

BioDelivery Sciences (BDSI - \$1.90)

If You Don't Change Direction, You May End Up Where You're Heading

BDSI announced a shift in strategy yesterday at their aptly-named Belbuca-focused analyst & investor event in NYC – specifically that going forward they will focus their efforts on Belbuca, at the expense of Bunavail. Given that Belbuca is ~2.5x as profitable than Bunavail (according to BDSI) due to lower COGS and gross to net discounts, and it doesn't face the 800lb gorilla Suboxone like Bunavail does, we believe this shift in focus makes sense. If one definition of insanity is doing something over and over again and expecting a different result; we can reasonably conclude that BDSI management isn't insane. We too, believe that the strategic shift to Belbuca away from Bunavail makes good sense. While BDSI has rightly touted their 2016 managed care wins as the catalyst for Bunavail growth, there seems to be little to show for them yet as TRx's remain mired in the 2,300 TRx/week range. By contrast Belbuca, after dipping in December following ENDP returning the product to BDSI, appears to be resilient in the ~1,400 TRx/week range. Hopefully it will start growing again as BDSI's team takes over the launch. With a \$20M-\$30M run rate already in hand from ENDP we believe BDSI has ample opportunity to maintain momentum with Belbuca and continue to grow sales week to week. Management noted the multiple inbound calls from potential partners for both Bunavail and Belbuca, and we continue to believe that absent a meaningful ramp of Belbuca sales the company needs to explore strategic alternatives. We are maintaining our Buy and our \$8 price target.

- **Belbuca is a better drug, coverage & price remain hurdles.** BDSI KOLs Silverman & Passik agree that while Belbuca is superior from an abuse liability & ease of prescribing standpoint; lack of formulary coverage remains a hurdle to a branded drug like Belbuca priced at a significant premium to generic opioids.
- **BDSI to target 94% of the top Belbuca doctors.** With ~4,400 doctors having written a Belbuca Rx in the last 6 months and ~2,400 docs that should be using it (high prescribing pain specialists) BDSI has ample room for continued growth.
- **Bunavail reduced to 95% of current detail calls.** This is in-line with the company strategy to de-emphasize Bunavail and focus on the more profitable Belbuca sales.
- **Maintain Buy rating \$8 price target.** 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	(0.22)	(0.15)	(0.13)	(0.12)	(0.60)	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

Healthcare/Biotechnology

Ticker:	BDSI
Rating:	Buy
Price Target:	↓ \$8.00

Trading Data:

Last Price (02/01/2017)	\$1.90
52-Week High (03/08/2016)	\$4.39
52-Week Low (11/23/2016)	\$1.50
Market Cap. (MM)	\$102.8
Shares Out. (MM)	54.1

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Source: Company data and Laidlaw & Company estimates

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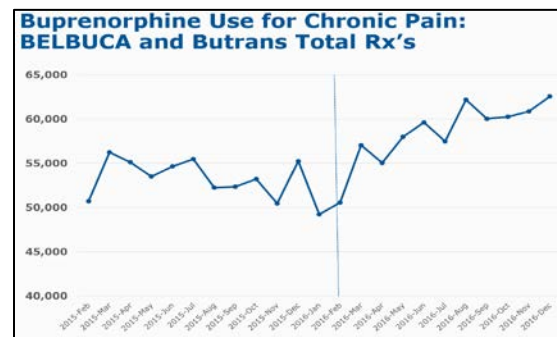
Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca sales	\$380,828	\$6.0
Net cash (end '17) & tech	\$107,572	\$2.0
SUM	\$511,011	\$8
Shares out '17E (000)		63,675

Source: Laidlaw & Company estimates.

- Belbuca has had a positive impact on overall buprenorphine TRx volumes since launch (grey line in Figure 2 below). The question remains if BDSI can continue to generate excitement among pain specialists through 2017.

Figure 2: Belbuca impact on buprenorphine TRx's



Source: Company presentation.

- BDSI targeting ~94% of recent BELBUCA TRx's; 1,246 of Belbuca prescribers meet high potential criteria with a heavy focus on pain management. BDSI is adding 19 Belbuca reps, 14 of which come over from ENDP.

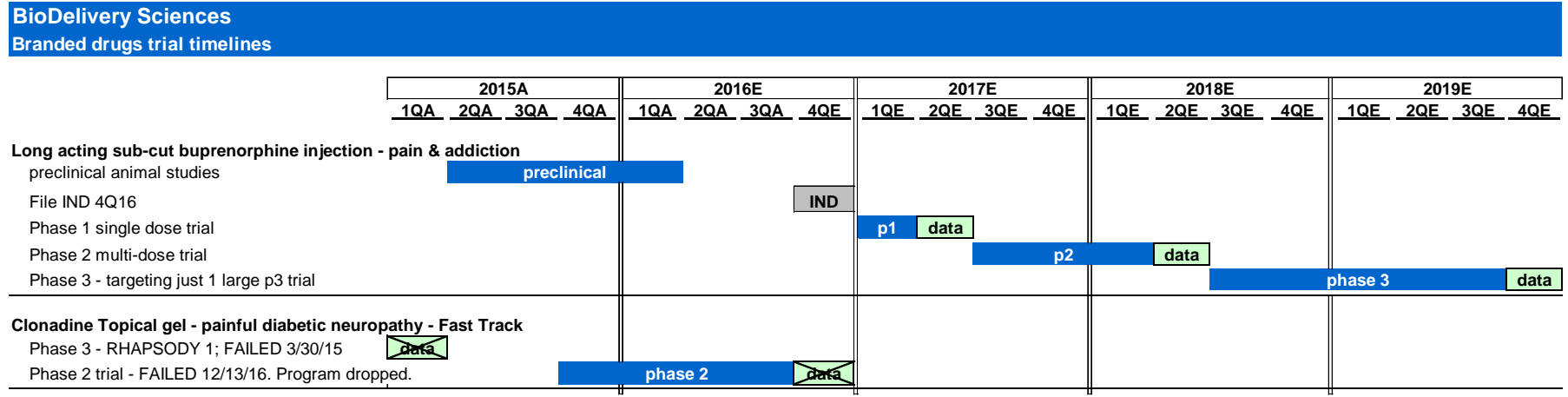
Figure 3: Belbuca target prescribers

Target Type	Targets	BELBUCA TRx's	Butrans TRx's	LAO TRx's
High Potential Non-Prescribers	2,367	0	20,097	212,858
BELBUCA Prescribers	4,433	33,368	96,360	484,418
Total	6,800	33,368	116,457	697,276

July 2016 – December 2016 PHAST Data

Source: Company presentation.

Figure 4: Clinical trials timeline



Source: Company Reports; Laidlaw & Company estimates

Figure 5: 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	863	1,163
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	\$3,211	\$12,326
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	1,532	3,848
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)	(13,031)	(62,107)
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)	(13,756)	(65,293)
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)	(13,756)	(65,293)
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 6: 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)	-	1,163	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	\$12,326	\$36,109	\$55,311	
Expenses:					
Cost of Revenue (COGS)	8,101	8,478	6,235	5,156	
Gross Margin	389	3,848	29,873	50,155	
Research and development	20,624	18,537	16,000	16,000	
General and administrative	54,685	47,418	49,000	43,500	Re-aligning costs with revenues
Related party SG&A	-	-	-	-	
Total operating expenses	75,309	65,955	65,000	59,500	
Income (loss) from Operations	(74,920)	(62,107)	(35,127)	(9,345)	
Interest income (expense), net	(2,518)	(3,228)	(2,000)	(1,000)	
Other expenses, net	-	42	100	100	
Income (loss) before taxes	(77,413)	(65,293)	(37,027)	(10,245)	
Income tax exp (benefit)	-	-	-	-	Sig. tax loss carryforwards
Adj NI ex 1x milestones	(\$77,413)	(\$65,293)	(\$37,027)	(\$10,245)	
Net income as reported	(\$37,413)				
Adj EPS ex-1x & non-cash	(\$1.48)	(\$1.22)	(\$0.60)	(\$0.15)	
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	\$39,342	\$57,572	\$76,333	Assume 2017 fund raise

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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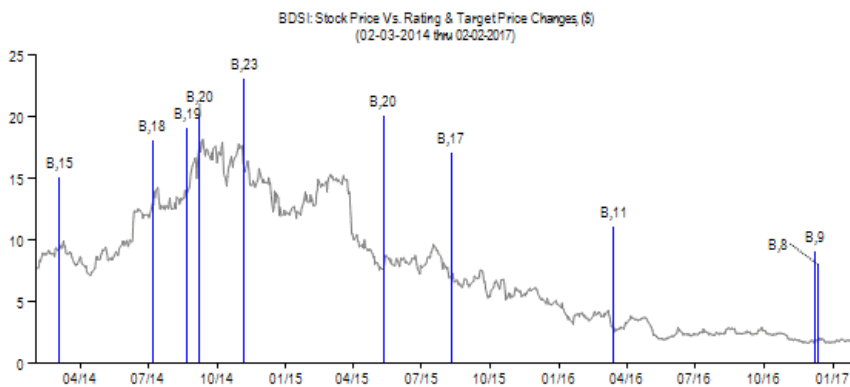
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Rating and Price Target Change History



Source: Laidlaw & Company

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3 Year Rating Change History

Date	Rating	Closing Price (\$)
03/05/2014	Buy (B)	9.60

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
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	1.85
12/13/2016	8.00	1.95

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.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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Endo International (ENDP – Not Rated)

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