

## BioDelivery Sciences (BDSI - \$ 3.98)

Healthcare/Biotechnology

### JAMA Article Highlights the Belbuca Opportunity re: Vicodin

An article in the January Journal of the American Medical Association (JAMA), Internal Medicine looks at the effect on prescribing of the 2014 decision to move all hydrocodone combination products (Vicodin-like) to the more restrictive schedule II status (from schedule III before). Looking at the 12 months before and the 12 months after the rescheduling there is a clear downturn in Rx's (see Figure 2 below) following the October 2014 change. The JAMA article (see link below) notes that in the year following the scheduling change there were 26.3M fewer Vicodin-like Rx's written in the US. We believe that the relatively lower prescribing burden of schedule III opioids (Doctor can call in the Rx, write refills.) plays a significant role in the prescribing algorithm. We further believe that Belbuca - with Endo International (ENDP) behind the launch - as the only oral schedule III drug on the market, should be able to capture a significant portion of these "missing" Rx's. ENDP has more than doubled their sales force to launch Belbuca next month, and we believe it has the opportunity to significantly surpass ENDP CEO De Silva's recent projection of "over \$250M in sales in 2019". With BDSI in line to pick up significant sales royalties from Belbuca we reiterate our Buy rating and our \$17 price target.

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

- **JAMA article highlights the opportunity for Belbuca.** The link to the JAMA article is here: <http://archinte.jamanetwork.com/article.aspx?articleid=2484293>. What seems clear is that moving Vicodin-like opioids to schedule II has left a yawning Rx chasm in the treatment algorithm. If the goal of pain therapy is to give the least drug for as long as possible, then the 26M "missing" Vicodin-like Rx's is a perfect target for what will be the only schedule III opioid approved – Belbuca.
- **Can ENDP walk through the door Vicodin has opened?** ENDP certainly seems to recognize the potential of Belbuca for their own franchise – let alone BDSI's – and have recently announced that they have more than doubled their pain-focused sales force to launch Belbuca. The 26M "missing" Rx's since Vicodin-like opioids went to schedule II represents an ~\$4.5B sales opportunity for an oral schedule III opioid (at ~\$250/Rx) like Belbuca. ENDP doesn't need to get much to get to their over \$250M in sales by 2019 guidance. We have a more aggressive estimate of \$500M+ in Belbuca sales by 2019.
- **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.

#### Trading Data:

Last Price (1/25/2015)	\$3.98
52-Week High (03/19/2015)	\$15.50
52-Week Low (12/15/2015)	\$3.04
Market Cap. (MM)	\$207.5
Shares Out. (MM)	52.67

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	(0.31)	(0.27)	(0.26)	0.08	(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

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Source: Company data and Laidlaw & Company estimates

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- ENDP will pay a significant % of BDSI's market cap in sales milestones by 2019.** At a recent healthcare conference ENDP CEO De Silva guided investors to expect Belbuca could be over \$250M in sales by 2019. Below in Figure 1 we highlight what this means in royalties paid to BDSI by 2019 and 2020 based on our assumptions (top) and CEO De Silva's assumptions (bottom). Even in the CEO's conservative scenario ENDP will have paid almost half of BDSI's current market cap in sales royalties cumulatively by 2019, and almost two thirds by 2020. We continue to believe that on any success at launch ENDP remains the likely acquirer of BDSI.

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

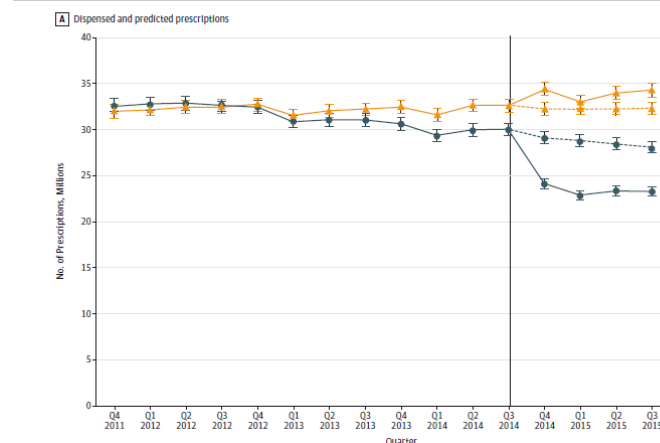
BioDelivery Sciences					
Belbuca end sales & royalty projections					
(M)	2016E	2017E	2018E	2019E	2020E
End sales by ENDP	\$50	\$270	\$450	\$540	\$621
Royalty rate	15%	15%	18%	18%	18%
Royalties to BDSI	\$8	\$41	\$81	\$97	\$112
cumulative		\$48	\$129	\$226	\$338
<b>BDSI mkt cap 1/25/16</b>				<b>\$209</b>	<b>\$209</b>
% of mkt cap in royalties				108%	162%
<b>Rajiv projections</b>					
End sales by ENDP	\$35	\$78	\$168	\$275	\$350
Royalty rate	15%	15%	18%	18%	18%
Royalties to BDSI	\$5	\$12	\$30	\$50	\$63
cumulative		\$17	\$47	\$97	\$160
<b>BDSI mkt cap 1/25/16</b>				<b>\$209</b>	<b>\$209</b>
% of mkt cap in royalties				46%	76%

Source: Laidlaw & Company estimates.

- JAMA analysis shows significant drop-off in hydrocodone combination prescriptions since moved to schedule 3.** Figure 2 below highlights the sharp drop-off in hydrocodone-combination products once they went to schedule III. We continue to believe this represents an opportunity for Belbuca to “pick up the slack” as the only oral schedule 3 opioid on the market.

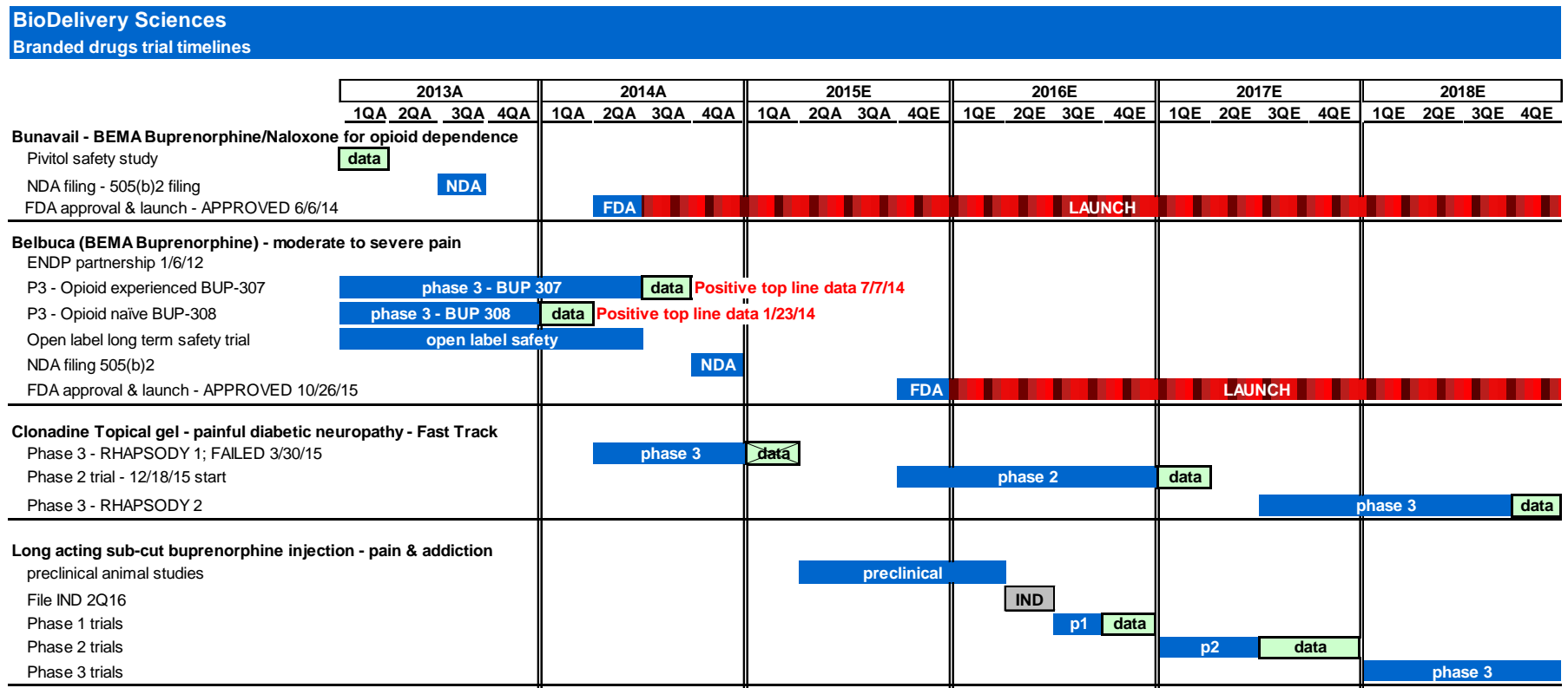
Figure 2: JAMA analysis of Hydrocodone combo products

Figure. Dispensed and Predicted Hydrocodone Combination Product (Blue) and Nonhydrocodone Combination Product (Orange) Opioid Analgesic Prescriptions and Tablets



Source: JAMA and Laidlaw & Company estimates.

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

## 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.

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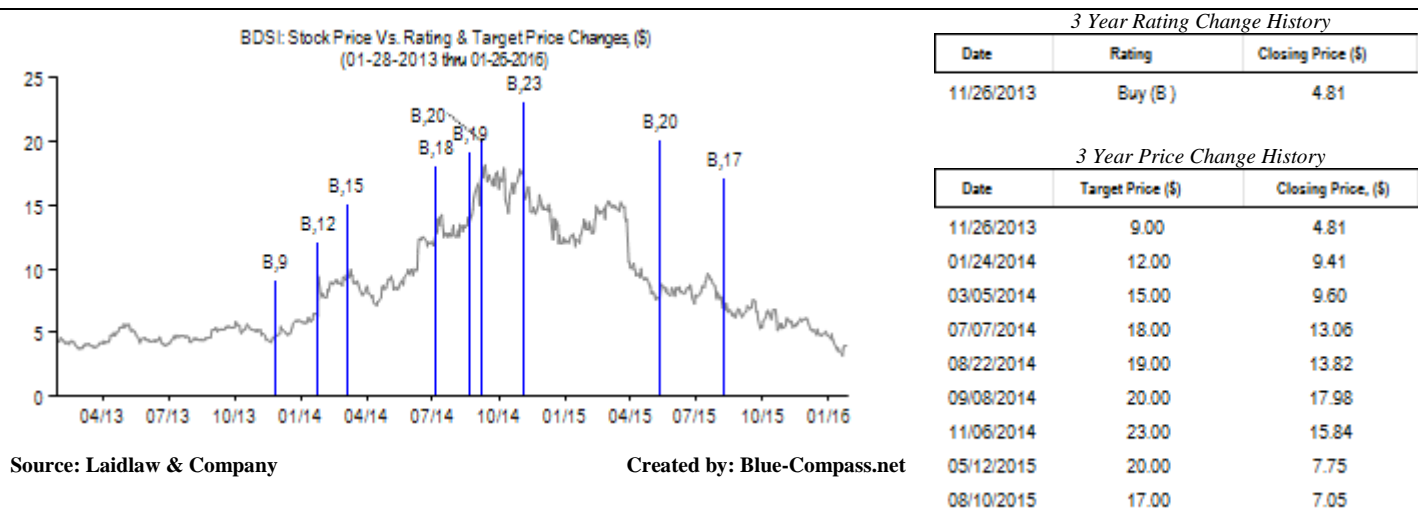
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			Investment Banking	Brokerage
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<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Endo International (ENDP – Not Rated)

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