BioDelivery Sciences Provides Corporate Update and Reports Fourth Quarter and Full-Year 2016 Financial Results

March 17, 2017

Reacquired worldwide rights to BELBUCA® from Endo; net sales run rate of over $20 million at year end

Debt financing of up to $75 million secured with CRG; initial net proceeds aid in extending cash runway into second half of 2018

BELBUCA creates potential to bring BDSI's commercial operations to profitability as early as the end of first quarter 2017

BELBUCA reacquisition provides potential commercial licensing and other business opportunities

BUNAVAIL prescriptions up 64% in 2016 over 2015; net revenue doubled to $8.3 million

RALEIGH, N.C., March 17, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (BDSI) today reported financial results for the fourth quarter and full year ended December 31, 2016, and provided an update on recent business highlights and upcoming milestones.

In January 2017, BDSI reacquired worldwide rights to BELBUCA® (buprenorphine) buccal film (CIII) from Endo Pharmaceuticals. The transfer of worldwide rights back to BDSI followed a strategic decision announced by Endo in December 2016 to discontinue commercial efforts for the U.S. branded pain business. Based on the agreement, BDSI will have no future financial obligations to Endo including royalties or milestone payments. The return of BELBUCA immediately adds additional top-line revenue, with a run-rate for BELBUCA net sales at year-end 2016 in excess of $20 million.

As discussed in detail at the BDSI Analyst and Investor event in early February 2017, BDSI is leveraging its existing sales force and capitalizing on commercial synergies with BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) for a focused commercial approach targeting identified healthcare providers. BDSI believes that this strategy creates the potential to incrementally grow BELBUCA sales while minimizing the need for significant additional resources. BDSI is also exploring other commercial options for longer-term growth for BELBUCA, both within and outside of the U.S.

BELBUCA sales creates the potential for BDSI to achieve profitability in its commercial operations as early as the end of first quarter 2017. Following a post-acquisition expansion of its sales force by 20 sales representatives to 65, BDSI is currently focusing much of its current commercial efforts, on growing BELBUCA sales given the significant commercial opportunity for a well-differentiated, Schedule III product for chronic pain and the greater profitability of BELBUCA per prescription when compared to BUNAVAIL.

"We were extremely pleased to have reacquired worldwide commercial rights to BELBUCA under very attractive financial terms," said Dr. Mark A. Mark Sirgo, President and Chief Executive Officer. "This transaction can truly be transformative for us, as it will enable our commercial business to potentially reach profitability as early as the end of the current quarter. Most importantly, we believe BELBUCA is a clearly differentiated product that can be part of a real solution to the current opioid crisis in the U.S., and thus, has significant future potential. BELBUCA has demonstrated potent analgesic efficacy in both opioid naïve and experienced patients, tolerability comparable to placebo in the double-blind portion of our Phase 3 study in

opioid-experienced patients and is classified as a Schedule III drug, which means it is deemed to have less abuse and addiction potential relative to Schedule II drugs, such as morphine, hydrocodone and oxycodone. In addition, from a safety perspective, buprenorphine has also been shown to have a ceiling effect on respiratory depression."

BUNAVAIL sales continued to grow in 2016, with nearly 115,000 prescriptions dispensed, an increase of 64% over 2015. BDSI also secured several managed care contracts in the second half of 2016 that it expects will help to increase access to BUNAVAIL in 2017.

BUNAVAIL net revenue for the three months ended December 31, 2016, was $2.0 million, comparable to the prior quarter, and up from $1.5 million versus the fourth quarter of 2015. BDSI anticipates that the potential for BUNAVIAL growth in 2017 will be driven by the impact of managed care contracts and key regulatory trends that support increased access to medication assisted treatment with buprenorphine.

BDSI's total net revenue for the three-months ended December 31, 2016, was $3.9 million, as compared to $32.2 million for the same period the prior year, and $3.6 million for the quarter ended September 30, 2016. The decrease from the prior year is primarily attributable to receipt in November of 2015 of the $50 million BELBUCA-related FDA approval milestone payment, of which $30 million was recognized as fourth quarter 2016 revenue.

"We believe that BUNAVAIL is a terrific companion product for BELBUCA, and that these two products represent a powerful product combination for BDSI," continued Dr. Sirgo. "We continue to support BUNAVAIL high prescribers, which total approximately 1,200 physicians covering approximately 95 percent of the BUNAVAIL prescriptions written over the last six months. We continue to see growth opportunities with our recent managed care wins. However, given the magnitude of the opportunity with BELBUCA, our sales force will focus much of their efforts behind BELBUCA as we move through 2017."

"As we look ahead, our recent senior credit transaction with CRG materially strengthens our balance sheet and provides capital for the execution of our BELBUCA commercial plan. The upfront net proceeds from this credit facility aid in the extension of BDSI's cash runway into the second half of 2018. Moreover, we intend to evaluate an array of BELBUCA-related business and commercial partnership opportunities and expect to be in a position to potentially advance more than one ex-U.S. opportunity toward finalization in 2017," concluded Dr. Sirgo.

FINANCIAL HIGHLIGHTS

Fourth Quarter Ended December 31, 2016 Financial Results Overview

- Net revenue for the fourth quarter ended December 31, 2016, was approximately $3.9 million, compared to approximately $32.2 million in the same period of 2015, with the difference mainly attributed to a one-time milestone payment received from Endo in 2015.
- Total operating expenses for the fourth quarter ended December 31, 2016, were $16.8 million, compared to $18.6 million in the fourth quarter of 2015.
- Net loss for the fourth quarter ended December 31, 2016, was $15.9 million, or ($0.29) per diluted share, compared to a net income of $10.2 million, or $0.19 per diluted share, in the same period of 2015, with the difference mainly attributed to a one-time milestone payment received from Endo in 2015.

Year Ended December 31, 2016 Financial Results Overview

- Total revenues for the year ended December 31, 2016, were $15.5 million, compared to $48.2 million in the same period of 2015.
- Total operating expenses for the year ended December 31, 2016, were $68.2 million, compared to $75.3 million for the same period of 2015.
- Net loss for the year ended December 31, 2016, was $67.1 million, or ($1.25) per diluted share, compared to a net loss of $37.7 million, or ($0.72) per diluted share, in the same period of 2015.
- BDSI had cash and cash equivalents of approximately $32.0 million at December 31, 2016. This compares to cash and cash equivalents of approximately $83.6 million at December 31, 2015.
- Net proceeds from the initial funding under the CRG facility in February 2017 added cash of approximately $14 million to BDSI's balance sheet.

CORPORATE UPDATE AND RECENT ACCOMPLISHMENTS

BELBUCA (buprenorphine) buccal film (CIII)

- Reacquired worldwide rights to BELBUCA from Endo under attractive financial terms.
    - Transaction closed in early January 2017; BDSI sales force initiated promotional efforts by late January.
    - BDSI does not owe any future royalties or milestone payments to Endo.
    - Inherited a solid managed care platform to drive growth in 2017 and beyond, including preferred status with United Healthcare that began on January 1, 2017.
    - BELBUCA ended 2016 with an annual run-rate of over $20 million in net sales.

BUNAVAIL (buprenorphine and naloxone) buccal film (CIII)

- BUNAVAIL commercial efforts focused on approximately 1,200 physicians who are current prescribers of BUNAVAIL; covers 95% of BUNAVAIL scripts written over last 6 months.
- BUNAVAIL total prescriptions increased 64% in 2016 over 2015, with a 4% increase in fourth quarter 2016 versus the prior quarter.

Development Pipeline: Sustained Release Buprenorphine Injection – Pain & Opioid Dependence

- Development focused on the maintenance treatment of opioid dependence and chronic pain, with both areas complementary to BDSI's current portfolio and expertise and where buprenorphine has been demonstrated to be effective.
- First trial will assess single, ascending doses of SR buprenorphine injection in treatment-seeking, opioid use disorder subjects. This study will assess the pharmacokinetics, pharmacodynamics of each ascending dose and will also include efficacy benchmarks and assessment of tolerability.
- Results from the first cohort expected in third quarter of this year, which will be important in confirming the duration of action.

Corporate

- Secured debt financing with CRG LP, a healthcare-focused investment firm, to retire BDSI's existing credit facility, and provide additional working capital.
    - Consists of $45 million to be drawn at closing and the ability to access additional funding of up to an aggregate of $30 million in two equal tranches for a total of up to $75million based on the achievement of certain financial milestones through September 30, 2018.
    - Under its current operating plan, BDSI believes that the upfront net proceeds from the CRG facility, together with funds on hand, and revenue inflows from BELBUCA and BUNAVAIL, provide sufficient capital into the second half of 2018.

Key Anticipated 2017 Milestones

- BELBUCA sales create the potential for BDSI to achieve commercial profitability as early as the end of first quarter 2017, although not full enterprise profitability.
- Will seek to execute up to two commercial transactions for BELBUCA by the end of the year.
- Expect approval of BELBUCA in Canada in the first half of 2017.
- Initiation of, and initial results from, an ascending, single dose pharmacokinetic study of sustained release buprenorphine injection. Results from the first dosing cohort expected to be available in the third quarter.
- Regulatory submission later this year to qualify the new manufacturer for ONSOLIS (product licensed to Collegium Pharmaceutical) and, if approved, allows the product to return to market early in the first half of 2018.
- Orange Book listing of a patent extending exclusivity of ONSOLIS from 2020 to July 2027, which triggers a milestone payment to BDSI from Collegium.

Conference Call & Webcast

Friday, March 17 @ 8:00 am Eastern Time

Domestic: 888-587-0611

International: 719-457-2698

Passcode: 5409170

Webcast: http://public.viavid.com/index.php?id=123315

Replays available through March 31st:

Domestic: 844-512-2921

International: 412-317-6671

Conference ID: 5409170

About BELBUCA (buprenorphine) buccal film (CIII)

INDICATION

BELBUCA® (buprenorphine) buccal film is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioid formulations, reserve BELBUCA® for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

BELBUCA® is not indicated as an as-needed (prn) analgesic.

IMPORTANT SAFETY INFORMATION about BELBUCA®

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; AND NEONATAL OPIOID WITHDRAWAL SYNDROME AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

BELBUCA® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk prior to prescribing BELBUCA®, and monitor patients regularly these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of BELBUCA®. Monitor for respiratory depression, especially during initiation of BELBUCA® or following a dose increase. Misuse or abuse of BELBUCA® by chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in the uncontrolled delivery of buprenorphine and pose a significant risk of overdose and death.

Accidental Exposure

Accidental exposure to even one dose of BELBUCA®, especially by children, can result in a fatal overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of BELBUCA® during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks from Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS

BELBUCA® is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus, hypersensitivity (e.g., anaphylaxis) to buprenorphine

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse

BELBUCA® contains buprenorphine, a Schedule III controlled substance. As an opioid, BELBUCA® exposes users to the risks of addiction, abuse, and misuse. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed BELBUCA® and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused.

Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing BELBUCA®, and monitor all patients receiving BELBUCA® for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as BELBUCA®, but use in such patients necessitates intensive counseling about the risks and proper use of BELBUCA®, along with intensive monitoring for signs of addiction, abuse, or misuse.

Abuse or misuse of BELBUCA® by swallowing may cause choking, overdose, and death.

Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing BELBUCA®. Strategies to reduce the risk include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper disposal of unused drug.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death.

While serious, life-threatening or fatal respiratory depression can occur at any time during the use of BELBUCA®, the risk is greatest during initiation of therapy or following a dosage increase. Monitor patients closely for respiratory depression when initiating therapy with BELBUCA® and following dosage increases.

To reduce the risk of respiratory depression, proper dosing and titration of BELBUCA® are essential. Overestimating the dose of BELBUCA® when converting patients from another opioid product may result in fatal overdose with the first dose.

Accidental exposure to BELBUCA®, especially in children, can result in respiratory depression and death due to an overdose of buprenorphine.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of BELBUCA® during pregnancy can result in withdrawal in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and treated and requires management according to protocols developed by neonatology experts. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using opioids for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Risks due to Interactions with Benzodiazepines or Other Central Nervous System Depressants

Profound sedation, respiratory depression, coma, and death may result from the concomitant use of BELBUCA® with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

If the decision is made to prescribe a benzodiazepine or other CNS depressant concomitantly with an opioid analgesic, prescribe the lowest effective dosages and minimum durations of concomitant use. Follow patients closely for signs and symptoms of respiratory depression and sedation.

Risk of Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients

The use of BELBUCA® in patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment is contraindicated.

Patients with Chronic Pulmonary Disease: BELBUCA®-treated patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive, including apnea, even at recommended dosages of BELBUCA®.

Life-threatening respiratory depression is more likely to occur in in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared with younger, healthier patients

Monitor such patients closely, particularly when initiating and titrating BELBUCA® and when BELBUCA® is given concomitantly with other drugs that depress respiration.

Adrenal Insufficiency

Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non-specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

QTc Prolongation

BELBUCA® has been observed to prolong the QTc interval in some subjects participating in clinical trials. Consider these observations in clinical decisions when prescribing BELBUCA® ™to patients with hypokalemia, hypomagnesemia, or clinically unstable cardiac disease, including unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, or active myocardial ischemia. Periodic electrocardiographic (ECG) monitoring is recommended in these patients. Avoid the use of BELBUCA® in patients with a history of Long QT Syndrome (or an immediate family member with this condition) or those taking Class IA antiarrhythmic medications (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic medications (e.g., sotalol, amiodarone, dofetilide), or other medications that prolong the QT interval.

Severe Hypotension

BELBUCA® may cause severe hypotension, including orthostatic hypotension and syncope, in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension after initiating or titrating the dosage of BELBUCA®., In patients with circulatory shock BELBUCA® may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of BELBUCA® in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness

In patients who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors), BELBUCA® may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy with BELBUCA®.

Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of BELBUCA® in patients with impaired consciousness or coma.

Hepatotoxicity

Cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving sublingual formulations of buprenorphine for the treatment of opioid dependence, both in clinical trials and in post-marketing adverse events reports. For patients at increased risk of hepatotoxicity (e.g., patients with a history of excessive alcohol intake, intravenous drug abuse or liver disease), obtain baseline liver enzyme levels and monitor periodically during treatment with BELBUCA®.

Risk of Overdose in Patients With Moderate or Severe Hepatic Impairment

In a pharmacokinetic study of subjects dosed with buprenorphine sublingual tablets, buprenorphine plasma levels were found to be higher and the half-life was found to be longer in subjects with moderate and severe hepatic impairment but not in subjects with mild hepatic impairment. For patients with severe hepatic impairment, a dose adjustment is recommended, and patients with moderate or severe hepatic impairment should be monitored for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

Anaphylactic/Allergic Reactions

Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in post-marketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported.

Risk of Use in Patients with Gastrointestinal Conditions

BELBUCA® is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus.

BELBUCA® may cause spasm of the sphincter of Oddi. Opioids may cause increases in the serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

Increased Risk of Seizures in Patients with Seizure Disorders

The buprenorphine in BELBUCA® may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during BELBUCA® therapy.

Risks of Use in Cancer Patients with Oral Mucositis

Cancer patients with oral mucositis may absorb buprenorphine more rapidly than intended and are likely to experience transiently higher plasma levels of the opioid. A dose reduction is recommended in these patients. Monitor carefully for signs and symptoms of toxicity or overdose caused by increased levels of buprenorphine.

Risks of Driving and Operating Machinery

BELBUCA® may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to side effects of BELBUCA® and know how they will react to the medication.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) reported by patients treated with BELBUCA® in the clinical trials were nausea, constipation, headache, vomiting, fatigue, dizziness, somnolence, diarrhea, dry mouth, and upper respiratory tract infection.

Please see full Prescribing Information, including Boxed Warning and Medication Guide, for BELBUCA®.

To report SUSPECTED ADVERSE REACTIONS, contact BioDelivery Sciences International, Inc. at 1-800-469-0261 or FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch.

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 the 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 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 in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet: www.bdsi.com

Facebook: Facebook.com/BioDeliverySI

Twitter: @BioDeliverySI

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and BELBUCA® (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. *ONSOLIS*® (fentanyl buccal soluble film) (CII) is licensed in the U.S. to Collegium Pharmaceutical pursuant to the U.S. licensing and development agreement between BDSI and Collegium. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS, please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit www.belbuca.com and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.com.

Cautionary Note on Forward-Looking Statements

This press release, the conference call described herein, and any statements of employees, 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 development, commercialization and strategic initiatives) 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, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(U.S. dollars, in thousands, except share and per share amounts)

	December 31,	
	2016	**2015**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,019	$ 83,560
Accounts receivable	3,569	2,488
Inventory	3,368	2,558
Prepaid expenses and other current assets	4,136	3,933
	43,092	92,539

Property and equipment, net	4,230	4,262
Goodwill	2,715	2,715
Other intangible assets, net	2,285	3,256
Total assets	**$ 52,322**	**$ 102,772**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities, other	$ 18,174	$ 19,501
Notes Payable, current	-	6,707
Deferred revenue, current	1,716	1,875
Total current liabilities	19,890	28,083
Notes payable, current maturities, net (1)	29,272	22,168
Deferred revenue, long term	20,000	20,000
Other Long Term liabilities	825	825
Total liabilities	69,987	71,076
Commitments and contingencies (Notes 7 and 14)		
Stockholders' equity:		
Preferred Stock, $.001 par value; 5,000,000 shares authorized; 2,093,155 and 2,093,155 shares of Series A Non-Voting Convertible Preferred Stock outstanding at December 31, 2016 and 2015, respectively.	2	2
Common Stock, $.001 par value; 75,000,000 shares authorized; 54,133,511 and 52,730,799 shares issued; 54,118,020 and 52,715,308 shares outstanding at December 31, 2016 and 2015, respectively	54	53
Additional paid-in capital	292,667	274,891
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(310,341)	(243,203)
Total stockholders' deficit	(17,665)	31,696
Total liabilities and stockholders' deficit	**$ 52,322**	**$ 102,772**

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars, in thousands, except SHARE AND per share amounts)

	Year Ended December 31,		
	2016	**2015**	**2014**
Revenues:			
Product Sales	8,266	4,157	76
Product Royalties	3,646	1,406	3,407
Sponsored reserarch revenue	1,134	909	12,712
Contract revenue	2,500	41,759	22,749
Total Revenues	15,546	48,231	38,944
Cost of sales	11,258	8,101	4,939
Expenses:			
Research and development:	18,878	20,624	34,285
Sales, general and administrative	49,345	54,685	38,460
Total expenses	68,223	75,309	72,745
Loss from operations	(63,935)	(35,179)	(38,740)
Interest expense, net	(3,267)	(2,518)	(2,016)
Derivative loss	-	-	(13,167)
Other income (expenses)	64	25	(295)
Net loss	$ (67,138)	$ (37,672)	$ (54,218)
Basic and diluted loss per share	$ (1.25)	$ (0.72)	$ (1.12)
Weighted average common stock shares outstanding, basic and diluted	53,679,134	52,384,876	48,355,200

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BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. DOLLARS, IN THOUSANDS)

	Year Ended December 31,		
	2016	**2015**	**2014**
Operating activities:			
Net loss	$ (67,138)	$ (37,672)	$ (54,218)
Adjustments to reconcile net (loss) income to net cash flows from operating activities			
Depreciation	437	329	123
Accretion of discount	397	500	642
Amortization of Intangible Assets	971	970	971
Derivative (gain) loss	-	-	13,167
Loss on disposal of assets	-	-	295
Purchase of Arcion license with commn stock	-	-	-
Stock based compensation	14,931	14,249	6,883
Changes in assets and liabilities:			
Accounts receivable	(1,081)	653	(347)
Inventories	(810)	(730)	(1,828)
Prepaid expenses and other assets	(203)	(1,365)	(2,251)
Accounts payable and accrued expenses	(1,327)	5,072	4,325
Deferred Revenue	(159)	14,262	3,405
Net cash flows from operating activities	(53,982)	(3,732)	(28,833)
Investing activities:			
Purchase of equipment	(405)	(701)	(1,603)
Net cash flows from investing activities	(405)	(701)	(1,603)
Financing activities:			
Proceeds from sales of securities	40	(40)	72,662
Proceeds from exercise of stock options	297	755	4,580
Proceeds from exercise of common stock warrants	-	1	7,741
Issuance of warrants	49	-	-

Issuance of common stock	2,460	-	-
Payment on note payable	-	(3,335)	(7,333)
Proceeds from notes payable	-	20,667	-
Return on short swing profits	-	6	82
Deferred Financing fees	-	(533)	-
Net cash flows from financing activities	2,846	17,521	77,732
Net change in cash and cash equivalents	(51,541)	13,088	47,296
Cash and cash equivalents at beginning of year	83,560	70,472	23,176
Cash and cash equivalents at end of year	**$ 32,019**	**$ 83,560**	**$ 70,472**
Cash paid for interest	$ 2,870	$ 1,885	$ 1,386

SOURCE BioDelivery Sciences International, Inc.

For further information: Investors: Matthew P. Duffy, Managing Director, LifeSci Advisors, LLC, 212-915-0685, matthew@lifesciadvisors.com, or Al Medwar, Senior Vice President, Corporate and Business Development, BioDelivery Sciences International, Inc., 919-582-9050, amedwar@bdsi.com; Media:Susan Forman/Laura Radocaj, Dian Griesel Int'l., 212-825-3210, sforman@dgicomm.com orlradocaj@dgicomm.com