

## BioDelivery Sciences (BDSI - \$1.89)

*Healthcare/Biotechnology*

### Strategic Alternatives Need to be Explored at BDSI - Now

BDSI reported their 3Q16 yesterday before the open with revenues in-line with expectations, which is a small positive given the bottom line miss due to higher COGS and SG&A than our estimates. We continue to target profitability in 2018, but we need to see Bunavail & Belbuca sales improve materially from current levels. In fact we believe that the best way to realize shareholder value at this point is a fundamental change in thinking at BDSI, and the company needs to seriously explore strategic alternatives (ie: sale) of Bunavail & the Belbuca royalty to a third party. It seems clear that the current plan isn't working (Bunavail sales have remained plateaued at ~\$2m/Q for the past 3 Q's in a row) and even a sell-side analyst can see that spending \$37M in SG&A to sell \$6M in Bunavail year to date is no way to run a railroad (on top of \$55M in 2015 to sell \$4M). We view the six recent managed care wins since July and patient cap lift from 100 to 275 patients per doctor as a real positive, but we have lost confidence that the current structure at BDSI is in any way capable of realizing that potential, given the disastrous results to date. We still see value in the assets at BDSI, as few smaller companies have two FDA approved drugs in the market, but we think these should be boxed up & sold to another party to realize their full potential for investors, so despite the incredible underperformance to date we continue to maintain our Buy rating and our \$11 price target.

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

#### Trading Data:

Last Price (11/10/2016)	\$1.89
52-Week High (11/30/2015)	\$6.40
52-Week Low (11/10/2016)	\$1.70
Market Cap. (MM)	\$102.3
Shares Out. (MM)	54.1

- **Bunavail 1H17 potential growth, Belbuca still reason to own BDSI here.** While with six Bunavail Managed Care Agreements have been secured since July and the patient cap increase from 100 to 275 patients per doctor (~500K Rx's annually), management reiterated their conviction in 1H17 growth. However, we maintain that at this point, Belbuca represents a \$360M sales opportunity and the reason to own BDSI.
- **Near term shift in focus, 4Q16 pipeline catalysts.** As Bunavail represents a 2017 story, BDSI is expecting data read-out of their phase 2b for Clonidine Topical Gel in December (ahead of our 1Q17 estimate) as well as IND submission of their buprenorphine 30-Day injection in 4Q16.
- **Maintain Buy rating \$11 price target.** We value Belbuca at \$8/share, Bunavail at \$0/share, and cash (end' 17) and tech value of \$3/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	(0.19)	(0.12)	(0.09)	(0.05)	(0.45)	NM
<b>FY-16E</b>	(0.36)A	(0.31)A	(0.30)A	(0.25)	(1.22)	NM
<b>FY-15A</b>	(0.35)	(0.37)	(0.39)	(0.37)	(1.48)	NM
<b>FY-14A</b>	(0.22)	(0.26)	(0.39)	(0.37)	(1.26)	NM

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Source: Company data and Laidlaw & Company estimates

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- **Top-line stabilized, Bottom line miss due to higher COGS and SG&A.** Bunavail sales and Belbuca royalty were stabilized and in-line with expectations, which we view as a positive as subsequent to the lowered cost structure implemented in 2Q16. COGS of \$2.31M vs LL: \$1.03M were higher than expected but should be reduced by ~30% by 2H17, when BDSI foresees profitability.

Figure 1: Variance analysis

BioDelivery Sciences Variance analysis					
(000's except per share)	3Q15A	3Q16A	3Q16E	Variance	% Y/Y
Bunavail sales		\$2,009	\$2,142	(\$133)	NA
Belbuca royalty		1,065	1,125	(\$60)	NA
Royalty revenue	\$100	0	200	(200)	-100%
Research fees	0	497	0	497	NA
<b>Total Revenue</b>	<b>\$1,235</b>	<b>\$3,571</b>	<b>\$3,467</b>	<b>\$104</b>	<b>189%</b>
COGS	1,699	2,314	1,028	1,286	36%
<b>Gross Profit</b>	<b>(464)</b>	<b>1,257</b>	<b>2,439</b>	<b>(1,182)</b>	<b>-371%</b>
SG&A Expense	14,715	12,054	9,500	2,554	-18%
R&D Expense	4,473	4,402	4,500	(98)	-2%
<b>Operating Income</b>	<b>(19,652)</b>	<b>(15,199)</b>	<b>(11,561)</b>	<b>(3,638)</b>	<b>-23%</b>
Int. inc. (expense), net	(785)	(786)	(750)	(36)	0%
Other (exp) gain, net	(2)	8	25	(17)	-500%
<b>Pretax Income</b>	<b>(20,439)</b>	<b>(15,977)</b>	<b>(12,286)</b>	<b>(3,691)</b>	<b>-22%</b>
Income Tax exp (benefit)	0	0	0	0	NA
<b>Net income (loss)</b>	<b>(20,439)</b>	<b>(15,977)</b>	<b>(12,286)</b>	<b>(3,691)</b>	<b>-22%</b>
Weighted avg. shares (000)	52,543	53,767	54,095	(328)	2%
Fully diluted shares (000)	62,286	63,754	64,345	(591)	2%
<b>Earning per Share (EPS)</b>	<b>(\$0.39)</b>	<b>(\$0.30)</b>	<b>(\$0.23)</b>	<b>(\$0.07)</b>	<b>-24%</b>

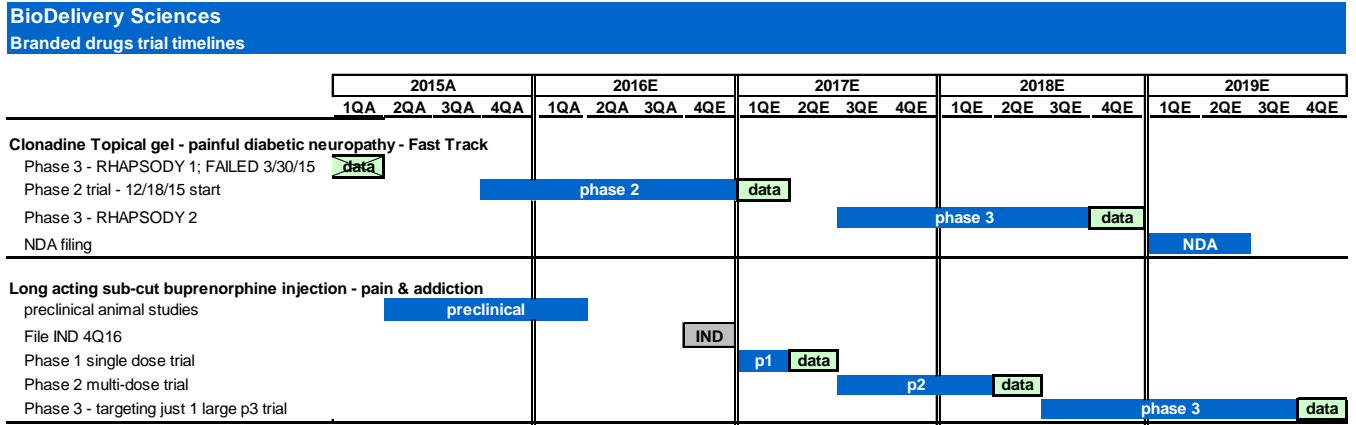
Source: Laidlaw &amp; Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca royalty	\$511,391	\$8.0
Net cash (end '17) & tech	\$148,135	\$3.0
<b>SUM</b>	<b>\$752,111</b>	<b>\$11</b>
Shares out '17E (000)		63,675

Source: JAMA and Laidlaw &amp; Company estimates.

Figure 3: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

BioDelivery Sciences										
Quarterly income statement										
(\$000 except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
ENDP Milestones (not in rev)	\$10,000			\$30,000	\$40,000					
Bunavail sales	677	\$800	\$1,135	1,500	\$4,157	\$2,102	\$2,110	\$2,009	\$2,148	\$8,369
Belbuca royalty						0	0	300	750	1,050
Royalty revenue - Onsolis	194	469	100	617	1,380	938	394	765	200	2,297
Contract rev	1,408	0	0	351	1,759	0		0	0	0
Research fees	775	431			909			497		497
<b>Total Rev ex-milestones</b>	<b>\$3,054</b>	<b>\$1,733</b>	<b>\$1,235</b>	<b>\$2,468</b>	<b>\$8,205</b>	<b>\$3,040</b>	<b>\$2,504</b>	<b>\$3,571</b>	<b>\$3,098</b>	<b>\$12,213</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	1,124	2,621	1,699	2,657	8,101	2,550	1,935	2,314	1,680	8,478
<b>Gross Margin</b>	<b>1,930</b>	<b>(888)</b>	<b>(464)</b>	<b>(189)</b>	<b>389</b>	<b>490</b>	<b>569</b>	<b>1,257</b>	<b>1,418</b>	<b>3,735</b>
Research and development	6,549	4,506	4,473	5,096	20,624	5,377	4,008	4,402	4,750	18,537
General and administrative	13,181	13,287	14,715	13,502	54,685	13,055	12,496	12,054	9,500	47,105
Related party G&A					-					-
Total operating expenses	19,730	17,793	19,188	18,598	75,309	18,432	16,504	16,456	14,250	65,642
<b>Income (loss) from Operations</b>	<b>(17,800)</b>	<b>(18,681)</b>	<b>(19,652)</b>	<b>(18,787)</b>	<b>(74,920)</b>	<b>(17,942)</b>	<b>(15,935)</b>	<b>(15,199)</b>	<b>(12,832)</b>	<b>(61,907)</b>
Interest income (expense), net	(420)	(527)	(785)	(786)	(2,518)	(778)	(914)	(786)	(750)	(3,228)
Other (exp) gain, net	27	(3)	(2)	(22)	-	(13)	22	8	25	42
<b>Income (loss) before taxes</b>	<b>(18,193)</b>	<b>(19,211)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,413)</b>	<b>(18,733)</b>	<b>(16,827)</b>	<b>(15,977)</b>	<b>(13,557)</b>	<b>(65,093)</b>
Income tax exp (benefit)										
<b>Adj NI ex 1x milestones</b>	<b>(18,193)</b>	<b>(19,211)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,413)</b>	<b>(18,733)</b>	<b>(16,827)</b>	<b>(15,977)</b>	<b>(13,557)</b>	<b>(65,093)</b>
1x items & non-cash exp	10,000	-	-	30,000	40,000					-
<b>Net income as reported</b>	<b>(8,193)</b>			<b>10,430</b>	<b>(37,413)</b>					
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$0.35)</b>	<b>(\$0.37)</b>	<b>(\$0.39)</b>	<b>(\$0.37)</b>	<b>(\$1.48)</b>	<b>(\$0.36)</b>	<b>(\$0.31)</b>	<b>(\$0.30)</b>	<b>(\$0.25)</b>	<b>(\$1.22)</b>
<b>EPS as reported</b>	<b>(\$0.16)</b>			<b>\$0.20</b>	<b>(\$0.71)</b>					
Weighted avg. shares (000)	51,909	52,402	52,543	52,686	52,385	52,231	53,595	53,767	54,267	53,465
Fully diluted shares (000)	61,309	61,902	62,286	63,198	62,174	62,344	64,086	63,754	64,517	63,675

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

Figure 5: Annual Income Statement

BioDelivery Sciences					
Annual income statement					
(\$000 except per share)	2015A	2016E	2017E	2018E	Comments
<b>Revenues</b>					
ENDP Milestones (not in rev)	40,000	-	-	-	Not in top line revenue
Bunavail sales	4,157	8,369	9,727	11,560	Launched 11/3/14
Belbuca royalty		1,050	11,325	51,300	2/22/16 luanch by ENDP
Royalty revenue - Onsolis	1,380	2,297	800	800	
Contract revenue	1,759	-	-	-	
Research fees	909	497	-	-	
<b>Total Rev ex-milestones</b>	<b>\$8,205</b>	<b>\$12,213</b>	<b>\$21,852</b>	<b>\$63,660</b>	
<b>Expenses:</b>					
Cost of Revenue (COGS)	8,101	8,478	6,459	5,387	
<b>Gross Margin</b>	<b>389</b>	<b>3,735</b>	<b>15,393</b>	<b>58,273</b>	
Research and development	20,624	18,537	14,250	15,750	
General and administrative	54,685	47,105	26,688	24,250	Re-aligning costs with revenues
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	65,642	40,938	40,000	
<b>Income (loss) from Operations</b>	<b>(74,920)</b>	<b>(61,907)</b>	<b>(25,545)</b>	<b>18,273</b>	
Interest income (expense), net	(2,518)	(3,228)	(2,000)	(1,000)	
Other expenses, net	-	42	100	100	
<b>Income (loss) before taxes</b>	<b>(77,413)</b>	<b>(65,093)</b>	<b>(27,445)</b>	<b>17,373</b>	
Income tax exp (benefit)	-	-	-	2,190	Sig. tax loss carryforwards
<b>Adj NI ex 1x milestones</b>	<b>(\$77,413)</b>	<b>(\$65,093)</b>	<b>(\$27,445)</b>	<b>\$15,183</b>	
Adjustments to Income for Dilutive	\$0	\$0	\$0	\$0	
1x items & non-cash exp	40,000	0	0	0	
<b>Net income as reported</b>	<b>(\$37,413)</b>				
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$1.48)</b>	<b>(\$1.22)</b>	<b>(\$0.45)</b>	<b>\$0.20</b>	
<b>EPS as reported</b>	<b>(\$0.71)</b>				
Weighted avg. shares (000)	52,385	53,465	61,455	67,767	
Fully diluted shares (000)	62,174	63,675	71,455	77,767	
Cash balance	\$83,560	\$13,445	\$41,257	\$85,446	Assume 2017 fund raise

Source: Bloomberg LP; Company reports; Laidlaw & 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.

**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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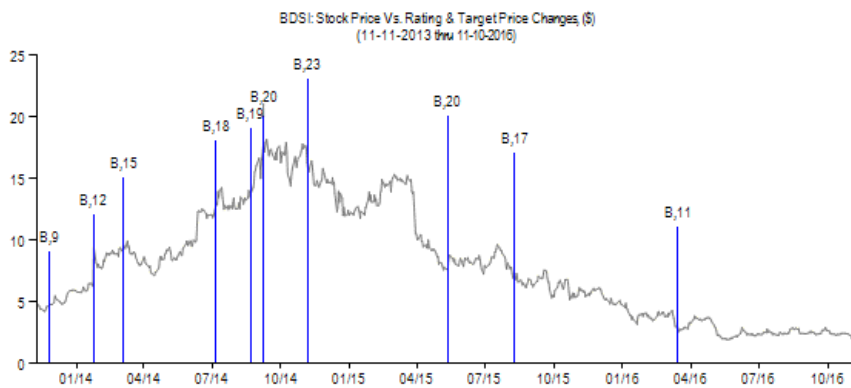
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#### 3 Year Rating Change History

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

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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