

BioDelivery Sciences (BDSI - \$ 5.34)

Healthcare/Biotechnology

Third Quarter Roughly In-Line, Waiting for ENDP in 1Q16

BDSI reported 3Q15 last night after the close more or less in line with our expectations. The recent uptick in Bunavail TRx's should start to drive higher sales in 4Q15. More importantly, in our opinion, was the approval of Belbuca in the 3Q and the potential that product has to drive significant earnings for both BDSI and marketing partner ENDP. We anticipate Belbuca has a strong uptake as the only schedule 3 opioid in the marketplace, and we expect Belbuca to exceed \$500M in sales by year 4 after launch. While this is an aggressive launch we see a real chance to a significant percentage of patients who are currently written strong opioids (Oxycontin, morphine) will stop at Belbuca before proceeding to stronger opioids. Given the push for less abuse-resistant/less-addictive drugs we see little reason why doctors won't prescribe Belbuca immediately after launch. And given the high-mid teen sales royalty and (up to) \$55M in sales milestones ENDP owes BDSI this launch could be the catalyst for an outright acquisition of BDSI by ENDP. We continue to see BDSI as one of the more de-risked names we follow following the recent FDA approval of Belbuca and we reiterate our Buy rating, \$17 price target.

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

Trading Data:

Last Price (10/27/2015)	\$5.34
52-Week High (10/31/2014)	\$18.33
52-Week Low (09/29/2015)	\$4.66
Market Cap. (MM)	\$280.1
Shares Out. (MM)	52.54

- **Belbuca significantly de-risks the story.** While we had expected FDA approval for Belbuca, PDUFA dates can be challenging to predict correctly. Not only was the drug approved, but it received Schedule 3 designation meaning it will be the *only* orally available opioid that can be called into the pharmacy, written with refills, and not require a doctor visit to refill every Rx. This is a huge advantage for any opioid, and one of the key reasons Vicodin was the most prescribed drugs in the world before being moved up to Schedule 2 in late 2014.
- **Bunavail launch appears to be gaining steam.** This product is only \$1 of our \$17 PT following our prior significant lowering of revenue expectations, but any improvement in the TRx's would be a positive in our opinion. The recent Rx trends have been extremely favorable due to the TennCare Medicaid win, and could be the start of a meaningful ramp in TRx's.
- **Patient limits could be raised in early 2016.** CEO Sirgo expects that HHS could increase the patient limit for addiction specialists from the current 100 patient cap to ~250 as soon as 1Q16. This could significantly help Bunavail adoption.
- **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
FY-16E	(0.31)	(0.27)	(0.26)	0.08	(0.65)	NM
FY-15E	(0.31)A	(0.37)A	(0.39)A	(0.34)	(1.41)	NM
FY-14A	(0.22)	(0.05)	(0.39)	(0.34)	(1.03)	NM
FY-13A	(0.37)	(0.36)	(0.46)	(0.33)	(1.52)	NM

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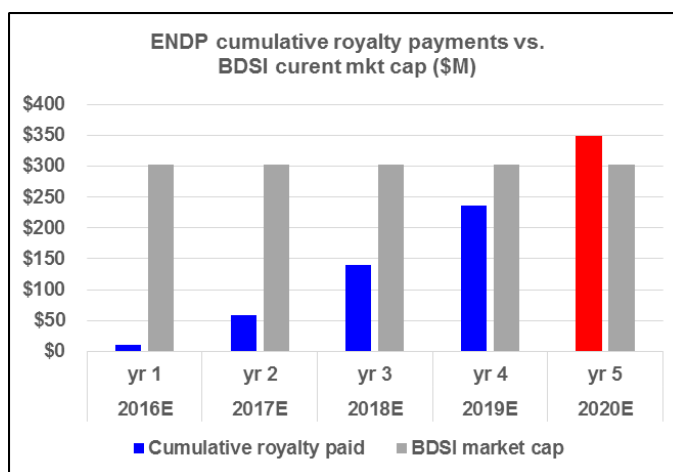
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Source: Company data and Laidlaw & Company estimates

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- ENDP will pay BDSI's market cap in royalties & milestones in 5 yrs.** We estimate 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 late 2015/early 2016.
- ENDP 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 seeing some attractive opportunities at much lower prices following the recent market dislocation for acquisition, 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
SUM	\$1,078,749	\$17
Shares out '16E (000)		62,668

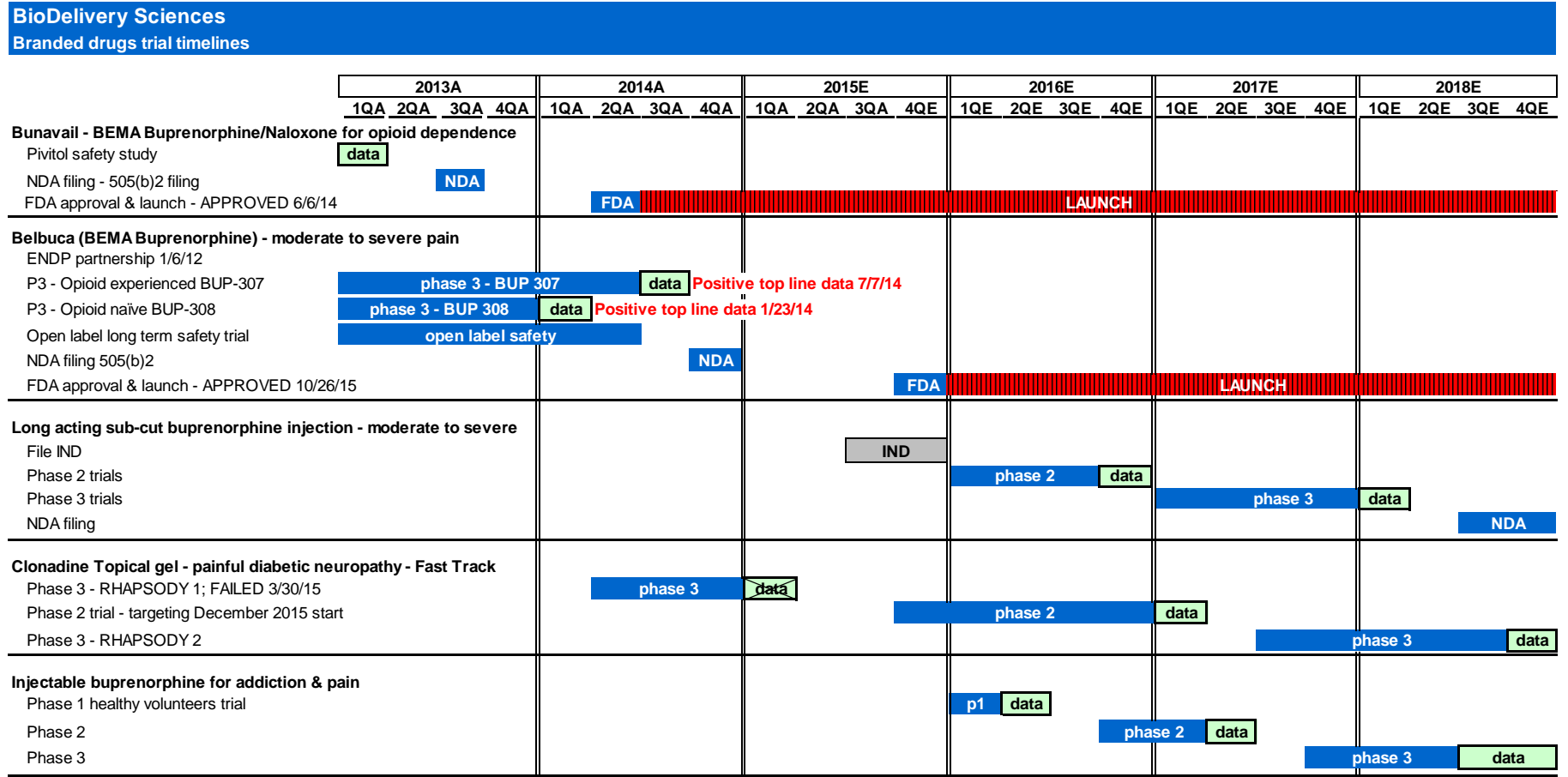
Source: Bloomberg LP.

Figure 3: Variance analysis

BioDelivery Sciences					
Quarterly variance analysis					
(000's except per share)	3Q14A	3Q15A	3Q15E	Variance	% Y/Y
Bunavail sales		\$1,135	\$1,008	\$127	NA
Royalty revenue	\$12	100	100	0	747%
Contract rev / milestones	513	0	0	0	-100%
Research fees	1,298	0	0	0	-100%
Total Revenue	\$1,822	\$1,235	\$1,108	\$127	-32%
COGS	463	1,699	1,203	495	267%
Gross Profit	1,360	(464)	(96)	(368)	-134%
SG&A Expense	13,649	14,715	13,000	1,715	8%
R&D Expense	6,770	4,473	5,000	(527)	-34%
Operating Income	(19,059)	(19,652)	(18,096)	(1,556)	3%
Int. inc. (expense), net	(515)	(785)	(200)	(585)	53%
Other (exp) gain, net	25	(2)	25	(27)	-108%
Pretax Income	(25,233)	(20,439)	(18,271)	(2,168)	-19%
Income Tax exp (benefit)	0	0	0	0	NA
Net income (loss)	(25,233)	(20,439)	(18,271)	(2,168)	-19%
1x items & non-cash exp	(5,685)	0	0	0	-100%
Adj NI ex-1x/non cash	(19,549)	0	0	0	-100%
Weighted avg. shares (000)	49,556	52,543	53,152	(609)	6%
Fully diluted shares (000)	55,556	62,286	62,552	(265)	12%
Earning per Share (EPS)	(\$0.51)	(\$0.39)	(\$0.34)	(\$0.05)	-24%
Adj EPS ex-1x & non-cash	(\$0.39)	\$0.00	\$0.00	\$0.00	-100%

Source: Company reports; Laidlaw & Company estimates.

Figure 4: 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	
Revenues										
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
Total Revenue	\$20,690	\$13,885	\$1,822	\$2,547	\$38,944	\$13,054	\$1,745	\$1,235	\$1,696	\$17,730
Expenses:										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	2,621	1,699	1,468	6,912
Gross Margin	19,965	13,198	1,360	(517)	34,005	11,930	(876)	(464)	228	10,818
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
Income (loss) from Operations	714	(2,041)	(19,059)	(18,351)	(38,740)	(7,800)	(18,669)	(19,652)	(18,022)	(64,143)
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
Income (loss) before taxes	(4,644)	(6,671)	(25,233)	(17,666)	(54,218)	(8,193)	(19,199)	(20,439)	(18,097)	(65,928)
Income tax exp (benefit)										
Net Income (Loss)	(4,644)	(6,671)	(25,233)	(17,666)	(54,215)	(8,193)	(19,199)	(20,439)	(18,097)	(65,928)
Earning per Share (EPS)	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.34)	(\$1.12)	(\$0.16)	(\$0.37)	(\$0.39)	(\$0.34)	(\$1.26)
Adj EPS ex-1x & non-cash items	(\$0.22)	(\$0.05)	(\$0.39)	(\$0.34)	(\$1.03)	(\$0.31)				(\$1.41)
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 & Company estimates.

Figure 5: Annual Income Statement

BioDelivery Sciences						
Annual income statement						
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
Revenues						
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	-	-	-	
Total Revenue	\$38,944	\$17,730	\$71,170	\$62,250	\$106,250	
Expenses:						
Cost of Revenue (COGS)	4,939	6,912	4,983	4,243	5,118	
Gross Margin	34,005	10,818	66,187	58,008	101,133	
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	
Income (loss) from Operations	(38,740)	(64,143)	(10,813)	(21,793)	18,883	
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	
Income (loss) before taxes	(54,218)	(65,928)	(10,138)	(20,118)	21,208	
Income tax exp (benefit)	-	-	-	(18)	3,864	Sig. tax loss carryforwards
Net Income (Loss)	(\$54,215)	(\$65,928)	(\$10,138)	(\$20,099)	\$17,344	
Adjustments to Income for Dilutive	\$0	\$0	\$0	\$0	\$0	
1x items & non-cash exp	(4,631)	7,757	34,000	0	0	
Adj NI less non cash & 1x items	(\$49,584)	(\$73,685)	(\$44,138)			
Earning per Share	(\$1.12)	(\$1.26)	(\$0.19)	(\$0.35)	\$0.25	
Adj EPS ex-1x & non-cash items	(\$1.03)	(\$1.41)	(\$0.70)			
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	
Margin & Expense Analysis						
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%	
Year-over-year change						
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 & Company estimates.

Major risks

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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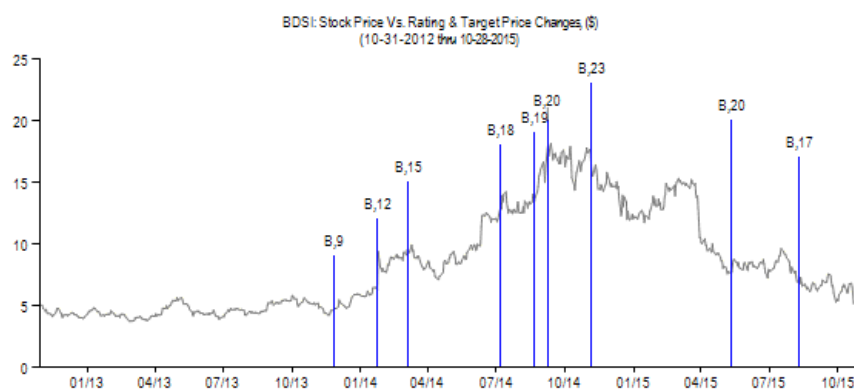
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Rating and Price Target Change History



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
11/06/2014	23.00	15.84
05/12/2015	20.00	7.75
08/10/2015	17.00	7.05

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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.	74.19%	25.81%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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Endo International (ENDP – Not Rated)

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