

BioDelivery Sciences (BDSI - \$1.60)

Belbuca Back to BDSI, but Strategic Alternatives for the Entire Business Still the Best Option, In Our View - PT to \$9 from \$11

Yesterday before the open, BDSI announced that they had reacquired the license to Belbuca (effective on 1/6/17) from Endo Pharmaceuticals. While Belbuca should be near-term accretive to BDSI's topline as they will book all the revenues instead of a royalty, payments to ENDP and a higher operating expenses (increase of ~15% to 20% of sales reps) to maintain Belbuca's current \$27M run-rate, could limit the benefit to BDSI. Importantly, and unlike Bunavail, BDSI isn't starting from zero with Belbuca as they plan to leverage Belbuca's existing commercial footprint and bring in some of the top ENDP sales reps. BDSI will focus on the 8K-10K US pain specialists who write 90% of opioid Rx's, as opposed to primary care doctors. Picking up where ENDP left off could initially be challenging for BDSI but we see BDSI as a more attractive acquisition target with Belbuca back in-house. We continue to see strategic alternatives as the best way to monetize the Belbuca & Bunavail opportunity and return value to shareholders, given the disastrous record of the Bunavail self-launch. Additionally BDSI is expecting Phase 2 top-line data from their Clonidine Topical gel for painful diabetic neuropathy this month, which if positive, could be a catalyst for a transaction, in our opinion. We are reiterating our Buy rating but lowering the price target to \$9/share (from \$11/share previously).

- **Belbuca comes back home and becomes BDSI's key priority.** Although terms of the transaction were not disclosed, ENDP will be eliminating their 375-member U.S. Branded pain sales field force as new management re-prioritizes their portfolio (more details on BDSI's commercial plans to come in late January). Bunavail efforts will be limited to current prescribers as we still expect 1Q17 to show a positive ramp in sales from recent Managed Care Agreements.
- **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.
- **Maintain Buy rating, lowering price target to \$9 from \$11.** 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.

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	(0.15)	(0.10)	(0.06)	(0.05)	(0.35)	NM
FY-16E	(0.36)A	(0.31)A	(0.30)A	(0.25)	(1.22)	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

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	BDSI
Rating:	Buy
Price Target:	↓ \$9.00

Trading Data:

Last Price (12/08/2016)	\$1.60
52-Week High (12/17/2015)	\$5.48
52-Week Low (11/23/2016)	\$1.50
Market Cap. (MM)	\$86.6
Shares Out. (MM)	54.1

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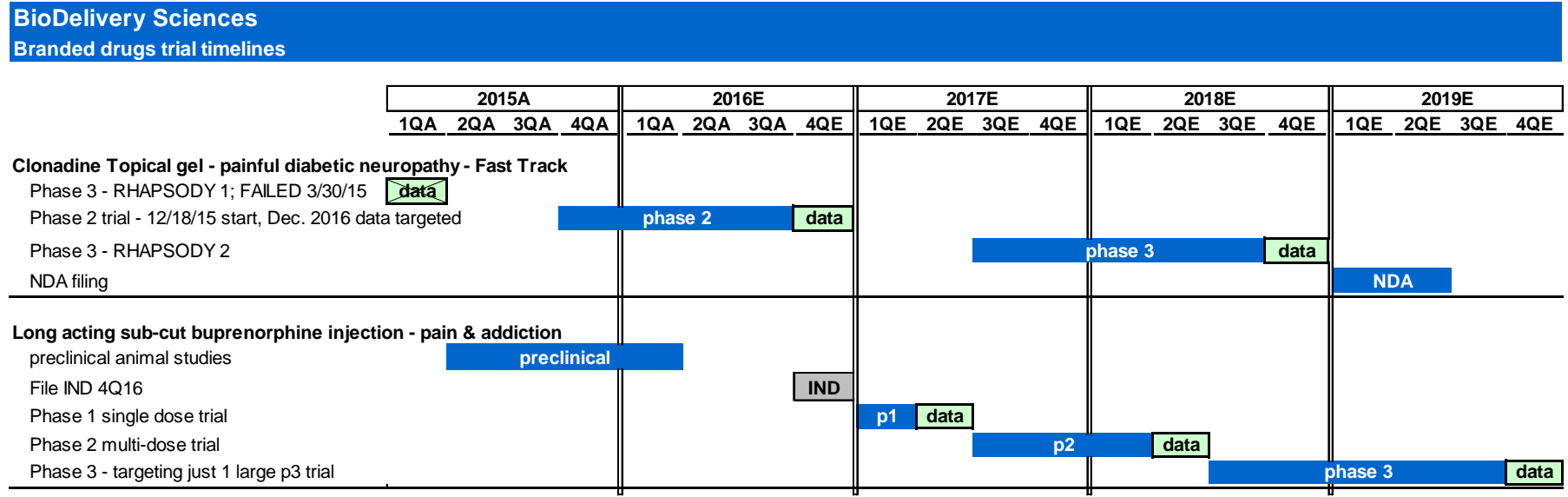
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Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca sales	\$380,828	\$6.0
Net cash (end '17) & tech	\$123,044	\$3.0
SUM	\$572,037	\$9
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	
Revenues										
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
Total Rev ex-milestones	\$3,054	\$1,733	\$1,235	\$2,468	\$8,205	\$3,040	\$2,504	\$3,571	\$3,225	\$12,340
Expenses:										
Cost of Revenue (COGS)	1,124	2,621	1,699	2,657	8,101	2,550	1,935	2,314	1,680	8,478
Gross Margin	1,930	(888)	(464)	(189)	389	490	569	1,257	1,546	3,862
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
Income (loss) from Operations	(17,800)	(18,681)	(19,652)	(18,787)	(74,920)	(17,942)	(15,935)	(15,199)	(13,017)	(62,093)
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
Income (loss) before taxes	(18,193)	(19,211)	(20,439)	(19,570)	(77,413)	(18,733)	(16,827)	(15,977)	(13,742)	(65,279)
Income tax exp (benefit)										
Adj NI ex 1x milestones	(18,193)	(19,211)	(20,439)	(19,570)	(77,413)	(18,733)	(16,827)	(15,977)	(13,742)	(65,279)
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)	(\$0.30)	(\$0.25)	(\$1.22)
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	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 & 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	8,369	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	-	-	
Total Rev ex-milestones	\$8,205	\$12,340	\$36,109	\$55,311	
Expenses:					
Cost of Revenue (COGS)	8,101	8,478	6,527	5,156	
Gross Margin	389	3,862	29,582	50,155	
Research and development	20,624	18,537	14,250	14,500	
General and administrative	54,685	47,418	35,000	29,950	Re-aligning costs with revenues
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	65,955	49,250	44,450	
Income (loss) from Operations	(74,920)	(62,093)	(19,668)	5,705	
Interest income (expense), net	(2,518)	(3,228)	(2,000)	(1,000)	
Other expenses, net	-	42	100	100	
Income (loss) before taxes	(77,413)	(65,279)	(21,568)	4,805	
Income tax exp (benefit)	-	-	-	630	Sig. tax loss carryforwards
Adj NI ex 1x milestones	(\$77,413)	(\$65,279)	(\$21,568)	\$4,175	
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)	(\$1.22)	(\$0.35)	\$0.05	
EPS as reported	(\$0.71)				
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	\$73,044	\$106,225	Assume 2017 fund raise
Margin & Expense Analysis					
COGS as % of Revenues	99%	69%	18%	9%	
R&D	251%	150%	39%	26%	
SG&A	666%	384%	97%	54%	
Gross Profit	1%	31%	82%	91%	
Op. margin cont. ops	-913%	-503%	-54%	10%	
Taxes	0%	0%	0%	13%	
Net margin	-943%	-529%	-60%	8%	
Year-over-year change					
Net revenue	-57%	50%	193%	53%	
R&D	60%	90%	77%	102%	
SG&A	42%	-13%	-26%	-14%	
Operating income	28%	-17%	-68%	-129%	

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.

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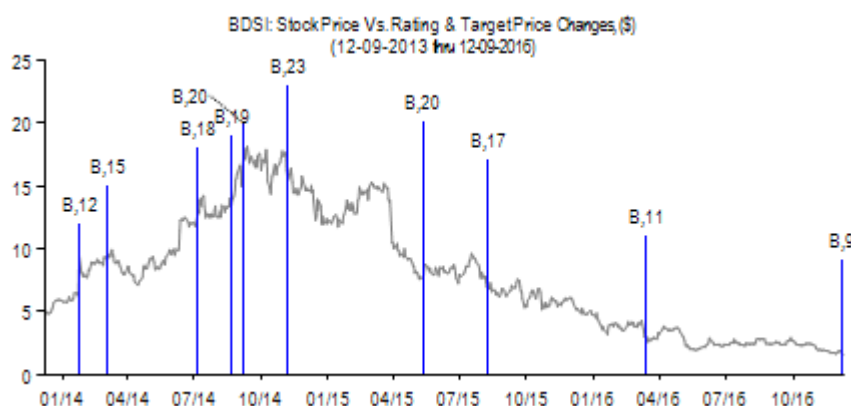
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Rating and Price Target Change History



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	1.60*

Source: Laidlaw & Company

Created by: Blue-Compass.net

* Previous Close 12/8/2016

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
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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Endo International (ENDP – Not Rated)
UnitedHealth Group Inc. (UNH – Not Rated)

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December 9, 2016

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