

BioDelivery Sciences (BDSI - \$2.66)

Healthcare/Biotechnology

Partner ENDP's Belbucal Launch Remains the Reason to Own BDSI

BDSI recently reported 2Q16, missing the topline due to a quarter lag in recognizing Belbucal royalty stream (which we had anticipated would be \$1.2M in 2Q16). BDSI reduced Bunavail related COGS by 16%, increasing gross profit for the film strip by ~200% from last quarter. Although adjusted COGS (\$2.84M) was still more than twice our estimated \$1.24M, lower operating expenses led to bottom line roughly in-line with our estimates as BDSI follows through with their commitment to bring operating expenses in-line with Bunavail sales. Management continues to guide for Bunavail breakeven by 2H17, which will require ~2K more TRx's/week than Bunavail's current run rate, which ought to be do-able with the two recent managed care formulary wins. We currently attribute zero value on the Bunavail franchise at these levels, but getting to breakeven would be a positive first step. Belbucal (launched February 22nd by partner ENDP) continues to be the reason to own BDSI at this point. With a modest ramp priced in, we still think Belbucal sales could reach \$350M in 2018, which would generate over \$60M in royalties to BDSI. We maintain our Buy rating and our \$11 price target.

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

- **Topline miss due to Belbucal revenue recognition lag.** Topline of \$2.5M missed our \$3.54M estimate due to a lag in recognizing the Belbucal royalty stream. While Bunavail related COGS (~50% taken out due to Contract revenue) have decreased by 16% and gross profit increased by ~200%, COGS of \$2.84M were still more than twice our estimated \$1.24M. Lower SG&A (\$12.5M vs LL: \$13.25M) and R&D (\$4M vs LL: \$5.5M) are encouraging and led to bottom line (\$0.33) roughly in-line with our (\$0.31) estimate. We removed the \$2.5M contract revenue from the top line to get to ex-1x sales for 2Q16.
- **Guidance for Bunavail profitability 2H17, Belbucal still reason to own at this point.** While BDSI guided for 2H16/1H17 ramp up in sales for Bunavail with profitability expected 2H17 based on additional managed care wins, higher patient cap and lower expenses; we still believe Belbucal represents a \$360M sales opportunity (to ENDP) and ~\$65M in royalties to BDSI by 2020.

- **Maintain Buy rating \$11 price target.** We value Belbucal at \$8/share, **Earnings Estimates:** (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.11)	(0.09)	(0.04)	0.00	(0.25)	NM
FY-16E	(0.36)A	(0.33)A	(0.23)	(0.19)	(1.10)	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

Trading Data:

Last Price (08/11/2016)	\$2.66
52-Week High (09/25/2015)	\$7.79
52-Week Low (05/23/2016)	\$1.86
Market Cap. (MM)	\$142.7
Shares Out. (MM)	53.6

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Source: Company data and Laidlaw & Company estimates

Bunavail at \$0/share, and cash (end' 17) and tech value of \$3/share.

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Figure 1: Variance analysis

BioDelivery Sciences					
Variance analysis					
(000's except per share)	2Q15A	2Q16A	2Q16E	Variance	% Y/Y
Bunavail sales		\$2,110	\$2,138	(\$28)	NA
Belbuca royalty		0	1,200	(\$1,200)	NA
Royalty revenue	\$469	394	200	194	-16%
Research fees	431	0	0	0	-100%
Total Revenue	\$1,733	\$2,504	\$3,538	(\$1,034)	44%
COGS	2,621	2,844	1,241	1,603	9%
Gross Profit	(888)	(340)	2,297	(2,637)	-62%
SG&A Expense	13,287	12,496	13,250	(754)	-6%
R&D Expense	4,506	4,008	5,500	(1,492)	-11%
Operating Income	(18,681)	(16,844)	(16,453)	(391)	-10%
Int. inc. (expense), net	(527)	(914)	0	(914)	73%
Other (exp) gain, net	(3)	22	25	(3)	-833%
Pretax Income	(19,211)	(17,736)	(16,428)	(1,308)	-8%
Income Tax exp (benefit)	0	0	0	0	NA
Net income (loss)	(19,211)	(17,736)	(16,428)	(1,308)	-8%
1x items & non-cash exp	0	1,250	0	1,250	NA
Adj NI ex-1x/non cash	0	(16,486)	0	(16,486)	NA
Weighted avg. shares (000)	52,402	53,595	52,981	614	2%
Fully diluted shares (000)	61,902	64,086	62,731	1,355	4%
Earning per Share (EPS)	(\$0.37)	(\$0.33)	(\$0.31)	(\$0.02)	-10%
Adj EPS ex-1x & non-cash	\$0.00	(\$0.31)		(\$0.31)	

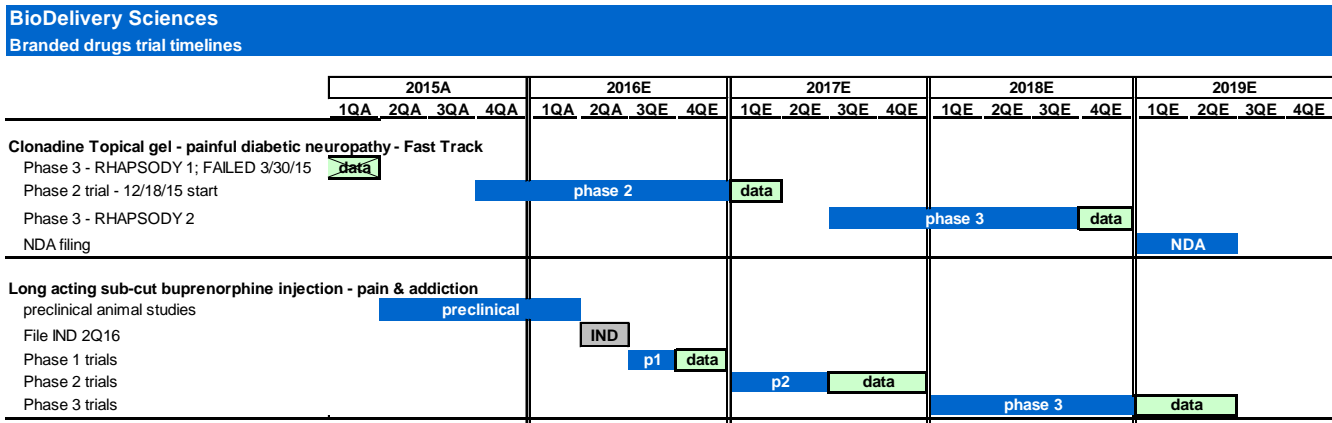
Source: Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca royalty	\$609,622	\$8.0
Net cash (end '17) & tech	\$119,727	\$3.0
SUM	\$830,781	\$11
Shares out '17E (000)		64,405

Source: JAMA and Laidlaw & 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	3QE	4QE	
Revenues										
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	\$2,142	\$2,569	\$8,923
Royalty revenue - Onsolis	194	469	100	617	1,380	938	394	200	200	1,732
Contract rev	1,408	0	0	351	1,759	0		0	0	0
Research fees	775	431			909					0
Total Rev ex-milestones	\$3,054	\$1,733	\$1,235	\$2,468	\$8,205	\$3,040	\$2,504	\$3,467	\$4,119	\$13,130
Expenses:										
Cost of Revenue (COGS)	1,124	2,621	1,699	2,657	8,101	2,550	2,844	1,028	985	7,408
Gross Margin	1,930	(888)	(464)	(189)	389	490	(340)	2,439	3,134	5,723
Research and development	6,549	4,506	4,473	5,096	20,624	5,377	4,008	4,500	4,750	18,635
General and administrative	13,181	13,287	14,715	13,502	54,685	13,055	12,496	9,500	8,250	43,301
Related party G&A					-					-
Total operating expenses	19,730	17,793	19,188	18,598	75,309	18,432	16,504	14,000	13,000	61,936
Income (loss) from Operations	(17,800)	(18,681)	(19,652)	(18,787)	(74,920)	(17,942)	(16,844)	(11,561)	(9,866)	(56,213)
Interest income (expense), net	(420)	(527)	(785)	(786)	(2,518)	(778)	(914)	(750)	(750)	(3,192)
Other (exp) gain, net	27	(3)	(2)	(22)	-	(13)	22	25	25	59
Income (loss) before taxes	(18,193)	(19,211)	(20,439)	(19,570)	(77,413)	(18,733)	(17,736)	(12,286)	(10,591)	(59,346)
Income tax exp (benefit)										
Adj NI ex 1x milestones	(18,193)	(19,211)	(20,439)	(19,570)	(77,413)	(18,733)	(17,736)	(12,286)	(10,591)	(59,346)
Adj EPS ex-1x & non-cash	(\$0.35)	(\$0.37)	(\$0.39)	(\$0.37)	(\$1.48)	(\$0.36)	(\$0.33)	(\$0.23)	(\$0.19)	(\$1.10)
EPS as reported	(\$0.16)			\$0.20	(\$0.71)		(\$0.31)			(\$1.07)
Weighted avg. shares (000)	51,909	52,402	52,543	52,686	52,385	52,231	53,595	54,095	56,595	54,129
Fully diluted shares (000)	61,309	61,902	62,286	63,198	62,174	62,344	64,086	64,345	66,845	64,405

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

Figure 5: Annual Income Statement

BioDelivery Sciences					
Annual income statement					
(\$'000 except per share)	2015A	2016E	2017E	2018E	Comments
Revenues					
ENDP Milestones (not in rev)	40,000	-	-	-	Not in top line revenue
Bunavail sales	4,157	8,923	10,142	11,491	Launched 11/3/14
Belbuca royalty		2,475	16,500	51,300	2/22/16 luanch by ENDP
Royalty revenue - Onsolis	1,380	1,732	800	800	
Contract revenue	1,759	-	-	-	
Research fees	909	-	-	-	
Total Rev ex-milestones	\$8,205	\$13,130	\$27,442	\$63,591	
Expenses:					
Cost of Revenue (COGS)	8,101	7,408	3,516	4,264	
Gross Margin	389	5,723	23,926	59,327	
Research and development	20,624	18,635	15,750	14,250	
General and administrative	54,685	43,301	20,938	23,500	60 Bunavail reps
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	61,936	36,688	37,750	
Income (loss) from Operations	(74,920)	(56,213)	(12,761)	21,577	
Interest income (expense), net	(2,518)	(3,192)	(2,000)	(1,000)	
Other expenses, net	-	59	100	100	
Income (loss) before taxes	(77,413)	(59,346)	(14,661)	20,677	
Income tax exp (benefit)	-	-	-	2,516	Sig. tax loss carryforwards
Adj NI ex 1x milestones	(\$77,413)	(\$59,346)	(\$14,661)	\$18,160	
Net income as reported	(\$37,413)				
Adj EPS ex-1x & non-cash	(\$1.48)	(\$1.10)	(\$0.25)	\$0.25	
EPS as reported	(\$0.71)	(\$1.07)			
Weighted avg. shares (000)	52,385	54,129	58,470	61,595	
Fully diluted shares (000)	62,174	64,405	68,470	71,595	
Margin & Expense Analysis					
COGS as % of Revenues	99%	56%	13%	7%	
R&D	251%	142%	57%	22%	
SG&A	666%	330%	76%	37%	
Gross Profit	1%	44%	87%	93%	
Op. margin cont. ops	-913%	-428%	-47%	34%	
Taxes	0%	0%	0%	12%	
Net margin	-943%	-452%	-53%	29%	
Year-over-year change					
Net revenue	-57%	60%	109%	132%	
R&D	60%	90%	85%	90%	
SG&A	42%	-21%	-52%	12%	
Operating income	28%	-25%	-77%	-269%	

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.

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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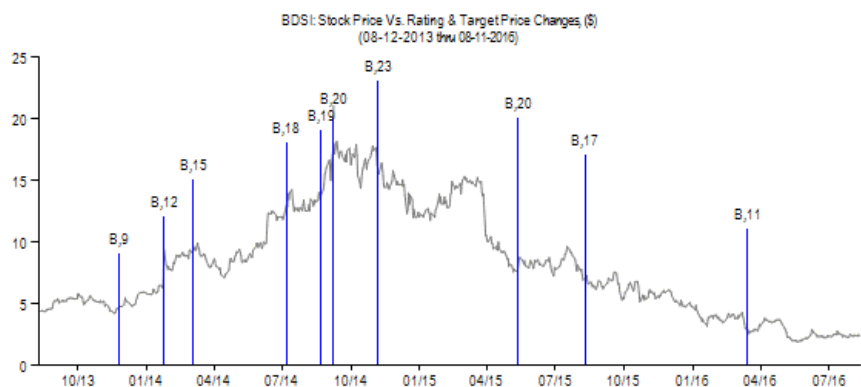
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RATINGS INFORMATION

Rating and Price Target Change History



Source: Laidlaw & Company

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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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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Endo International (ENDP – Not Rated)

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