

## BioDelivery Sciences (BDSI - \$1.88)

### Clonidine We Hardly Knew Ye – Lowering PT to \$8 from \$9

This morning before the open, BDSI announced that the Phase 2b trial for Clonidine topical gel for painful diabetic neuropathy failed to hit statistical significance and that BDSI will be shuttering the program. It's never a good thing to shutter your most advanced clinical program, but we had only modeled in \$1/share of value for this compound. By shuttering it the company expects to save ~\$16M in R&D expenses that would have been spent in 2017 to continue development, which extends the cash runway for the company into 4Q17. We continue to see BDSI as an attractive acquisition target with both Belbuca & Bunavail wholly owned in-house by BDSI; and we have to believe that management is seriously considering strategic alternatives for the business as the best way to return value to shareholders. Given the disastrous record of the Bunavail self-launch, and the lack of confidence that this sales group would be meaningfully better at launching & growing Belbuca, we believe it is past time to recognize reality and find a bidder for these assets. We are maintaining our Buy rating but lowering the price target to \$8/share (from \$9/share previously).

- **BDSI now a more attractive acquisition target.** With Belbuca possibly replacing Butrans as the preferred brand and Butrans potentially being excluded (UnitedHealth formulary), BDSI should be able to get significant partnering or M&A interest, in our opinion.
- **Clonidine faced a challenging environment.** We were always muted on our expectations for Clonidine gel, given the inherent challenges of a topical neuropathic product, so we are not overly disheartened by its discontinuation.
- **Still working on a depot buprenorphine injection.** BDSI still contemplates filing an IND for their long-acting subcutaneous buprenorphine injection, which could enter and finish Phase 1 trials as early as 1H17-mid-17.
- **Maintain Buy rating, lowering price target to \$8 from \$9.** Our price target is based on a sum-of-the-parts with Belbuca at \$6/share, cash (end '17E) & tech value at \$3/share, and Bunavail at \$0/share.

*Healthcare/Biotechnology*

Ticker:	<b>BDSI</b>
Rating:	<b>Buy</b>
Price Target:	↓ <b>\$8.00</b>

#### Trading Data:

Last Price (12/13/2016)	\$1.88
52-Week High (12/17/2015)	\$5.48
52-Week Low (11/23/2016)	\$1.50
Market Cap. (MM)	\$101.5
Shares Out. (MM)	54.1

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	(0.22)	(0.15)	(0.13)	(0.12)	(0.60)	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

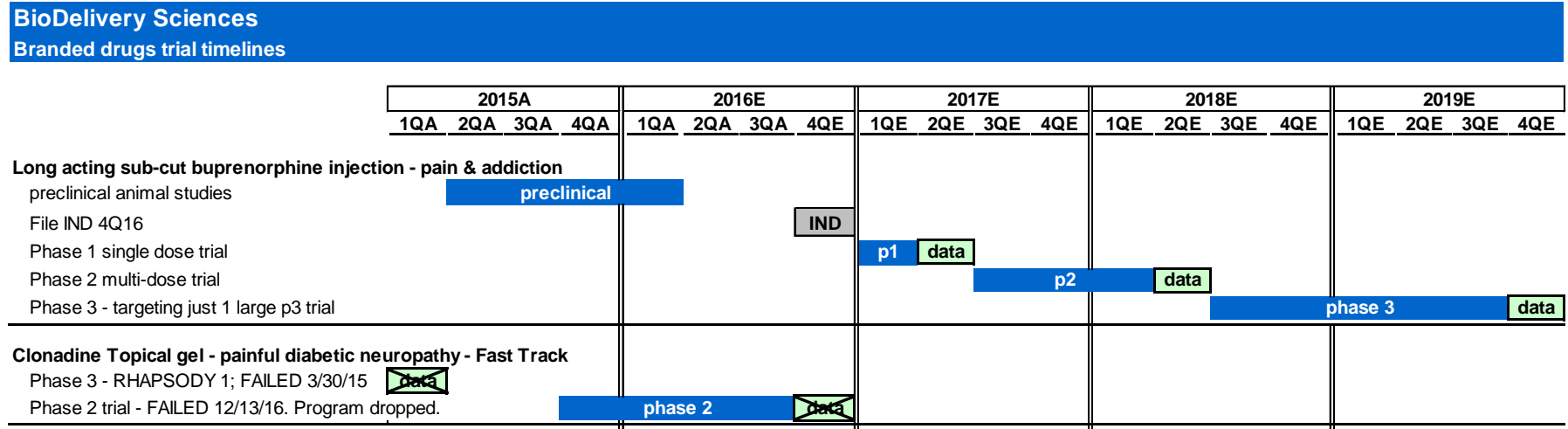
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Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca sales	\$380,828	\$6.0
Net cash (end '17) & tech	\$107,586	\$2.0
<b>SUM</b>	<b>\$511,025</b>	<b>\$8</b>
Shares out '17E (000)		63,675

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company Reports; Laidlaw & Company estimates

Figure 3: 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			\$6,221		
Bunavail sales	677	\$800	\$1,135	1,500	\$4,157	\$2,102	\$2,110	\$2,009	\$2,148	\$8,369
Belbuca sales (starting 1Q17)						0	0	300	877	1,177
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>\$3,225</b>	<b>\$12,340</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>1,546</b>	<b>3,862</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	9,813	47,418
Total operating expenses	19,730	17,793	19,188	18,598	75,309	18,432	16,504	16,456	14,563	65,955
<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>(13,017)</b>	<b>(62,093)</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>(13,742)</b>	<b>(65,279)</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>(13,742)</b>	<b>(65,279)</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 4: Annual Income Statement

<b>BioDelivery Sciences</b>					
<b>Annual income statement</b>					
(\$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 sales (starting 1Q17)		1,177	25,582	42,951	Returned 12/7/16 to BDSI
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>\$12,340</b>	<b>\$36,109</b>	<b>\$55,311</b>	
<b>Expenses:</b>					
Cost of Revenue (COGS)	8,101	8,478	6,235	5,156	
<b>Gross Margin</b>	<b>389</b>	<b>3,862</b>	<b>29,873</b>	<b>50,155</b>	
Research and development	20,624	18,537	16,000	16,000	
General and administrative	54,685	47,418	49,000	43,500	Re-aligning costs with revenues
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	65,955	65,000	59,500	
<b>Income (loss) from Operations</b>	<b>(74,920)</b>	<b>(62,093)</b>	<b>(35,127)</b>	<b>(9,345)</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>(65,279)</b>	<b>(37,027)</b>	<b>(10,245)</b>	
Income tax exp (benefit)	-	-	-	-	Sig. tax loss carryforwards
<b>Adj NI ex 1x milestones</b>	<b>(\$77,413)</b>	<b>(\$65,279)</b>	<b>(\$37,027)</b>	<b>(\$10,245)</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>(\$0.60)</b>	<b>(\$0.15)</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	\$39,356	\$57,586	\$76,347	Assume 2017 fund raise
<b>Margin &amp; Expense Analysis</b>					
COGS as % of Revenues	99%	69%	17%	9%	
R&D	251%	150%	44%	29%	
SG&A	666%	384%	136%	79%	
Gross Profit	1%	31%	83%	91%	
Op. margin cont. ops	-913%	-503%	-97%	-17%	
Taxes	0%	0%	0%	0%	
Net margin	-943%	-529%	-103%	-19%	
<b>Year-over-year change</b>					
Net revenue	-57%	50%	193%	53%	
R&D	60%	90%	86%	100%	
SG&A	42%	-13%	3%	-11%	
Operating income	28%	-17%	-43%	-73%	

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

## DISCLOSURES:

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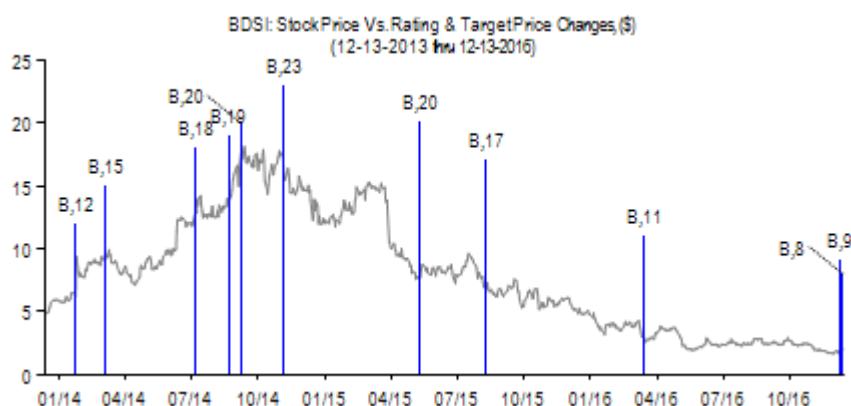
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*Additional information available upon request.*

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#### Rating and Price Target Change History



Source: Laidlaw & Company

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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
01/24/2014	Buy (B)	9.41

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
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
12/09/2016	9.00	1.85
12/13/2016	8.00	2.00*

\* Previous Close 12/12/2016

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%

### ADDITIONAL COMPANIES MENTIONED

UnitedHealth Group Inc. (UNH – Not Rated)

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