

BioDelivery Sciences International (BDSI - \$ 13.15)

Healthcare / Biotechnology

BDSI Provides Pivotal Phase III Clonidine Trial Update

BioDelivery Sciences gave an update from an independent interim analysis of its on-going pivotal Phase III trial of Clonidine Topical Gel for painful diabetic neuropathy (PDN). Top-line data is expected by the end of 1Q15.

Ticker: **BDSI**
Rating: **Buy**
Price Target: **\$ 18.00**

- Clonidine Topical Gel Interim Analysis Results.** This morning, BDSI provided an update from the interim analysis of the first 50% of enrolled patients in its on-going pivotal Phase III trial of Clonidine Topical Gel for painful diabetic neuropathy (PDN). As a result of the analysis, the trial will require an additional 80 patients to maintain statistical significance at 90% confidence. With the additional patients the total enrollment for the trial will be 220 patients. The trial progress remains ahead of schedule and we believe the increased number of patients suggests an increased probability of success and FDA approval. Top-line data is expected by the end of 1Q15, at which the time the second pivotal Phase III will be initiated. We expect an NDA filing in 2016 and potential approval for 2017.
- Large Potential Market.** About 25.8 million people in the U.S. have diabetes according to the American Diabetes Association. A substantial number of these people have neuropathy as manifested by impaired sensation and pain in the extremities. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life. We believe the peak market potential for Clonidine Topical Gel for the treatment of PDN patients with functional nerve receptors is greater than \$280 million annually and we estimate annual sales could reach \$100 million by 2020.
- Increasing R&D Expense Expectations, Slightly Lowering EPS Estimates.** As a result of increased costs associated with the additional patient enrollment, we are increasing our expected R&D expense estimates for 2014 and 2015. We are slightly decreasing our 2014 and 2015 EPS estimates by 2 cents each, to a loss of \$0.49 and a loss of \$0.39, respectively.
- Reiterate Buy Rating and \$18 Price Target.** We are maintaining our Buy rating and \$18 price target. Our price target is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis.

Trading Data:

Last Price (08/06/2014)	\$ 13.15
52-Week High (7/15/2014)	\$ 14.44
52-Week Low (11/14/2013)	\$ 4.16
Market Cap. (MM)	\$ 637
Shares Out. (MM)	48

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.39	NM
FY_14E	0.00A	-0.15	-0.07	-0.26	-0.49	NM
FY_13A	-0.37	-0.36	-0.46	-0.33	-1.52	NM
FY_12A	0.29	0.23	-0.46	0.17	0.24	54.8

Edward White

Senior Managing Director/Senior Analyst
(212) 953-4910
ewhite@laidlawltd.com

Christopher Wolpert

Associate Equity Analyst
cwolpert@laidlawltd.com

Source: Laidlaw & Company estimates

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

Figure 1: Catalyst Summary

BEMA Buprenorphine Phase III Data

- Announced strong top-line data from opioid naive patient trial on January 23, 2014. Received \$10 million milestone payment from Endo as a result of database lock.
- Positive top-line experienced patient data announced July 7, 2014. Database lock resulted in \$10 million milestone payment from Endo.
- NDA filing expected by late 2014 / early 2015. NDA filing will trigger an additional \$10 million milestone payment, approval will result in \$50 million payment.

Bunavail Approval, Commercialization

- FDA approved June 6, 2014.
- Commercialization is planned for late 3Q14. BDSI will market in U.S. without a partner and has entered into agreements for sales force, market and trade support. Expect commercialization strategy to be announced at upcoming analyst meeting.

Phase III Clonidine Topical Gel Trial (Fast Track Designation)

- Enrollment of first pivotal Phase III completed. Interim Analysis results announced August 6, 2014, study requires approximately 80 additional patients to power statistical significance at 90% confidence.
- Topline results for the first Phase III trial are projected by end of 1Q15 (study remains ahead of schedule) with the second Phase III trial to be initiated. We expect NDA filing in 2016 and potential approval in 2017.

Onsolis Re-launch in US

- Working with partner Meda Pharmaceuticals to market the drug in the US by 2H14.

Source: Company reports; Laidlaw & Company estimates

Risks to Owning the Stock

There are many standard risks for development stage specialty pharmaceutical companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with relying on third parties to formulate and manufacture products and the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include: patent infringement risk, financing risk, currency risk, product liability (both clinical and non-clinical), patent protection risk and potential governmental price controls. The stock of small cap specialty pharmaceutical companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. BioDelivery is susceptible to all of these risks.

The value of the stock is hinged on binary events, including the FDA approval of BEMA Buprenorphine. Longer-term value for the company is based on the ultimate market potential and expectations for the company's drugs, and the successful commercialization of BEMA Buprenorphine and the FDA approved Bunavail.

BioDelivery is exposed to litigation by third parties based on claims that its technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that it has misappropriated the trade secrets of others. On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol RX, LLC filed an action against BioDelivery relating to Bunavail the United States District Court for the Eastern District of North Carolina for alleged patent infringement. The plaintiffs claim that the formulation for Bunavail, which has never been disclosed publicly, infringes its patent (U.S. Patent No. 8,475,832). This action could be in response to a recent decision in which the FDA ruled in favor of BioDelivery's position in two Citizen Petitions filed by the plaintiffs that sought to prevent the FDA from accepting and filing BioDelivery's NDA for Bunavail. The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505(b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as Bunavail), unless such application references the NDA for Suboxone (buprenorphine/naloxone) sublingual film (and not the Suboxone sublingual tablet NDA).

Figure 2: Income Statement

BioDelivery Sciences <i>Income Statement (millions, except per share data)</i>	FY 2013				FY 2014E				FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E Dec	FY_16E Dec
	Q1_13 Mar	Q2_13 Jun	Q3_13 Sept	Q4_13 Dec	Q1_14 Mar	Q2_14E Jun	Q3_14E Sept	Q4_14E Dec						
Product sales	-	-	-	-	-	-	2.0	7.5	-	-	-	9.5	28.1	42.2
Product royalty revenues	-	0.9	0.9	(0.0)	1.0	1.0	0.9	0.9	2.7	1.1	1.8	3.7	8.5	13.0
Research revenues	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-	-
Research and development reimbursements	-	-	-	2.8	8.5	4.2	3.4	1.7	1.2	-	2.8	17.7	2.0	-
Contract revenues	1.6	1.9	2.1	1.2	11.3	2.5	11.8	1.7	0.3	53.4	6.8	27.3	37.3	50.0
Revenue	1.6	2.8	3.0	4.0	20.7	7.7	18.1	11.8	4.5	54.5	11.4	58.3	76.0	105.1
Cost of product royalties	0.4	0.7	0.6	0.4	0.7	0.7	0.7	0.7	1.8	1.9	2.1	2.8	6.0	9.1
Cost of sales	-	-	-	-	-	-	1.4	3.4	-	-	-	4.8	8.4	10.5
Gross Profit	1.2	2.1	2.4	3.6	20.0	7.0	16.1	7.8	2.7	52.6	9.3	50.8	61.6	94.6
<i>Operating expenses:</i>														
Selling, general and administrative	2.9	3.1	3.0	3.2	4.6	6.2	13.0	13.1	7.6	10.1	12.3	36.8	52.3	54.9
Research and development	12.0	12.8	16.4	12.1	14.6	7.3	6.2	6.8	20.8	35.4	53.3	34.9	27.4	20.0
Related party general and administrative, net	0.0	0.0	0.0	0.0	0.0	-	-	-	0.1	0.1	0.0	0.0	-	-
Other non-GAAP adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses (ex-COGS)	15.0	15.9	19.4	15.4	19.3	13.5	19.2	19.9	28.5	45.6	65.7	71.8	79.7	74.9
Total Operating Expenses (non-GAAP, ex-COGS)	15.0	15.9	19.4	15.4	19.3	13.5	19.2	19.9	28.5	45.6	65.7	71.8	79.7	74.9
Operating Income/(loss)	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(6.5)	(3.1)	(12.1)	(25.8)	7.1	(56.4)	(21.0)	(18.1)	19.7
Operating Income/(loss) non-GAAP	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(6.5)	(3.1)	(12.1)	(25.8)	7.1	(56.4)	(21.0)	(18.1)	19.7
<i>Other Income:</i>														
Interest income	0.1	0.1	(0.5)	(0.6)	(0.6)	(0.3)	(0.2)	(0.1)	0.2	0.3	(0.9)	(1.2)	(0.7)	(0.2)
Derivative gain (loss)	1.0	0.4	(0.9)	(0.4)	(4.8)	0.0	0.0	0.0	3.5	(5.6)	0.1	(4.8)	0.0	0.0
Other (expense) income, net	(0.0)	(0.1)	(0.0)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	(0.2)	0.0	0.0	0.0
Income (loss) before provision for income taxes (GAAP)	(12.6)	(13.4)	(18.5)	(12.9)	(4.6)	(6.8)	(3.3)	(12.2)	(22.1)	1.8	(57.4)	(27.0)	(18.8)	19.5
Income (loss) before provision for income taxes (non-GAAP)	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(6.8)	(3.3)	(12.2)	(25.6)	7.4	(57.5)	(22.1)	(18.8)	19.5
<i>Tax: (%) non-GAAP</i>														
Income tax provision GAAP	0.1	0.0	-	-	-	-	-	-	-	0.1	0.1	0.0	-	-
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	(12.7)	(13.4)	(18.5)	(12.9)	(4.6)	(6.8)	(3.3)	(12.2)	(22.1)	1.7	(57.5)	(27.0)	(18.8)	19.5
Net income (loss) non-GAAP	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(6.8)	(3.3)	(12.2)	(25.6)	7.2	(57.6)	(22.1)	(18.8)	19.5
EPS (GAAP)	(\$0.34)	(\$0.35)	(\$0.49)	(\$0.34)	(\$0.11)	(\$0.15)	(\$0.07)	(\$0.26)	(\$0.78)	\$0.05	(\$1.51)	(\$0.59)	(\$0.39)	\$0.39
EPS (non-GAAP)	(\$0.37)	(\$0.36)	(\$0.46)	(\$0.33)	\$0.00	(\$0.15)	(\$0.07)	(\$0.26)	(\$0.90)	\$0.24	(\$1.52)	(\$0.49)	(\$0.39)	\$0.39
Weighted Diluted Shares outstanding (millions)	37.5	38.0	38.1	38.2	44.0	44.9	45.8	46.7	28.3	30.7	37.9	45.4	47.6	50.6
Weighted Diluted Shares YOY change (%)	26.8%	22.0%	26.6%	24.4%	17.4%	18.2%	20.3%	22.4%		8.4%	23.6%	19.6%	5.0%	6.1%

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Figure 3: Balance Sheet

BioDelivery Sciences	FY 2012				FY 2013				FY 2014E				FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E Dec
	Q1_12 Mar	Q2_12 Jun	Q3_12 Sept	Q4_12 Dec	Q1_13 Mar	Q2_13 Jun	Q3_13 Sept	Q4_13 Dec	Q1_14 Mar	Q2_14E Jun	Q3_14E Sept	Q4_14E Dec					
<i>Balance Sheet (\$ millions, except per share data)</i>																	
Assets:																	
Cash and cash equivalents	32.1	43.0	31.3	63.2	49.7	37.4	38.3	23.2	88.2	81.9	77.7	67.1	10.8	63.2	23.2	67.1	45.7
Accounts receivable, other	0.2	0.0	0.0	0.5	0.2	0.5	0.9	2.8	2.5	0.9	2.2	1.4	0.1	0.5	2.8	1.4	4.3
Prepaid expenses and other current assets	0.6	0.1	0.2	0.2	0.5	0.3	0.5	0.6	0.7	0.3	0.6	0.4	0.2	0.2	0.6	0.4	0.4
Total Current Assets	32.9	43.2	31.6	63.9	50.4	38.2	39.6	26.6	91.4	83.1	80.6	69.0	11.1	63.9	26.6	69.0	50.4
Equipment, net	3.2	3.1	2.9	2.8	2.7	2.6	0.2	0.2	0.2	0.3	0.3	0.3	3.3	2.8	0.2	0.3	1.2
Idle Equipment, net	-	-	-	-	-	-	-	2.8	3.3	3.3	3.3	3.3	-	-	2.8	3.3	3.3
Goodwill	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7
Total other intangible assets	6.9	6.7	6.4	6.2	5.9	5.7	2.5	5.2	5.0	5.0	5.0	5.0	6.2	6.2	5.2	5.0	5.0
Derivative asset, warrant	0.7	0.4	0.2	0.1	0.0	-	5.4	-	-	-	-	-	0.4	0.1	-	-	-
Other assets	0.0	0.0	0.0	0.0	-	-	0.1	0.5	0.4	0.4	0.4	0.4	0.0	0.0	0.5	0.4	0.4
Total Assets	46.4	56.1	43.9	75.7	61.8	49.3	50.6	38.0	103.0	94.7	92.2	80.6	23.6	75.7	38.0	80.6	63.0
Liabilities & Shareholders' Equity:																	
Accounts payable and other accrued liabilities	5.0	5.8	7.4	10.8	9.5	12.0	11.1	10.4	8.8	6.2	8.8	9.1	5.1	10.8	10.4	9.1	10.1
Notes payable, current	-	-	-	-	-	-	5.3	7.3	7.3	7.3	7.3	7.3	-	-	7.3	7.3	7.3
Deferred revenue, current	12.5	15.1	22.7	8.0	7.2	5.6	4.1	2.9	1.9	0.7	1.7	1.1	12.5	8.0	2.9	1.1	1.4
Derivative liabilities	2.4	5.6	8.9	4.5	3.5	3.0	3.9	4.3	7.5	7.5	7.5	7.5	0.3	4.5	4.3	7.5	7.5
Total Current Liabilities	20.0	26.5	39.1	23.2	20.2	20.6	24.4	25.0	25.6	21.7	25.3	25.0	17.9	23.2	25.0	25.0	26.4
Note Payable, less current maturities	-	-	-	-	-	-	13.8	11.8	9.9	7.9	5.8	3.8	-	-	11.8	3.8	0.0
Deferred revenue, long-term	1.6	1.5	4.3	2.7	1.9	1.6	1.3	1.3	2.2	0.8	2.9	1.9	1.6	2.7	1.3	1.9	2.5
Other long-term liabilities	-	-	-	-	-	-	-	0.7	0.7	0.7	0.7	0.7	-	-	0.7	0.7	0.7
Total Liabilities	21.5	28.0	43.3	26.0	22.1	22.2	39.5	38.8	38.4	31.1	34.8	31.4	19.5	26.0	38.8	31.4	29.6
Stockholders' Equity	24.9	28.1	0.6	49.8	39.7	27.1	11.0	(0.8)	64.6	27.1	57.4	49.2	4.1	49.8	-0.8	49.2	33.5
Total Liabilities & Equity	46.4	56.1	43.9	75.7	61.8	49.3	50.6	38.0	103.0	58.2	92.2	80.6	23.6	75.7	38.0	80.6	63.0

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Figure 4: Cash Flow Statement

BioDelivery Sciences	FY_11	FY_12	FY_13	FY_14E	FY_15E
<i>Non-GAAP Cash Flow Cont. Ops. (\$ millions, except per share data)</i>	Dec	Dec	Dec	Dec	Dec
Cash flows from operating activities:					
Net income	(22.1)	1.7	(57.4)	(27.0)	(18.8)
Adjustments to reconcile net income to net cash provided by operating activities:					
Depreciation and amortization	1.3	1.5	1.3	1.3	1.3
Accretion of Discount	-	-	0.2	0.3	0.3
Derivative (gain) loss	(3.5)	5.6	(0.1)	4.8	-
Purchase of Arcion license with common stock	-	-	2.1	-	-
Stock-based compensation expense	1.2	1.6	3.3	4.6	4.6
Changes in assets and liabilities:					
Accounts receivable	0.5	(0.4)	(2.3)	1.4	(2.8)
Prepaid expenses and other assets	0.0	0.0	(0.1)	0.2	-
Accounts payable and other accrued expenses	0.4	5.6	(0.7)	(1.0)	(1.0)
Income tax payable	-	0.1	-	0.3	-
Deferred revenue	0.0	(3.4)	(6.5)	0.8	(0.3)
Net cash provided by (used in) operating activities	(22.0)	12.2	(60.1)	(14.2)	(16.7)
Cash flow from investing activities:					
Purchases of property and equipment	(0.3)	(0.0)	(0.1)	(0.9)	(1.0)
Purchases of intangible assets	-	(1.1)	-	-	-
Cash provided by investing activities	(0.3)	(1.1)	(0.1)	(0.9)	(1.0)
Cash flows from financing activities:					
Proceeds from sale of securities	14.0	38.4	-	62.0	-
Proceeds from exercise of stock options	0.3	2.1	0.4	2.6	-
Proceeds from exercise of common stock warrants	-	-	0.1	2.6	-
Proceeds from notes payable and warrants	-	-	20.0	-	-
Deferred financing activities	-	-	(0.2)	-	-
Repayment of note	-	-	-	(8.2)	(3.8)
Return of short swing profits	-	-	-	0.1	-
Change in amounts due to related parties	0.0	(0.0)	-	-	-
Other	1.7	0.9	-	-	-
Cash (used in) provided by financing activities	16.1	41.3	20.2	59.1	(3.8)
Effect of exchange rates on cash	-	-	-	-	-
Net (decrease) increase in cash and cash equivalents	(6.2)	52.4	(40.0)	44.0	(21.4)
Cash and cash equivalents at beginning of the period	18.2	10.8	63.2	23.2	67.1
Cash and cash equivalents at end of period	-	12.0	23.2	67.1	45.7

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

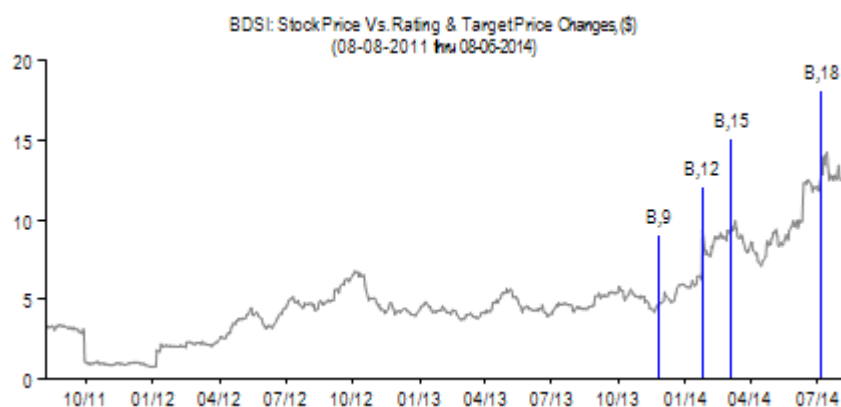
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Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/26/2013	Buy (B)	4.81

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/26/2013	9.00	4.81
01/24/2014	12.00	9.41
03/05/2014	15.00	9.60
07/07/2014	18.00	13.06

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	94.44%	33.33%	11.11%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.56%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Endo Health Solutions Inc. (ENDP, Not Rated)
Reckitt Benckiser Group PLC (RB/LN, Not Rated)

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

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