

## Avadel Pharmaceuticals (AVDL - \$11.57)

### Solid Guidance Highlights a Catalyst-filled 2017

Avadel (AVDL - formerly Flamel Technologies) yesterday set their 2017 guidance which was more or less in-line with Laidlaw and consensus estimates. Strong top line growth guidance (~30% Y-Y) gets muted by the continued nagging high tax rate (70%-80% guidance) which should start to ameliorate over 2018-2020 as the newer Eclat launches Akovaz and the recently announced AV001 (NDA filing 4Q17) contribute through AVDL's new Irish corporate structure. Positively AVDL's key pipeline compound FT218 (sodium oxybate formulation that eliminates middle-of-the-night dosing) remains on-track to complete enrollment by 4Q17 with data possible by mid-2018 (see trial details next page). FT218 would also flow through Ireland, helping bring down the high current tax rate to more reasonable 20%-25% level, in our opinion. With a significant number of catalysts through 2017 including potential upside from the Eclat portfolio and the completion of enrollment in the sodium oxybate Phase 3 trial; we are reiterating our Buy rating and our \$25 price target.

- **Now unlikely that Akovaz gets the whole market.** With the 483 lifted from AKRX's Decatur facility we now believe the FDA will not remove AKRX's ephedrine sulfate from the market. That said, AVDL's guidance anticipates two competitors in the market, with a potential third (ENDP) entering mid-2017 (low end of guidance) or late-2017 (high end of guidance).
- **Sodium oxybate enrolling in-line.** This is the main value driver at AVDL, in our opinion, and the trial remains on-track for a 4Q17 enrollment completion. This should mean a mid-2018 data read out as the dosing portion is only three months, and there remains a chance that the trial could enroll the trial faster than the one year guidance.
- **Maintain our BUY rating, \$25 price target.** Our price target is based on a sum-of-the-parts analysis with sodium oxybate at \$11.50/share, the Eclat portfolio at \$8/share, the pipeline, royalties & tech value worth \$13/share, and cash (end '17E) worth \$3/share.

*Healthcare/Biotechnology*

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

#### Trading Data:

Last Price (01/05/2017)	\$11.57
52-Week High (08/24/2016)	\$15.45
52-Week Low (03/01/2016)	\$7.56
Market Cap. (MM)	\$477.2
Shares Out. (MM)	41.2

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	0.01	0.08	0.10	0.11	0.30	38.6x
<b>FY-16E</b>	0.03A	(0.02)A	(0.08)A	(0.03)	(0.10)	NM
<b>FY-15A</b>	0.10	0.34	0.27	0.32	0.99	11.7x
<b>FY-14A</b>	(0.94)	(0.55)	(0.26)	(0.69)	(2.34)	NM

#### Analysts

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Source: Company data and Laidlaw & Company estimates

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Figure 1: FT218 Clinical Trial Details

Phase 3: REST-ON trial for FT218 (Micropump sodium oxybate)	
Aim	Determine whether FT218 is safe and effective for the treatment of excessive daytime sleepiness and cataplexy in subjects with narcolepsy.
Design	Double-blind, randomized, placebo controlled, crossover, two-arm multi-center study
Dosing	With active group all receiving 6, 7.5 and 9 grams
Endpoints	1) Longer Maintenance of Wakefulness Test (MWT) sleep latency (time frame:13 weeks); Improvement Clinical Global Impression (CGI) (time frame:13weeks); Fewer cataplexy attacks as recorded by Sleep and Symptom Daily Diary (time frame: 13 weeks.) 2)Fewer (PSG) transitions from N1, N2, N3, and REM sleep to wake sleep and from N2, N3, and REM sleep to N1 (time frame:13 weeks).
Patients	n=264 randomized across ~60 centers in USA, Canada, Europe
Results	Enrollment targeting 4Q17 completion, data expected mid-2018

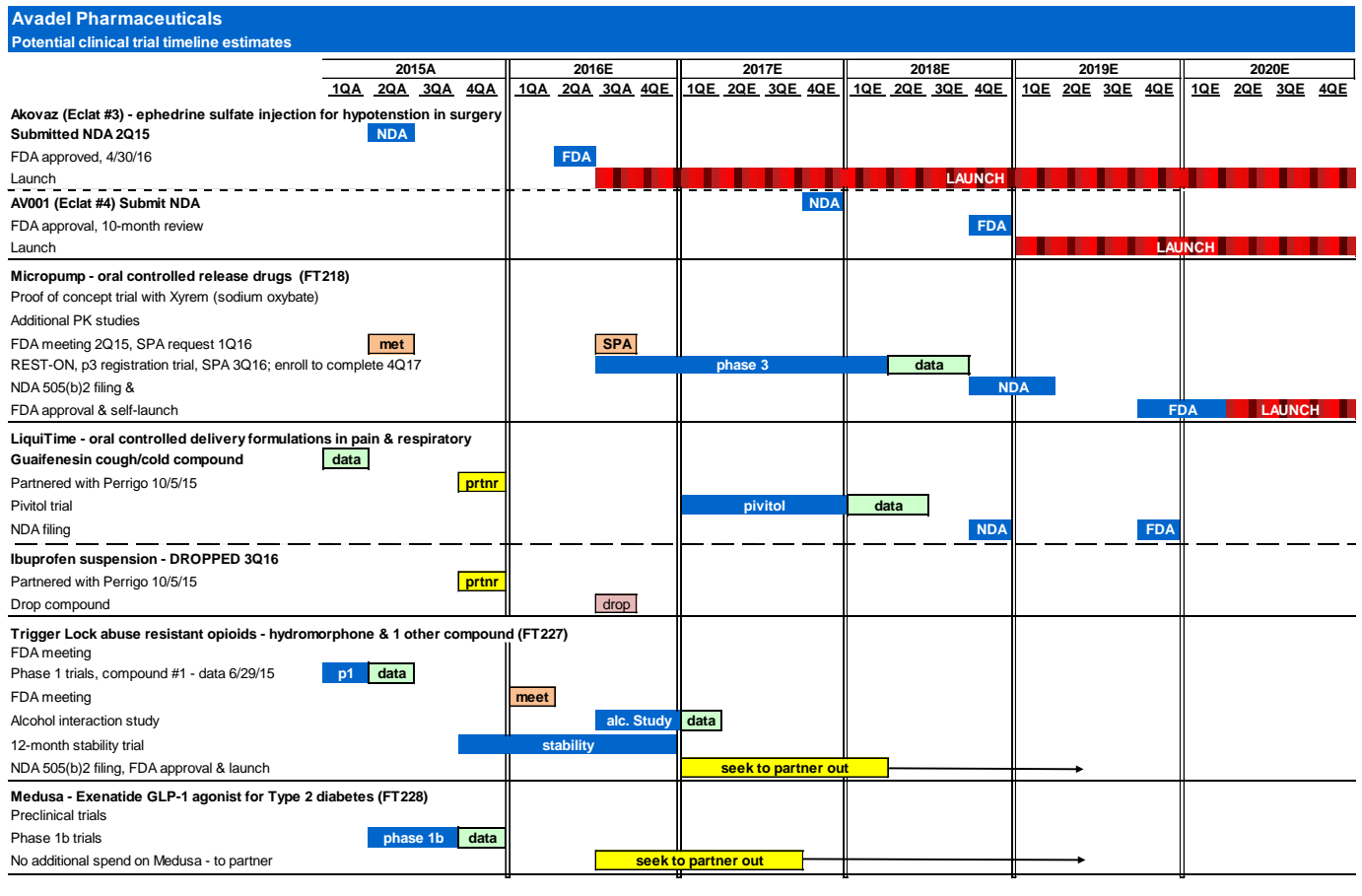
Source: Company reports; Laidlaw & Company estimates.

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	\$425,314	\$8.00
Cash (end of '17E) & tech value	\$312,536	\$5.50
	\$1,293,929	<b>\$25.00</b>
2017 fully diluted shares out		48,791

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	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
<b>Revenues</b>										
Bloxivertz (neostigmine)	\$28,642	\$44,283	\$41,243	\$34,860	\$149,028	\$24,747	\$25,620	\$15,591	\$14,116	\$80,074
Vazculep (phenylephrine hci)	3,524	3,627	5,605	7,394	20,151	9,406	10,421	9,340	9,750	38,917
FSC products						1,200	2,124	841	900	5,065
Akovaz & Eclat #4						863	0	5,568	8,500	14,068
License & research										
Product sales & service	(38)	662	465	393	2,054					
1x, other, (licenses deals)	53	30	6	721	721		693	747	50	1,490
<b>Total Revenues</b>	<b>\$32,726</b>	<b>\$49,795</b>	<b>\$47,338</b>	<b>\$43,368</b>	<b>\$173,209</b>	<b>\$36,216</b>	<b>\$38,858</b>	<b>\$32,087</b>	<b>\$33,316</b>	<b>\$140,477</b>
<b>Expenses</b>										
Cost of Goods Sold	3,630	2,756	2,087	2,448	10,921	3,392	3,145	2,844	3,010	12,391
<b>Gross Margin</b>	<b>29,096</b>	<b>47,039</b>	<b>45,251</b>	<b>40,920</b>	<b>162,288</b>	<b>32,824</b>	<b>35,713</b>	<b>29,243</b>	<b>30,306</b>	<b>128,086</b>
R&D	6,022	7,204	7,221	5,161	25,608	5,388	7,604	8,143	9,500	30,635
SG&A	4,463	5,873	4,568	6,808	21,712	9,461	11,290	12,740	11,188	44,679
<b>Total Operating Expenses</b>	<b>10,485</b>	<b>13,077</b>	<b>11,789</b>	<b>11,969</b>	<b>47,320</b>	<b>14,849</b>	<b>18,894</b>	<b>20,883</b>	<b>20,688</b>	<b>75,314</b>
<b>Income (loss) from Ops</b>	<b>18,611</b>	<b>33,962</b>	<b>33,462</b>	<b>28,951</b>	<b>114,968</b>	<b>17,975</b>	<b>16,819</b>	<b>8,360</b>	<b>9,619</b>	<b>52,773</b>
Royalty payments - Eclat	(5,796)	(10,649)	(10,239)	(8,016)	(40,851)	(7,240)	(7,933)	(6,669)	(6,662)	(28,504)
Interest income/(exp)	657	312	75	934	2,651	200	127	226	200	753
FOREX gain/(loss)	2,264	480	192	1,651	1,500					0
1x milestones						0	0	0	0	0
Other income/(loss)	(852)	(2)	50	(32)		(175)	0		100	(75)
<b>Pretax Income (Loss)</b>	<b>14,884</b>	<b>24,103</b>	<b>23,540</b>	<b>23,488</b>	<b>78,268</b>	<b>10,760</b>	<b>9,013</b>	<b>1,917</b>	<b>3,256</b>	<b>24,946</b>
Income tax exp/(benefit)	10,473	10,242	12,018	9,613	35,167	9,210	9,998	5,416	4,500	29,124
<b>Adj Net income/(loss)</b>	<b>4,411</b>	<b>13,861</b>	<b>11,522</b>	<b>13,875</b>	<b>43,101</b>	<b>1,550</b>	<b>(985)</b>	<b>(3,499)</b>	<b>(1,244)</b>	<b>(4,178)</b>
<b>EPS - adjusted</b>	<b>\$0.10</b>	<b>\$0.34</b>	<b>\$0.27</b>	<b>\$0.32</b>	<b>\$0.99</b>	<b>\$0.03</b>	<b>(\$0.02)</b>	<b>(\$0.08)</b>	<b>(\$0.03)</b>	<b>(\$0.10)</b>
<b>EPS as reported</b>	<b>\$0.27</b>	<b>(\$0.43)</b>	<b>(\$0.73)</b>	<b>\$1.75</b>	<b>\$0.93</b>	<b>(\$0.15)</b>	<b>(\$0.48)</b>	<b>(\$0.54)</b>	<b>(\$0.54)</b>	<b>(\$1.85)</b>
Shares out (000)	40,207	40,353	40,625	41,125	40,580	41,241	41,241	41,241	41,541	41,316
Fully diluted shares (000)	42,879	40,748	42,875	43,430	43,619	47,838	47,837	47,741	48,041	47,864

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

Figure 5: Annual Income Statement

Avadel Pharmaceuticals							Comments
Annual income statement							
( '\$000's except per share )	2015A	2016E	2017E	2018E	2019E	2020E	
<b>Revenues</b>							
Bloxivert ( neostigmine )	\$149,028	\$80,074	\$52,810	\$49,999	\$51,220	\$50,639	WestWard entry 1Q16
Vazculep ( phenylephrine hci )	20,151	38,917	43,500	42,000	37,500	32,500	Generics 2H16
FSC products		5,065	4,750	6,000	10,000	11,500	FSC underperforming
Akovaz & Eclat #4		14,068	79,500	87,500	123,000	115,000	Akovaz ~\$350M mkt (7M vials)
LiquiTime royalty				0	0	750	Licensed to Perrigo
Sodium Oxybate ( Xyrem-like )						75,000	Eliminates middle night dosing
1x milestones ( license deals )	721	1,490	200	200	0	200	
<b>Total Revenues</b>	<b>\$173,209</b>	<b>\$140,477</b>	<b>\$180,760</b>	<b>\$185,699</b>	<b>\$221,720</b>	<b>\$285,589</b>	<b>2016 Guide: high end \$133M-\$143M</b> <b>2017 Guide: \$170M-\$200M</b>
<b>Expenses</b>							
Cost of Goods Sold	10,921	12,391	16,174	16,514	19,055	23,083	
<b>Gross Margin</b>	<b>162,288</b>	<b>128,086</b>	<b>164,585</b>	<b>169,185</b>	<b>202,665</b>	<b>262,507</b>	
R&D	25,608	30,635	36,500	33,750	30,000	32,500	2016 Guide: \$30M-\$35M
SG&A	21,712	44,679	45,250	47,000	48,250	58,750	2016 Guide: ~\$40M
<b>Total Operating Expenses</b>	<b>47,320</b>	<b>75,314</b>	<b>81,750</b>	<b>80,750</b>	<b>78,250</b>	<b>91,250</b>	
<b>Income (loss) from Ops</b>	<b>114,968</b>	<b>52,773</b>	<b>82,835</b>	<b>88,435</b>	<b>124,415</b>	<b>171,257</b>	
Royalty payments - Eclat	(40,851)	(28,504)	(36,189)	(36,948)	(43,580)	(40,785)	Deerfield & Broadfin payments
Interest income	2,651	753	1,000	1,200	1,500	2,000	
FOREX gain/(loss)	1,500	0	0	0	0	0	non-cash item
Other income/(loss)	0	(75)	400	400	400	400	
<b>Pretax Income (Loss)</b>	<b>78,268</b>	<b>24,946</b>	<b>48,047</b>	<b>53,087</b>	<b>82,735</b>	<b>132,872</b>	Domicile structure drives tax rate
Taxes	35,167	29,124	33,500	27,750	31,500	27,000	2017 Guide: 70%-80% rate
<b>Adj Net income/(loss)</b>	<b>43,101</b>	<b>(4,178)</b>	<b>14,547</b>	<b>25,337</b>	<b>51,235</b>	<b>105,872</b>	
Non cash & 1x-items	2,442	72,445					
<b>Net inc/(loss) as reported</b>	<b>40,659</b>	<b>(76,623)</b>					
<b>EPS - adjusted</b>	<b>\$0.99</b>	<b>(\$0.10)</b>	<b>\$0.30</b>	<b>\$0.50</b>	<b>\$1.00</b>	<b>\$2.05</b>	<b>2017 Guide: \$0.20-\$0.35</b>
<b>EPS as reported</b>	<b>\$0.93</b>	<b>(\$1.85)</b>					<b>+15% CAGR 2015-2020</b>
Shares out (000)	40,580	41,316	42,291	43,491	44,243	44,845	
Fully diluted shares (000)	43,619	47,864	48,791	50,241	50,993	51,595	
<b>Margin &amp; expense analysis</b>							
COGS	6%	9%	9%	9%	9%	8%	
R&D	15%	22%	20%	18%	14%	11%	
SG&A	13%	32%	25%	25%	22%	21%	
Operating margin	66%	38%	46%	48%	56%	60%	Normalize w/Akovaz & Sod. Oxybate
Taxes	45%	117%	70%	52%	38%	20%	2017 Guide: 70%-80% rate
Net margin	25%	-3%	8%	14%	23%	37%	
<b>Year-over-year change</b>							
Net revenue	536%	-19%	29%	3%	19%	29%	
COGS	89%	13%	31%	2%	15%	21%	
Gross margin	656%	-21%	28%	3%	20%	30%	
R&D	-3%	20%	19%	-8%	-11%	8%	
SG&A	32%	106%	1%	4%	3%	22%	
Operating income	-634%	-54%	57%	7%	41%	38%	
Net income	-299%	-110%	-448%	74%	102%	107%	

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

## Major risks

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**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.

## DISCLOSURES:

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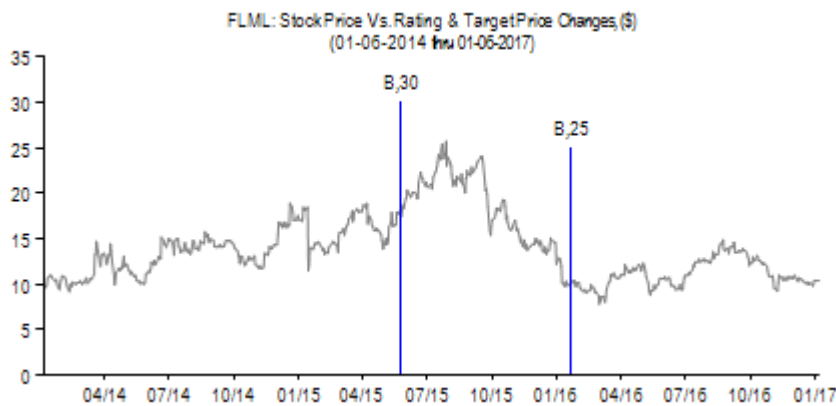
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**Additional information available upon request.**

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#### Rating and Price Target Change History



Source: Laidlaw & Company

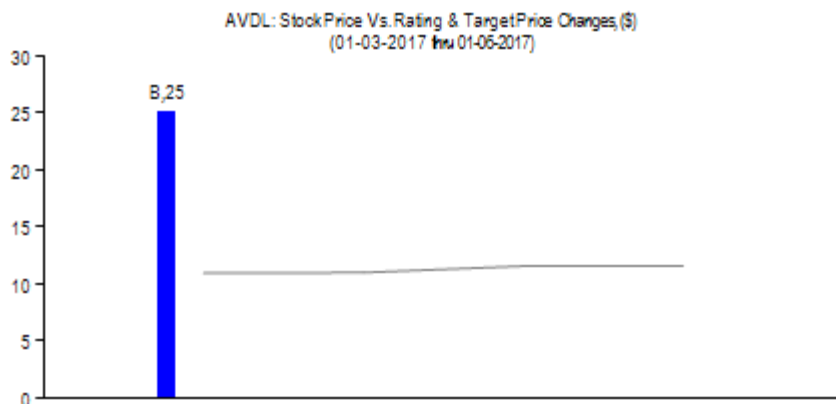
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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
05/26/2015	Buy (B)	17.48

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
05/26/2015	30.00	17.48
01/21/2016	25.00	10.25



Source: Laidlaw & Company

Created by: Blue-Compass.net

#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
01/03/2017	Buy (B)	10.95

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
01/03/2017	25.00	10.95

Note: Company name changed to Avadel Pharmaceuticals on 01/03/2017

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%

January 6, 2017

<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	58.54%	26.83%	2.44%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.88%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

**ADDITIONAL COMPANIES MENTIONED**

Akorn, Inc. (AKRX – Not Rated)

Endo International (ENDP – Not Rated)

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