

BioDelivery Sciences International (BDSI - \$ 9.06)

4Q13 Results Below Expectations, Long Term Outlook Strong

BioDelivery posted 4Q13 adjusted EPS of a loss of \$0.33, below our estimate of a loss of \$0.26. However, we are raising our revenue and EPS estimates for 2014 and 2015. We continue our BUY-rating and \$15 price target.

- 4Q13 Results.** BDSI reported 4Q13 non-GAAP EPS of a loss of \$0.33, \$0.07 cents below our and the consensus estimate of a loss of \$0.26. Non-GAAP EPS for FY13 was a loss of \$1.52, \$0.06 below our estimate of a loss \$1.45 and \$0.12 below the consensus estimate of \$1.40. FY13 revenue was \$11.4 million, \$1.2 million above our estimate of \$10.2 million and \$2.0 million below consensus. Revenue included reimbursement for contractual research and development expenses totaling \$2.8 million. Total R&D expense for FY13 was \$53.3 million, up 50.6% from FY12. Ongoing development of BEMA Buprenorphine resulted in \$41.8 million of R&D expense and Bunavail related costs resulted in \$7.1 million of the total full-year expense. BDSI had \$23.2 million in cash at the end of 4Q13, down from \$63.2 million from the year ago period. This balance does not reflect the proceeds of the direct equity offering of \$60.0 million, \$3.9 million from an "at-the-market" offering program in January 2014 and \$10.0 million milestone received from Endo in February 2014. The company reported a balance of \$89.8 million as of February 28, 2014.
- No Partner for Bunavail.** BDSI recently announced plans to market Bunavail in the U.S. through a direct sales force and partner the drug in the rest of the world. The PDUFA date for Bunavail is June 7, 2014 and if approved, the launch is expected in late 3Q14. Management stated that it is in discussions with potential partners in several geographic areas outside the U.S. We raised our risk-adjusted U.S. Bunavail sales estimates to \$32 million from \$10 million in 2014 growing to \$214 million by 2020.
- Raising Estimates.** We are raising our 2014 revenue estimate to \$71.7 million from \$52.6 million due to higher product sales expectations. In addition, we are increasing our 2015 revenue estimate to \$119.4 million from \$83.7 million. We are raising our non-GAAP EPS estimates for FY14 to a loss of \$0.12 from a loss of \$0.27 and FY15 to \$0.47 from \$0.16.
- Maintain BUY Rating and Raising Price Target.** We are maintaining our BUY rating and price target of \$15. Our price target is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	0.47	19.3
FY_14E	-0.14	-0.24	0.02	0.19	-0.12	NA
FY_13A	-0.37	-0.36	-0.46	-0.33	-1.52	NA
FY_12A	0.29	0.23	-0.46	0.17	0.24	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker: **BDSI**
 Rating: **Buy**
 Price Target: **\$ 15.00**

Trading Data:

Last Price (03/17/2014)	\$ 9.06
52-Week High (3/11/2014)	\$ 10.20
52-Week Low (3/22/2013)	\$ 3.82
Market Cap. (MM)	\$ 426
Shares Out. (MM)	48

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Operating Results Review

Fourth Quarter 2013 Results

Figure 1: BioDelivery Sciences International 4Q13 Yr/Yr and Qtr/Qtr comparison, (\$ millions, except per share data)

(\$ millions, except per share data)	Deviation from Laidlaw Estimates			Year/Year Change			Sequential Change		
	Actual 4Q13	Est. 4Q13	% Difference	3Q12	Change	% Difference	3Q13	Change	% Difference
Total Revenues	4.0	3.7	7.4%	19.9	(15.9)	-80.0%	3.0	1.0	32.6%
Selling, General and Administrative Expense	3.2	2.9	11.8%	2.1	1.2	56.5%	3.0	0.2	6.7%
R&D Expense	12.1	9.0	35.0%	11.6	0.6	5.1%	16.4	(4.8)	-25.9%
Operating Income/loss (GAAP)	(11.8)	(8.8)	NM	5.4	(17.2)	NM	(17.1)	5.3	NM
Operating Income/loss (Non-GAAP)	(11.8)	(3.1)	NM	5.4	(17.2)	NM	(17.1)	5.3	NM
Net Income (GAAP)	(12.9)	(10.1)	NM	8.6	(21.4)	NM	(18.5)	5.6	NM
Net Income (Non-GAAP)	(12.5)	(4.4)	NM	5.3	(17.8)	NM	(17.6)	5.1	NM
Diluted EPS (GAAP)	-\$0.34	-\$0.26	NM	\$0.28	-\$0.62	NM	-\$0.49	\$0.15	NM
Diluted EPS (Non-GAAP)	-\$0.33	-\$0.26	NM	\$0.17	-\$0.45	NM	-\$0.46	\$0.13	NM
Non-GAAP Diluted Shares Outstanding	38.2	38.8	-1.6%	30.7	7.5	24.4%	38.1	0.1	0.3%

Source: Company reports; Laidlaw & Company estimates

Figure 2: BDSI 2014 Catalysts

BEMA Buprenorphine Phase III Data

- Announced strong top-line data from opioid naive patient trial on January 23, 2014. Received \$10 million milestone payment as a result of database lock.
- Experienced patient database lock expected for late June / early July, will result in an additional \$10 million milestone payment from Endo.
- NDA filing expected by late 2014 / early 2015. NDA Filing will trigger additional \$10 million milestone payment.

PDUFA Date For Bunavail, Possible Commercialization

- Review by FDA expected to be completed by June 7, 2014.
- Commercialization of Bunavail is planned for 3Q14 assuming approval. Company announced plans to market in U.S. without a partner.

Initiation of Phase III Clonidine Topical Gel Trial

- The study will begin March 2014 with interim results expected by 4Q14.
- Topline results for the Phase III trial are projected by 1Q15. We expect an NDA filing in 2016.

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.

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).

Figure3: Income Statement

BioDelivery Sciences <i>Income Statement (millions, except per share data)</i>	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_14E Mar	Q2_14E Jun	Q3_14E Sept	Q4_14E Dec					
Product sales	-	-	-	-	-	-	-	-	-	-	10.0	22.0	-	-	-	32.0	56.3
Product royalty revenues	-	-	-	1.1	-	0.9	0.9	(0.0)	-	-	0.9	0.9	2.7	1.1	1.8	1.8	5.3
Research revenues	0.0	-	-	(0.0)	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-
Research and development reimbursements	-	-	-	0.0	-	-	-	2.8	-	-	-	-	1.2	-	2.8	-	-
Contract revenues	16.5	16.3	1.9	18.8	1.6	1.9	2.1	1.2	11.8	2.5	11.8	11.7	0.3	53.4	6.8	37.9	57.9
Revenue	16.5	16.3	1.9	19.9	1.6	2.8	3.0	4.0	11.8	2.5	22.7	34.6	4.5	54.5	11.4	71.7	119.4
Cost of product royalties	0.4	0.4	0.4	0.8	0.4	0.7	0.6	0.4	0.4	0.4	0.7	0.7	1.8	1.9	2.1	2.0	6.0
Cost of sales	-	-	-	-	-	-	-	-	-	-	5.5	9.9	-	-	-	15.4	21.4
Gross Profit	16.1	15.9	1.5	19.1	1.2	2.1	2.4	3.6	11.5	2.2	16.6	24.1	2.7	52.6	9.3	54.2	92.0
<i>Operating expenses:</i>																	
Selling, general and administrative	2.8	2.2	3.0	2.1	2.9	3.1	3.0	3.2	5.4	6.8	10.0	10.1	7.6	10.1	12.3	32.2	37.0
Research and development	4.7	6.5	12.5	11.6	12.0	12.8	16.4	12.1	12.2	6.1	5.2	3.4	20.8	35.4	53.3	27.0	27.7
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	15.4	17.6	12.9	15.2	13.5	28.5	45.6	65.7	59.2	64.7
Total Operating Expenses (non-GAAP, ex-COGS)	7.6	8.8	15.6	13.7	15.0	15.9	19.4	15.4	17.6	12.9	15.2	13.5	28.5	45.6	65.7	59.2	64.7
Operating Income/(loss)	8.6	7.1	(14.1)	5.4	(13.7)	(13.8)	(17.1)	(11.8)	(6.2)	(10.7)	1.4	10.6	(25.8)	7.1	(56.4)	(4.9)	27.4
Operating Income/(loss) non-GAAP	8.6	7.1	(14.1)	5.4	(13.7)	(13.8)	(17.1)	(11.8)	(6.2)	(10.7)	1.4	10.6	(25.8)	7.1	(56.4)	(4.9)	27.4
<i>Other income:</i>																	
Interest income	0.1	0.1	0.1	0.1	0.1	0.1	(0.5)	(0.6)	(0.4)	(0.3)	(0.2)	(0.1)	0.2	0.3	(0.9)	(1.0)	0.0
Derivative gain (loss)	(1.9)	(3.5)	(3.5)	3.3	1.0	0.4	(0.9)	(0.4)	0.0	0.0	0.0	0.0	3.5	(5.6)	0.1	0.0	0.0
Other (expense) income, net	(0.0)	0.1	0.0	(0.0)	(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
Income (loss) before provision for income taxes (GAAP)	6.8	3.8	(17.5)	8.7	(12.6)	(13.4)	(18.5)	(12.9)	(6.6)	(11.0)	1.2	10.5	(22.1)	1.8	(57.4)	(5.9)	27.4
Income (loss) before provision for income taxes (non-GAAP)	8.6	7.3	(14.0)	5.4	(13.7)	(13.8)	(17.6)	(12.5)	(6.6)	(11.0)	1.2	10.5	(25.6)	7.4	(57.5)	(5.9)	27.4
<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>0.0%</i>	<i>0.0%</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	-	-	-	-	-	-	-	0.1	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)	(12.9)	(6.6)	(11.0)	1.2	10.5	(22.1)	1.7	(57.5)	(5.9)	27.4
Net income (loss) non-GAAP	8.6	7.3	(14.0)	5.3	(13.7)	(13.8)	(17.6)	(12.5)	(6.6)	(11.0)	1.2	10.5	(25.6)	7.2	(57.6)	(5.9)	27.4
EPS (GAAP)	\$0.23	\$0.12	(\$0.58)	\$0.28	(\$0.34)	(\$0.35)	(\$0.49)	(\$0.34)	(\$0.14)	(\$0.24)	\$0.02	\$0.19	(\$0.78)	\$0.05	(\$1.51)	(\$0.12)	\$0.47
EPS (non-GAAP)	\$0.29	\$0.23	(\$0.46)	\$0.17	(\$0.37)	(\$0.36)	(\$0.46)	(\$0.33)	(\$0.14)	(\$0.24)	\$0.02	\$0.19	(\$0.90)	\$0.24	(\$1.52)	(\$0.12)	\$0.47
Weighted Diluted Shares outstanding (millions)	29.6	31.1	30.1	30.7	37.5	38.0	38.1	38.2	45.7	46.6	53.5	54.0	28.3	30.7	37.9	49.9	58.7
Weighted Diluted Shares YOY change (%)					26.8%	22.0%	26.6%	24.4%	21.8%	22.6%	40.4%	41.4%		8.4%	23.6%	31.6%	17.5%

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

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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

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.	85.71%	28.57%	14.29%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	7.14%	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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