

BioDelivery Sciences (BDSI - \$ 7.91)

USPTO patent ruling favorable for BDSI and a nice positive

Yesterday the US Patent Office (USPTO) ruled on an Inter-Partes Review (IPR) on Indivior's (RB Pharmaceuticals) patent #8,475,832 (the '832 patent) that claims 15-19 are unpatentable due to prior art based on a preponderance of the evidence. Patent '832 is a key formulation of matter patent for Indivior's sublingual Suboxone film strip that Indivior had asserted BDSI was infringing with their Bunavail for opioid dependence. We see this as a nice positive for BDSI and further bolsters our positive rating on the stock, in our opinion. A patent challenge can be hard to handicap, given the inherent uncertainties in the legal system, but BDSI continues to win ruling after ruling against Indivior (RB, MonoSol) and we believe that BDSI will ultimately prevail in demonstrating that the BEMA technology in Bunavail does not violate any prior patentable art. We continue to rate BDSI a Buy with a \$20 PT 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.

- **Patent case in North Carolina remains "stayed".** Indivior & BDSI are currently involved in a patent lawsuit in the US District Court for the Eastern District of North Carolina regarding the '832 patent – and also the '080 and '378 patents. This case is currently "stayed" awaiting the USPTO IPR ruling on the '832 patent and a pending reexamination of a previous IPR (in BDSI's favor) on the '080 patent.
- **Indivior also fending off generics on the other side.** Indivior is defending the Suboxone film strip against generic challenges from Par, Watson & Teva. The Par/Watson case was initially supposed to happen in August 2015, but it has recently been moved to November 2015. We believe this suggests the case will ultimately be settled, as most generic challenges seem to be these days. With patents as far out as March 2030 we believe it is more probable than not that the settlement will ultimately prevent generic entrants to the Suboxone film strip into the mid-2020's.
- **USPTO expected to rule on another patent in July/August 2015.** We anticipate that the USPTO will rule on a separate Indivior's IPR challenge to BDSI's 7,579,019 patent (the '019 patent) which could occur as soon as July 2015 (the IPR was initiated in August 2014).
- **Maintain Buy rating \$20 PT.** We value BDSI 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	(0.15)	(0.07)	(0.02)	0.30	0.10	NM
FY-15E	(0.29)A	(0.30)	(0.26)	(0.21)	(0.92)	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

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:/

Last Price (06/30/2015)	\$7.96
52-Week High (09/12/2014)	\$18.48
52-Week Low (06/29/2015)	\$7.17
Market Cap. (MM)	\$417.1
Shares Out. (MM)	52.4

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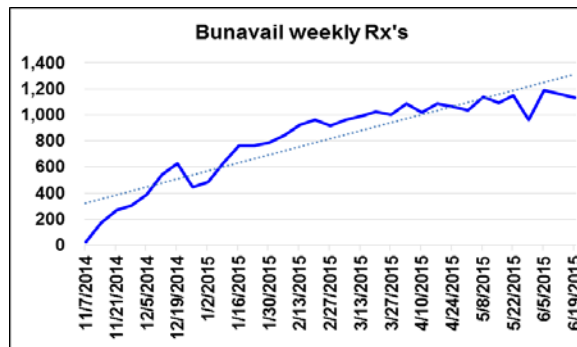
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Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$777,542	\$12.0
Bunavail	\$254,820	\$4.0
Cash (end '16) & tech value	\$220,580	\$4.0
SUM	\$1,294,445	\$20
Shares out '16E (000)		64,034

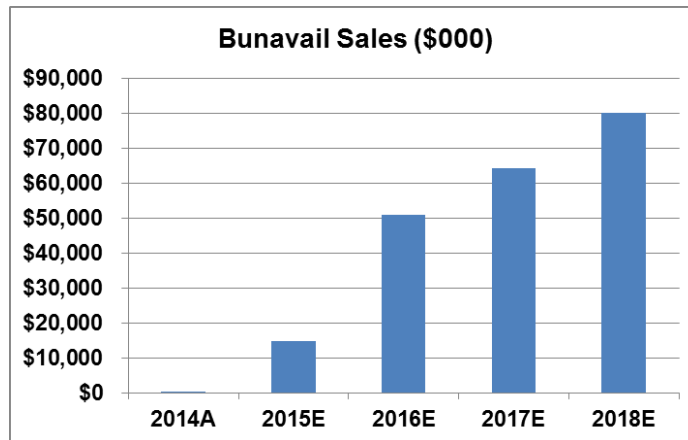
Source: Laidlaw & Company estimates.

Figure 2: Bunavail launch trajectory by week



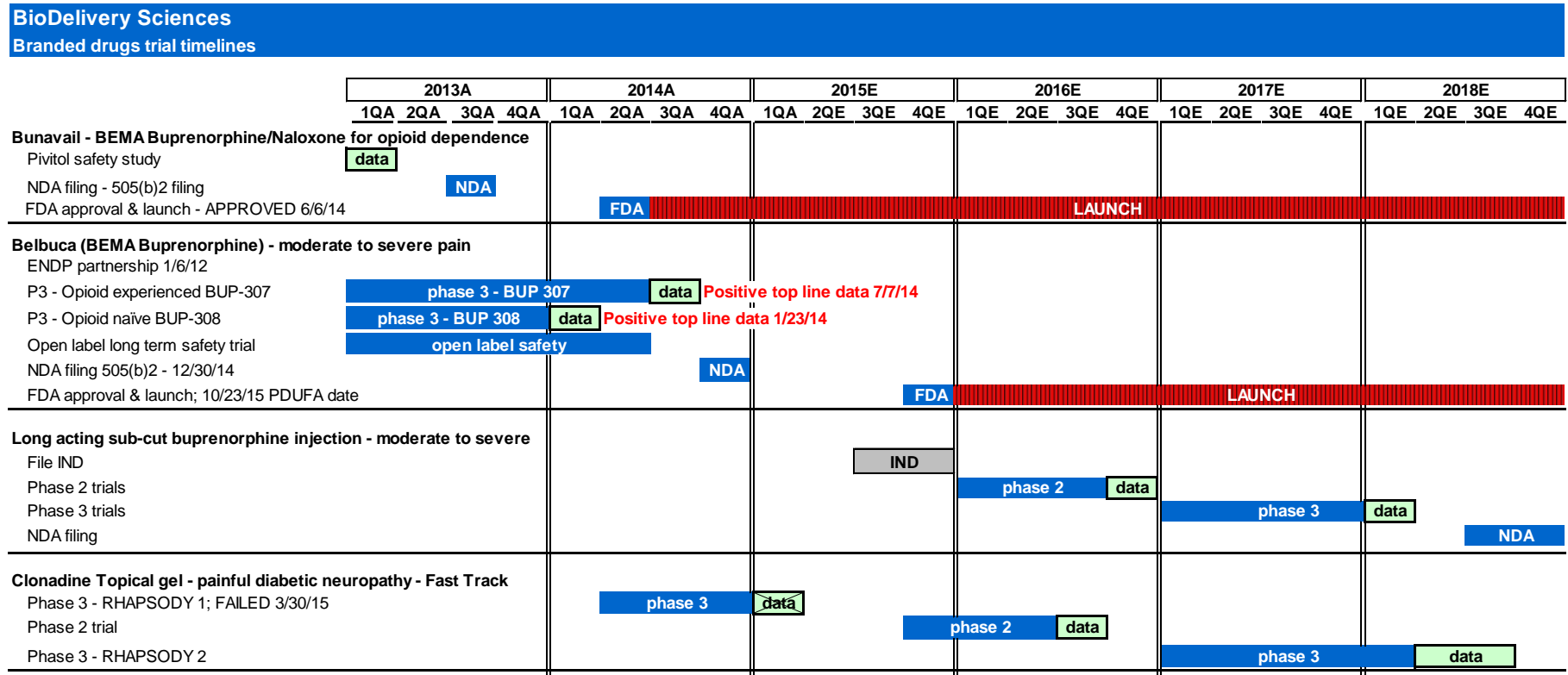
Source: Bloomberg LP.

Figure 3: Bunavail sales projections



Source: Company reports; Laidlaw & Company estimates.

Figure 1: Clinical trials timeline



Source: Company reports and SSRP estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 2: 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	\$3,052	\$4,385	\$6,698	\$14,835
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	\$6,052	\$7,385	\$9,698	\$36,189
Expenses:										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	1,513	1,627	1,755	6,019
Gross Margin	19,965	13,198	1,360	(517)	34,005	11,930	4,539	5,758	7,943	30,170
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	13,250	53,431
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	19,250	78,230
Income (loss) from Operations	714	(2,041)	(19,059)	(18,351)	(38,740)	(7,800)	(15,211)	(13,742)	(11,307)	(48,060)
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)	(15,536)	(13,917)	(11,382)	(49,028)
Income tax exp (benefit)										
Net Income (Loss)	(4,644)	(6,671)	(25,233)	(17,666)	(54,215)	(8,193)	(15,536)	(13,917)	(11,382)	(49,028)
Earning per Share (EPS)	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.34)	(\$1.12)	(\$0.16)	(\$0.30)	(\$0.26)	(\$0.21)	(\$0.92)
Adj EPS ex-1x & non-cash items	(\$0.22)	(\$0.05)	(\$0.39)	(\$0.34)	(\$1.03)	(\$0.29)				(\$1.05)
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 3: Annual Income Statement

BioDelivery Sciences						
Annual income statement						
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
Revenues						
Bunavail sales	76	14,835	50,805	64,250	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	\$36,189	\$125,055	\$124,500	\$175,250	
Expenses:						
Cost of Revenue (COGS)	4,939	6,019	7,989	9,468	11,828	
Gross Margin	34,005	30,170	117,067	115,033	163,423	
Research and development	34,285	24,799	24,000	25,000	26,000	
General and administrative	38,460	53,431	53,750	55,000	56,000	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	78,230	77,750	80,000	82,000	
Income (loss) from Operations	(38,740)	(48,060)	39,317	35,033	81,423	
Interest income (expense), net	(2,016)	(1,070)	700	1,575	2,225	
Derivative (loss) gain	(13,167)	-	-	-	-	
Other expenses, net	(295)	102	100	100	100	
Income (loss) before taxes	(54,218)	(49,028)	40,117	36,708	83,748	
Income tax exp (benefit)	-	-	-	3,183	20,101	Sig. tax loss carryforwards
Net Income (Loss)	(\$54,215)	(\$49,028)	\$40,117	\$33,524	\$63,646	
Adj NI less non cash & 1x items	(\$49,584)	(\$55,828)	\$6,117			
Earning per Share	(\$1.12)	(\$0.92)	\$0.63	\$0.50	\$0.90	
Adj EPS ex-1x & non-cash items	(\$1.03)	(\$1.05)	\$0.10			
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%	17%	6%	8%	7%	
R&D	88%	69%	19%	20%	15%	
SG&A	99%	148%	43%	44%	32%	
Gross Profit	87%	83%	94%	92%	93%	
Op. margin cont. ops	-99%	-133%	31%	28%	46%	
Taxes	0%	0%	0%	-9%	-24%	
Net margin	-139%	-135%	32%	27%	36%	
Year-over-year change						
Net revenue	243%	-7%	246%	0%	41%	
R&D	64%	72%	97%	104%	104%	
SG&A	213%	39%	1%	2%	2%	
Operating income	-31%	24%	-182%	-11%	132%	

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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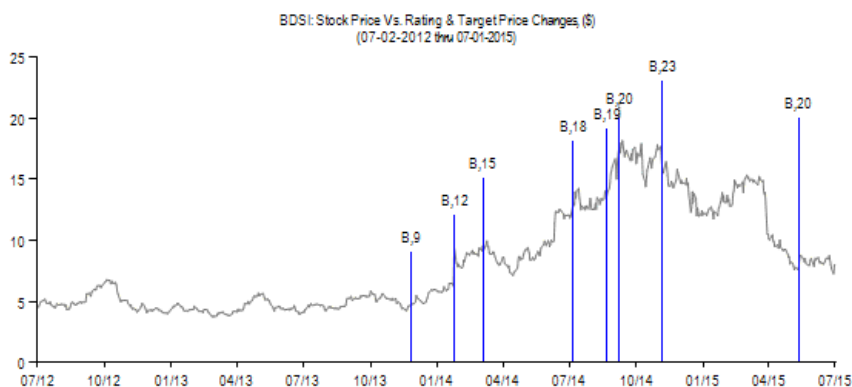
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Rating and Price Target Change History



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

Source: Laidlaw & Company

Created by: Blue-Compass.net

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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Teva Pharmaceuticals (TEVA – Not Rated)

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