

BioDelivery Sciences (BDSI - \$ 7.64)

Healthcare/Biotechnology

Transferring coverage, maintaining Buy rating, setting \$20 PT

We are transferring research coverage of BDSI to Jim Molloy with a Buy rating and setting a \$20 price target. BDSI reported 1Q15 yesterday before the open and the focus remains on the ongoing launch of their opioid abuse product Bunavail. While the roll-out went out into the teeth of the year-end holidays last year, and has struggled somewhat to regain footing in the 1H15, we believe that the poor launch is more than priced into the shares at current levels. Any improvement in the launch uptake ought to reflect in the shares, and we are buyers at current levels. Our \$20 price target is based on a sum-of-the-parts with Belbuca valued at \$12/share, Bunavail valued at \$4/share, and cash (end-'16) and tech value (clonidine, IV buprenorphine) valued at \$4/share.

Ticker:	BDSI
Rating:	Buy
Price Target:	\$ 20.00

Trading Data:

Last Price (05/11/2015)	\$ 7.64
52-Week High	\$18.48
52-Week Low	\$7.53
Market Cap. (MM)	\$399.6
Shares Out. (MM)	52.30

- **BDSI beats revenues & EPS, Bunavail sales remain murky.** BDSI reported 1Q15 yesterday before the open with top line revenues of \$13.1MM vs. consensus of \$12.1 as it appears the slow Bunavail launch is getting factored into consensus. Operating expenses were more or less in-line and the EPS loss of (\$0.16) also came in above consensus loss of (\$0.19). Bunavail sales were ~\$700K in the 1Q15, but that included Dec/Jan/Feb due to the accounting for returns still skewing actual quarterly sales reporting until returns can be accurately estimated.
- **Belbuca remains the main value driver at BDSI.** With an October 23rd PDUFA (FDA action) date and the Schedule 3 opioid space devoid of alternatives since Vicodin-like products were moved up to Schedule 2, we believe that Belbuca could drive significant shareholder value upon approval and launch. Partner Endo Pharmaceuticals remains one of the dominant companies in the pain space, and should be able to drive sales to Belbuca.
- **IV buprenorphine potentially by early 2016.** BDSI is planning on filing an IND by 2H16 and potentially be in humans by 1H16 on a long-acting depot formulation of buprenorphine for both pain and addiction. This could effectively eliminate diversion issues and increase ease of dosing with a 1x/month injection.
- **Maintain Buy rating, setting \$20 price target.** Our price target is based on a sum-of-the-parts with Belbuca valued at \$12/share, Bunavail valued at \$4/share, and cash (end-'16) and tech value (clonidine, IV buprenorphine) valued at \$4/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	(0.16)	(0.09)	(0.04)	0.29	0.05	NM
FY-15E	(0.29)	(0.31)	(0.28)	(0.22)	(1.10)	NM
FY-14A	(0.22)	(0.05)	(0.39)	(0.34)	(1.03)	NM
FY-13A	(0.37)	(0.36)	(0.46)	(0.33)	(1.52)	NM

James Molloy

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Source: Company data and Laidlaw & Company estimates

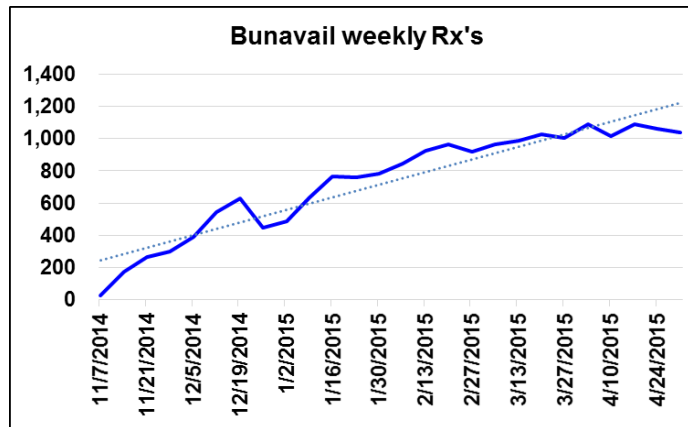
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Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$776,211	\$12.0
Bunavail	\$254,820	\$4.0
Cash (end '16) & tech value	\$220,580	\$4.0
SUM	\$1,293,115	\$20
Shares out '16E (000)		64,034

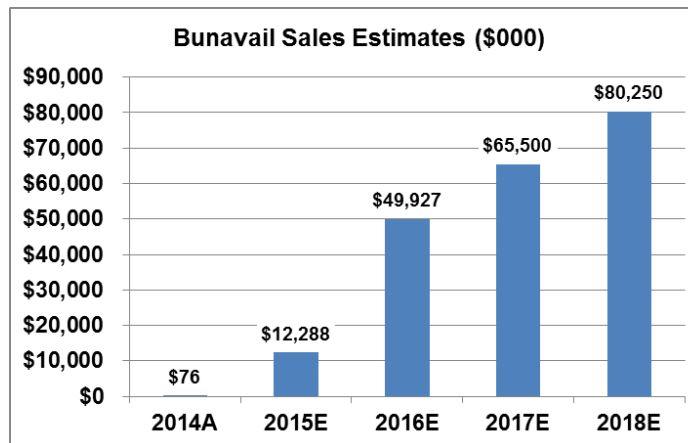
Source: Laidlaw & Company estimates.

Figure 2: Bunavail launch trajectory by week



Source: Bloomberg LP.

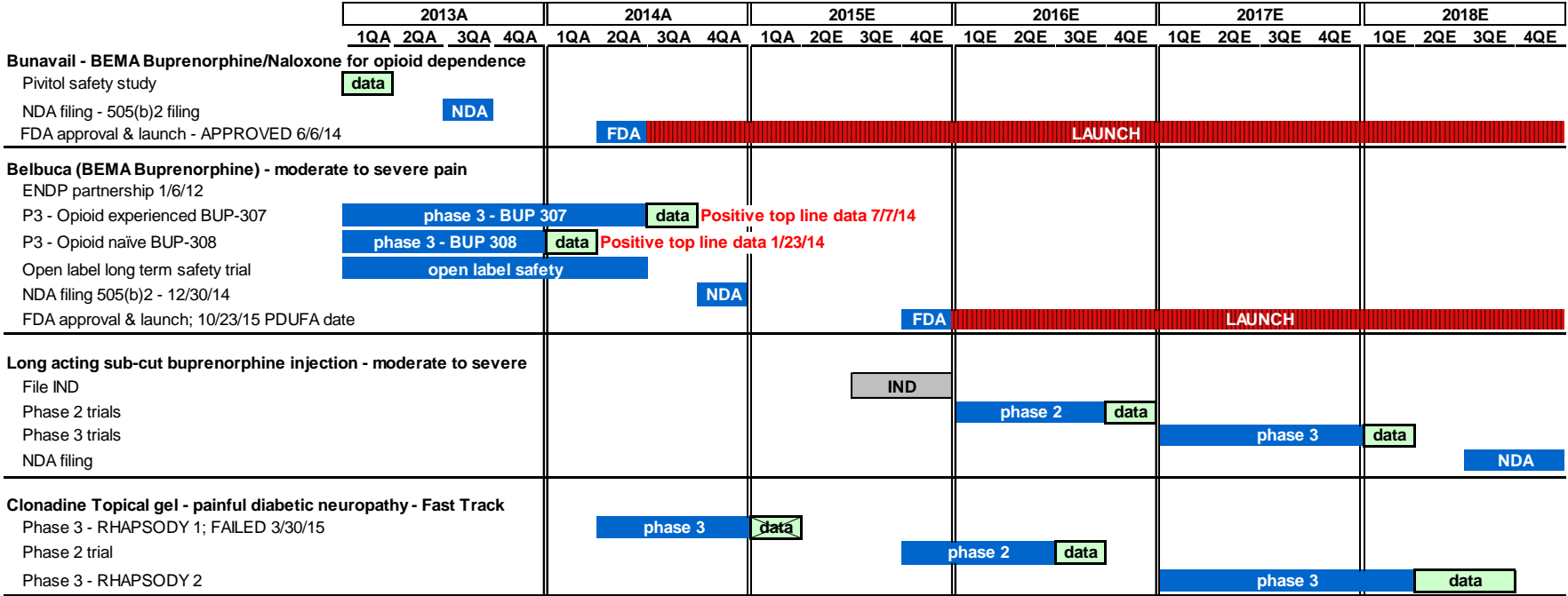
Figure 3: Bunavail sales projections



Source: Company reports; Laidlaw & Company estimates.

Figure 4: Clinical trials timeline

BioDelivery Sciences
Branded drugs trial timelines



Source: Company reports and SSRP estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 5: Quarterly Income Statement

BioDelivery Sciences										
Quarterly income statement										
(\$'000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
Bunavail sales				\$76	\$76	\$700	\$1,912	\$3,297	\$6,379	\$12,288
Royalty revenue - Onsolis	\$954	\$892	12	1,549	3,407	1,000	1,000	1,000	1,000	4,000
Contract rev / milestones	11,284	10,675	513	277	22,749	10,000	0	0	0	10,000
Research fees	8,452	2,318	1,298	645	12,712	1,354	2,000	2,000	2,000	7,354
Total Revenue	\$20,690	\$13,885	\$1,822	\$2,547	\$38,944	\$13,054	\$4,912	\$6,297	\$9,379	\$33,642
Expenses:										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	1,228	1,409	1,707	5,468
Gross Margin	19,965	13,198	1,360	(517)	34,005	11,930	3,684	4,888	7,672	28,174
Research and development	14,623	7,983	6,770	4,909	34,285	6,549	6,250	6,000	6,000	24,799
General and administrative	4,622	7,250	13,649	12,925	38,460	13,181	13,500	13,500	13,500	53,681
Related party G&A	6	6								-
Total operating expenses	19,251	15,239	20,418	17,834	72,745	19,730	19,750	19,500	19,500	78,480
Income (loss) from Operations	714	(2,041)	(19,059)	(18,351)	(38,740)	(7,800)	(16,066)	(14,612)	(11,828)	(50,306)
Interest income (expense), net	(555)	(519)	(515)	(427)	(2,016)	(420)	(350)	(200)	(100)	(1,070)
Derivative (loss) gain	(4,825)	(4,120)	(5,685)	1,464	(13,167)					-
Other (exp) gain, net	23	9	25	(352)	(295)	27	25	25	25	102
Income (loss) before taxes	(4,644)	(6,671)	(25,233)	(17,666)	(54,218)	(8,193)	(16,391)	(14,787)	(11,903)	(51,274)
Income tax exp (benefit)										
Net Income (Loss)	(4,644)	(6,671)	(25,233)	(17,666)	(54,215)	(8,193)	(16,391)	(14,787)	(11,903)	(51,274)
Earning per Share (EPS)	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.34)	(\$1.12)	(\$0.16)	(\$0.31)	(\$0.28)	(\$0.22)	(\$0.97)
Adj EPS ex-1x & non-cash items	(\$0.22)	(\$0.05)	(\$0.39)	(\$0.34)	(\$1.03)	(\$0.29)				(\$1.10)
Weighted avg. shares (000)	44,035	48,521	49,556	51,308	48,355	51,909	52,659	53,409	54,159	53,034
Fully diluted shares (000)	48,166	55,321	55,556	54,505	53,387	58,909	59,659	60,409	61,159	60,034

Source: Company reports and Laidlaw estimates

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

Figure 6: Annual Income Statement

BioDelivery Sciences						
Annual income statement						
('\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
Revenues						
Bunavail sales	76	12,288	49,927	65,500	80,250	Launched 11/3/14
Royalty - Belbuca (BEMA Bup.)	-	-	11,250	47,250	81,000	10/23/15 PDUFA date
Royalty revenue - Onsolis	3,407	4,000	5,000	5,000	6,000	Smaller product
Contract revenue	22,749	10,000	50,000	-	-	ENDP milestones here
Research fees	12,712	7,354	8,000	8,000	8,000	
Total Revenue	\$38,944	\$33,642	\$124,177	\$125,750	\$175,250	
Expenses:						
Cost of Revenue (COGS)	4,939	5,468	8,090	9,605	11,828	
Gross Margin	34,005	28,174	116,087	116,145	163,423	
Research and development	34,285	24,799	24,750	25,000	26,000	
General and administrative	38,460	53,681	54,500	54,750	56,000	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	78,480	79,250	79,750	82,000	
Income (loss) from Operations	(38,740)	(50,306)	36,837	36,395	81,423	
Interest income (expense), net	(2,016)	(1,070)	575	1,575	2,225	
Derivative (loss) gain	(13,167)	-	-	-	-	
Other expenses, net	(295)	102	100	100	100	
Income (loss) before taxes	(54,218)	(51,274)	37,512	38,070	83,748	
Income tax exp (benefit)	-	-	-	1,032	13,389	Sig. tax loss carryforwards
Net Income (Loss)	(\$54,215)	(\$51,274)	\$37,512	\$37,038	\$70,358	
Adj NI less non cash & 1x items	(\$49,584)	(\$58,074)	\$3,512			
Earning per Share	(\$1.12)	(\$0.97)	\$0.59	\$0.55	\$1.00	
Adj EPS ex-1x & non-cash items	(\$1.03)	(\$1.10)	\$0.05			
Weighted avg. shares (000)	48,355	53,034	56,034	59,034	62,159	
Fully diluted shares (000)	53,387	60,034	64,034	67,534	70,659	
Margin & Expense Analysis						
COGS as % of Revenues	13%	16%	7%	8%	7%	
R&D	88%	74%	20%	20%	15%	
SG&A	99%	160%	44%	44%	32%	
Gross Profit	87%	84%	93%	92%	93%	
Op. margin cont. ops	-99%	-150%	30%	29%	46%	
Taxes	0%	0%	0%	3%	16%	
Net margin	-139%	-152%	30%	29%	40%	
Year-over-year change						
Net revenue	243%	-14%	269%	1%	39%	
R&D	64%	72%	100%	101%	104%	
SG&A	213%	40%	2%	0%	2%	
Operating income	-31%	30%	-173%	-1%	124%	

Source: Company reports and Laidlaw estimates

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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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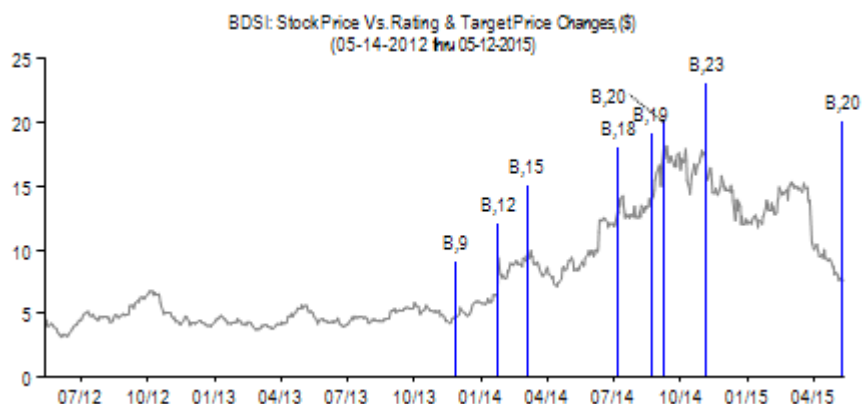
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RATINGS INFORMATION

Rating and Price Target Change History



Source: Laidlaw & Company

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	7.64*

* Previous Close 5/11/2015

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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.	73.08%	30.77%	7.69%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.85%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Endo Pharmaceuticals (ENDO – Not Rated)

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