

BioDelivery Sciences International (BDSI - \$ 16.33)

Healthcare / Biotechnology

Highlights from Investor Day, Increasing Price Target

- Bunavail Launch Outlined.** On Friday, BDSI hosted an analyst and investor meeting and provided details on the launch of Bunavail for the treatment of opioid dependence. A panel of members of senior management as well as key opinion leaders (KOLs) presented. BDSI management outlined details of the marketing and sales campaign including emphasis on the technology behind the BEMA delivery platform and the physicians and geographies to be targeted. Pricing for Bunavail is going to be at parity with Suboxone, as we had expected. It was announced that the sales team marketing Bunavail was active as of September 5th. Overall, the launch is more substantial than we had anticipated. The 56 person sales force is larger than our initial projection and we have increased our Bunavail related SG&A expectations. Previously highlighted Bunavail product attributes and comparable product side effects were discussed by the KOLs. Of note, the physicians highlighted the ability of Bunavail patients to both speak and swallow while using the product as well as a 68% decrease in patient constipation when using Bunavail compared to Suboxone sublingual tablets in clinical trials. Bunavail offers significant opportunity for quality of life improvement compared to existing treatment options, in our opinion.
- Tweaking Estimates.** We are making changes to our revenue and SG&A expectations to account for a more organized launch than we had expected as well as a larger sales force increasing employee compensation. We are slightly decreasing our FY14 revenue expectations to \$50.2 million from \$52.2 million and slightly increasing our SG&A expense estimate for a net effect of a lower EPS of a loss of \$0.53 from a loss of \$0.49. We are raising both our 2015 and 2016 revenue estimates to \$83.5 million from \$80.1 million and to \$126.0 million from \$120.5 million, respectively.
- Pipeline Comments.** During the conference management reiterated its optimistic view on the possible sales of Clonidine Gel, once again stating that it has the most potential of any its portfolio products. KOL comments on the rescheduling of hydrocodone combination products and the resulting market opportunity for chronic pain patients also reinforced our view that BEMA Buprenorphine sales could be substantially greater than previously expected.
- Maintaining BUY Rating, Increasing Price Target.** We are raising our price target to \$20 from \$19. Our price target is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis.

Ticker: **BDSI**
 Rating: **Buy**
 Price Target: ↑ raise **\$ 20.00**

Trading Data:

Last Price (09/05/2014)	\$ 16.33
52-Week High (9/3/2014)	\$ 16.82
52-Week Low (11/14/2013)	\$ 4.16
Market Cap. (MM)	\$ 805
Shares Out. (MM)	49

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.12	NM
FY_14E	0.00A	-0.05A	-0.26	-0.20	-0.53	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	68.0

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Source: Laidlaw & Company estimates

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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. BSI 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 the company's analyst meeting on September 5, 2014.

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.
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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. In addition, 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. 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 drug Bunavail.

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_14 Jun	Q3_14E Sept	Q4_14E Dec						
Product sales	-	-	-	-	-	-	-	7.5	-	-	-	7.5	37.5	61.3
Product royalty revenues	-	0.9	0.9	(0.0)	1.0	0.9	0.9	0.9	2.7	1.1	1.8	3.6	8.5	14.7
Research revenues	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-	-
Research and development reimbursements	-	-	-	2.8	8.5	2.3	1.9	0.9	1.2	-	2.8	13.6	2.0	-
Contract revenues	1.6	1.9	2.1	1.2	11.3	10.7	1.8	1.7	0.3	53.4	6.8	25.5	35.5	50.0
Revenue	1.6	2.8	3.0	4.0	20.7	13.9	4.6	11.0	4.5	54.5	11.4	50.2	83.5	126.0
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	2.7	6.0	10.3
Cost of sales	-	-	-	-	-	-	-	2.6	-	-	-	2.6	10.9	14.7
Gross Profit	1.2	2.1	2.4	3.6	20.0	13.2	3.9	7.8	2.7	52.6	9.3	44.8	66.7	111.3
<i>Operating expenses:</i>														
Selling, general and administrative	2.9	3.1	3.0	3.2	4.6	7.2	9.8	11.1	7.6	10.1	12.3	32.8	44.5	47.6
Research and development	12.0	12.8	16.4	12.1	14.6	8.0	6.8	6.8	20.8	35.4	53.3	36.2	27.4	22.0
Related party general and administrative, net	0.0	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	15.2	16.6	17.9	28.5	45.6	65.7	69.0	71.9	69.6
Total Operating Expenses (non-GAAP, ex-COGS)	15.0	15.9	19.4	15.4	19.3	15.2	16.6	17.9	28.5	45.6	65.7	69.0	71.9	69.6
Operating Income/(loss)	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(2.0)	(12.6)	(10.2)	(25.8)	7.1	(56.4)	(24.1)	(5.2)	41.6
Operating Income/(loss) non-GAAP	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(2.0)	(12.6)	(10.2)	(25.8)	7.1	(56.4)	(24.1)	(5.2)	41.6
<i>Other Income:</i>														
Interest income	0.1	0.1	(0.5)	(0.6)	(0.6)	(0.5)	(0.2)	(0.1)	0.2	0.3	(0.9)	(1.4)	(0.9)	(0.4)
Derivative gain (loss)	1.0	0.4	(0.9)	(0.4)	(4.8)	(4.1)	0.0	0.0	3.5	(5.6)	0.1	(8.9)	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)	(6.7)	(12.8)	(10.3)	(22.1)	1.8	(57.4)	(34.4)	(6.1)	41.3
Income (loss) before provision for income taxes (non-GAAP)	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(2.6)	(12.8)	(10.3)	(25.6)	7.4	(57.5)	(25.5)	(6.1)	41.3
<i>Tax: (%) non-GAAP</i>	<i>NM</i>	<i>NM</i>	<i>0.0%</i>	<i>1.8%</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</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)	(6.7)	(12.8)	(10.3)	(22.1)	1.7	(57.5)	(34.4)	(6.1)	41.3
Net income (loss) non-GAAP	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(2.6)	(12.8)	(10.3)	(25.6)	7.2	(57.6)	(25.5)	(6.1)	41.3
EPS (GAAP)	(\$0.34)	(\$0.35)	(\$0.49)	(\$0.34)	(\$0.11)	(\$0.14)	(\$0.26)	(\$0.20)	(\$0.78)	\$0.05	(\$1.51)	(\$0.71)	(\$0.12)	\$0.76
EPS (non-GAAP)	(\$0.37)	(\$0.36)	(\$0.46)	(\$0.33)	\$0.00	(\$0.05)	(\$0.26)	(\$0.20)	(\$0.90)	\$0.24	(\$1.52)	(\$0.53)	(\$0.12)	\$0.76
Weighted Diluted Shares outstanding (millions)	37.5	38.0	38.1	38.2	44.0	48.5	49.5	50.5	28.3	30.7	37.9	48.1	51.4	54.4
Weighted Diluted Shares YOY change (%)	26.8%	22.0%	26.6%	24.4%	17.4%	27.7%	30.0%	32.2%		8.4%	23.6%	26.9%	6.9%	5.8%

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

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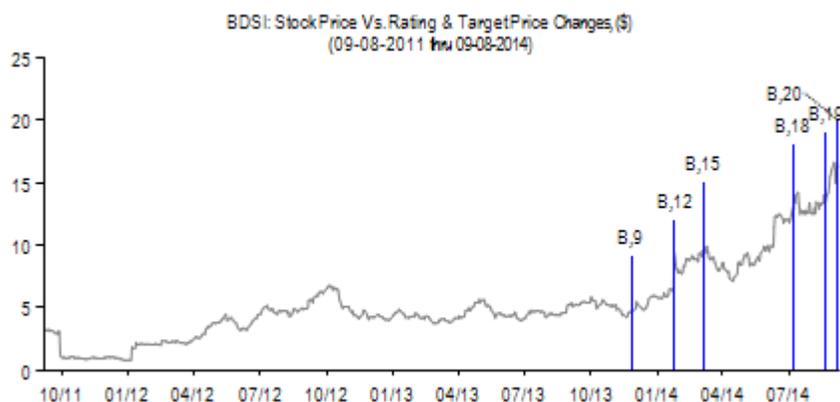
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Rating and Price Target Change History



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
07/07/2014	18.00	13.06
08/22/2014	19.00	13.82
09/08/2014	20.00	16.33*

Source: Laidlaw & Company

Created by: Blue-Compass.net

* Previous Close 9/5/2014

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			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.	94.74%	31.58%	10.53%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.26%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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