

Avadel Pharmaceuticals (AVDL - \$9.84)

Healthcare/Biotechnology

A Solid Beat and Reiterate, but EPS Death by Taxes, Again

Avadel (AVDL) reported their 4Q16 before the open with a substantial top-line beat of \$43.1M vs Laidlaw: \$33.3M and the highest estimate: \$36.8M. AVDL's Eclat portfolio is yet again showing impressive resiliency as Bloxiverz, Vazculep and Akovaz have maintained stability in pricing and volume and all beat our estimates. AVDL reiterated their 2017 revenue and EPS guidance, which is a nice positive with ENDP's ephedrine sulfate injection (Akovaz) entering the market in 1H17, earlier than we anticipated. Positively, AVDL's key value driver FT-218 (sodium oxybate, Xyrem-like formulation that eliminates middle-of-the-night dosing) is still expected to complete enrollment by 4Q17 with potential data read-out in mid-2018. Importantly any sales of FT-218 would flow through Ireland which should help lower AVDL's draconian current 70%-80% tax rate. We estimate an FT-218 launch in 2020, with the tax rate normalizing to the low-20% range. We reiterate our Buy rating, \$25 price target.

Ticker:	AVDL
Rating:	Buy
Price Target:	\$25.00

Trading Data:

Last Price (03/07/2017)	\$9.84
52-Week High (02/23/2017)	\$12.30
52-Week Low (03/01/2016)	\$8.97
Market Cap. (MM)	\$405.8
Shares Out. (MM)	41.24

- **Eclat portfolio drives top-line beat.** AVDL was able to maintain pricing and volume for Bloxiverz and Vazculep, and Akovaz is holding its own amidst growing competition (AKRX and ENDP). Higher R&D expenses related to the sodium oxybate REST-ON phase 3 trial and taxes of \$6.9M vs LL: \$4.5M lead to bottom line \$0.00 vs our estimated (\$0.03).
- **Guidance 2017 reiterated, ENDP competition could soften 2H17.** It's encouraging, in our opinion, to see AVDL reiterate their FY17 revenue guidance of \$170M - \$200M and EPS of \$0.20-\$0.35 as Akovaz now faces competition from both ENDP's ephedrine sulfate, approved by the FDA on 1/30/17, on top of AKRX's product approved 3/2/17.
- **REST-ON enrollment timing on track.** As REST-ON remains the main value driver at AVDL. AVDL reiterated their 4Q17 enrollment completion goal, with a potential read-out mid-2018. We anticipate and updated enrollment timing following 2Q17.
- **Maintain our BUY rating, \$25 price target.** Our price target is based on a sum-of-the-parts analysis with the FT-218 at \$11.50/share, the Eclat portfolio at \$8/share, and cash (end '17) and tech value at \$5.5/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	0.16	0.22	0.08	0.05	0.50	19.7x
FY-17E	(0.05)	0.03	0.10	0.11	0.20	49.2x
FY-16A	0.03	(0.02)	(0.08)	0.00	(0.06)	NM
FY-15A	0.27	0.34	0.27	0.25	0.98	10.0x

Analyst

Jim Molloy/Spec Pharma & Biotech
(857) 317-5061
jmolloy@laidlawltd.com

Francois Brisebois,
MSc/Associate (857)317-5362
fbrisebois@laidlawltd.com

Source: Company data and Laidlaw & Company estimates

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Figure 1: Variance analysis

Avadel Pharmaceuticals Quarterly variance analysis										
(\$000 except per share)	4Q15A	4Q16A	4Q16E	Variance	% Y/Y	FY15A	FY16A	FY16E	Variance	% Y/Y
Bloxivertz (neostigmine)	\$36,009	\$16,938	\$14,116	\$2,822	-53.0%	\$150,083	\$82,896	\$80,074	\$2,822	-44.8%
Vazculep		10,629	9,750	879	NM		39,796	38,917	879	NM
Akovaz		11,263	8,500	2,763	NM		16,831	14,068	2,763	NM
FSC products		3,534	900	2,634	NM		7,699	5,065	2,634	NM
1x milestones (license deals)	721	721	50	671	0.0%	721	2,161	1,490	671	199.7%
Total Revenue	\$44,568	\$43,085	\$33,316	\$9,769	-3.3%	\$173,009	\$150,246	\$140,477	\$9,769	-13.2%
COGS	2,937	3,610	3,010	600	22.9%	10,921	12,742	12,391	351	16.7%
Gross Profit	41,631	39,475	30,306	9,169	-5.2%	162,088	137,504	128,086	9,418	-15.2%
SG&A Expense	6,808	10,688	11,188	(500)	57.0%	21,712	44,179	44,679	(500)	103.5%
R&D Expense	5,161	13,476	9,500	3,976	161.1%	25,608	34,611	30,635	3,976	35.2%
Operating Inc (loss)	29,662	15,311	9,619	5,692	-48%	114,768	58,714	52,773	5,941	-49%
Interest inc (exp)	65	(261)	200	(461)	-501.5%	2,651	672	753	(81)	-74.7%
Other inc (exp)	(32)	(463)	100	(563)	1346.9%	0	(3,636)	(75)	(3,561)	NM
Pretax Income	20,414	6,942	3,256	3,686	-66.0%	78,068	28,784	24,946	3,838	-63.1%
Income Taxes/(benefit)	9,687	6,875	4,500	2,375	-29.0%	35,167	31,373	29,124	2,249	-10.8%
Adj Net income/(loss)	10,727	67	(1,244)	1,311	NM	42,901	(2,589)	(4,178)	1,589	NM
1x & non cash exp	(62,222)	19,750	19,750	0	-131.7%	2,442	38,687	72,445	(33,758)	1484.2%
NI/(loss) as reported	72,949	(22,297)	(22,297)	0	NM	40,459	(41,276)	(76,623)	35,347	NM
Shares out (000)	41,125	42,808	41,541	1,267	4.1%	40,580	41,248	41,316	(68)	1.6%
Fully diluted shares (000)	43,430	49,308	48,041	1,267	13.5%	43,619	48,181	47,864	317	10.5%
Adj EPS ex-1x & non cash	\$0.25	\$0.00	(\$0.03)	\$0.03	NM	\$0.98	(\$0.06)	(\$0.10)	\$0.04	NM
EPS as reported	\$1.68	(\$0.52)	(\$0.54)	\$0.02		\$0.93	(\$1.00)	(\$1.85)	\$0.85	

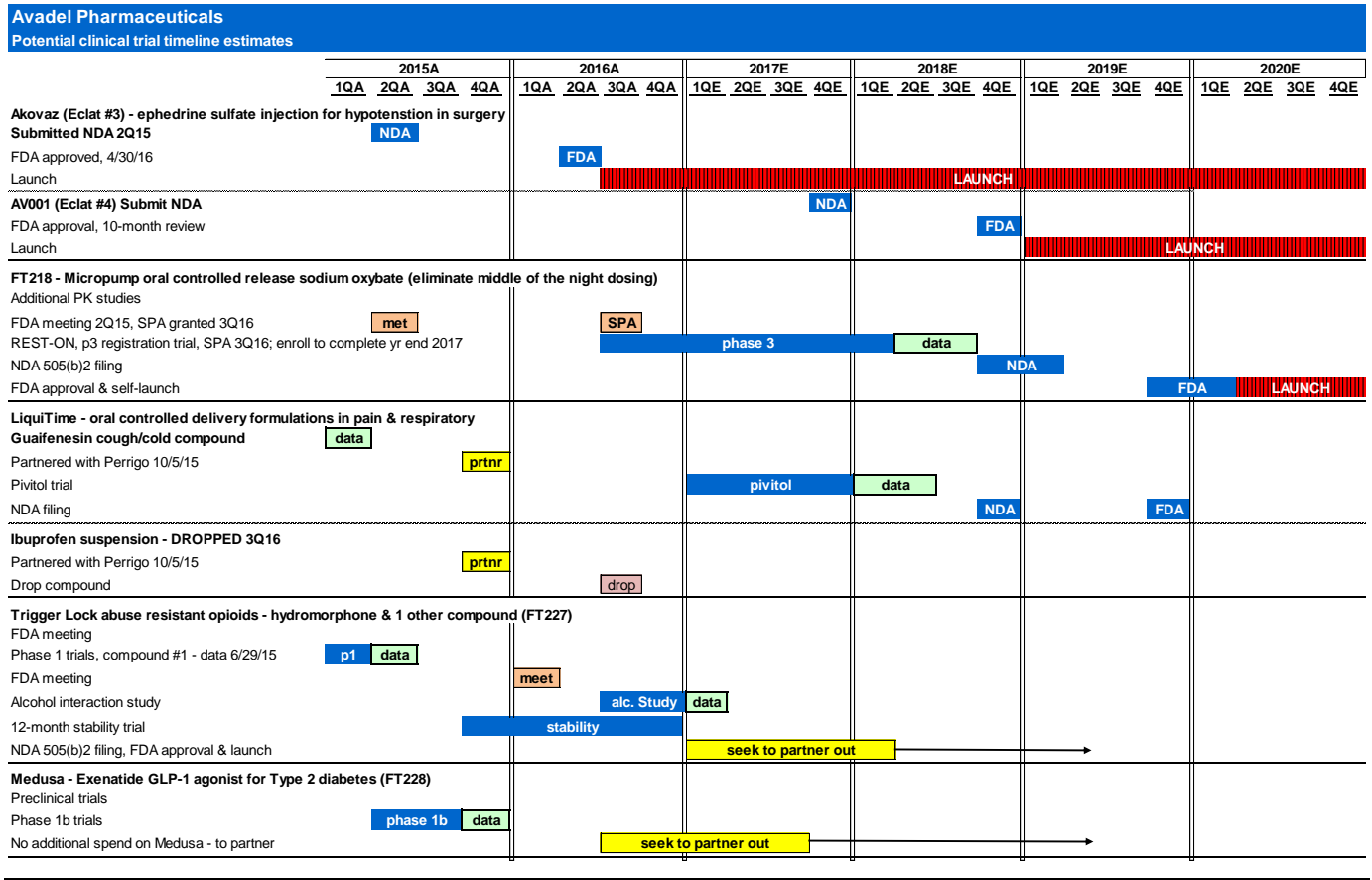
Source: Company reports & Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Sodium Oxybate (FT 218)	\$556,078	\$11.50
Eclat products	\$390,358	\$8.00
Cash (end of '17E) & tech value	\$278,249	\$5.50
	\$1,224,685	\$25.00
2017 fully diluted shares out		50,058

Source: Laidlaw & Company estimates.

Figure 3: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

Avadel Pharmaceuticals										
Quarterly income statement										
(\$000's except per share)	2015A				2015A Year	2016A				2016A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
Bloxivertz (neostigmine)	\$28,642	\$44,283	\$41,243	\$36,009	\$150,083	\$24,747	\$25,620	\$15,591	\$16,938	\$82,896
Vazculep (phenylephrine hci)	3,524	3,627	5,605	7,394	20,151	9,406	10,421	9,340	10,629	39,796
FSC products						1,200	2,124	841	3,534	7,699
Akovaz & Eclat #4							0	5,568	11,263	16,831
License & research						863				
Product sales & service	(38)	662	465	444	2,054					
1x, other, (licenses deals)	53	30	6	721	721		693	747	721	2,161
Total Revenues	\$32,726	\$49,795	\$47,338	\$44,568	\$173,009	\$36,216	\$38,858	\$32,087	\$43,085	\$150,246
Expenses										
Cost of Goods Sold	3,630	2,756	2,087	2,937	10,921	3,392	3,145	2,844	3,610	12,742
Gross Margin	29,096	47,039	45,251	41,631	162,088	32,824	35,713	29,243	39,475	137,504
R&D	6,022	7,204	7,221	5,161	25,608	5,388	7,604	8,143	13,476	34,611
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	11,290	12,740	10,688	44,179
Total Operating Expenses	10,485	13,077	11,789	11,969	47,320	14,849	18,894	20,883	24,164	78,790
Income (loss) from Ops	18,611	33,962	33,462	29,662	114,768	17,975	16,819	8,360	15,311	58,714
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,158)	(40,851)	(7,240)	(7,933)	(6,669)	(7,645)	(26,966)
Interest income/(exp)	657	312	75	65	2,651	200	127	226	(261)	672
FOREX gain/(loss)	2,264	480	192	(1,123)	1,500					0
1x milestones						0	0	0	0	0
Other income/(loss)	(852)	(2)	50	(32)		(175)	0		(463)	(3,636)
Pretax Income (Loss)	14,884	24,103	23,540	20,414	78,068	10,760	9,013	1,917	6,942	28,784
Income tax exp/(benefit)	10,473	10,242	12,018	9,687	35,167	9,210	9,998	5,416	6,875	31,373
Adj Net income/(loss)	4,411	13,861	11,522	10,727	42,901	1,550	(985)	(3,499)	67	(2,589)
EPS - adjusted	\$0.10	\$0.34	\$0.27	\$0.25	\$0.98	\$0.03	(\$0.02)	(\$0.08)	\$0.00	(\$0.06)
EPS as reported	\$0.27	(\$0.43)	(\$0.73)	\$1.68	\$0.93	(\$0.15)	(\$0.48)	(\$0.54)	(\$0.52)	(\$1.00)
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,241	41,241	42,808	41,248
Fully diluted shares (000)	42,879	40,748	42,875	43,430	43,619	47,838	47,837	47,741	49,308	48,181

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

Figure 5: Annual Income Statement

Avadel Pharmaceuticals						
Annual income statement						
(\$000's except per share)	2016A	2017E	2018E	2019E	2020E	Comments
Revenues						
Bloxivert (neostigmine)	\$82,896	\$56,835	\$49,999	\$51,220	\$50,639	WestWard entry 1Q16
Vazculep (phenylephrine hci)	39,796	43,500	42,000	37,500	32,500	Generics 2H16
FSC products	7,699	4,750	6,000	10,000	11,500	FSC underperforming
Akovaz & Eclat #4	16,831	79,500	87,500	123,000	115,000	AKRX & ENDP in market 1Q17
LiquiTime royalty			0	0	750	Licensed to Perrigo
Sodium Oxybate (Xyrem-like)					75,000	Eliminates middle night dosing
1x milestones (license deals)	2,161	200	200	0	200	
Total Revenues	\$150,246	\$184,785	\$185,699	\$221,720	\$285,589	2017 Guide: \$170M-\$200M
Expenses						
Cost of Goods Sold	12,742	16,545	16,514	19,055	23,083	
Gross Margin	137,504	168,240	169,185	202,665	262,507	
R&D	34,611	44,500	33,500	30,000	35,000	2017 Guide: \$40M-\$50M
SG&A	44,179	44,750	47,000	49,750	59,250	2017 Guide: flat from 2016
Total Operating Expenses	78,790	89,250	80,500	79,750	94,250	
Income (loss) from Ops	58,714	78,990	88,685	122,915	168,257	
Royalty payments - Eclat	(26,966)	(37,017)	(36,948)	(43,580)	(40,785)	Deerfield & Broadfin payments
Interest income	672	1,000	1,200	1,500	2,000	
Other income/(loss)	(3,636)	400	400	400	400	
Pretax Income (Loss)	28,784	43,373	53,337	81,235	129,872	Domicile structure drives tax rate
Taxes	31,373	33,500	27,750	31,500	27,000	2017 Guide: 70%-80% tax rate
Adj Net income/(loss)	(2,589)	9,873	25,587	49,735	102,872	
Non cash & 1x-items	38,687					
Net inc/(loss) as reported	(41,276)					
EPS - adjusted	(\$0.06)	\$0.20	\$0.50	\$0.95	\$1.95	2017 Guide: \$0.20-\$0.35
EPS as reported	(\$1.00)					+15% CAGR 2015-2020
Shares out (000)	41,248	43,558	44,758	45,510	46,112	
Fully diluted shares (000)	48,181	50,058	51,508	52,260	52,862	

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.

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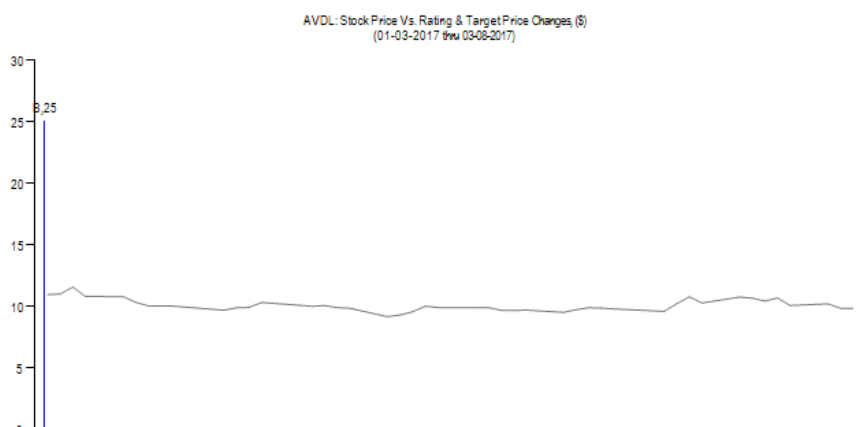
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
01/03/2...	Buy (B)	10.95

3 Year Price Change History

Date	Target Price (\$)	Closing Price (\$)
01/03/2...	25.00	10.95

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			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%

ADDITIONAL COMPANIES MENTIONED

Endo International (ENDP – Not Rated)
Akorn Inc. (AKRX – Not Rated)

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March 8, 2017

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