

BioDelivery Sciences International (BDSI - \$ 6.39)

Management Meeting Highlights - 2014: A Year Full of Catalysts for BDSI

BioDelivery has significant opportunity to capitalize on its pipeline in 2014.

- Anticipated Database Lock, Milestone Payment.** BDSI announced that the database lock for its BEMA Buprenorphine Phase III trial in opioid naïve patients with moderate to severe pain is highly likely in the near-term. The database lock will result in a \$10 million milestone payment from Endo Health Solutions. In addition, the company expects data for the trial to be available in late January or early February. BEMA Buprenorphine, a partial mu-opioid agonist for treatment of moderate to severe chronic pain, is also in a second Phase III trial for opioid experienced patients. We expect the database for this trial to be locked by mid-2014 triggering another milestone payment. An NDA for BEMA Buprenorphine could be filed in late 2014, in our opinion. We continue to estimate that the drug could generate \$500 million in annual peak sales.
- Development Plans for Bunavail.** Pending FDA approval of Bunavail, management is targeting a late 3Q14 launch for the drug following the PDUFA date of June 7, 2014. Bunavail combines BEMA Buprenorphine and naloxone, an abuse deterrent agent. The opioid dependence market represents a significant opportunity for BioDelivery, with sales of comparable drugs over \$1.4 billion in 2013 according to Symphony Health. We continue to estimate that Bunavail will generate \$5 million of sales in 2014 growing to about \$150 million by 2020 in the U.S. BioDelivery is continuing with its commercial launch plans, but the company could still partner the drug under the right circumstances.
- Clonidine Phase III Program Confirmed by FDA.** On December 2, 2013, BioDelivery announced that the FDA had agreed with its clinical development program for Clonidine Topical Gel and that it would be launching pivotal Phase III studies in 2014. The first study for treatment of painful diabetic neuropathy (PDN) is expected to begin enrollment in 1Q14, with results targeted for the end of FY14. We expect the second Phase III trial will start in early 2015. We project an NDA could be filed in 2016 with approval in 2017 and Clonidine peak sales of \$300 million.
- Maintain BUY Rating and Price Target.** Our price target of \$9 is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis. This implies an approximate 42% upside potential.

Healthcare / Specialty Pharma

Ticker: **BDSI**
Rating: **Buy**
Price Target: **\$ 9.00**

Trading Data:

Last Price (01/22/2014)	\$ 6.39
52-Week High (1/21/2014)	\$ 6.75
52-Week Low (3/1/2013)	\$ 3.52
Market Cap. (MM)	\$ 241
Shares Out. (MM)	38

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.09	N.M.
FY_14E	-0.33	-0.06	-0.30A	0.00	-0.69	N.M.
FY_13E	-0.37A	-0.36A	-0.46A	-0.26	-1.45	N.M.
FY_12A	0.29	0.23	-0.46	0.17	0.24	N.M.

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Source: Laidlaw & Company estimates

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Figure 1: BDSI 2014 Catalysts

BEMA Buprenorphine Phase III Data

- Expected data from both opioid naive (1Q14) and experienced (3Q14) patient trials to result in milestone payments from Endo.

PDUFA Date For Bunavail, Possible Commercialization

- Review by FDA expected to be completed by June 7, 2014.
- Commercialization of Bunavail is planned for 2H14 assuming approval.

Initiation of Phase III Clonidine Topical Gel Trial

- The study is expected to begin in 1Q14 with completed enrollment targeted for end of year.

Onsolis Re-launch in US

- Working with partner Meda Pharmaceuticals to market the drug in the US by 2H14. Re-launch has been postponed since March 2012.

Source: Company reports

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.

Downside risks specific to BioDelivery include the likelihood of the need to sell more stock to raise capital for the continuation of the company's clinical trials and the launch of Bunavail. However, we believe investors already assume that the company will have to raise funds for the continued development of the company's products and the launch. We expect the company will have to raise capital in each of the next two years and have included those assumptions in our models. The value of the stock is hinged on binary events, including the success of the two Phase III trials for BEMA Buprenorphine and the FDA approval of Bunavail. 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 these drugs.

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 2012				FY 2013E				FY 2014E				FY_11 Dec	FY_12 Dec	FY_13E Dec	FY_14E Dec	FY_15E Dec	
	Q1_12	Q2_12	Q3_12	Q4_12	Q1_13	Q2_13	Q3_13	Q4_13E	Q1_14E	Q2_14E	Q3_14	Q4_14E						
	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec						
Product sales	-	-	-	-	-	-	-	-	-	-	-	1.0	4.0	-	-	5.0	14.3	
Product royalties	-	-	-	1.1	-	0.9	0.9	1.0	1.1	1.1	1.2	1.3	-	2.7	1.1	2.8	4.6	5.6
Research revenues	0.0	-	-	(0.0)	-	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-
Contract revenues	16.5	16.3	1.9	18.8	1.6	1.9	2.1	1.8	1.8	16.8	1.8	16.7	0.3	53.4	7.4	37.2	57.2	
Revenue	16.5	16.3	1.9	19.9	1.6	2.8	3.0	2.8	2.9	17.9	4.0	22.0	3.3	54.5	10.2	46.8	77.0	
Cost of product royalties	0.4	0.4	0.4	0.8	0.4	0.7	0.6	0.7	0.7	0.8	0.8	0.9	1.8	1.9	2.4	3.2	3.9	
Cost of sales	-	-	-	-	-	-	-	-	-	-	2.0	6.0	-	-	-	8.0	10.0	
Gross Profit	16.1	15.9	1.5	19.1	1.2	2.1	2.4	2.1	2.1	17.2	1.2	15.1	1.5	52.6	7.8	35.6	63.2	
<i>Operating expenses:</i>																		
Selling, general and administrative	2.8	2.2	3.0	2.1	2.9	3.1	3.0	2.9	4.5	8.3	8.4	9.6	7.6	10.1	12.0	30.7	32.1	
Research and development	4.7	6.5	12.5	11.6	12.0	12.8	16.4	9.0	9.1	9.2	4.1	3.4	20.8	35.4	50.2	25.9	26.1	
Related party general and administrative, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-	-	-	-	0.1	0.1	0.0	-	-	
Other non-GAAP adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total Operating Expenses (ex-COGS)	7.6	8.8	15.6	13.7	15.0	15.9	19.4	11.9	13.6	17.5	12.5	13.0	28.5	45.6	62.2	56.6	58.2	
Total Operating Expenses (non-GAAP, ex-COGS)	7.6	8.8	15.6	13.7	15.0	15.9	19.4	11.9	13.6	17.5	12.5	13.0	28.5	45.6	62.2	56.6	58.2	
Operating Income/(loss)	8.6	7.1	(14.1)	5.4	(13.7)	(13.8)	(17.1)	(9.8)	(11.5)	(0.3)	(11.3)	2.1	(27.0)	7.1	(54.4)	(20.9)	4.9	
Operating Income/(loss) non-GAAP	8.6	7.1	(14.1)	5.4	(13.7)	(13.8)	(17.1)	(9.8)	(11.5)	(0.3)	(11.3)	2.1	(27.0)	7.1	(54.4)	(20.9)	4.9	
<i>Other Income:</i>																		
Interest income	0.1	0.1	0.1	0.1	0.1	0.1	(0.5)	(0.4)	(1.6)	(2.2)	(2.2)	(2.2)	0.2	0.3	(0.7)	(8.2)	(8.8)	
Derivative gain (loss)	(1.9)	(3.5)	(3.5)	3.3	1.0	0.4	(0.9)	-	-	-	-	-	3.5	(5.6)	0.5	0.0	0.0	
Other (expense) income, net	(0.0)	0.1	0.0	(0.0)	(0.0)	(0.1)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(0.2)	0.0	0.0	
Income (loss) before provision for income taxes (GAAP)	6.8	3.8	(17.5)	8.7	(12.6)	(13.4)	(18.5)	(10.2)	(13.1)	(2.5)	(13.5)	(0.0)	(23.3)	1.8	(54.8)	(29.1)	(3.9)	
Income (loss) before provision for income taxes (non-GAAP)	8.6	7.3	(14.0)	5.4	(13.7)	(13.8)	(17.6)	(10.2)	(13.1)	(2.5)	(13.5)	(0.0)	(26.8)	7.4	(55.3)	(29.1)	(3.9)	
<i>Tax: (% non-GAAP)</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>2.4%</i>	<i>NM</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	<i>NM</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>1.8%</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	
Income tax provision GAAP	0.0	0.0	0.0	0.1	0.1	0.0	-	-	0.0	0.0	-	-	-	0.1	0.1	0.0	-	
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net income (loss) GAAP	6.8	3.8	(17.5)	8.6	(12.7)	(13.4)	(18.5)	(10.2)	(13.1)	(2.5)	(13.5)	(0.0)	(23.3)	1.7	(54.8)	(29.1)	(3.9)	
Net income (loss) non-GAAP	8.6	7.3	(14.0)	5.3	(13.7)	(13.8)	(17.6)	(10.2)	(13.1)	(2.5)	(13.5)	(0.0)	(26.8)	7.2	(55.3)	(29.1)	(3.9)	
EPS (GAAP)	\$0.23	\$0.12	(\$0.58)	\$0.28	(\$0.34)	(\$0.35)	(\$0.49)	(\$0.26)	(\$0.33)	(\$0.06)	(\$0.30)	(\$0.00)	(\$0.82)	\$0.05	(\$1.44)	(\$0.69)	(\$0.09)	
EPS (non-GAAP)	\$0.29	\$0.23	(\$0.46)	\$0.17	(\$0.37)	(\$0.36)	(\$0.46)	(\$0.26)	(\$0.33)	(\$0.06)	(\$0.30)	(\$0.00)	(\$0.95)	\$0.24	(\$1.45)	(\$0.69)	(\$0.09)	
Weighted Diluted Shares outstanding (millions)	29.6	31.1	30.1	30.7	37.5	38.0	38.1	38.8	39.6	40.4	44.8	45.2	28.3	30.7	38.1	42.5	45.2	
Weighted Diluted Shares YOY change (%)	-	-	-	-	26.8%	22.0%	26.6%	26.6%	5.6%	6.3%	17.6%	16.5%	-	8.4%	24.2%	11.6%	6.2%	

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

Figure 3: Balance Sheet

BioDelivery Sciences	FY 2012				FY 2013E				FY_11 Dec	FY_12 Dec	FY_13E 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_13E 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	25.2	10.8	63.2	25.2	12.3	17.5
Accounts receivable, other	0.2	0.0	0.0	0.5	0.2	0.5	0.9	0.8	0.1	0.5	0.8	5.8	8.6
Prepaid expenses and other current assets	0.6	0.1	0.2	0.2	0.5	0.3	0.5	0.4	0.2	0.2	0.4	0.4	0.4
Total Current Assets	32.9	43.2	31.6	63.9	50.4	38.2	39.6	26.4	11.1	63.9	26.4	18.5	26.6
Equipment, net	3.2	3.1	2.9	2.8	2.7	2.6	0.2	0.2	3.3	2.8	0.2	0.2	0.2
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
Total other intangible assets	6.9	6.7	6.4	6.2	5.9	5.7	2.5	2.5	6.2	6.2	2.5	2.5	2.5
Derivative asset, warrant	0.7	0.4	0.2	0.1	0.0	-	5.4	5.4	0.4	0.1	5.4	5.4	5.4
Other assets	0.0	0.0	0.0	0.0	-	-	0.1	0.1	0.0	0.0	0.1	0.1	0.1
Total Assets	46.4	56.1	43.9	75.7	61.8	49.3	50.6	37.4	23.6	75.7	37.4	29.5	37.6
Liabilities & Shareholders' Equity:													
Accounts payable and other accrued liabilities	5.0	5.8	7.4	10.8	9.5	12.0	11.1	6.8	5.1	10.8	6.8	6.2	6.4
Notes payable, current	-	-	-	-	-	-	5.3	5.3	-	-	5.3	5.3	5.3
Deferred revenue, current	12.5	15.1	22.7	8.0	7.2	5.6	4.1	3.8	12.5	8.0	3.8	3.6	4.0
Derivative liabilities	2.4	5.6	8.9	4.5	3.5	3.0	3.9	3.9	0.3	4.5	3.9	3.9	3.9
Total Current Liabilities	20.0	26.5	39.1	23.2	20.2	20.6	24.4	19.9	17.9	23.2	19.9	19.1	19.6
Note Payable, less current maturities	-	-	-	-	-	-	13.8	13.3	-	-	-	-	-
Deferred revenue, long-term	1.6	1.5	4.3	2.7	1.9	1.6	1.3	1.3	1.6	2.7	1.3	4.8	4.8
Total Liabilities	21.5	28.0	43.3	26.0	22.1	22.2	39.5	34.5	19.5	26.0	21.2	23.8	24.4
Stockholders' Equity	24.9	28.1	0.6	49.8	39.7	27.1	11.0	2.9	4.1	49.8	16.2	5.6	13.1
Total Liabilities & Equity	46.4	56.1	43.9	75.7	61.8	49.3	50.6	37.4	23.6	75.7	37.4	29.5	37.6

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

Figure 4: Cash flow Statement

BioDelivery Sciences	FY_11	FY_12	FY_13E	FY_14E	FY_15E
<i>Balance Sheet (\$ millions, except per share data)</i>	Dec	Dec	Dec	Dec	Dec
Assets:					
Cash and cash equivalents	10.8	63.2	25.2	12.3	17.5
Accounts receivable, other	0.1	0.5	0.8	5.8	8.6
Prepaid expenses and other current assets	0.2	0.2	0.4	0.4	0.4
Total Current Assets	11.1	63.9	26.4	18.5	26.6
Equipment, net	3.3	2.8	0.2	0.2	0.2
Goodwill	2.7	2.7	2.7	2.7	2.7
Total other intangible assets	6.2	6.2	2.5	2.5	2.5
Derivative asset, warrant	0.4	0.1	5.4	5.4	5.4
Other assets	0.0	0.0	0.1	0.1	0.1
Total Assets	23.6	75.7	37.4	29.5	37.6
Liabilities & Shareholders' Equity:					
Accounts payable and other accrued liabilities	5.1	10.8	6.8	6.2	6.4
Notes payable, current	-	-	5.3	5.3	5.3
Deferred revenue, current	12.5	8.0	3.8	3.6	4.0
Derivative liabilities	0.3	4.5	3.9	3.9	3.9
Total Current Liabilities	17.9	23.2	19.9	19.1	19.6
Note Payable, less current maturities	-	-	-	-	-
Deferred revenue, long-term	1.6	2.7	1.3	4.8	4.8
Total Liabilities	19.5	26.0	21.2	23.8	24.4
Stockholders' Equity	4.1	49.8	16.2	5.6	13.1
Total Liabilities & Equity	23.6	75.7	37.4	29.5	37.6

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

DISCLOSURES:

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Rating and Price Target Change History



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

Date	Target Price (\$)	Closing Price, (\$)
11/26/2013	9.00	4.81

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.	83.33%	33.33%	16.67%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	16.67%	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)

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NOTES: