

## BioDelivery Sciences International (BDSI - \$ 17.33)

Healthcare / Biotechnology

### BDSI Management Provides Bunavail Launch Update

This morning BDSI hosted a conference call detailing the Bunavail launch efforts to date. While slightly delayed, we are maintaining our expectations for the launch.

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

- Bunavail Launch Update.** This morning, BioDelivery Sciences provided an update on the launch of its prescription opioid addiction product, Bunavail. Largely in-line with the company's September 5th Investor Day, management highlighted its managed market progress, wholesale distribution efforts and anecdotal evidence of prescribing physician and pharmacy acceptance of the product. The company reiterated that the drug is priced at parity to Suboxone and highlighted wholesale demand above expectations with orders from the top 15 prescription wholesalers and anticipated stocking at 115 distribution centers. Management did note that, due to increased demand for Bunavail, additional inventory is being manufactured. As a result of the added time required for inventory manufacturing, prescription flow will not begin until early to mid-November. Previous guidance was for sales of the drug in the month of October. The additional inventory is approximately one month worth of supply and the delay is attributed to the need to deliver uninterrupted supply of the drug. The company has made over 3,500 sales calls to top buprenorphine/naloxone prescribers and over 2,000 calls on pharmacies that will stock the drug. We are maintaining our conservative projections for the Bunavail rollout and do not view this delay as a detriment to the ultimate success of the drug. Our sales and expense estimates for 4Q14 remain unchanged. We expect 4Q14 Bunavail sales of \$7.5 million, growing to \$37.5 million in 2015. We continue to expect peak sales of Bunavail of \$250.0 million by 2020. We view the delay as a high class problem as it is due to higher demand than expected.
- BEMA Buprenorphine NDA Filing on the Horizon.** We continue to expect an NDA filing for BEMA Buprenorphine by the end of 2014 or in early 2015. The filing of an NDA will result in a \$10 million milestone payment, with a \$50 million payment if the drug is approved.
- Maintaining BUY Rating, Increasing Price Target.** We are maintaining our price target of \$20, which is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis.

#### Trading Data:

Last Price (10/07/2014)	\$ 17.33
52-Week High (9/12/2014)	\$ 18.48
52-Week Low (11/14/2013)	\$ 4.16
Market Cap. (MM)	\$ 854
Shares Out. (MM)	49

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY_16E</b>	NA	NA	NA	NA	0.76	22.8
<b>FY_15E</b>	NA	NA	NA	NA	-0.12	NM
<b>FY_14E</b>	0.00A	-0.05A	-0.26	-0.20	-0.53	NM
<b>FY_13A</b>	-0.37	-0.36	-0.46	-0.33	-1.52	NM

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Source: Laidlaw & Company estimates

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**Figure 1: Catalyst Summary**

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**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 underway with a team of approximately 60 sales representatives. Expect first weekly prescription sales data in early to mid-November.

**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

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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
<b>Revenue</b>	<b>1.6</b>	<b>2.8</b>	<b>3.0</b>	<b>4.0</b>	<b>20.7</b>	<b>13.9</b>	<b>4.6</b>	<b>11.0</b>	<b>4.5</b>	<b>54.5</b>	<b>11.4</b>	<b>50.2</b>	<b>83.5</b>	<b>126.0</b>
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
<b>Gross Profit</b>	<b>1.2</b>	<b>2.1</b>	<b>2.4</b>	<b>3.6</b>	<b>20.0</b>	<b>13.2</b>	<b>3.9</b>	<b>7.8</b>	<b>2.7</b>	<b>52.6</b>	<b>9.3</b>	<b>44.8</b>	<b>66.7</b>	<b>111.3</b>
<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	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses (ex-COGS)</b>	<b>15.0</b>	<b>15.9</b>	<b>19.4</b>	<b>15.4</b>	<b>19.3</b>	<b>15.2</b>	<b>16.6</b>	<b>17.9</b>	<b>28.5</b>	<b>45.6</b>	<b>65.7</b>	<b>69.0</b>	<b>71.9</b>	<b>69.6</b>
<b>Total Operating Expenses (non-GAAP, ex-COGS)</b>	<b>15.0</b>	<b>15.9</b>	<b>19.4</b>	<b>15.4</b>	<b>19.3</b>	<b>15.2</b>	<b>16.6</b>	<b>17.9</b>	<b>28.5</b>	<b>45.6</b>	<b>65.7</b>	<b>69.0</b>	<b>71.9</b>	<b>69.6</b>
<b>Operating Income/(loss)</b>	<b>(13.7)</b>	<b>(13.8)</b>	<b>(17.1)</b>	<b>(11.8)</b>	<b>0.7</b>	<b>(2.0)</b>	<b>(12.6)</b>	<b>(10.2)</b>	<b>(25.8)</b>	<b>7.1</b>	<b>(56.4)</b>	<b>(24.1)</b>	<b>(5.2)</b>	<b>41.6</b>
<b>Operating Income/(loss) non-GAAP</b>	<b>(13.7)</b>	<b>(13.8)</b>	<b>(17.1)</b>	<b>(11.8)</b>	<b>0.7</b>	<b>(2.0)</b>	<b>(12.6)</b>	<b>(10.2)</b>	<b>(25.8)</b>	<b>7.1</b>	<b>(56.4)</b>	<b>(24.1)</b>	<b>(5.2)</b>	<b>41.6</b>
<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
<b>Income (loss) before provision for income taxes (GAAP)</b>	<b>(12.6)</b>	<b>(13.4)</b>	<b>(18.5)</b>	<b>(12.9)</b>	<b>(4.6)</b>	<b>(6.7)</b>	<b>(12.8)</b>	<b>(10.3)</b>	<b>(22.1)</b>	<b>1.8</b>	<b>(57.4)</b>	<b>(34.4)</b>	<b>(6.1)</b>	<b>41.3</b>
<b>Income (loss) before provision for income taxes (non-GAAP)</b>	<b>(13.7)</b>	<b>(13.8)</b>	<b>(17.6)</b>	<b>(12.5)</b>	<b>0.2</b>	<b>(2.6)</b>	<b>(12.8)</b>	<b>(10.3)</b>	<b>(25.6)</b>	<b>7.4</b>	<b>(57.5)</b>	<b>(25.5)</b>	<b>(6.1)</b>	<b>41.3</b>
<i>Tax: (%) non-GAAP</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>	<i>0.0%</i>
<b>Income tax provision GAAP</b>	0.1	0.0	-	-	-	-	-	-	-	0.1	-	0.0	-	-
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net income (loss) GAAP</b>	<b>(12.7)</b>	<b>(13.4)</b>	<b>(18.5)</b>	<b>(12.9)</b>	<b>(4.6)</b>	<b>(6.7)</b>	<b>(12.8)</b>	<b>(10.3)</b>	<b>(22.1)</b>	<b>1.7</b>	<b>(57.4)</b>	<b>(34.4)</b>	<b>(6.1)</b>	<b>41.3</b>
<b>Net income (loss) non-GAAP</b>	<b>(13.7)</b>	<b>(13.8)</b>	<b>(17.6)</b>	<b>(12.5)</b>	<b>0.2</b>	<b>(2.6)</b>	<b>(12.8)</b>	<b>(10.3)</b>	<b>(25.6)</b>	<b>7.2</b>	<b>(57.5)</b>	<b>(25.5)</b>	<b>(6.1)</b>	<b>41.3</b>
<b>EPS (GAAP)</b>	<b>(\$0.34)</b>	<b>(\$0.35)</b>	<b>(\$0.49)</b>	<b>(\$0.34)</b>	<b>(\$0.11)</b>	<b>(\$0.14)</b>	<b>(\$0.26)</b>	<b>(\$0.20)</b>	<b>(\$0.78)</b>	<b>\$0.05</b>	<b>(\$1.51)</b>	<b>(\$0.71)</b>	<b>(\$0.12)</b>	<b>\$0.76</b>
<b>EPS (non-GAAP)</b>	<b>(\$0.37)</b>	<b>(\$0.36)</b>	<b>(\$0.46)</b>	<b>(\$0.33)</b>	<b>\$0.00</b>	<b>(\$0.05)</b>	<b>(\$0.26)</b>	<b>(\$0.20)</b>	<b>(\$0.90)</b>	<b>\$0.24</b>	<b>(\$1.52)</b>	<b>(\$0.53)</b>	<b>(\$0.12)</b>	<b>\$0.76</b>
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
<i>Weighted Diluted Shares YOY change (%)</i>	<i>26.8%</i>	<i>22.0%</i>	<i>26.6%</i>	<i>24.4%</i>	<i>17.4%</i>	<i>27.7%</i>	<i>30.0%</i>	<i>32.2%</i>	<i>8.4%</i>	<i>23.6%</i>	<i>26.9%</i>	<i>26.9%</i>	<i>6.9%</i>	<i>5.8%</i>

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

Figure 3: Balance Sheet

BioDelivery Sciences	FY 2013				FY 2014E				FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E 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					
<b>BioDelivery Sciences</b>													
<i>Balance Sheet (\$ millions, except per share data)</i>													
<b>Assets:</b>													
Cash and cash equivalents	49.7	37.4	38.3	23.2	88.2	78.4	76.2	61.4	10.8	63.2	23.2	61.4	38.9
Accounts receivable, other	0.2	0.5	0.9	2.8	2.5	12.6	4.2	8.0	0.1	0.5	2.8	8.0	15.2
Inventory	-	-	-	-	-	0.8	4.0	7.5	-	-	-	7.5	17.5
Prepaid expenses and other current assets	0.5	0.3	0.5	0.6	0.7	0.6	0.2	0.5	0.2	0.2	0.6	0.5	0.5
<b>Total Current Assets</b>	<b>50.4</b>	<b>38.2</b>	<b>39.6</b>	<b>26.6</b>	<b>91.4</b>	<b>92.4</b>	<b>84.6</b>	<b>77.4</b>	<b>11.1</b>	<b>63.9</b>	<b>26.6</b>	<b>77.4</b>	<b>72.1</b>
Equipment, net	2.7	2.6	0.2	0.2	0.2	0.2	0.3	0.3	3.3	2.8	0.2	0.3	1.4
Idle Equipment, net	-	-	-	2.8	3.3	3.5	3.5	3.5	-	-	2.8	3.5	3.5
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	5.9	5.7	2.5	5.2	5.0	4.7	4.7	4.7	6.2	6.2	5.2	4.7	4.7
Derivative asset, warrant	0.0	-	5.4	-	-	-	-	-	0.4	0.1	-	-	-
Other assets	-	-	0.1	0.5	0.4	0.3	0.3	0.3	0.0	0.0	0.5	0.3	0.3
<b>Total Assets</b>	<b>61.8</b>	<b>49.3</b>	<b>50.6</b>	<b>38.0</b>	<b>103.0</b>	<b>103.8</b>	<b>96.0</b>	<b>88.9</b>	<b>23.6</b>	<b>75.7</b>	<b>38.0</b>	<b>88.9</b>	<b>84.7</b>
<b>Liabilities &amp; Shareholders' Equity:</b>													
Accounts payable and other accrued liabilities	9.5	12.0	11.1	10.4	8.8	9.5	10.3	11.2	5.1	10.8	10.4	11.2	11.6
Notes payable, current	-	-	5.3	7.3	7.3	7.3	7.3	7.3	-	-	7.3	7.3	7.3
Deferred revenue, current	7.2	5.6	4.1	2.9	1.9	1.3	0.4	1.0	12.5	8.0	2.9	1.0	1.7
Derivative liabilities	3.5	3.0	3.9	4.3	7.5	10.8	10.8	10.8	0.3	4.5	4.3	10.8	10.8
<b>Total Current Liabilities</b>	<b>20.2</b>	<b>20.6</b>	<b>24.4</b>	<b>25.0</b>	<b>25.6</b>	<b>28.9</b>	<b>28.8</b>	<b>30.3</b>	<b>17.9</b>	<b>23.2</b>	<b>25.0</b>	<b>30.3</b>	<b>31.5</b>
Note Payable, less current maturities	-	-	13.8	11.8	9.9	8.0	6.0	3.9	-	-	11.8	3.9	0.1
Deferred revenue, long-term	1.9	1.6	1.3	1.3	2.2	4.4	2.5	5.9	1.6	2.7	1.3	5.9	9.9
Other long-term liabilities	-	-	-	0.7	0.7	0.7	0.7	0.7	-	-	0.7	0.7	0.7
<b>Total Liabilities</b>	<b>22.1</b>	<b>22.2</b>	<b>39.5</b>	<b>38.8</b>	<b>38.4</b>	<b>42.0</b>	<b>38.0</b>	<b>40.8</b>	<b>19.5</b>	<b>26.0</b>	<b>38.8</b>	<b>40.8</b>	<b>42.2</b>
<b>Stockholders' Equity</b>	<b>39.7</b>	<b>27.1</b>	<b>11.0</b>	<b>(0.8)</b>	<b>64.6</b>	<b>61.8</b>	<b>58.0</b>	<b>48.1</b>	<b>4.1</b>	<b>49.8</b>	<b>-0.8</b>	<b>48.1</b>	<b>42.5</b>
<b>Total Liabilities &amp; Equity</b>	<b>61.8</b>	<b>49.3</b>	<b>50.6</b>	<b>38.0</b>	<b>103.0</b>	<b>103.8</b>	<b>96.0</b>	<b>88.9</b>	<b>23.6</b>	<b>75.7</b>	<b>38.0</b>	<b>88.9</b>	<b>84.7</b>

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

Figure4: Cash Flow Statement

<b>BioDelivery Sciences</b>	<b>FY_11</b>	<b>FY_12</b>	<b>FY_13</b>	<b>FY_14E</b>	<b>FY_15E</b>
<i>Non-GAAP Cash Flow Cont. Ops. (\$ millions, except per share data)</i>	<b>Dec</b>	<b>Dec</b>	<b>Dec</b>	<b>Dec</b>	<b>Dec</b>
<b>Cash flows from operating activities:</b>					
<b>Net income</b>	(22.1)	1.7	(57.4)	(34.4)	(6.1)
<i>Adjustments to reconcile net income to net cash provided by operating activities:</i>					
Depreciation and amortization	1.3	1.5	1.3	0.9	0.9
Accretion of Discount	-	-	0.2	0.8	0.8
Derivative (gain) loss	(3.5)	5.6	(0.1)	8.9	-
Purchase of Arcion license with common stock	-	-	2.1	-	-
Stock-based compensation expense	1.2	1.6	3.3	5.1	5.1
<i>Changes in assets and liabilities:</i>					
Accounts receivable	0.5	(0.4)	(2.3)	(5.2)	(7.2)
Inventory	-	-	-	(0.8)	(10.0)
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)	(0.5)	(0.5)
Income tax payable	-	0.1	-	1.7	-
Deferred revenue	0.0	(3.4)	(6.5)	1.8	(0.7)
<b>Net cash provided by (used in) operating activities</b>	<b>(22.0)</b>	<b>12.2</b>	<b>(60.1)</b>	<b>(21.5)</b>	<b>(17.6)</b>
<b>Cash flow from investing activities:</b>					
Purchases of property and equipment	(0.3)	(0.0)	(0.1)	(1.1)	(1.1)
Purchases of intangible assets	-	(1.1)	-	-	-
<b>Cash provided by investing activities</b>	<b>(0.3)</b>	<b>(1.1)</b>	<b>(0.1)</b>	<b>(1.1)</b>	<b>(1.1)</b>
<b>Cash flows from financing activities:</b>					
Proceeds from sale of securities	14.0	38.4	-	62.0	-
Proceeds from exercise of stock options	0.3	2.1	0.4	2.8	-
Proceeds from exercise of common stock warrants	-	-	0.1	4.0	-
Proceeds from notes payable and warrants	-	-	20.0	-	-
Deferred financing activities	-	-	(0.2)	-	-
Repayment of note	-	-	-	(8.1)	(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	-	-	-
<b>Cash (used in) provided by financing activities</b>	<b>16.1</b>	<b>41.3</b>	<b>20.2</b>	<b>60.8</b>	<b>(3.8)</b>
Effect of exchange rates on cash	-	-	-	-	-
Net (decrease) increase in cash and cash equivalents	(6.2)	52.4	(40.0)	38.2	(22.5)
Cash and cash equivalents at beginning of the period	18.2	10.8	63.2	23.2	61.4
Cash and cash equivalents at end of period	<b>12.0</b>	<b>63.2</b>	<b>23.2</b>	<b>61.4</b>	<b>38.9</b>

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

## DISCLOSURES:

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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

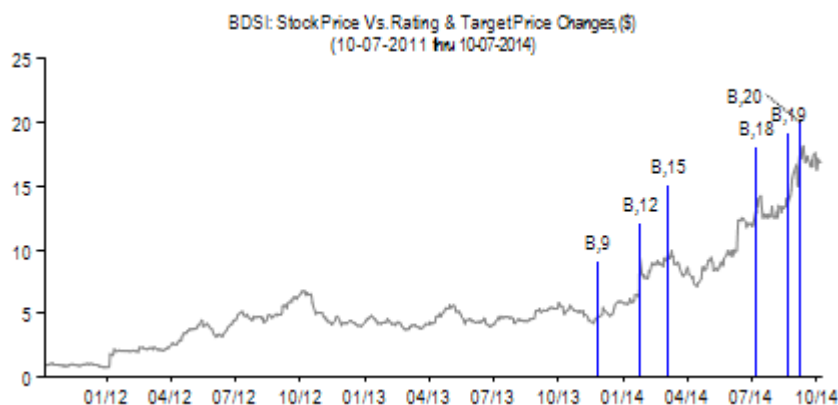
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*Additional information available upon request.*

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### 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
08/22/2014	19.00	13.82
09/08/2014	20.00	17.98

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	95.24%	33.33%	14.29%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.76%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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**NOTES:**