authorizations for BDSI's first FDA approved product, ONSOLIS, for management of breakthrough pain in opioid tolerant patients with cancer
- *Buprenorpine Depot Injection*: Signed an exclusive agreement with Evonik Corporation for an injectable buprenorphine formulation potentially capable of providing 30 days of continuous therapy for the maintenance treatment of opioid dependence, as well as for the treatment of chronic pain
- Added two Board Members with the appointments of Charles Bramlage, a pharmaceutical industry executive with extensive experience in marketing, sales and other commercial functions, and Dr. Barry Feinberg, a noted, board certified specialist in the area of pain management

"The past year has been a transformational one for BDSI with multiple key milestones achieved and significant stockholder value created," said Dr. Mark A. Sirgo, President and Chief Executive Officer. "We saw the approval of BUNAVAIL in June and the subsequent launch in November through our own contract 60 person sales force, around which we continue to see favorable acceptance, as noted by positive feedback on the overall convenience and performance of the drug from patients and their healthcare providers. We look forward to and anticipate further commercial progress with BUNAVAIL quarter by quarter as we move through 2015. We were also pleased, along with our partner, Endo Pharmaceuticals, to have the NDA

submission for BELBUCA accepted and look forward to the potential approval of this product later this year. This would trigger up to an additional $50 million milestone payment from Endo. In addition, we continue to execute our clinical development plan for Clonidine Topical Gel, with top-line Phase 3 data available later this month, and, if positive, we anticipate a regulatory submission to occur in the E.U. during the second half of this year, along with initiation and completion of patient enrollment in our second pivotal study required for the U.S. NDA. We also moved ahead to expand our product opportunity portfolio with the in-licensing of Buprenorphine Depot Injection for potential use in opioid dependence and pain. In summary, we accomplished our predetermined goals for 2014, and this puts us in a strong position as we move forward in 2015 and beyond."

Fourth Quarter 2014 Financial Results Overview

- Net revenue for the fourth quarter ended December 31, 2014, was $2.5 million, compared to $4.0 million in the corresponding period of 2013
- Total operating expenses for the fourth quarter ended December 31, 2014, were $17.8 million, compared to $15.4 million in the corresponding period of 2013
- Net loss for the fourth quarter ended December 31, 2014, was $17.6 million, or $0.51 per diluted share, compared to $12.8 million, or $0.33 per diluted share, in the corresponding period of 2013

Full-Year 2014 Financial Results Overview

- Net revenue was $38.9 million, compared to $11.4 million for full-year 2013
- Total operating expenses for full-year 2014 were $72.7 million, compared to $65.7 millionfor full-year 2013
- Net loss for the year-ended ended December 31, 2014, was $54.2 million, or $1.12 per diluted share, compared to $57.4 million, or $1.51 per diluted share, for the year-ended December 31, 2013
- As of December 31, 2014, BDSI had $70.5 million in cash and cash equivalents, as compared to $23.2 million as of December 31, 2013

"We ended the year in a strong cash position with $70.5 million in cash to support our existing programs and our growth initiatives," said Ernest R. De Paolantonio, Chief Financial Officer. "As we expected, our operating expenses decreased in the fourth quarter, principally from the leveling off of the commercial spending for the BUNAVAIL launch and a decrease in the R&D spending as the BELBUCA Phase 3 program ended. In 2015, we expect total expenses to be in the mid- to high-teens range on a quarterly basis, as the commercial and research and development spending better stabilizes."

Key 2015 Anticipated Milestones

- Acceptance of BELBUCA NDA filing in February triggered a $10 million milestone payment form Endo Pharmaceuticals
- Results of first Phase 3 study for Clonidine Topical Gel for treatment of painful diabetic neuropathy anticipated at the end of March, along with initiation of a second Phase 3 trial
    - Positive results expected to allow for EU regulatory submission during the second half of 2015 and the initiation of discussions around an E.U. partnership
- Potential approval of BELBUCA (October PDUFA date) and an associated milestone payment from Endo of up to $50 million
- Filing of a data package with FDA before the end of the current quarter for review in order to reintroduce ONSOLIS into the U.S. marketplace, which could allow for an FDA decision by the end of 2015
- Completion of an induction study for BUNAVAIL and sNDA submission by the fourth quarter of 2015
- Filing of an Investigational New Drug (IND) application for Buprenorphine Depot Injection by end of 2015

Conference Call & Webcast

Monday, March 16, 2015 @ 5pm Eastern/2:00pm Pacific	
Domestic:	888-510-1785
International:	719-457-1035
Conference ID:	1385073
Webcast:	http://public.viavid.com/player/index.php?id=113525
Replay available following the call:	
Domestic:	877-870-5176

International:	858-384-5517
Conference ID:	1385073

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, please visit or follow us:	
Internet:	**www.bdsi.com**
Facebook:	**Facebook.com/BioDeliverySI**
Twitter:	**@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 lifethreatening 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 breastfeeding or plan to breastfeed 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 1800-469-0261. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1800FDA1088.

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 employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto (including, without limitation, the presentation 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 presentations or otherwise, except as required by applicable law.

BioDelivery Sciences International

Condensed Consolidated Statements of Operations

(in thousands, except share data)

Statement of Profits and Losses	**Twelve Months Ended**	
	12/31/2014	**12/31/2013**
Revenues:		
Net Revenues	$38,944	$11,356
Costs and Expenses:		
Cost of Goods Sold	4,939	2,082
Operating expenses:		
Research & Development	34,285	53,327
Selling, General and Administrative	38,460	12,349

Total Operating Expenses	72,745	65,676
(Loss) / Income From Operations	(38,740)	(56,402)
Interest (expense) income net	(2,016)	(903)
Derivitive (loss) gain	(13,167)	121
Other (expenses) income, net	(295)	(210)
(Loss) / Income before taxes	(54,218)	(57,394)
Income tax expense	-	-
Net (loss)/ income	**$(54,218)**	**$(57,394)**
(Loss)/ income per share, basic	**$(1.12)**	**$(1.51)**
(Loss)/ income per share, diluted	**$(1.12)**	**$(1.51)**
Shares used in computing net income/(loss) per share, basic	**48,355,200**	**37,941,044**
Shares used in computing net income/(loss) per share, basic	**48,355,200**	**37,941,044**

BioDelivery Sciences International

Condensed Consolidated Statements of Operations

(in thousands)

Balance Sheet	12/31/2014	12/31/2013
Assets		
Cash and cash equivalents	$70,472	$23,176
Accounts receivable, net	3,141	2,794
Inventory	1,828	-
other assets	13,870	12,035
Total Assets	**$89,311**	**$38,005**
Liabilities and Stockholders' Equity:		
Accounts Payable and other liabilities	$22,742	$19,639
Notes payable short and long term	12,173	19,178

Total Liabilities and Notes Payable	34,915	38,817
Preferred Stock	2	3
Common Stock	52	39
Additional paid-in capital	259,920	150,506
Treasury Stock at cost	(47)	(47)
Accumulated Deficit	(205,531)	(151,313)
Total stockholder' equity	54,396	(812)
Total liabilities and stockholders' equity (deficit)	**$89,311**	**$38,005**

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/biodelivery-sciences-provides-corporate-update-and-reports-fourth-quarter-and-year-end-2014-financial-results-300051179.html

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For further information: Matthew Duffy, Managing Director, LifeSci Advisors, (212) 915-0685, matthew@lifesciadvisors.com, or Al Medwar, Vice President, Marketing and Corporate Development, BioDelivery Sciences International, Inc., 919-582-9050, amedwar@bdsi.com