

## BioDelivery Sciences (BDSI - \$ 3.10)

### Bunavail gets some good news from HHS - finally

Yesterday the Department of Health & Human Services announced a proposed rule change lifting the physician cap on patients from 100 patients currently to 200 patients by year end. While this is below the 250 patient limit that we had thought might be suggested, it still potentially doubles the market opportunity for addiction medicine in general, and potentially increases by 5x-6x the opportunity for Bunavail specifically. We reach this number by looking at the 10-15 patients (out of the 100 patient limit) that are either “new starts” or patients who are not currently well controlled by their addiction medicine (Suboxone, Zubsolv, etc.) who are the prime candidates for Bunavail. With 100 potential de-novo patients joining each addiction specialist’s practice group we see a real potential for a dramatic uptick in Bunavail Rx’s. Given the current mismatch in 2015 SG&A spend (\$54.7M) and Bunavail sales levels (\$4.2M), we have removed any Bunavail value from our model and our \$11 PT. If BDSI can seize the opportunity in front of them should the cap limit get raised to 200, we could see the opportunity to potentially revisit the value Bunavail could add to company. We continue to believe that with ENDP behind the ongoing Belbuca launch sales of that product could reach \$350M in 2018, generating over \$60M in royalties to BDSI, and we maintain our Buy rating and our \$11 price target.

- **HHS comments a significant positive.** Secretary Burwell followed up yesterday on an announcement made in a speech last September about expanding the use of Medication-Assisted-Treatment (MAT) which means more buprenorphine & naloxone treatment (ie.: Bunavail, Suboxone, etc.). HHS will open public comment on the rule for 60 days, and Secretary Burwell anticipates the new 200 patient cap could be enacted by year end 2016.
- **Belbuca remains the key value driver at BDSI.** ENDP has more than doubled their pain-focused sales force for the Belbuca launch, and the 26M “missing” Rx’s since Vicodin-like opioids went to schedule II represents an ~\$4.5B sales opportunity for an oral schedule III opioid like Belbuca (at ~\$250/Rx). ENDP doesn’t need to get much to get to their guidance of over \$250M in sales by 2019. We have a more aggressive estimate of ~\$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)	(0.06)	(0.01)	(0.30)	NM
<b>FY-16E</b>	(0.32)	(0.31)	(0.24)	(0.19)	(1.05)	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 (03/29/2016)	\$3.10
52-Week High (03/31/2015)	\$10.66
52-Week Low (03/17/2016)	\$2.53
Market Cap. (MM)	\$165.8
Shares Out. (MM)	53.47

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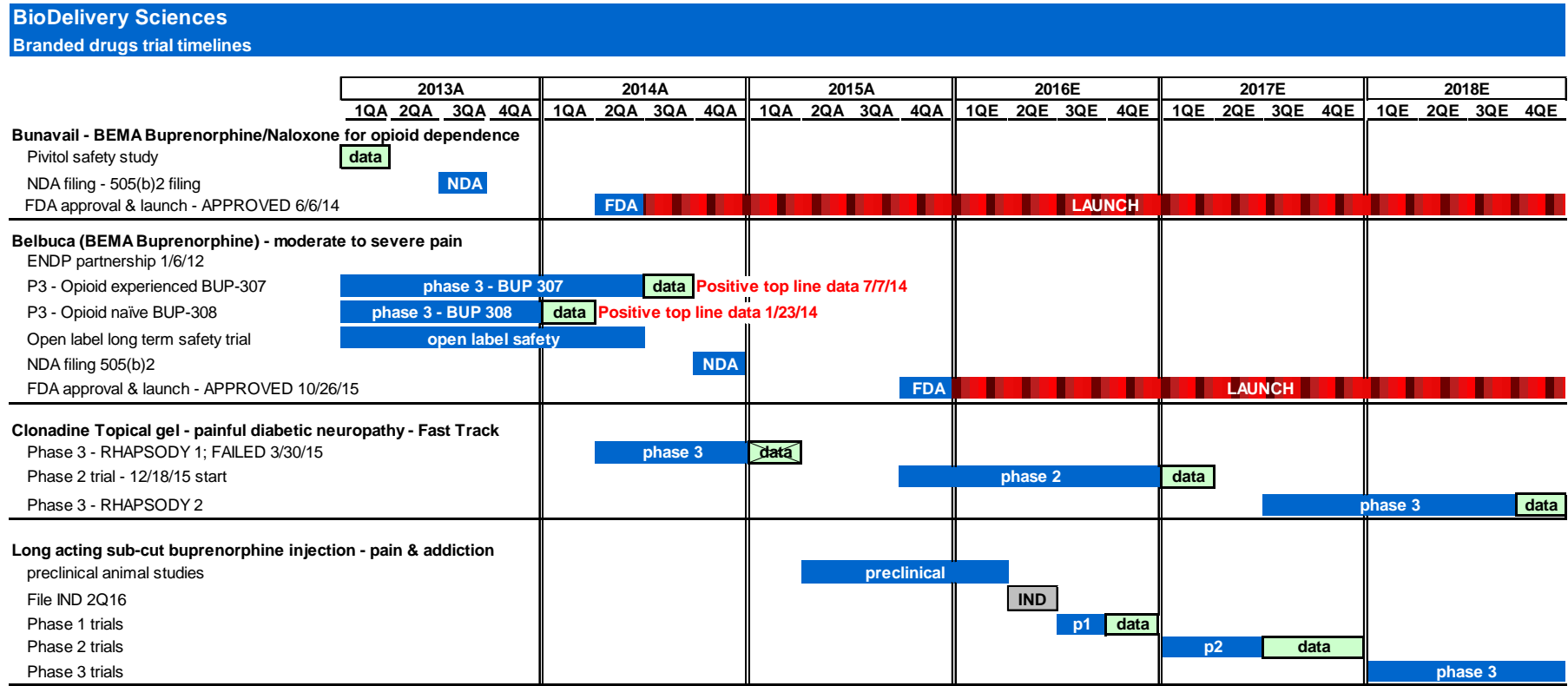
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Figure 1: Valuation

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
<b>SUM</b>	<b>\$745,233</b>	<b>\$11</b>
Shares out '16E (000)		65,249

Source: JAMA and Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports and Laidlaw estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 3: 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	
<b>Revenues</b>										
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
<b>Total Rev ex-milestones</b>	<b>\$10,690</b>	<b>\$3,885</b>	<b>\$1,822</b>	<b>\$2,547</b>	<b>\$18,944</b>	<b>\$3,054</b>	<b>\$1,745</b>	<b>\$1,235</b>	<b>\$2,468</b>	<b>\$8,231</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	2,621	1,699	2,657	8,101
<b>Gross Margin</b>	<b>9,965</b>	<b>3,198</b>	<b>1,360</b>	<b>(517)</b>	<b>14,005</b>	<b>1,930</b>	<b>(876)</b>	<b>(464)</b>	<b>(189)</b>	<b>401</b>
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
<b>Income (loss) from Operations</b>	<b>(9,286)</b>	<b>(12,041)</b>	<b>(19,059)</b>	<b>(18,351)</b>	<b>(58,740)</b>	<b>(17,800)</b>	<b>(18,669)</b>	<b>(19,652)</b>	<b>(18,787)</b>	<b>(74,908)</b>
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)	-
<b>Income (loss) before taxes</b>	<b>(9,818)</b>	<b>(12,551)</b>	<b>(19,549)</b>	<b>(19,130)</b>	<b>(61,051)</b>	<b>(18,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,401)</b>
Income tax exp (benefit)										
<b>Adj NI ex 1x milestones</b>	<b>(9,818)</b>	<b>(12,551)</b>	<b>(19,549)</b>	<b>(19,130)</b>	<b>(61,048)</b>	<b>(18,193)</b>	<b>(19,199)</b>	<b>(20,439)</b>	<b>(19,570)</b>	<b>(77,401)</b>
<b>Adj EPS ex-1x &amp; non-cash</b>	<b>(\$0.22)</b>	<b>(\$0.26)</b>	<b>(\$0.39)</b>	<b>(\$0.37)</b>	<b>(\$1.26)</b>	<b>(\$0.35)</b>	<b>(\$0.37)</b>	<b>(\$0.39)</b>	<b>(\$0.37)</b>	<b>(\$1.48)</b>
<b>EPS as reported</b>	<b>(\$0.11)</b>	<b>(\$0.14)</b>	<b>(\$0.51)</b>	<b>(\$0.34)</b>	<b>(\$1.12)</b>	<b>(\$0.16)</b>			<b>\$0.20</b>	<b>(\$0.71)</b>
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 &amp; Company estimates.

Figure 4: 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	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	-	-	-	
<b>Total Rev ex-milestones</b>	<b>\$18,944</b>	<b>\$8,231</b>	<b>\$14,579</b>	<b>\$34,050</b>	<b>\$74,280</b>	
<b>Expenses:</b>						
Cost of Revenue (COGS)	4,939	8,101	3,942	3,417	4,153	
<b>Gross Margin</b>	<b>14,005</b>	<b>401</b>	<b>10,637</b>	<b>30,632</b>	<b>70,127</b>	
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	
<b>Income (loss) from Operations</b>	<b>(58,740)</b>	<b>(74,908)</b>	<b>(58,113)</b>	<b>(18,305)</b>	<b>21,377</b>	
Interest income (expense), net	(2,016)	(2,518)	-	-	-	
Other expenses, net	(295)	-	100	100	100	
<b>Income (loss) before taxes</b>	<b>(61,051)</b>	<b>(77,401)</b>	<b>(58,013)</b>	<b>(18,205)</b>	<b>21,477</b>	
Income tax exp (benefit)	-	-	-	-	2,954	Sig. tax loss carryforwards
<b>Adj NI ex 1x milestones</b>	<b>(\$61,048)</b>	<b>(\$77,401)</b>	<b>(\$58,013)</b>	<b>(\$18,205)</b>	<b>\$18,523</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>(\$1.05)</b>	<b>(\$0.30)</b>	<b>\$0.25</b>	
<b>EPS as reported</b>	<b>(\$1.12)</b>	<b>(\$0.71)</b>				
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	
<b>Margin &amp; Expense Analysis</b>						
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%	
<b>Year-over-year change</b>						
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 &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.

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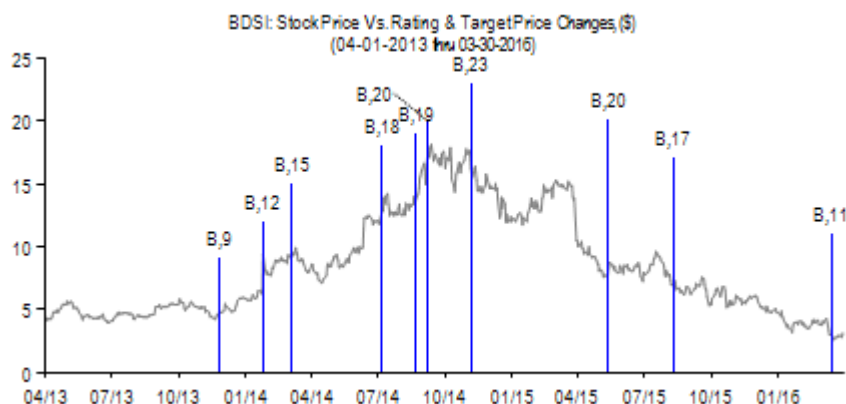
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*Additional information available upon request.*

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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.	65.71%	25.71%	2.86%
<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%

### ADDITIONAL COMPANIES MENTIONED

Endo International (ENDP – Not Rated)

### ADDITIONAL DISCLOSURES

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