

BioDelivery Sciences (BDSI - \$2.43)

In addiction medicine, patience isn't just a river in Egypt

We recently hosted a KOL dinner with addiction specialist Dr. Michael Frost to discuss the opioid epidemic phenomenon as well as Bunavail's slower than anticipated rollout and the potential for the drug going forward. Dr. Frost emphasized the "glacier-like pace" of the addiction medicine field over the past century and the challenges for new drugs to gain traction. Dr. Frost believes that BDSI's Bunavail is the superior treatment option for patients, given the improved delivery and lower drug content, but he notes that ~25% of doctors are hesitant to potentially disrupt the "annuity revenue stream" aspect of patient care by introducing a new treatment like Bunavail, regardless of the benefits. Bunavail also has to deal with the legacy of Orexo's Zubsolv which "forced" itself onto the market by heavily discounting their less efficient product, which has left a sour taste with the prescribers for novel therapies. And while the Bunavail launch is certainly taking too long from an investment standpoint Dr. Frost believes BDSI and its sales force have done an exceptional job of patiently advancing a field that has been stagnant for a decade. We continue to believe the tailwinds behind BDSI and the addiction medicine space bode well for 2017 and beyond, and we maintain our Buy rating and our \$11 price target.

- **Emerging from the Zubsolv shadow is harder than expected.** Our KOL believes that Zubsolv's is an inferior product to Bunavail, which led ORX to heavily discount the product to "buy" its way into the market, which our KOL believes has left a hesitancy by physicians to try novel therapies in the addiction space.
- **BDSI: more progress in past year than in the past decade.** Our KOL emphasized the importance of the patient pull-through demand (blogs, word to mouth, etc.) being as important as convincing the payers to cover Bunavail.
- **Bunavail 1st choice for ~95% of new clients.** Our KOL stated that all new patients in his practice are started on Bunavail, unless they are transferring from another practice where they were stable on Suboxone already.
- **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 (10/26/2016)	\$2.43
52-Week High (11/30/2015)	\$6.40
52-Week Low (05/23/2016)	\$1.86
Market Cap. (MM)	\$130.3
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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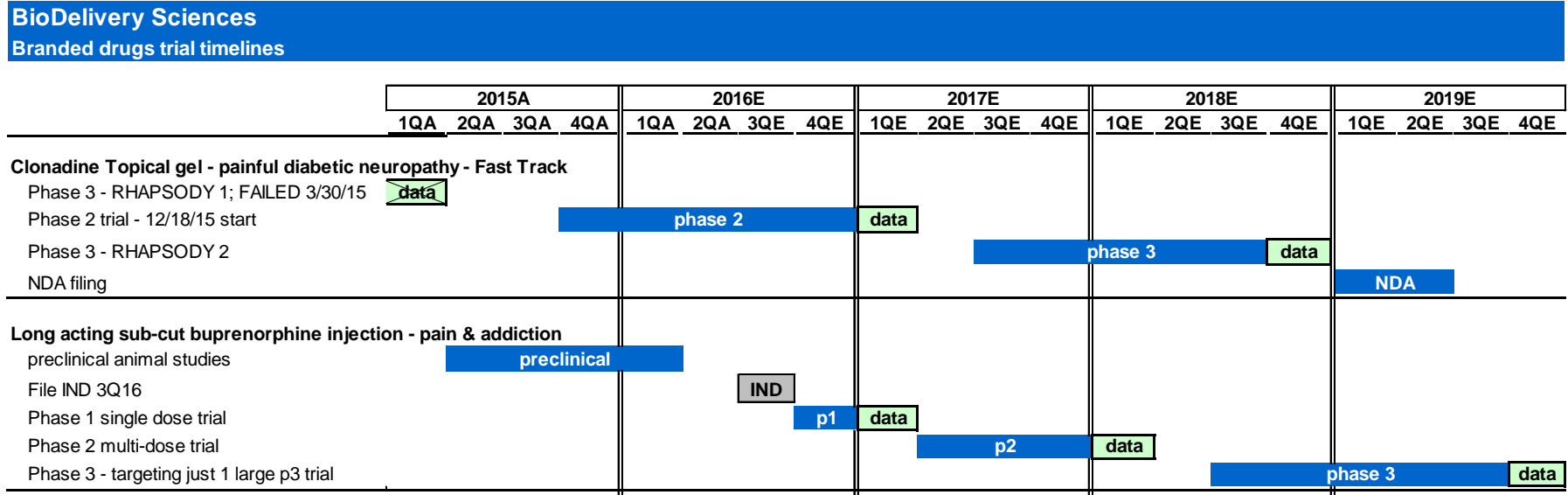
- Addiction Medicine: It’s not Show “Friends”, it’s Show “Business”.** Our KOL notes that while most doctors are patient focused, the business side of addiction medicine is never far behind (or indeed first) Notably many doctors see their addiction patients as an annuity revenue stream to the practice, which discourages them from experimenting with novel therapies that may upset that annuity. Dr. Frost noted that we live in an imperfect world, and dishonest doctors are out there and may turn a blind eye to patients who are simply reselling their Suboxone prescription, thus obviating the benefits of Bunavail therapy.

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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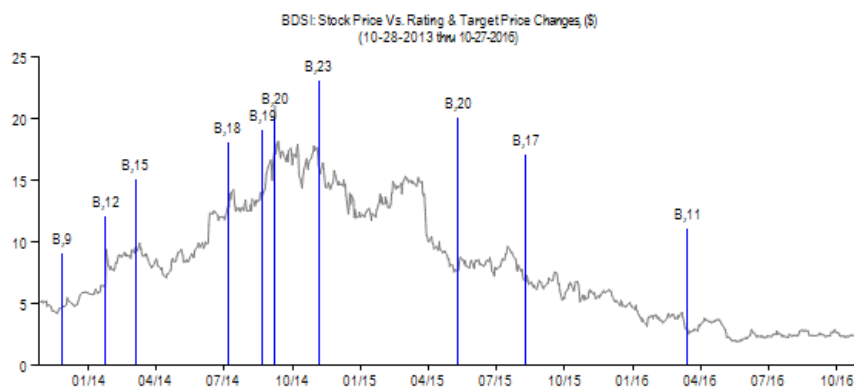
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Rating and Price Target Change History



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

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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Orexo (ORX – Not Rated)

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