

## BioDelivery Sciences (BDSI - \$2.18)

### “Other than *that*, Mrs. Lincoln...” Strategic Options Should Be On the Table for BDSI

BDSI reported 1Q16 with a top line beat as Bunavail sales beat our significantly lowered estimates. The EPS miss was driven by higher than expected COGS as other operating expenses were in-line with our estimates. The key highlight from the call was BDSI’s strategic consolidation of their sales force, which we have been expecting (and modeled in) since their 4Q15 conference call back in March as the company needs to align expenses with revenues more equitably. Additionally we believe management needs to examine much more closely strategic options for BDSI as a whole to try to return value to shareholders. Although the newly realigned sales force under new head of sales Scott Plesha has just been completed; this product has been on-market for over a year now and clearly current management hasn’t been able to get sufficient traction with the launch. BDSI expects to save ~\$20M through 2017 with 95% of their top Bunavail writers still being covered. We still believe Belbuca (launched February 22<sup>nd</sup> by partner ENDP) remains the reason to own BDSI because of the dearth of options for less addictive Schedule 3 opioids ever since Vicodin-like opioids were moved to Schedule 2 in late 2014. ENDP doubled their sales force for Belbuca’s launch and we continue to believe Belbuca sales could reach \$350M in 2018, generating over \$60M in royalties to BDSI. We maintain our Buy rating and our \$11 price target.

- **Strategic consolidation of Bunavail sales force.** With \$13M in 1Q16 SG&A spend to generate \$2.1M in sales we believe that realignment may not be enough for this group. We believe a more efficient way to achieve returns to shareholders could involve selling the asset outright, or even the entire company before Bunavail costs over \$45M to generate \$10M in 2016 sales.
- **Belbuca still reason to own BDSI.** With ENDP’s pain-focused sales force having doubled, and the 26M “missing” Rx’s since Vicodin-like opioids went to schedule II, we still believe there is a ~\$4.5B sales opportunity for an oral Schedule III opioid like Belbuca (at ~\$250/Rx). We maintain our estimated ~\$400M in Belbuca sales by 2019.
- **Maintain Buy rating \$11 price target.** 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
<b>FY-17E</b>	(0.14)	(0.09)	(0.05)	0.00	(0.28)	NM
<b>FY-16E</b>	(0.36)A	(0.31)	(0.24)	(0.18)	(1.08)	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

Source: Company data and Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>BDSI</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$11.00</b>

#### Trading Data:

Last Price (05/10/2016)	\$2.18
52-Week High (07/17/2015)	\$9.91
52-Week Low (05/09/2016)	\$1.91
Market Cap. (MM)	\$116.6
Shares Out. (MM)	53.47

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- Top line beats thanks to Bunavail.** Bunavail sales of \$2.459M beat our estimates by \$0.593M leading to a top line beat of \$3.040M vs. our estimated \$2.459M. BDSI noted that in 1Q16, more than 3,000 physicians prescribed Bunavail with 350 new prescribers in the quarter. Although operating expenses were in line with expectations, bottom line (\$0.36) missed our expected (\$0.32) mainly due to higher than expected cost of goods sold. That said BDSI needs to generate much more meaningful sales for Bunavail to justify continuing to carry this asset, or at least start to show a realistic path towards profitability for Bunavail. At current SG&A spend-sales levels, our \$0 valuation for Bunavail in our sum-of-the-parts might even be too high still. We estimate that BDSI is on track to spend \$45.6M in SG&A in 2016 to generate \$10M in sales, which we believe is an inefficient use of shareholder capital.

Figure 1: Variance analysis

BioDelivery Sciences Variance analysis					
(000's except per share)	1Q15A	1Q16A	1Q16E	Variance	% Y/Y
Bunavail sales		\$2,102	\$1,509	\$593	NA
Royalty revenue	\$194	938	200	738	384%
Contract rev / milestones	1,408	0	0	0	-100%
Research fees	775	0	0	0	-100%
<b>Total Revenue</b>	<b>\$3,054</b>	<b>\$3,040</b>	<b>\$2,459</b>	<b>\$581</b>	<b>0%</b>
COGS	1,124	2,550	1,053	1,497	127%
<b>Gross Profit</b>	<b>1,930</b>	<b>490</b>	<b>1,407</b>	<b>(916)</b>	<b>-75%</b>
SG&A Expense	13,181	13,055	13,250	(195)	-1%
R&D Expense	6,549	5,377	5,500	(123)	-18%
<b>Operating Income</b>	<b>(17,800)</b>	<b>(17,942)</b>	<b>(17,343)</b>	<b>(598)</b>	<b>1%</b>
Int. inc. (expense), net	(420)	(778)	0	(778)	85%
Other (exp) gain, net	27	(13)	25	(38)	-148%
<b>Pretax Income</b>	<b>(18,193)</b>	<b>(18,733)</b>	<b>(17,318)</b>	<b>(1,414)</b>	<b>3%</b>
Income Tax exp (benefit)	0	0	0	0	NA
<b>Net income (loss)</b>	<b>(18,193)</b>	<b>(18,733)</b>	<b>(17,318)</b>	<b>(1,414)</b>	<b>3%</b>
1x items & non-cash exp	10,000	0	0	0	-100%
<b>Adj NI ex-1x/non cash</b>	<b>(8,193)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-100%</b>
Weighted avg. shares (000)	51,909	52,231	53,436	(1,206)	1%
Fully diluted shares (000)	61,309	61,981	63,186	(1,206)	1%
<b>Earning per Share (EPS)</b>	<b>(\$0.35)</b>	<b>(\$0.36)</b>	<b>(\$0.32)</b>	<b>(\$0.03)</b>	<b>2%</b>
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$0.16)</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>-100%</b>

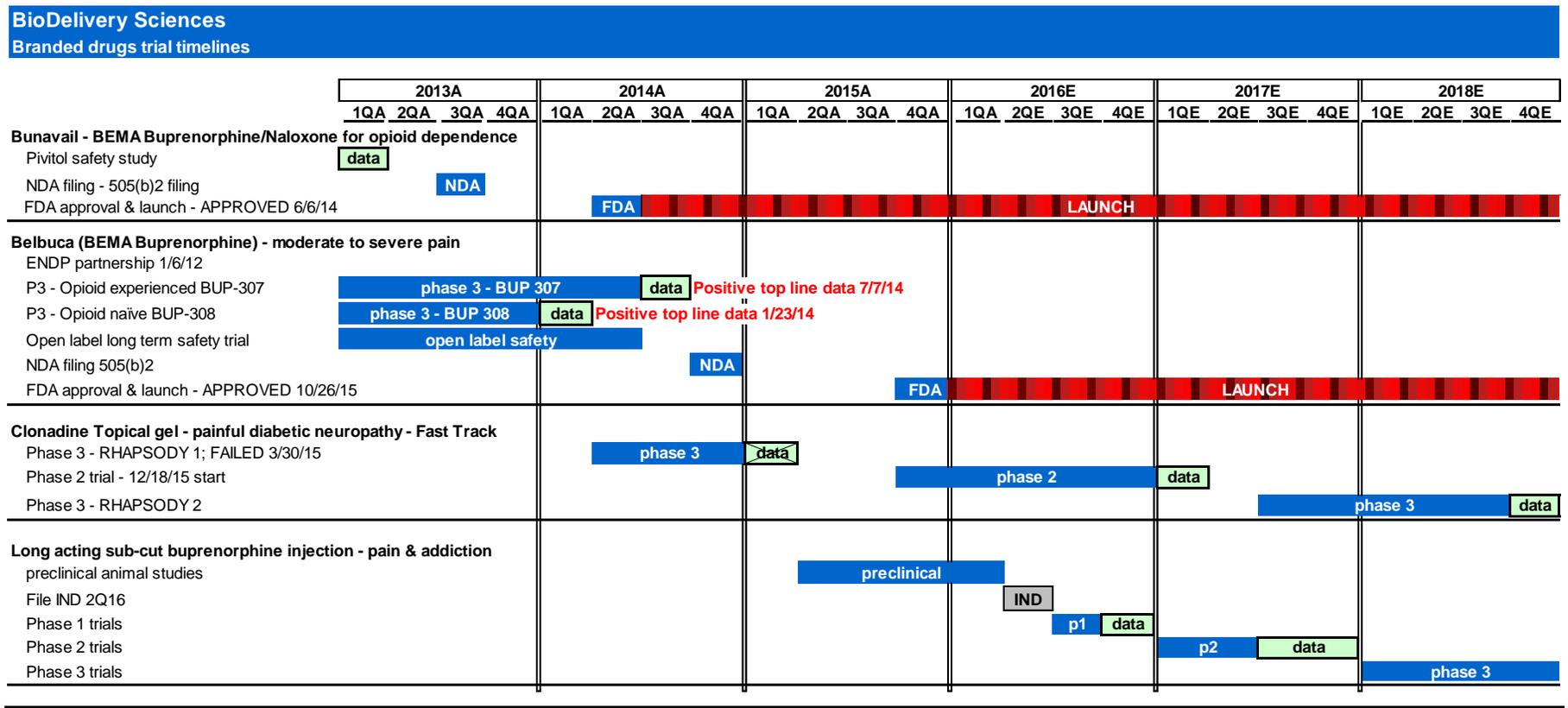
Source: Laidlaw &amp; Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca royalty	\$608,164	\$9.5
Net cash (end '16) & tech	\$73,228	\$1.5
<b>SUM</b>	<b>\$739,823</b>	<b>\$11</b>
Shares out '16E (000)		65,249

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	2QE	3QE	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	\$2,138	\$2,574	\$3,065	\$9,879
Royalty revenue - Onsolis	194	495	100	617	1,406	938	200	200	200	1,538
Contract rev	1,408	0	0	351	1,759	0	0	0	0	0
Research fees	775	450			909					0
<b>Total Rev ex-milestones</b>	<b>\$3,054</b>	<b>\$1,745</b>	<b>\$1,235</b>	<b>\$2,468</b>	<b>\$8,231</b>	<b>\$3,040</b>	<b>\$3,538</b>	<b>\$4,574</b>	<b>\$5,515</b>	<b>\$16,667</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	1,124	2,621	1,699	2,657	8,101	2,550	1,241	1,115	1,060	5,966
<b>Gross Margin</b>	<b>1,930</b>	<b>(876)</b>	<b>(464)</b>	<b>(189)</b>	<b>401</b>	<b>490</b>	<b>2,297</b>	<b>3,459</b>	<b>4,455</b>	<b>10,701</b>
Research and development	6,549	4,506	4,473	5,096	20,624	5,377	5,500	6,000	6,000	22,877
General and administrative	13,181	13,287	14,715	13,502	54,685	13,055	13,250	10,500	8,750	45,555
Related party G&A					-					-
Total operating expenses	19,730	17,793	19,188	18,598	75,309	18,432	18,750	16,500	14,750	68,432
<b>Income (loss) from Operations</b>	<b>(17,800)</b>	<b>(18,669)</b>	<b>(19,652)</b>	<b>(18,787)</b>	<b>(74,908)</b>	<b>(17,942)</b>	<b>(16,453)</b>	<b>(13,041)</b>	<b>(10,295)</b>	<b>(57,731)</b>
Interest income (expense), net	(420)	(527)	(785)	(786)	(2,518)	(778)				(778)
Other (exp) gain, net	27	(3)	(2)	(22)	-	(13)	25	25	25	62
<b>Income (loss) before taxes</b>	<b>(18,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,401)</b>	<b>(18,733)</b>	<b>(16,428)</b>	<b>(13,016)</b>	<b>(10,270)</b>	<b>(58,447)</b>
Income tax exp (benefit)										
<b>Adj NI ex 1x milestones</b>	<b>(18,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,401)</b>	<b>(18,733)</b>	<b>(16,428)</b>	<b>(13,016)</b>	<b>(10,270)</b>	<b>(58,447)</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>(\$0.24)</b>	<b>(\$0.18)</b>	<b>(\$1.08)</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	52,981	54,981	56,981	54,293
Fully diluted shares (000)	61,309	61,902	62,286	63,198	62,174	61,981	62,731	64,731	66,731	64,043

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

Figure 5: Annual Income Statement

BioDelivery Sciences						
Annual income statement						
(\$000 except per share)	2014A	2015A	2016E	2017E	2018E	Comments
<b>Revenues</b>						
ENDP Milestones (not in rev)	20,000	40,000	-	-	-	Not in top line revenue
Bunavail sales	76	4,157	9,879	11,461	12,985	Launched 11/3/14
Belbuca royalty			5,250	24,000	63,000	2/22/16 launch by ENDP
Royalty revenue - Onsolis	3,407	1,406	1,538	800	800	
Contract revenue	2,749	1,759	-	-	-	
Research fees	12,712	909	-	-	-	
<b>Total Rev ex-milestones</b>	<b>\$18,944</b>	<b>\$8,231</b>	<b>\$16,667</b>	<b>\$36,261</b>	<b>\$76,785</b>	
<b>Expenses:</b>						
Cost of Revenue (COGS)	4,939	8,101	5,966	3,661	4,428	
<b>Gross Margin</b>	<b>14,005</b>	<b>401</b>	<b>10,701</b>	<b>32,600</b>	<b>72,357</b>	
Research and development	34,285	20,624	22,877	24,000	23,000	
General and administrative	38,460	54,685	45,555	24,938	24,750	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	75,309	68,432	48,938	47,750	
<b>Income (loss) from Operations</b>	<b>(58,740)</b>	<b>(74,908)</b>	<b>(57,731)</b>	<b>(16,338)</b>	<b>24,607</b>	
Interest income (expense), net	(2,016)	(2,518)	(778)	-	-	
Other expenses, net	(295)	-	62	100	100	
<b>Income (loss) before taxes</b>	<b>(61,051)</b>	<b>(77,401)</b>	<b>(58,447)</b>	<b>(16,238)</b>	<b>24,707</b>	
Income tax exp (benefit)	-	-	-	-	3,227	Sig. tax loss carryforwards
<b>Adj NI ex 1x milestones</b>	<b>(\$61,048)</b>	<b>(\$77,401)</b>	<b>(\$58,447)</b>	<b>(\$16,238)</b>	<b>\$21,480</b>	
<b>Net income as reported</b>	<b>(\$54,222)</b>	<b>(\$37,401)</b>				
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$1.26)</b>	<b>(\$1.48)</b>	<b>(\$1.08)</b>	<b>(\$0.28)</b>	<b>\$0.30</b>	
<b>EPS as reported</b>	<b>(\$1.12)</b>	<b>(\$0.71)</b>				
Weighted avg. shares (000)	48,355	52,385	54,293	58,856	61,981	
Fully diluted shares (000)	56,540	62,174	64,043	68,856	71,981	
<b>Margin &amp; Expense Analysis</b>						
COGS as % of Revenues	26%	98%	36%	10%	6%	
R&D	181%	251%	137%	66%	30%	
SG&A	203%	664%	273%	69%	32%	
Gross Profit	74%	2%	64%	90%	94%	
Op. margin cont. ops	-310%	-910%	-346%	-45%	32%	
Taxes	0%	0%	0%	0%	13%	
Net margin	-322%	-940%	-351%	-45%	28%	
<b>Year-over-year change</b>						
Net revenue	67%	-57%	102%	118%	112%	
R&D	64%	60%	111%	105%	96%	
SG&A	213%	42%	-17%	-45%	-1%	
Operating income	4%	28%	-23%	-72%	-251%	

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.

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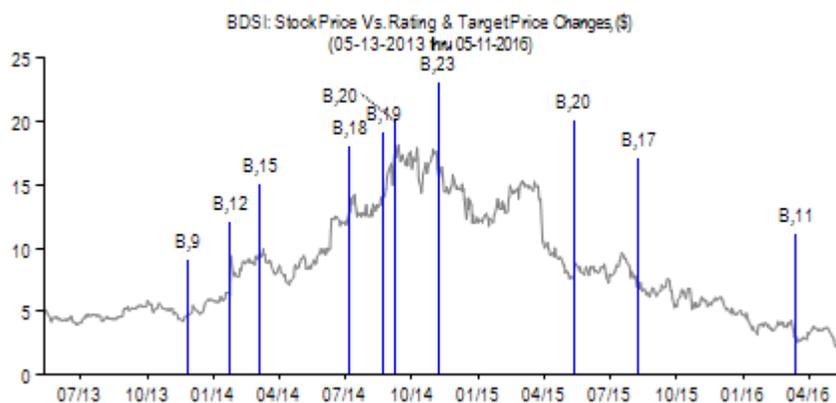
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*Additional information available upon request.*

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#### Rating and Price Target Change History



Source: Laidlaw & Company

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

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.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	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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