

BioDelivery Sciences (BDSI - \$ 3.00)

You Got to Know When to Hold 'em...Lowering PT to \$11

We are lowering our price target on BDSI to \$11 from \$17 previously in light of the continued lackluster roll-out of Bunavail and the likelihood, in our opinion, that sales are not likely to get materially better in the near term. In fact we believe that BDSI will need to do a dramatic scale-back of the sales infrastructure in 2H16 to better align the expenses associated with supporting Bunavail with the sales level. In fact we have removed all of Bunavail contribution to our valuation, and believe that if sales don't turn around dramatically - and soon - BDSI shareholders would be best served by BDSI dropping the drug entirely or finding someone who might buy it from them. That said, we continue to see a substantial opportunity for Belbuca (launched February 22nd by partner ENDP) given the sizeable need for a less abusable and less addictive Schedule 3 opioid following the Vicodin-like opioids being moved to Schedule 2 in late 2014. We continue to believe that with ENDP behind the launch Belbuca sales could reach \$350M in 2018, generating over \$60M in royalties to BDSI. So while the launch of Bunavail has fallen well below our expectations, and we now see no value in the drug, there remains considerable value in the potential royalty stream from ENDP on Belbuca. We are lowering our PT from \$17 to \$11 but maintain our Buy rating.

- **...and know when to fold 'em.** At the current disparity between Bunavail sales (\$4.1M in 2015) and the SG&A spend to support those sales (\$54.7M in 2015) we believe that absent a sharp uptick in Rx trends BDSI needs to take a close look at dramatically scaling back the Bunavail support infrastructure if not shutter it outright. Suboxone sales in the first two months of 2016 have been weak across the category, but Bunavail has been weaker still down -14% vs. the market at down -13%.
- **Know when to walk away...**Price per Rx (as determined by reported sales divided by TRx) dropped to under \$60 in 4Q15, and there's likely little reason to expect a dramatic reversal in pricing in 2016 given the competitive environment.
- **...and know when to run.** We have modeled in reps being cut from the current ~60 headcount to ~15 by mid-17 and non-rep SG&A spend dropping to \$5M-\$6M/Q from the current ~\$11M level. Again, barring a sharp and sustained uptick in Rx's near term we believe it may ultimately be more valuable to shareholders for BDSI to explore strategic options for Bunavail if not outright drop the drug.
- **Lowering PT from \$17 to \$11.** The main driver for our valuation at this point is Belbuca which we value at \$9.5/share, Bunavail at \$0/share, and cash (end '16) and technology value of \$1.5/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.14)	(0.09)	(0.06)	(0.01)	(0.30)	NM
FY-16E	(0.32)	(0.31)	(0.24)	(0.19)	(1.05)	NM
FY-15A	(0.35)	(0.37)	(0.39)	(0.37)	(1.48)	NM
FY-14A	(0.22)	(0.26)	(0.39)	(0.37)	(1.26)	NM

Healthcare/Biotechnology

Ticker:	BDSI
Rating:	Buy
Price Target:	↓ \$11.00

Trading Data:

Last Price (03/11/2016)	\$3.00
52-Week High (03/19/2015)	\$15.50
52-Week Low (03/11/2016)	\$2.90
Market Cap. (MM)	\$158.0
Shares Out. (MM)	52.67

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Variance analysis

BioDelivery Sciences Variance analysis										
(000's except per share)	4Q14A	4Q15A	4Q15E	Variance	% Y/Y	FY14A	FY15A	FY15E	Variance	% Y/Y
Bunavail sales		\$1,500	\$1,596	(\$96)	NA		\$4,157	\$4,208	(\$51)	NA
Royalty revenue	\$1,549	617	100	517	-60%	\$3,407	1,406	889	517	-59%
Contract rev / milestones	277	351	0	351	27%	2,749	1,759	11,408	(9,649)	-36%
Research fees	645	0	0	0	-100%	12,712	909	1,225	(316)	-93%
Total Revenue	\$2,547	\$2,468	\$1,696	\$772	-3%	\$18,944	\$8,231	\$17,730	(\$9,499)	-57%
COGS	3,064	2,657	1,468	1,189	-13%	4,939	8,101	6,912	1,189	64%
Gross Profit	(517)	(189)	228	(417)	-63%	14,005	401	10,818	(10,417)	-97%
SG&A Expense	12,925	13,502	13,250	252	4%	38,460	54,685	54,433	252	42%
R&D Expense	4,909	5,096	5,000	96	4%	34,285	20,624	20,528	96	-40%
Operating Income	(18,351)	(18,787)	(18,022)	(765)	2%	(58,740)	(74,908)	(64,143)	(10,765)	28%
Int. inc. (expense), net	(427)	(786)	(100)	(686)	84%	(2,016)	(2,518)	(1,832)	(686)	25%
Other (exp) gain, net	(352)	(22)	25	(47)	-94%	(295)	0	47	(47)	-100%
Pretax Income	(19,130)	(19,570)	(18,097)	(1,473)	2%	(61,051)	(77,401)	(65,928)	(11,473)	27%
Income Tax exp (benefit)	0	0	0	0	NA	0	0	0	0	NA
Net income (loss)	(19,130)	(19,570)	(18,097)	(1,473)	2%	(61,048)	(77,401)	(65,928)	(11,473)	27%
1x items & non-cash exp	1,464	30,000	0	30,000	1949%	6,826	40,000	7,757	32,243	486%
Adj NI ex-1x/non cash	(17,666)	10,430	0	10,430	-159%	(54,222)	(37,401)	(73,685)	36,285	-31%
Weighted avg. shares (000)	51,308	52,686	52,793	(107)	3%	48,355	52,385	52,412	(27)	8%
Fully diluted shares (000)	54,505	62,436	62,193	243	15%	54,954	61,983	61,922	61	13%
Earning per Share (EPS)	(\$0.37)	(\$0.37)	(\$0.34)	(\$0.03)	0%	(\$1.26)	(\$1.48)	(\$1.26)	(\$0.22)	17%
Adj EPS ex-1x & non-cash	(\$0.34)	\$0.20	\$0.00	\$0.20	-157%	(\$1.12)	(\$0.71)	(\$1.41)	\$0.69	-36%

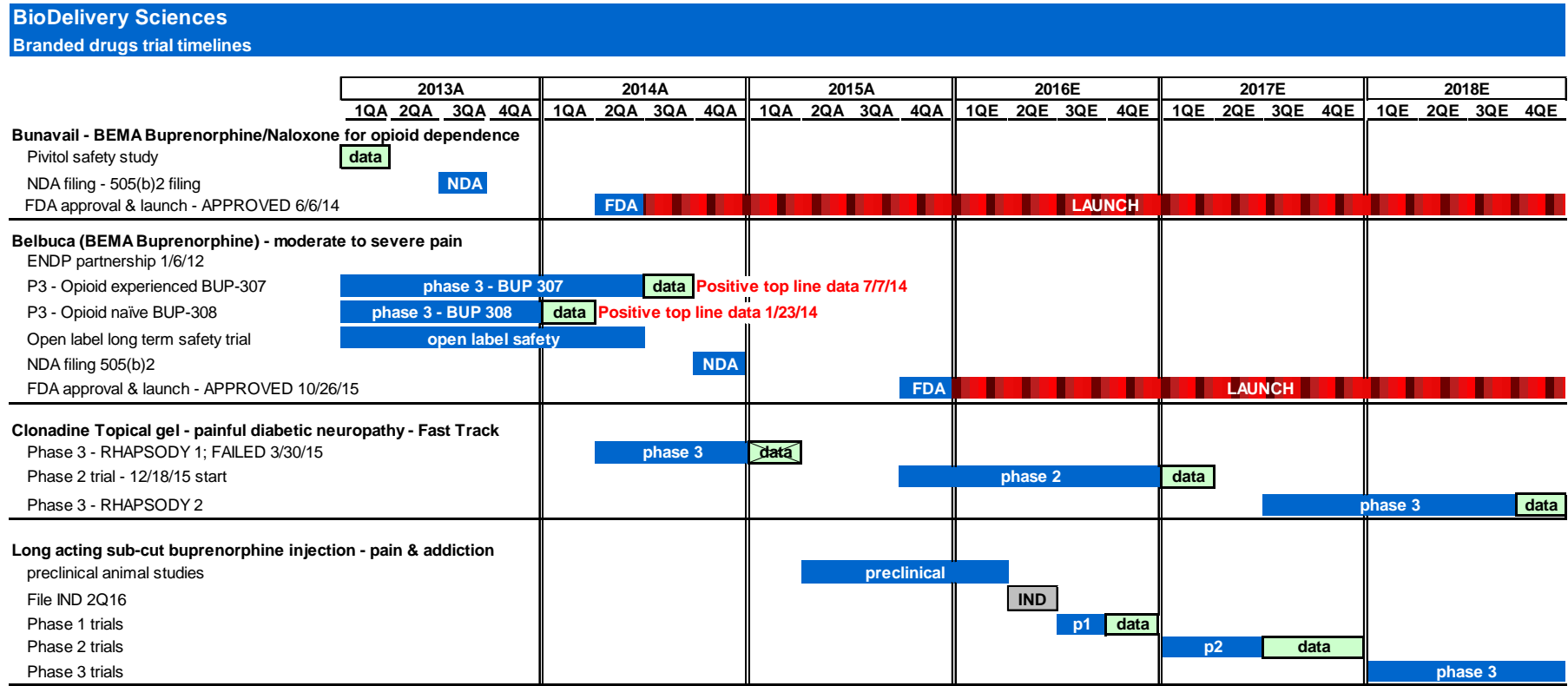
Source: Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca royalty	\$639,666	\$9.5
Net cash (end '16) & tech value	\$53,578	\$1.5
SUM	\$745,233	\$11
Shares out '16E (000)		65,249

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	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
ENDP Milestones (not in rev)	\$10,000	\$10,000			\$20,000	\$10,000			\$30,000	\$40,000
Bunavail sales				\$76	76	677	\$800	\$1,135	1,500	\$4,157
Royalty revenue - Onsolis	954	892	12	1,549	3,407	194	495	100	617	1,406
Contract rev	1,284	675	513	277	2,749	1,408	0	0	351	1,759
Research fees	8,452	2,318	1,298	645	12,712	775	450			909
Total Rev ex-milestones	\$10,690	\$3,885	\$1,822	\$2,547	\$18,944	\$3,054	\$1,745	\$1,235	\$2,468	\$8,231
Expenses:										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	2,621	1,699	2,657	8,101
Gross Margin	9,965	3,198	1,360	(517)	14,005	1,930	(876)	(464)	(189)	401
Research and development	14,623	7,983	6,770	4,909	34,285	6,549	4,506	4,473	5,096	20,624
General and administrative	4,622	7,250	13,649	12,925	38,460	13,181	13,287	14,715	13,502	54,685
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	18,598	75,309
Income (loss) from Operations	(9,286)	(12,041)	(19,059)	(18,351)	(58,740)	(17,800)	(18,669)	(19,652)	(18,787)	(74,908)
Interest income (expense), net	(555)	(519)	(515)	(427)	(2,016)	(420)	(527)	(785)	(786)	(2,518)
Other (exp) gain, net	23	9	25	(352)	(295)	27	(3)	(2)	(22)	-
Income (loss) before taxes	(9,818)	(12,551)	(19,549)	(19,130)	(61,051)	(18,193)	(19,199)	(20,439)	(19,570)	(77,401)
Income tax exp (benefit)										
Adj NI ex 1x milestones	(9,818)	(12,551)	(19,549)	(19,130)	(61,048)	(18,193)	(19,199)	(20,439)	(19,570)	(77,401)
Adj EPS ex-1x & non-cash	(\$0.22)	(\$0.26)	(\$0.39)	(\$0.37)	(\$1.26)	(\$0.35)	(\$0.37)	(\$0.39)	(\$0.37)	(\$1.48)
EPS as reported	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.34)	(\$1.12)	(\$0.16)			\$0.20	(\$0.71)
Weighted avg. shares (000)	44,035	48,521	49,556	51,308	48,355	51,909	52,402	52,543	52,686	52,385
Fully diluted shares (000)	54,435	55,321	55,556	54,505	54,954	61,309	61,902	62,286	62,436	61,983

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	2015A	2016E	2017E	2018E	Comments
Revenues						
ENDP Milestones (not in rev)	20,000	40,000	-	-	-	Not in top line revenue
Bunavail sales	76	4,157	7,779	9,250	10,480	Launched 11/3/14
Belbuca royalty			6,000	24,000	63,000	2/22/16 luanch by ENDP
Royalty revenue - Onsolis	3,407	1,406	800	800	800	
Contract revenue	2,749	1,759	-	-	-	
Research fees	12,712	909	-	-	-	
Total Rev ex-milestones	\$18,944	\$8,231	\$14,579	\$34,050	\$74,280	
Expenses:						
Cost of Revenue (COGS)	4,939	8,101	3,942	3,417	4,153	
Gross Margin	14,005	401	10,637	30,632	70,127	
Research and development	34,285	20,624	23,000	24,000	24,000	
General and administrative	38,460	54,685	45,750	24,938	24,750	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	75,309	68,750	48,938	48,750	
Income (loss) from Operations	(58,740)	(74,908)	(58,113)	(18,305)	21,377	
Interest income (expense), net	(2,016)	(2,518)	-	-	-	
Other expenses, net	(295)	-	100	100	100	
Income (loss) before taxes	(61,051)	(77,401)	(58,013)	(18,205)	21,477	
Income tax exp (benefit)	-	-	-	-	2,954	Sig. tax loss carryforwards
Adj NI ex 1x milestones	(\$61,048)	(\$77,401)	(\$58,013)	(\$18,205)	\$18,523	
Net income as reported	(\$54,222)	(\$37,401)				
Adj EPS ex-1x & non-cash	(\$1.26)	(\$1.48)	(\$1.05)	(\$0.30)	\$0.25	
EPS as reported	(\$1.12)	(\$0.71)				
Weighted avg. shares (000)	48,355	52,385	55,499	60,061	63,186	
Fully diluted shares (000)	54,954	61,983	65,249	70,061	73,186	
Margin & Expense Analysis						
COGS as % of Revenues	26%	98%	27%	10%	6%	
R&D	181%	251%	158%	70%	32%	
SG&A	203%	664%	314%	73%	33%	
Gross Profit	74%	2%	73%	90%	94%	
Op. margin cont. ops	-310%	-910%	-399%	-54%	29%	
Taxes	0%	0%	0%	0%	14%	
Net margin	-322%	-940%	-398%	-53%	25%	
Year-over-year change						
Net revenue	67%	-57%	77%	134%	118%	
R&D	64%	60%	112%	104%	100%	
SG&A	213%	42%	-16%	-45%	-1%	
Operating income	4%	28%	-22%	-69%	-217%	

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.

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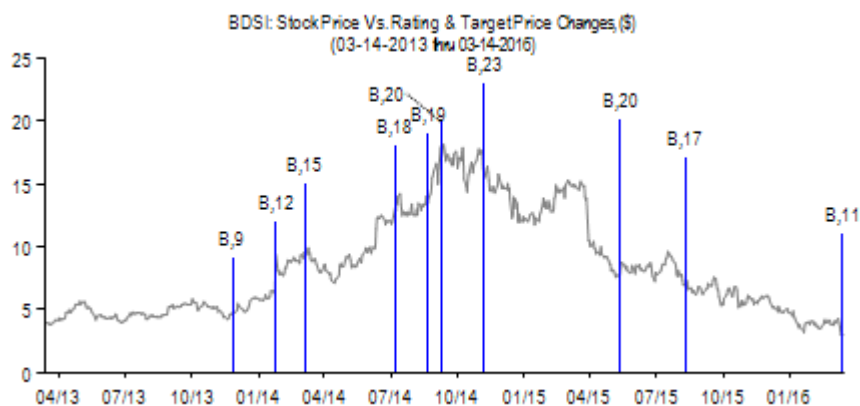
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Rating and Price Target Change History



Source: Laidlaw & Company

Created by: Blue-Compass.net

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
03/14/2016	11.00	3.00*

* Previous Close 3/11/2016

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			Investment Banking	Brokerage
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Buy (B)	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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March 14, 2016

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