

Avadel Pharmaceuticals (AVDL - \$8.81)

Another Strong Financial Quarter, Slight Sodium Oxybate Enrollment Delay Weighs on Stock

AVDL recently reported their 2Q17, beating once again with a strong financial quarter (top and bottom line beats). Total adjusted sales came in at \$47.4M vs. our estimated \$42.4M and consensus \$44.8M as Bloxiverz continued to show resilience amidst increased competition, posting revenues of \$13.7M vs. our estimated \$10.4M. We do, however, anticipate a softer 2H17 due to increased competition and anticipate sales of \$42M for FY17. Due to continued pricing pressure in the ephedrine market as well as increased competition in the neostigmine market, AVDL revised their top line FY17 guidance to \$165M-\$175M vs. prior \$170M-\$185M. In addition to the top line beat, lower than anticipated R&D expenses of \$6.8M vs. our anticipated \$12M led to an adjusted bottom line beat of \$0.17 vs. our estimated \$0.01. Management announced that enrollment of FT-218 (sodium oxybate, Xyrem-like formulation that eliminates the middle-of-the-night dosing) was slower than expected due to a recent change in internal processes of the release of Schedule 1 site licenses by the DEA. Although delayed, we are encouraged by the initiatives taken by AVDL to speed up the process, as well as the ultimate lack of timeline slippage (data still mid-2018). Aligned with the progress of REST-ON, we also see as a real positive AVDL's new R&D guidance of \$30M-\$40M vs. prior \$40M-\$50M as well as their reiteration of diluted adjusted EPS of \$0.30-\$0.45 for FY17. As AVDL posts another strong financial quarter and ultimate timing of REST-ON remains on track, we view the company as undervalued and reiterate our Buy rating and \$25 price target.

- **Top-line and bottom-line beat, Bloxiverz resilient and lower R&D.** While competition grows in the neostigmine market, we see as a real positive Bloxiverz's ability to maintain market with 2Q17 sales of \$13.7M vs. 1Q17 of \$13.9M. Although REST-ON trial is slightly delayed, we are encouraged by lower R&D expense guidance of \$30M-\$40M vs. prior \$40M-\$50M.
- **REST-ON enrollment hiccup, ultimate data read-out and NDA filing still on track.** Although REST-ON must deal with slower activation of certain US clinical sites, we are encouraged by the AVDL's confidence in a mid-2018 data read-out and end of year NDA filing.
- **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/share, the Eclat portfolio at \$8/share, and cash (end '18) and tech value at \$6/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	(0.03)	(0.02)	0.01	(0.02)	(0.06)	NA
FY-17E	0.24A	0.17A	(0.02)	(0.04)	0.34	25.9
FY-16A	0.03	(0.02)	(0.08)	0.02	(0.06)	NA
FY-15A	0.27	0.34	0.27	0.25	0.98	9.0

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **AVDL**
Rating: **Buy**
Price Target: **\$25**

Trading Data:

Last Price (08/08/2017)	\$8.81
52-Week High (08/24/16)	\$15.45
52-Week Low (05/10/2017)	\$8.75
Market Cap. (MM)	\$364.6
Shares Out. (MM)	41.4

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Figure 1: Variance analysis

Avadel Pharmaceuticals					
Quarterly variance analysis					
(\$000 except per share)	2Q16A	2Q17A	2Q17E	Variance	% Y/Y
Bloxiverz (neostigmine)	\$25,620	\$13,719	\$10,379	\$3,340	-46.5%
Vazculep		10,154	10,000	154	NM
Akovaz		20,912	20,000	912	NM
FSC products		2,320	2,000	320	NM
1x milestones (license deals)	693	306	0	306	-55.8%
Total Revenue	\$38,858	\$47,411	\$42,379	\$5,032	22.0%
COGS	3,145	4,561	3,715	846	45.0%
Gross Profit	35,713	42,850	38,664	4,186	20.0%
SG&A Expense	11,290	12,429	11,188	1,242	10.1%
R&D Expense	7,604	6,792	12,000	(5,208)	-10.7%
Operating Inc (loss)	16,819	23,629	15,477	8,152	40%
Interest inc (exp)	127	264	250	14	107.9%
Other inc (exp)	0	(1,166)	100	(1,266)	NM
Pretax Income	9,013	14,211	7,515	6,696	57.7%
Income Taxes/(benefit)	9,998	6,046	7,000	(954)	-39.5%
Adj Net income/(loss)	(985)	8,165	515	7,650	NM
1x & non cash exp	18,973	20,762	0	20,762	9.4%
NI/(loss) as reported	(19,958)	(12,597)	0	(12,597)	NM
Shares out (000)	41,241	42,487	43,110	(623)	3.0%
Fully diluted shares (000)	47,837	48,987	49,610	(623)	2.4%
Adj EPS ex-1x & non cash	(\$0.02)	\$0.17	\$0.01	\$0.16	NM
EPS as reported	(\$0.48)	(\$0.30)			

Source: Company reports & Laidlaw & Company estimates

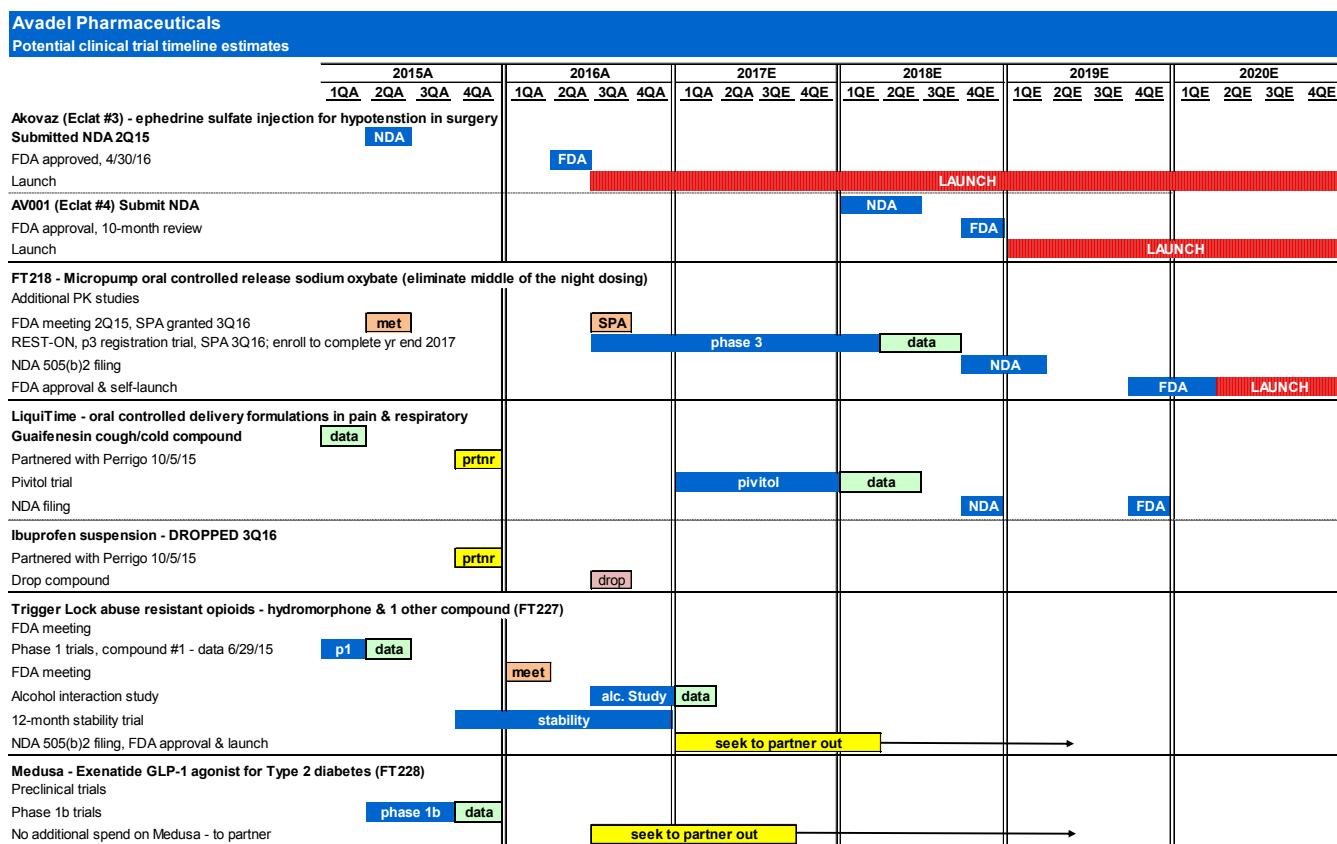
Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Sodium Oxybate (FT 218)	\$566,348	\$11.00
Eclat products	\$398,296	\$8.00
Cash (end of '18E) & tech value	\$312,192	\$6.00
	\$1,276,836	\$25.00
2018 fully diluted shares out		50,587

Source: Laidlaw & Company estimates.

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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)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
Bloxivierz (neostigmine)	\$24,747	\$25,620	\$15,591	\$16,938	\$82,896	\$13,902	\$13,719	\$7,341	\$6,729	\$41,691
Vazculep (phenylephrine hci)	9,406	10,421	9,340	10,629	39,796	10,179	10,154	10,000	10,000	40,333
FSC products	1,200	2,124	841	3,534	7,699	2,038	2,320	2,150	2,150	8,658
Akovaz & Eclat #4		0	5,568	11,263	16,831	25,638	20,912	18,000	17,500	82,050
License & research	863					750				
Product sales & service 1x, other, (licenses deals)		693	747	721	2,161		306	0	0	306
Total Revenues	\$36,216	\$38,858	\$32,087	\$43,085	\$150,246	\$52,507	\$47,411	\$37,491	\$36,379	\$173,038
Expenses										
Cost of Goods Sold	3,392	3,145	2,844	2,591	12,742	3,856	4,561	3,251	3,149	14,817
Gross Margin	32,824	35,713	29,243	40,494	137,504	48,651	42,850	34,240	33,230	158,971
R&D	5,388	7,604	8,143	13,476	34,611	7,206	6,792	10,000	10,000	33,998
SG&A	9,461	11,290	12,740	10,688	44,179	11,812	12,429	11,188	11,188	46,616
Total Operating Expenses	14,849	18,894	20,883	24,164	78,790	19,018	19,221	21,188	21,188	80,614
Income (loss) from Ops	17,975	16,819	8,360	16,330	58,714	29,633	23,629	13,052	12,043	78,357
Royalty payments - Eclat	(7,240)	(7,933)	(6,669)	(7,645)	(26,966)	(9,616)	(8,516)	(7,275)	(7,046)	(32,452)
Interest income/(exp)	200	127	226	(261)	672	266	264	250	250	1,030
FOREX gain/(loss)					0					0
1x milestones	0	0	0	0	0	0	0	0	0	0
Other income/(loss)	(175)	0		(463)	(3,636)	(1,299)	(1,166)	100	100	(2,265)
Pretax Income (Loss)	10,760	9,013	1,917	7,961	28,784	18,984	14,211	6,127	5,347	44,669
Income tax exp/(benefit)	9,210	9,998	5,416	6,875	31,373	7,692	6,046	7,000	7,250	27,988
Adj Net income/(loss)	1,550	(985)	(3,499)	1,086	(2,589)	11,292	8,165	(873)	(1,903)	16,681
EPS - adjusted	\$0.03	(\$0.02)	(\$0.08)	\$0.02	(\$0.06)	\$0.24	\$0.17	(\$0.02)	(\$0.04)	\$0.34
EPS as reported	(\$0.15)	(\$0.48)	(\$0.54)	(\$0.52)	(\$1.00)	(\$0.07)	(\$0.30)			
Shares out (000)	41,241	41,241	41,241	42,808	41,248	42,810	42,487	42,787	43,087	42,793
Fully diluted shares (000)	47,838	47,837	47,741	49,308	48,181	47,709	48,987	49,287	49,587	48,893

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						
Bloxivertz (neostigmine)	\$82,896	\$41,691	\$25,102	\$25,715	\$25,423	WestWard entry 1Q16
Vazculep (phenylephrine hci)	39,796	40,333	40,000	37,500	32,500	Generics 2H16
FSC products	7,699	8,658	10,000	11,500	12,000	FSC underperforming
Akovaz & Eclat #4	16,831	82,050	68,500	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	306	0	0	0	
Total Revenues	\$150,246	\$173,038	\$143,602	\$197,715	\$260,673	2017 Guide: \$170M-\$185M
Expenses						
Cost of Goods Sold	12,742	14,817	12,291	16,759	20,813	
Gross Margin	137,504	158,971	131,310	180,955	239,860	
R&D	34,611	33,998	33,500	30,000	35,000	2017 Guide: \$40M-\$50M
SG&A	44,179	46,616	47,000	49,750	59,250	2017 Guide: flat from 2016
Total Operating Expenses	78,790	80,614	80,500	79,750	94,250	
Income (loss) from Ops	58,714	78,357	50,810	101,205	145,610	
Royalty payments - Eclat	(26,966)	(32,452)	(27,501)	(38,330)	(35,595)	Deerfield & Broadfin payments
Interest income	672	1,030	1,200	1,500	2,000	
Other income/(loss)	(3,636)	(2,265)	400	400	400	
Pretax Income (Loss)	28,784	44,669	24,910	64,775	112,416	Domicile structure drives tax rate
Taxes	31,373	27,988	27,350	31,500	27,000	2017 Guide: 60%-70% tax rate
Adj Net income/(loss)	(2,589)	16,681	(2,440)	33,275	85,416	
Non cash & 1x-items	38,687					
Net inc/(loss) as reported	(41,276)					
EPS - adjusted	(\$0.06)	\$0.34	(\$0.06)	\$0.65	\$1.64	2017 Guide: \$0.30-\$0.45
EPS as reported	(\$1.00)					+15% CAGR 2015-2020
Shares out (000)	41,248	42,793	43,837	44,589	45,191	
Fully diluted shares (000)	48,181	48,893	50,587	51,339	51,941	

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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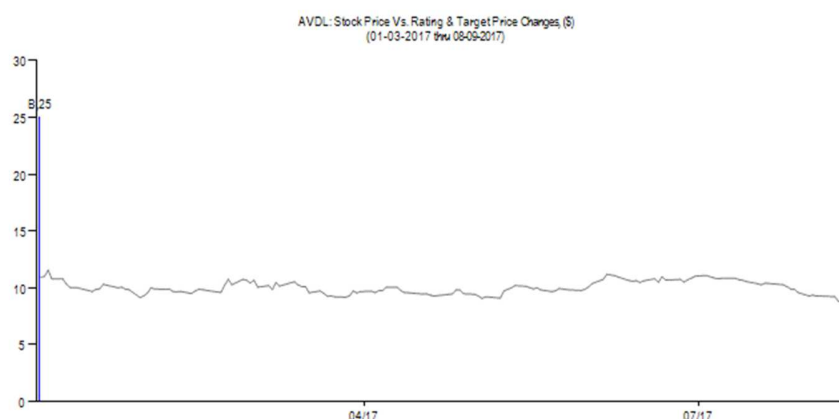
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
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

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.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	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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