

## BioDelivery Sciences (BDSI - \$ 4.89)

Healthcare/Biotechnology

### TennCare Experience Could Lead to Additional Medicaid Wins

We recently spoke with BDSI management in advance of the year end and upcoming early 2016 healthcare conferences. While BDSI's stock has performed well below both our and management's expectations, we continue to see positive developments in the Bunavail launch; and we continue to expect Belbuca to be a potential game-changer for the company. Management notes that there is evidence to suggest that the switch to Bunavail by TennCare has already drastically cut Suboxone diversion within the bellwether TN Medicaid system. Since Bunavail received preferred formulary status at TennCare Rx trends suggest that ~3K Rx's per month have "disappeared" from the TennCare system, which could be attributed to Bunavail having a lower "street" value and a lower diversion potential. This could be a significant marketing point for BDSI to exploit as they approach other state Medicaid systems. We continue to see BDSI as one of the more de-risked names we follow after the recent FDA approval of Belbuca and the positive trends in Bunavail since the TennCare win. We reiterate our Buy rating and our \$17 price target.

Ticker: **BDSI**  
Rating: **Buy**  
Price Target: **\$17.00**

#### Trading Data:

Last Price (12/24/2015)	\$4.89
52-Week High (03/19/2015)	\$15.50
52-Week Low (12/15/2015)	\$4.64
Market Cap. (MM)	\$257.5
Shares Out. (MM)	52.67

- **TennCare and the case of the missing prescriptions.** BDSI has averaged ~1K new TRx's per week (~4K/month) since winning TennCare preferred formulary status. Prior to Bunavail, TennCare was covering ~7K-7.5K Suboxone Rx's/month, suggesting that ~3K Rx's per month have gone missing, which could be due to Bunavail being harder to divert. We see these cost savings to the Medicaid system as a potential positive for BDSI as they attempt to have other states adopt exclusive preferred formulary status for Bunavail.
- **Sales force re-alignment completed.** Bunavail remains only \$1 of our \$17 PT due to its lackluster launch to date, but management has reorganized their sales reps (fired the bottom performers and enabled more access/communication between reps and managers in territories covered). The selling mentality will also be transitioning from a soft relationship type sell to a harder sell. We believe this could help the Bunavail uptrend continue and accelerate in 2016.
- **ENDP "all-in" for Belbuca 1Q16 launch.** ENDP controls the Belbuca launch, and on their 3Q15 conference call signaled that they will double their pain sales force to launch Belbuca, which could happen in February 2016. BDSI gets a mid-upper teen royalty and up to \$55M in sales milestones on Belbuca.
- **Reiterating Buy rating \$17 price target.** Our price target is based on a sum-of-the-parts with Belbuca valued at \$12/share, Bunavail valued at \$1/share (from \$4/share previously), and net cash (end-'16) and tech value (clonidine, IV buprenorphine) valued at \$4/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	(0.02)	(0.29)	(0.27)	(0.23)	(0.70)	NM
<b>FY-15E</b>	(0.31)A	(0.37)A	(0.39)A	(0.34)	(1.41)	NM
<b>FY-14A</b>	(0.22)	(0.05)	(0.39)	(0.34)	(1.03)	NM
<b>FY-13A</b>	(0.37)	(0.36)	(0.46)	(0.33)	(1.52)	NM

#### James Molloy

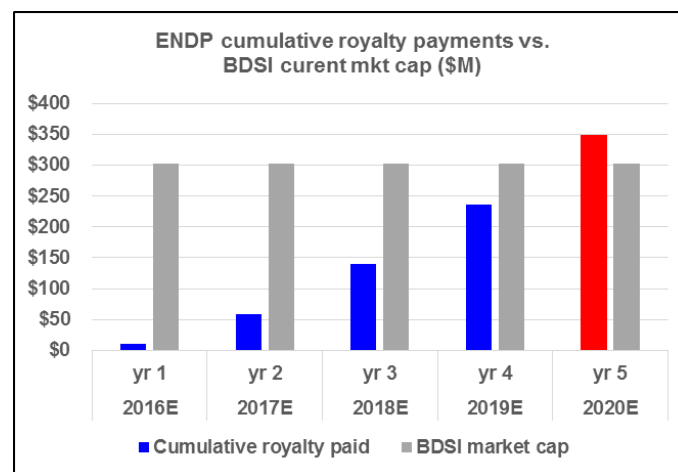
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Source: Company data and Laidlaw & Company estimates

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- ENDP still the most likely acquirer of BDSI.** We estimate that ENDP will pay BDSI’s market cap in royalties & milestones in 5 years. We project Belbuca end sales of by ENDP for 2016-2020 of \$50M, \$270M, \$450M, \$540M, and \$621M, respectively; with royalties to BDSI of \$8M, \$41M, \$81M, \$97M, and \$112M, respectively. On our base case sales growth estimates for Belbuca by 2020 (year 5 of launch) ENDP will have paid \$338M in royalties, which when including the \$50M approval milestones is ~11% greater than BDSI’s current \$305M market cap (see Figure 1 below). We continue to believe that there is a real potential for ENDP to acquire BDSI in 2016.
- ENDP still actively looking for “fold-in” acquisitions.** ENDP noted on their call that additional acquisitions are a priority once they de-lever their debt structure. ENDP is seeing some attractive opportunities at much lower prices following the recent market dislocation for acquisitions; which we interpret to mean that ENDP is looking closely at the outright acquisition of BDSI.

Figure 1: ENDP cumulative royalty payments vs BDSI mkt. cap.



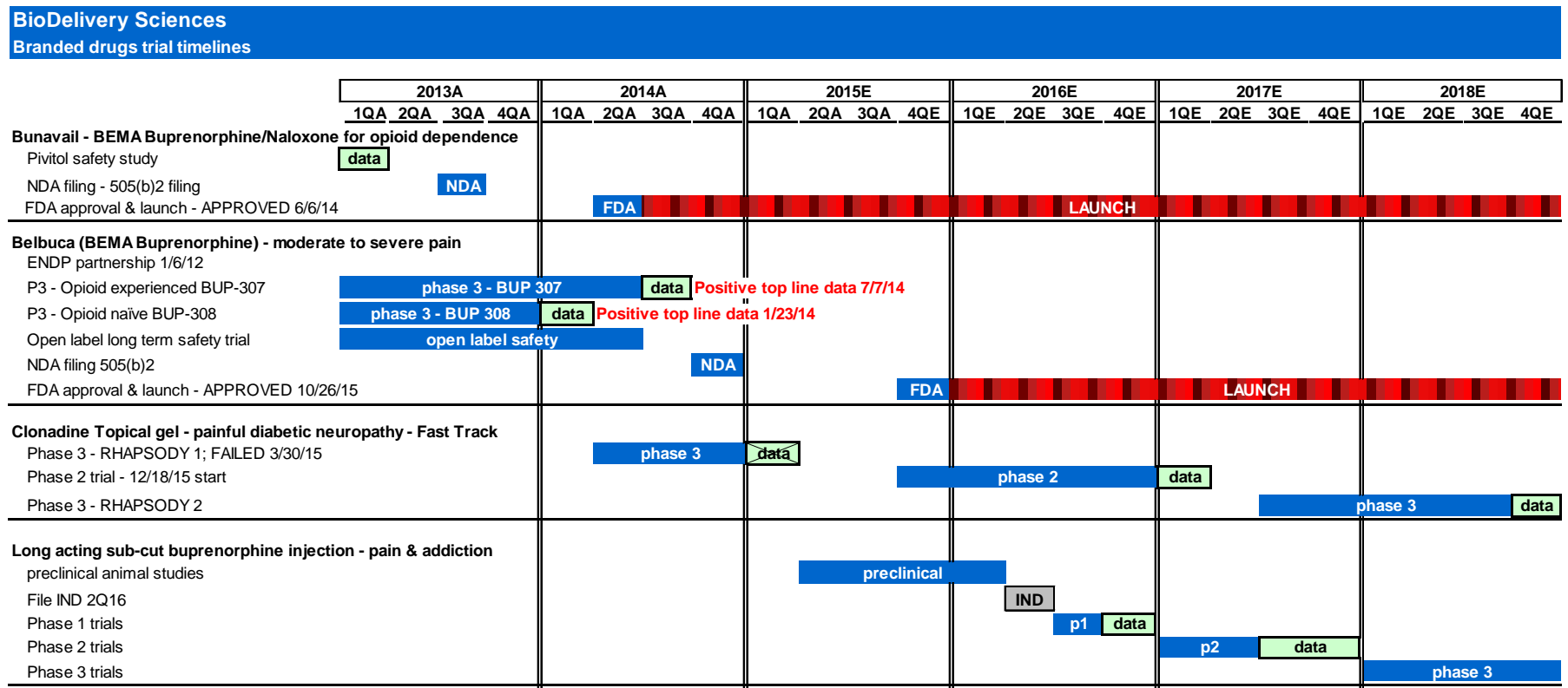
Source: Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$782,843	\$12.0
Bunavail	\$66,015	\$1.0
Net cash (end '16) & tech value	\$171,478	\$4.0
<b>SUM</b>	<b>\$1,078,749</b>	<b>\$17</b>
Shares out '16E (000)		62,668

Source: Bloomberg LP.

Figure 3: Clinical trials timeline



Source: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

BioDelivery Sciences										
Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
Bunavail sales				\$76	\$76	\$677	\$800	\$1,135	\$1,596	\$4,208
Royalty revenue - Onsolis	\$954	\$892	12	1,549	3,407	194	495	100	100	889
Contract rev / milestones	11,284	10,675	513	277	22,749	11,408	0	0	0	11,408
Research fees	8,452	2,318	1,298	645	12,712	775	450			1,225
<b>Total Revenue</b>	<b>\$20,690</b>	<b>\$13,885</b>	<b>\$1,822</b>	<b>\$2,547</b>	<b>\$38,944</b>	<b>\$13,054</b>	<b>\$1,745</b>	<b>\$1,235</b>	<b>\$1,696</b>	<b>\$17,730</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	2,621	1,699	1,468	6,912
<b>Gross Margin</b>	<b>19,965</b>	<b>13,198</b>	<b>1,360</b>	<b>(517)</b>	<b>34,005</b>	<b>11,930</b>	<b>(876)</b>	<b>(464)</b>	<b>228</b>	<b>10,818</b>
Research and development	14,623	7,983	6,770	4,909	34,285	6,549	4,506	4,473	5,000	20,528
General and administrative	4,622	7,250	13,649	12,925	38,460	13,181	13,287	14,715	13,250	54,433
Related party G&A	6	6								-
Total operating expenses	19,251	15,239	20,418	17,834	72,745	19,730	17,793	19,188	18,250	74,961
<b>Income (loss) from Operations</b>	<b>714</b>	<b>(2,041)</b>	<b>(19,059)</b>	<b>(18,351)</b>	<b>(38,740)</b>	<b>(7,800)</b>	<b>(18,669)</b>	<b>(19,652)</b>	<b>(18,022)</b>	<b>(64,143)</b>
Interest income (expense), net	(555)	(519)	(515)	(427)	(2,016)	(420)	(527)	(785)	(100)	(1,832)
Derivative (loss) gain	(4,825)	(4,120)	(5,685)	1,464	(13,167)					-
Other (exp) gain, net	23	9	25	(352)	(295)	27	(3)	(2)	25	47
<b>Income (loss) before taxes</b>	<b>(4,644)</b>	<b>(6,671)</b>	<b>(25,233)</b>	<b>(17,666)</b>	<b>(54,218)</b>	<b>(8,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(18,097)</b>	<b>(65,928)</b>
Income tax exp (benefit)										
<b>Net Income (Loss)</b>	<b>(4,644)</b>	<b>(6,671)</b>	<b>(25,233)</b>	<b>(17,666)</b>	<b>(54,215)</b>	<b>(8,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(18,097)</b>	<b>(65,928)</b>
<b>Earning per Share (EPS)</b>	<b>(\$0.11)</b>	<b>(\$0.14)</b>	<b>(\$0.51)</b>	<b>(\$0.34)</b>	<b>(\$1.12)</b>	<b>(\$0.16)</b>	<b>(\$0.37)</b>	<b>(\$0.39)</b>	<b>(\$0.34)</b>	<b>(\$1.26)</b>
<b>Adj EPS ex-1x &amp; non-cash items</b>	<b>(\$0.22)</b>	<b>(\$0.05)</b>	<b>(\$0.39)</b>	<b>(\$0.34)</b>	<b>(\$1.03)</b>	<b>(\$0.31)</b>				<b>(\$1.41)</b>
Weighted avg. shares (000)	44,035	48,521	49,556	51,308	48,355	51,909	52,402	52,543	52,793	52,412
Fully diluted shares (000)	54,435	55,321	55,556	54,505	54,954	61,309	61,902	62,286	62,193	61,922

Source: Company reports and Laidlaw estimates

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

Figure 5: Annual Income Statement

<b>BioDelivery Sciences</b>						
<b>Annual income statement</b>						
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
<b>Revenues</b>						
Bunavail sales	76	4,208	13,270	16,750	19,250	Launched 11/3/14
Royalty - Belbuca (BEMA Bup.)	-	-	7,500	40,500	81,000	1Q16 launch by partner ENDP
Royalty revenue - Onsolis	3,407	889	400	5,000	6,000	Smaller product
Contract revenue	22,749	11,408	50,000	-	-	ENDP milestones here
Research fees	12,712	1,225	-	-	-	
<b>Total Revenue</b>	<b>\$38,944</b>	<b>\$17,730</b>	<b>\$71,170</b>	<b>\$62,250</b>	<b>\$106,250</b>	
<b>Expenses:</b>						
Cost of Revenue (COGS)	4,939	6,912	4,983	4,243	5,118	
<b>Gross Margin</b>	<b>34,005</b>	<b>10,818</b>	<b>66,187</b>	<b>58,008</b>	<b>101,133</b>	
Research and development	34,285	20,528	23,000	25,000	26,500	
General and administrative	38,460	54,433	54,000	54,800	55,750	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	74,961	77,000	79,800	82,250	
<b>Income (loss) from Operations</b>	<b>(38,740)</b>	<b>(64,143)</b>	<b>(10,813)</b>	<b>(21,793)</b>	<b>18,883</b>	
Interest income (expense), net	(2,016)	(1,832)	575	1,575	2,225	
Derivative (loss) gain	(13,167)	-	-	-	-	
Other expenses, net	(295)	47	100	100	100	
<b>Income (loss) before taxes</b>	<b>(54,218)</b>	<b>(65,928)</b>	<b>(10,138)</b>	<b>(20,118)</b>	<b>21,208</b>	
Income tax exp (benefit)	-	-	-	(18)	3,864	Sig. tax loss carryforwards
<b>Net Income (Loss)</b>	<b>(\$54,215)</b>	<b>(\$65,928)</b>	<b>(\$10,138)</b>	<b>(\$20,099)</b>	<b>\$17,344</b>	
Adjustments to Income for Dilutive	\$0	\$0	\$0	\$0	\$0	
1x items & non-cash exp	(4,631)	7,757	34,000	0	0	
<b>Adj NI less non cash &amp; 1x items</b>	<b>(\$49,584)</b>	<b>(\$73,685)</b>	<b>(\$44,138)</b>			
<b>Earning per Share</b>	<b>(\$1.12)</b>	<b>(\$1.26)</b>	<b>(\$0.19)</b>	<b>(\$0.35)</b>	<b>\$0.25</b>	
<b>Adj EPS ex-1x &amp; non-cash items</b>	<b>(\$1.03)</b>	<b>(\$1.41)</b>	<b>(\$0.70)</b>			
Weighted avg. shares (000)	48,355	52,412	54,668	57,668	60,793	
Fully diluted shares (000)	54,954	61,922	62,668	66,168	69,293	
<b>Margin &amp; Expense Analysis</b>						
COGS as % of Revenues	13%	39%	7%	7%	5%	
R&D	88%	116%	32%	40%	25%	
SG&A	99%	307%	76%	88%	52%	
Gross Profit	87%	61%	93%	93%	95%	
Op. margin cont. ops	-99%	-362%	-15%	-35%	18%	
Taxes	0%	0%	0%	0%	18%	
Net margin	-139%	-372%	-14%	-32%	16%	
<b>Year-over-year change</b>						
Net revenue	243%	-54%	301%	-13%	71%	
R&D	64%	60%	112%	109%	106%	
SG&A	213%	42%	-1%	1%	2%	
Operating income	-31%	66%	-83%	102%	-187%	

Source: Company reports and Laidlaw estimates

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## Major risks

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**Exogenous events could impact our outlook.** We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

**Actual clinical results and the FDA's conclusions may deviate from expectations.** Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

**Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations.** Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Dales could run out. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

**Legal risks could lead to additional liabilities and revenue loss.** In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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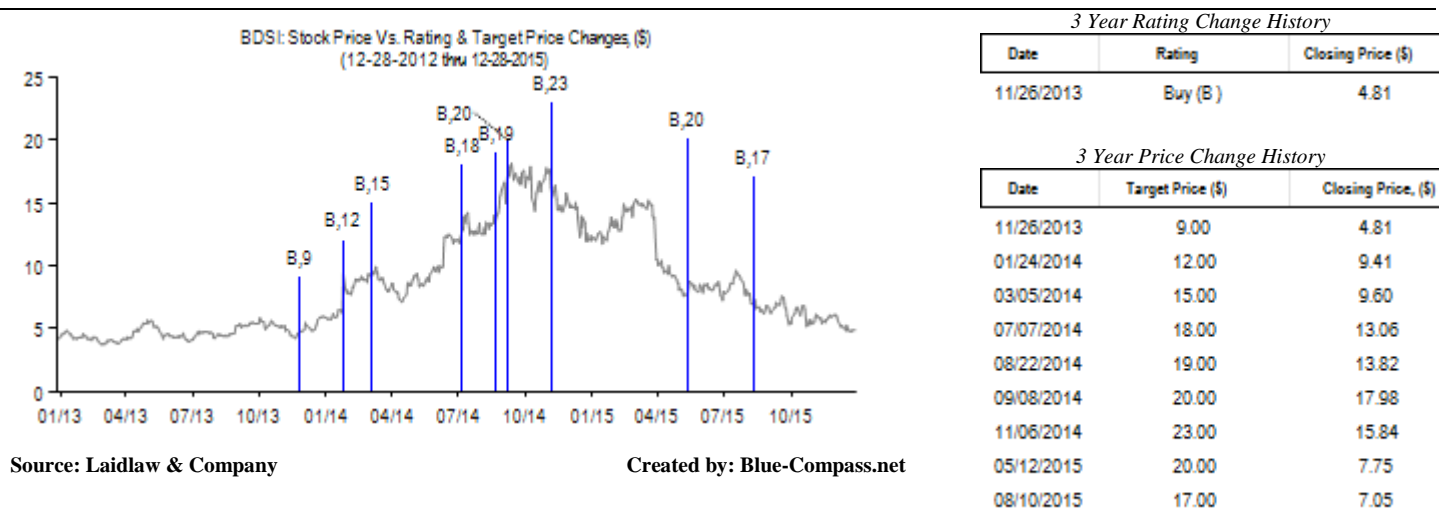
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*Additional information available upon request.*

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			Investment Banking	Brokerage
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<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	64.71%	26.47%	2.94%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	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%

### ADDITIONAL COMPANIES MENTIONED

Endo International (ENDP – Not Rated)

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