

BioDelivery Sciences (BDSI - \$ 5.34)

Healthcare/Biotechnology

C'mon man! Belbuca is a \$1B opportunity for BDSI & ENDP

This past Monday the FDA approved BDSI & partner ENDP's long acting opioid Belbuca. We believe this product – which will be the only Schedule 3 opioid on the market – has a legitimate chance to reach the \$1B “blockbuster” sales levels. With BDSI in-line to receive mid-upper teen royalties and (undisclosed) sales milestones the royalties alone from Belbuca at peak sales could be worth almost as much as BDSI's current market cap. The FDA approved Belbuca with a clean label which triggered the full \$50M milestone payment from ENDP and is worth \$0.80/share in cash by itself. Unquestionably, BDSI struggled with the launch of Bunavail and had a disappointing roll-out of that product, but recent script trends have improved dramatically (see Figure 2 next page) and the launch of Belbuca will be run by ENDP, completely outside of BDSI's hands. We see the current reaction as unfathomable given how de-risked this story has become following the recent FDA approval of Belbuca and we reiterate our Buy rating and our \$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)	52.46

- **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.
- **Belbuca label looks clean enough for \$50M from ENDP.** The product is a long-acting opioid so it contains standard language about caution with opioid naïve patients, but so does Oxycontin and that drug sells ~\$2B annually as a Schedule 2 drug.
- **Partner ENDP launching Belbuca in 1Q16.** BDSI's role in the Belbuca launch is to sit back and collect the mid-upper teen royalty payments. BDSI will not be participating in launching this drug, so a repeat of the underwhelming Bunavail launch (which is an entirely different target population anyway) is off the table. We conservatively model in 2016-2018 sales of \$75M, \$315M, and \$450M respectively by partner ENDP generating \$11.2M, \$47.2M, and \$81M in royalties.
- **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	(0.34)	(0.34)	(1.35)	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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Source: Company data and Laidlaw & Company estimates

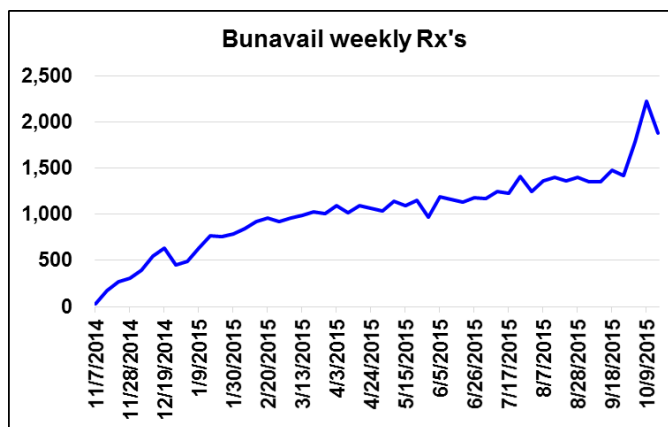
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Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$782,345	\$12.0
Bunavail	\$66,015	\$1.0
Net cash (end '16) & tech value	\$172,964	\$4.0
SUM	\$1,079,736	\$17
Shares out '16E (000)		63,777

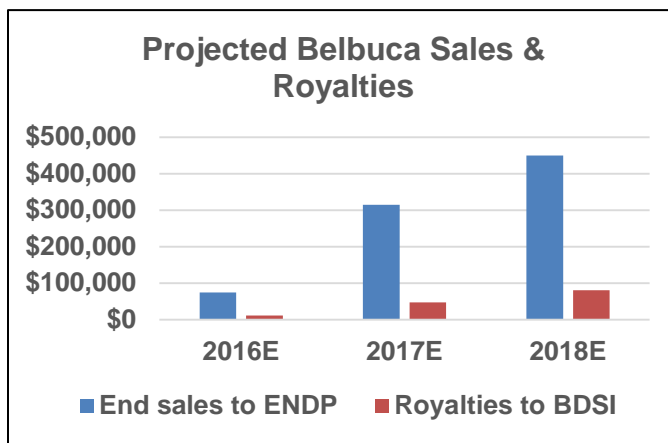
Source: Bloomberg LP.

Figure 2: Bunavail launch trajectory by week



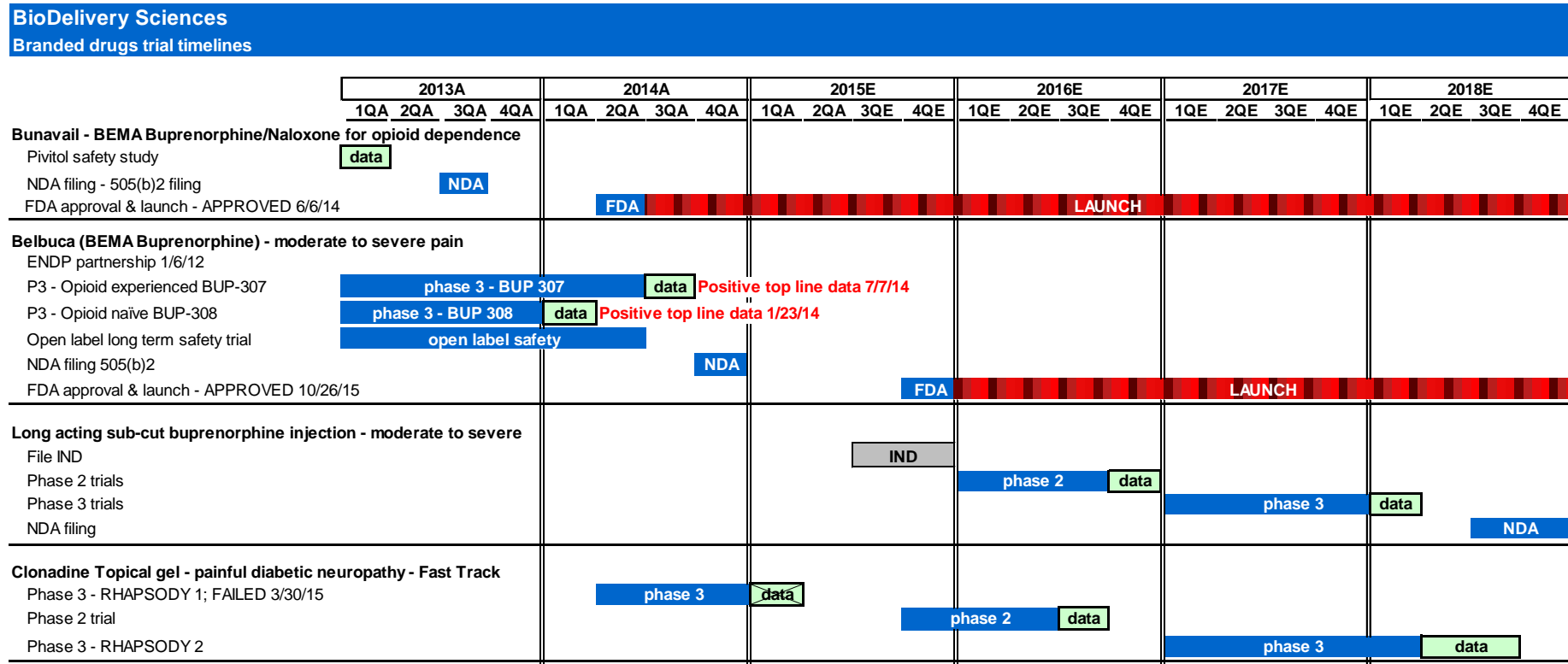
Source: Company reports; Laidlaw & Company estimates.

Figure 3: Belbuca ENDP end sales & BDSI royalty projections



Source: Laidlaw & Company estimates.

Figure 4: Clinical trials timeline



Source: Company reports and SSRP 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	3QE	4QE	
Revenues										
Bunavail sales				\$76	\$76	\$677	\$800	\$1,008	\$1,596	\$4,081
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	\$1,108	\$1,696	\$17,603
Expenses:										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	2,621	1,203	1,468	6,417
Gross Margin	19,965	13,198	1,360	(517)	34,005	11,930	(876)	(96)	228	11,186
Research and development	14,623	7,983	6,770	4,909	34,285	6,549	4,506	5,000	5,000	21,055
General and administrative	4,622	7,250	13,649	12,925	38,460	13,181	13,287	13,000	13,250	52,718
Related party G&A	6	6								-
Total operating expenses	19,251	15,239	20,418	17,834	72,745	19,730	17,793	18,000	18,250	73,773
Income (loss) from Operations	714	(2,041)	(19,059)	(18,351)	(38,740)	(7,800)	(18,669)	(18,096)	(18,022)	(62,587)
Interest income (expense), net	(555)	(519)	(515)	(427)	(2,016)	(420)	(527)	(200)	(100)	(1,247)
Derivative (loss) gain	(4,825)	(4,120)	(5,685)	1,464	(13,167)					-
Other (exp) gain, net	23	9	25	(352)	(295)	27	(3)	25	25	74
Income (loss) before taxes	(4,644)	(6,671)	(25,233)	(17,666)	(54,218)	(8,193)	(19,199)	(18,271)	(18,097)	(63,760)
Income tax exp (benefit)										
Net Income (Loss)	(4,644)	(6,671)	(25,233)	(17,666)	(54,215)	(8,193)	(19,199)	(18,271)	(18,097)	(63,760)
Earning per Share (EPS)	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.34)	(\$1.12)	(\$0.16)	(\$0.37)	(\$0.34)	(\$0.34)	(\$1.21)
Adj EPS ex-1x & non-cash items	(\$0.22)	(\$0.05)	(\$0.39)	(\$0.34)	(\$1.03)	(\$0.31)				(\$1.35)
Weighted avg. shares (000)	44,035	48,521	49,556	51,308	48,355	51,909	52,402	53,152	53,902	52,841
Fully diluted shares (000)	54,435	55,321	55,556	54,505	54,954	61,309	61,802	62,552	63,302	62,241

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	4,081	13,270	16,750	19,250	Launched 11/3/14
Royalty - Belbuca (BEMA Bup.)	-	-	11,250	47,250	81,000	10/23/15 PDUFA date
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	\$17,603	\$74,920	\$69,000	\$106,250	
Expenses:						
Cost of Revenue (COGS)	4,939	6,417	5,463	4,278	5,118	
Gross Margin	34,005	11,186	69,457	64,723	101,133	
Research and development	34,285	21,055	23,250	26,000	26,500	
General and administrative	38,460	52,718	54,500	55,000	55,750	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	73,773	77,750	81,000	82,250	
Income (loss) from Operations	(38,740)	(62,587)	(8,293)	(16,278)	18,883	
Interest income (expense), net	(2,016)	(1,247)	575	1,575	2,225	
Derivative (loss) gain	(13,167)	-	-	-	-	
Other expenses, net	(295)	74	100	100	100	
Income (loss) before taxes	(54,218)	(63,760)	(7,618)	(14,603)	21,208	
Income tax exp (benefit)	-	-	-	72	3,864	Sig. tax loss carryforwards
Net Income (Loss)	(\$54,215)	(\$63,760)	(\$7,618)	(\$14,674)	\$17,344	
Adj NI less non cash & 1x items	(\$49,584)	(\$71,517)	(\$41,618)			
Earning per Share	(\$1.12)	(\$1.21)	(\$0.14)	(\$0.25)	\$0.25	
Adj EPS ex-1x & non-cash items	(\$1.03)	(\$1.35)	(\$0.65)			
Weighted avg. shares (000)	48,355	52,841	55,777	58,777	61,902	
Fully diluted shares (000)	54,954	62,241	63,777	67,277	70,402	
Margin & Expense Analysis						
COGS as % of Revenues	13%	36%	7%	6%	5%	
R&D	88%	120%	31%	38%	25%	
SG&A	99%	299%	73%	80%	52%	
Gross Profit	87%	64%	93%	94%	95%	
Op. margin cont. ops	-99%	-356%	-11%	-24%	18%	
Taxes	0%	0%	0%	0%	18%	
Net margin	-139%	-362%	-10%	-21%	16%	
Year-over-year change						
Net revenue	243%	-55%	326%	-8%	54%	
R&D	64%	61%	110%	112%	102%	
SG&A	213%	37%	3%	1%	1%	
Operating income	-31%	62%	-87%	96%	-216%	

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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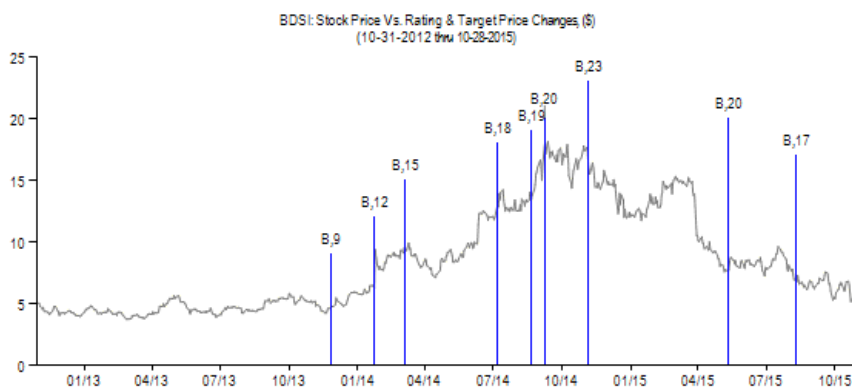
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Rating and Price Target Change History



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

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
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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