

BioDelivery Sciences (BDSI - \$2.88)

2H16 Catalysts Could Drive Significant Shareholder Value

We recently spent time with BDSI management and we continue to believe that 2H16 and early 2017 should be a dynamic period for BDSI as multiple catalysts could be coming that could positively impact shareholder value. The launch of Bunavail and Belbuca have been below expectations to date (Bunavail very much so) and the stock has gone from the high-teens in 2015 to under \$3 currently, but with that already priced in, investors note that any improvement ought to quickly get reflected in the stock. With two managed care (MCO) wins already in 2016, BDSI expects they could announce an additional 1-3 MCO wins in 2H16 as they are in discussions with 3-5 currently. BDSI has a concrete plan to get Bunavail to the 4200 Rx's/week profitability threshold in 2017. Additional MCO wins and the impact of the patient limit being lifted to 275/doc (from 100/doc prior) should help reach that goal. Raising the patient limit to 275/doc alone adds ~500K Rx's/year to the market. Endo continues to be supportive of Belbuca and they highlighted Belbuca prominently on their recent 2Q16 conference call as a key driver of future growth. BDSI just has to collect their high teen (15%-18%) royalty rate from ENDP. We still think Belbuca could reach \$350M by 2018, generating over \$60M in royalties to BDSI. We maintain our Buy rating and our \$11 price target.

- **TennCare Medicaid win should translate 2H16-2017 too.** Tennessee has been very vocal about the ~60% drop in Rx's when they mandated Bunavail replace Suboxone, saving the state Medicaid ~\$14M already in 1H16. TennCare presented a poster at the International Opioid Conference, and BDSI is preparing a manuscript for publication that ought to help additional state Medicaid programs to follow TennCare's lead.
- **Raising physician limit to 275 equals ~500K Rx's annually.** In August the patient limit was almost tripled, and RN's & PA's are now allowed to see/treat patients (instead of just the doc) representing ~500K new Rx's that Bunavail can compete for that they don't have to first get patients off another drug (like Suboxone). BDSI feels that they ought to be able to win at least 1/3 of these Rx's, or 165K Rx's which is 3K Rx's/wk - 140% more per week than the current run rate.
- **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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (08/19/2016)	\$2.88
52-Week High (09/25/2015)	\$7.79
52-Week Low (05/23/2016)	\$1.86
Market Cap. (MM)	\$154.5
Shares Out. (MM)	53.6

(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	(0.31)A	(0.23)	(0.19)	(1.08)	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

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Source: Company data and Laidlaw & Company estimates

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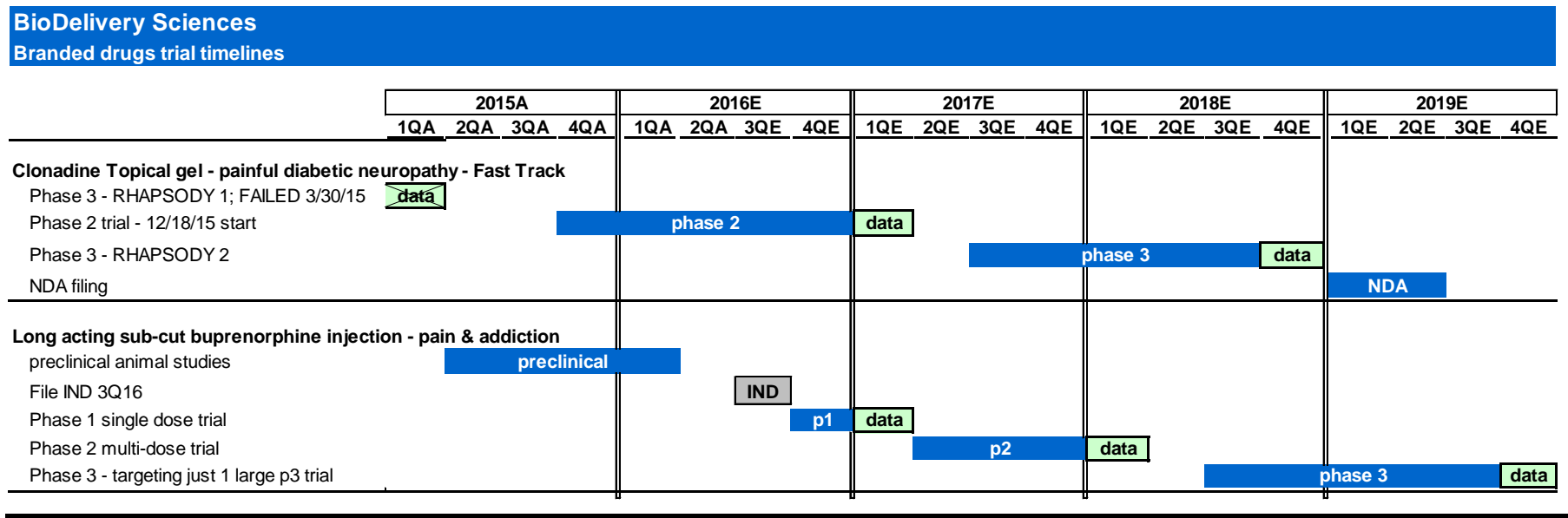
- **Significant Bunavail Rx growth possible 2H16/2017.** BDSI noted on their call that they won sole or co-preferred status (with Orexo's Zubsolv) on two formularies that together represent ~300K Rx's annually, or ~6K weekly. If BDSI wins only half of those Rx's they will be at the ~4300Rx/week run rate where Bunavail is profitable (up from 2200 Rx/week now). With just the managed care wins they have already announced they can get Bunavail to profitability/breakeven, and those Rx's should start being reflected in the Rx data starting late 2H16.
- **Endo remains very committed to Belbuca.** BDSI should start booking their Belbuca royalties in 3Q16, and notes that on ENDP's 2Q16 conference call ENDP remains invested in Belbuca and sees it as being a significant growth driver for them. BDSI collects a 15%-18% (we estimate) royalty on Belbuca, and if ENDP just hits their public guidance of \$250M in sales by 2019 they will have paid BDSI >\$90M in royalties, or 65% of BDSI's current market cap. We continue to see ENDP as the logical buyer of BDSI at some point.

Figure 1: 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: 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	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	\$2,299	\$8,653
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	\$3,849	\$12,860
Expenses:										
Cost of Revenue (COGS)	1,124	2,621	1,699	2,657	8,101	2,550	1,935	1,028	945	6,458
Gross Margin	1,930	(888)	(464)	(189)	389	490	569	2,439	2,904	6,402
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)	(15,935)	(11,561)	(10,096)	(55,534)
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)	(16,827)	(12,286)	(10,821)	(58,667)
Income tax exp (benefit)										
Adj NI ex 1x milestones	(18,193)	(19,211)	(20,439)	(19,570)	(77,413)	(18,733)	(16,827)	(12,286)	(10,821)	(58,667)
1x items & non-cash exp	10,000	-	-	30,000	40,000					-
Net income as reported	(8,193)			10,430	(37,413)					
Adj EPS ex-1x & non-cash	(\$0.35)	(\$0.37)	(\$0.39)	(\$0.37)	(\$1.48)	(\$0.36)	(\$0.31)	(\$0.23)	(\$0.19)	(\$1.08)
EPS as reported	(\$0.16)			\$0.20	(\$0.71)					
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 4: 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	8,653	10,396	12,400	Launched 11/3/14
Belbuca royalty		2,475	16,913	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	\$12,860	\$28,109	\$64,500	
Expenses:					
Cost of Revenue (COGS)	8,101	6,458	3,460	4,364	
Gross Margin	389	6,402	24,649	60,136	
Research and development	20,624	18,635	15,750	14,250	
General and administrative	54,685	43,301	21,438	24,500	Re-aligning costs with revenues
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	61,936	37,188	38,750	
Income (loss) from Operations	(74,920)	(55,534)	(12,539)	21,386	
Interest income (expense), net	(2,518)	(3,192)	(2,000)	(1,000)	
Other expenses, net	-	59	100	100	
Income (loss) before taxes	(77,413)	(58,667)	(14,439)	20,486	
Income tax exp (benefit)	-	-	-	2,518	Sig. tax loss carryforwards
Adj NI ex 1x milestones	(\$77,413)	(\$58,667)	(\$14,439)	\$17,968	
Adjustments to Income for Dilutive	\$0	\$0	\$0	\$0	
1x items & non-cash exp	40,000	0	0	0	
Net income as reported	(\$37,413)				
Adj EPS ex-1x & non-cash	(\$1.48)	(\$1.08)	(\$0.25)	\$0.25	
EPS as reported	(\$0.71)				
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%	50%	12%	7%	
R&D	251%	145%	56%	22%	
SG&A	666%	337%	76%	38%	
Gross Profit	1%	50%	88%	93%	
Op. margin cont. ops	-913%	-432%	-45%	33%	
Taxes	0%	0%	0%	12%	
Net margin	-943%	-456%	-51%	28%	
Year-over-year change					
Net revenue	-57%	57%	119%	129%	
R&D	60%	90%	85%	90%	
SG&A	42%	-21%	-50%	14%	
Operating income	28%	-26%	-77%	-271%	

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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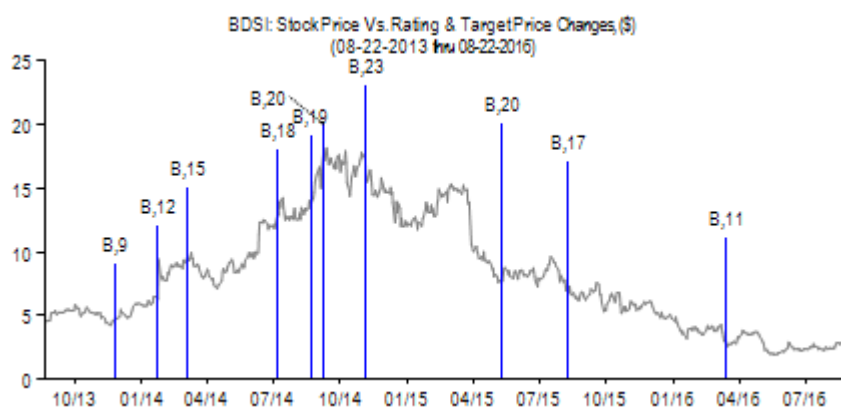
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Rating and Price Target Change History



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%
Buy (B)	Expected to outperform the sector average over 12 months.	62.16%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Endo International (ENDP – Not Rated)
Orexo (ORX – Not Rated)

ADDITIONAL DISCLOSURES

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August 22, 2016

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