

BioDelivery Sciences (BDSI - \$ 7.21)

Healthcare/Biotechnology

Bunavail's moderate launch continues, next catalyst: Belbuca

BDSI reported 2Q15 this AM before the open, missing both top & bottom line estimates driven by lower than expected Bunavail sales. The lackluster launch of Bunavail continues to be a drag on BDSI shares, and we are (again) lowering our sales estimates and our PT contribution for Bunavail. The next catalyst we are anticipating for BDSI is the October 23rd PDUFA date for the chronic pain drug Belbuca, at which point we expect FDA approval and the payment of up to \$50M from partner ENDP. We have adjusted our EPS estimates lower to account for our lower Bunavail sales ramp, and we are lowering our PT from \$20 to \$17, maintain Buy rating.

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

- **Lower Bunavail sales cause top and bottom line miss.** BDSI reported 2Q15 yesterday before the open with top line revenues of \$1.7MM vs. cons: \$3.3MM and Laidlaw: \$4.9MM. Bunavail sales were \$800K vs our \$1.9MM estimate due to a combination of lower Rx and a lower realized price per Rx in the Q (~\$60/Rx vs. our expectation of ~\$120/Rx by now). Although Operating expenses were mostly in-line, significantly higher COGs due to a 1x charge-back in the quarter and lower Bunavail sales contributed to EPS loss of (\$0.37) vs consensus & Laidlaw: (\$0.31).
- **Belbuca PDUFA 10/23/15 the next key catalyst.** Partnered with ENDP, we continue to expect FDA approval on the October PDUFA date. On their recent 2Q15 call ENDP also reiterated their expectations for FDA approval, which triggers an up to \$50M milestone payment to BDSI and potentially the outright acquisition of BDSI by ENDP.
- **Adjusting EPS estimates, lowering PT from \$20 to \$17.** We have adjusted our 2015E-2018E EPS estimates from (\$1.05), \$0.10, \$0.50, and \$0.90 to (\$1.35), (\$0.65), (\$0.25), and \$0.25 respectively. Our \$17 PT 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 (08/10/2015)	\$7.21
52-Week High (09/12/2014)	\$18.48
52-Week Low (08/07/2015)	\$6.37
Market Cap. (MM)	\$379.5
Shares Out. (MM)	52.4

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: Variance analysis

BioDelivery Sciences Quarterly variance analysis					
(000's except per share)	2Q14A	2Q15A	2Q15E	Variance	% Y/Y
Bunavail sales		\$800	\$1,912	(\$1,112)	NA
Royalty revenue	\$892	495	1,000	(\$505)	-45%
Contract rev / milestones	10,675	0	0	\$0	-100%
Research fees	2,318	450	2,000	(\$1,550)	-81%
Total Revenue	\$13,885	\$1,745	\$4,912	(\$3,167)	-87%
COGS	687	2,621	1,228	\$1,393	282%
Gross Profit	13,198	(876)	3,684	(\$4,560)	-107%
SG&A Expense	7,256	13,287	13,500	(\$213)	83%
R&D Expense	7,983	4,506	6,250	(\$1,744)	-44%
Operating Income	(2,041)	(18,669)	(16,066)	(\$2,603)	815%
Int. inc. (expense), net	(519)	(527)	(350)	(\$177)	2%
Other (exp) gain, net	9	(3)	25	(\$28)	-133%
Pretax Income	(6,671)	(19,199)	(16,391)	(\$2,808)	188%
Income Tax exp (benefit)	0	0	0	\$0	NA
Net income (loss)	(6,671)	(19,199)	(16,391)	(\$2,808)	188%
1x items & non-cash exp	(4,120)	0	0	\$0	-100%
Adj NI ex-1x/non cash	(2,551)	0	0	\$0	-100%
Weighted avg. shares (000)	48,521	52,402	52,659	(\$257)	8%
Fully diluted shares (000)	55,321	61,802	62,059	(\$257)	12%
Earning per Share (EPS)	(\$0.14)	(\$0.37)	(\$0.31)	(\$0.06)	166%
Adj EPS ex-1x & non-cash	(\$0.05)	\$0.00	\$0.00	\$0.00	-100%

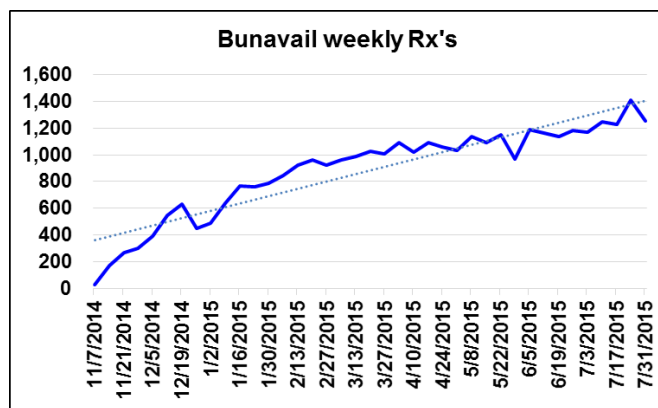
Source: Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$782,345	\$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

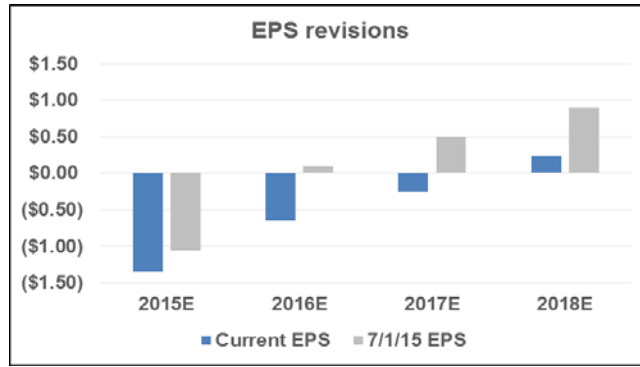
Source: Bloomberg LP.

Figure 3: Bunavail launch trajectory by week



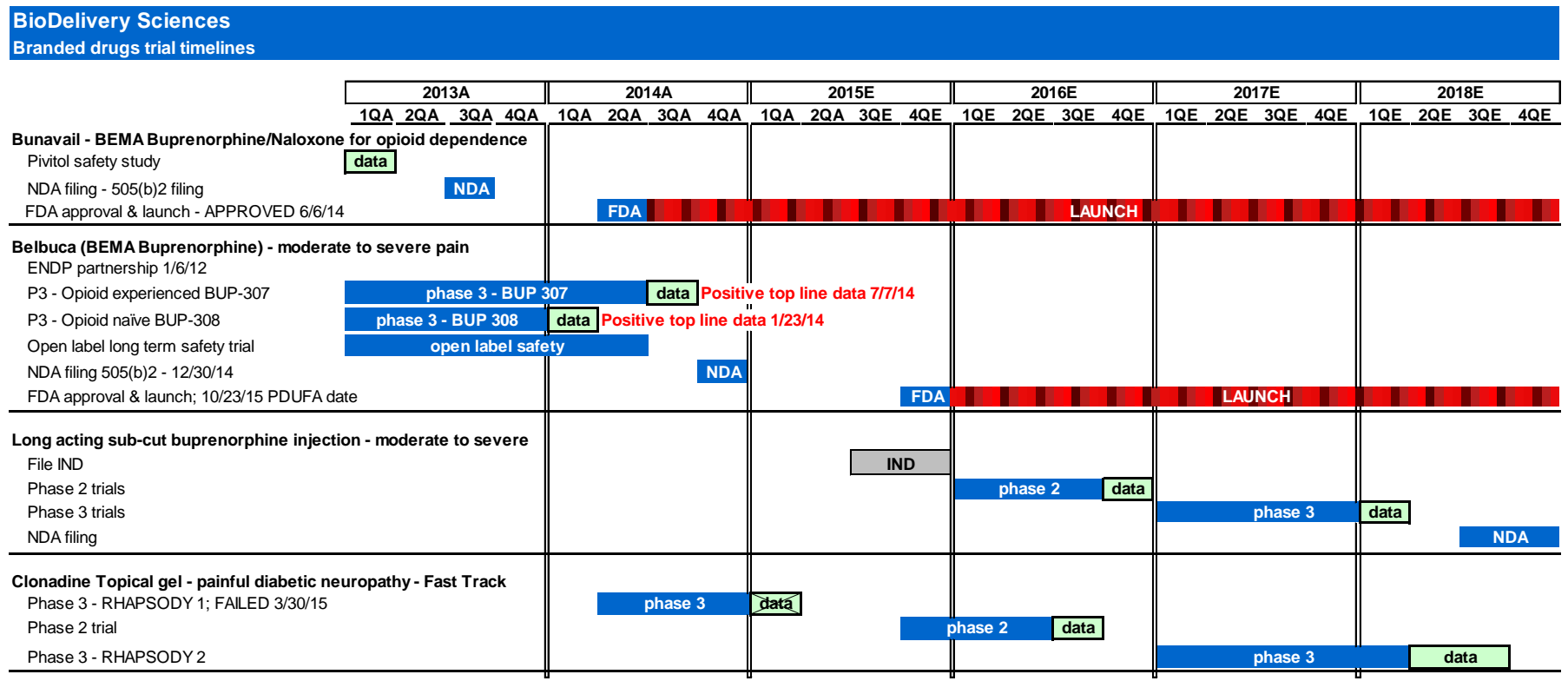
Source: Company reports; Laidlaw & Company estimates.

Figure 4: EPS estimate changes



Source: Company reports; Laidlaw & Company estimates.

Figure 5: Clinical trials timeline



Source: Company reports and SSRP estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 6: 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 7: 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. 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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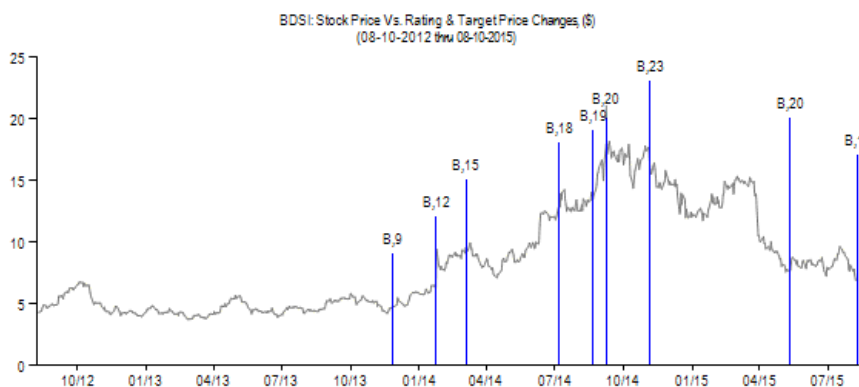
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Rating and Price Target Change History



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	6.96*

Source: Laidlaw & Company

Created by: Blue-Compass.net

* Previous Close 8/7/2015

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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.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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Teva Pharmaceuticals (TEVA – Not Rated)

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