

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY: Fast Track in Rett Syndrome

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The FDA has granted Fast Track Designation for the development of ANAVEX2-73 in Rett Syndrome. Given the orphan nature of this disease, and now Fast Track designation, good data could drive an expedited approval.

Investment Highlights

As a Reminder, The Preliminary Data Looks Good. Anavex late last year announced preliminary clinical data from the ANAVEX2-73-RS-001 study on the first six-patient cohort. Patients are continuing participation in the ANAVEX2-73-RS-001 open label extension study. Both efficacy endpoints, the Rett Syndrome Behavior Questionnaire (RSBQ) and the Clinical Global Impression - Improvement (CGI-I), showed significant improvement with respect to baseline after 7 weeks of treatment.

- The RSBQ Total average scores improved from 50 to 34 points (2-tailed Wilcoxon signed rank test, $p = 0.027$) and the CGI-I scores were positively correlated with RSBQ Total scores at 7 weeks (2-tailed Spearman's $\rho = 0.956$, $p = 0.003$).
- Plasma levels of the biomarker Glutamate also decreased significantly (Week 0 vs. Week 7; 2-tailed Wilcoxon signed rank test, $p = 0.046$) and levels of Glutamate at Week 7 were directly correlated with CGI-I scores at Week 7 (2-tailed Spearman's $\rho = 0.837$, $p = 0.038$) with greater decreases in Glutamate associated with greater improvement in these efficacy scores. Glutamate is the main excitatory neurotransmitter in the brain and is known to be higher in patients with Rett syndrome compared to healthy subjects in the brain.
- Additionally, the magnitude of GABA change was inversely correlated with the magnitude of decrease in RSBQ Total scores (2-tailed Spearman's $\rho = -0.812$, $p = 0.050$) and GABA changes demonstrated an inverse correlation of the magnitude of Glutamate changes (2-tailed Spearman's $\rho = -0.829$, $p = 0.042$). GABA is the main inhibitory neurotransmitter in the brain, known to be deficient in animal models of Rett syndrome.
- An independent DSMB review determined that ANAVEX2-73 (blarcamesine) was well tolerated, with no SAEs reported and with all patients completing the study. Therefore, the DSMB issued a positive recommendation for the continuation of the Phase 2 Rett syndrome study without any modifications. Detailed results are to be presented at the 6th European Rett Syndrome Conference in Tampere, Finland, September 27-28.

Valuation: We model ANAVEX2-73 in the Alzheimer's, Rett Syndrome, and Parkinson's Disease Dementia markets. We use just a 25% probability of success in our therapeutic models and a 30% discount rate in our FCF, discounted EPS, and sum-of-the-parts models to arrive at a \$16.00 price target.

Risk to our thesis, include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these risks in the risk section of this report.

Current Price **\$3.28**
 Price Target **\$16.00**

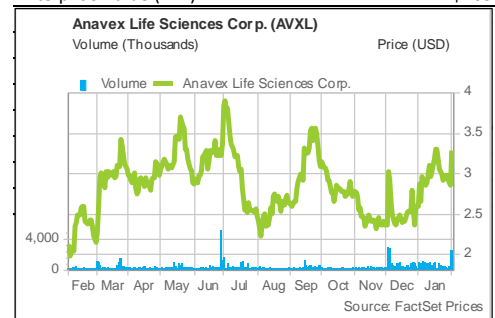
Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 31,158	\$ 32,116	\$ 33,342
1Q March	\$ 7,474	\$ 7,982	\$ 8,288
2Q June	\$ 8,140	\$ 8,013	\$ 8,320
3Q September	\$ 7,757	\$ 8,044	\$ 8,351
4Q December	\$ 7,787	\$ 8,076	\$ 8,383
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.65)	\$ (0.65)	\$ (0.33)
1Q March	\$ (0.16)	\$ (0.16)	\$ (0.08)
2Q June	\$ (0.17)	\$ (0.16)	\$ (0.08)
3Q September	\$ (0.16)	\$ (0.16)	\$ (0.08)
4Q December	\$ (0.16)	\$ (0.16)	\$ (0.08)

EBITDA/Share

EV/EBITDA (x)

Stock Data

52-Week Range	\$1.96	-	\$4.09
Shares Outstanding (mil.)	56.1		
Market Capitalization (mil.)	\$184		
Enterprise Value (mil.)	\$165		



Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, and as such, our share count is based on a fully diluted out year basis. Given the early nature of the company and its dependence on clinical trial outcomes in the CNS space, we apply just a 25% probability of success in our models. On top of this, we also add a 30% risk rate in our free cash flow to the firm (FCFF), our discounted EPS (dEPS) and sum-of-the-parts (SOP) models. We equal weight and average these metrics and then round to the nearest whole number to derive our price target.

Exhibit 1. FCFF Model

Average \$		16											
Price Target \$		16											
Year		2019											
DCF Valuation Using FCF (min):													
units ('000)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(17,381)	(31,184)	(32,144)	(26,730)	(32,884)	90,540	915,075	1,344,434	1,458,624	1,673,831	1,546,364	1,781,864	1,974,188
Tax Rate	0%	0%	0%	0%	5%	10%	18%	18%	30%	31%	31%	39%	39%
EBIT(1-t)	(17,381)	(31,184)	(32,144)	(26,730)	(31,239)	81,486	750,362	1,102,436	1,021,037	1,154,943	1,066,991	1,086,937	1,204,254
CapEx	-	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC (ex cash)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
FCF	(17,381)	(31,184)	(32,144)	(26,730)	(31,239)	81,486	750,362	1,102,436	1,021,037	1,154,943	1,066,991	1,086,937	1,204,254
PV of FCF	(22,595)	(31,184)	(24,726)	(15,817)	(14,219)	28,531	202,094	228,399	162,719	141,584	100,617	78,844	67,196
Discount Rate	30%												
Long Term Growth Rate	1%												
Terminal Cash Flow	4,194,127.66												
Terminal Value YE2030	234,026												
NPV	1,158,063												
NPV-Debt	-												
Projected Shares out (thousands)	73,395											2030E	
NPV Per Share	\$ 15.78												

Source: Dawson James

Exhibit 21. Discounted EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 16.40
NPV	\$ 13.73

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
Earnings Multiple	13.73	5%	10%	15%	20%	25%	30%
1		\$9.59	\$5.75	\$3.53	\$2.21	\$1.41	\$0.92
5		\$47.95	\$28.75	\$17.63	\$11.04	\$7.05	\$4.58
10		\$95.91	\$57.49	\$35.26	\$22.08	\$14.09	\$9.15
15		\$143.86	\$86.24	\$52.89	\$33.11	\$21.14	\$13.73
20		\$191.81	\$114.98	\$70.51	\$44.15	\$28.18	\$18.31
25		\$239.76	\$143.73	\$88.14	\$55.19	\$35.23	\$22.88
30		\$287.72	\$172.48	\$105.77	\$66.23	\$42.27	\$27.46
35		\$335.67	\$201.22	\$123.40	\$77.27	\$49.32	\$32.03

Source: Dawson James

Exhibit 3. Sum of the Parts Model

Anavex Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM\$	Term Val
AVXL 2-73 U.S. AD	1%	30%	5	50%	\$2,697	\$9,298.91
NPV						\$4.27
AVXL 2-73 ROW AD	1%	30%	5	50%	\$3,214	\$11,081.54
NPV						\$5.08
AVXL 2-73 Rett's Syndrome	1%	30%	3	50%	\$1,905	\$6,568.76
NPV						\$5.09
AVXL 2-73 PDD	1%	30%	3	50%	\$961	\$3,315.39
NPV						\$2.57
Net Margin						25%
MM Shrs OS (2030E)						73

Source: Dawson James

Exhibit 4. Income Statement

Anavex Life Sciences Corp																
Anavex: YE Sept 30	1Q19A	2Q19A	3Q19A	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.						-	-	-		191,826	338,892	498,171	666,126	533,641	622,073	674,171
Anavex2-73 AD ROW										555,169	735,599	617,903	642,619	551,582	675,136	803,412
Anavex2-73 Rett's Syndrome							6,642	67,744	207,296	317,162	395,395	439,967	448,767	457,742	466,897	476,235
Anavex2-73 Parkinson's Dementia PDD										14,229	58,055	88,824	120,801	184,826	219,943	240,366
Total Product Revenues	-	-	-	-	-	-	6,642	67,744	207,296	1,078,386	1,527,942	1,644,866	1,878,313	1,727,790	1,984,048	2,194,184
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)	-	-	-	-	-	-	6,642	67,744	207,296	1,078,386	1,527,942	1,644,866	1,878,313	1,727,790	1,984,048	2,194,184
Expenses																
Cost of Goods Sold (10%)						-	-	-		74,699	107,449	111,607	130,875	108,522	129,721	147,758
Accounting and Audit Fees					2	2	2	2	2	2	2	2	2	2	2	2
Amortization and depreciation	0	0	0	0	2	2	2	2	2	2	2	2	2	2	2	2
Bank charges and interest																
Consulting Fees																
Insurance																
Investor relations																
Legal fees																
Management fees																
Office and miscellaneous expense																
Registration and filing fees																
Rent and administration																
Research and Development	5,712	6,079	5,758	5,788	23,337	23,441	23,913	19,419	15,769	12,806	10,399	8,445	6,858	5,569	4,522	3,672
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	1,761	2,061	1,389	1,377	6,588	7,247	7,972	80,000	100,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	7,474	8,140	7,148	7,165	29,926	30,689	31,886	99,421	115,771	162,507	182,850	185,704	204,040	181,062	201,884	219,748
Oper. Inc. (Loss)	(7,474)	(8,140)	(7,148)	(7,165)	(29,926)	(30,689)	(25,245)	(31,677)	91,525	915,879	1,345,092	1,459,163	1,674,273	1,546,728	1,782,164	1,974,436
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1
Other income (expense)	75	75	75		224											
Research and Development incentive																
Interest and financing fees	79	51	35		165	(28)	(30)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Accretion of debt discount																
Change in fair value of derivative liability																
Debt conversion expense																
Loss on settlement of accounts payable				37												
Loss on extinguishment of debt																
Foreign exchange gain (loss)	(5)	54	(45)													
Financing related charges and adjustments																
Other non-operating income			(8)	-												
Non-operating Income (expense)	149	180	94	-	389	(28)	(30)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net																
Financial Expenses, Net																
Pretax Income	(7,325)	(7,960)	(7,054)	(7,165)	(29,537)	(30,717)	(25,275)	(31,702)	91,500	915,854	1,345,067	1,459,138	1,674,248	1,546,703	1,782,139	1,974,411
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(9)	(48)	(19)	-	-	-	(9,352)	(1,585)	9,150	164,854	390,069	481,515	602,729	603,214	695,034	770,020
Tax Rate	0	0	0	0	-	-	-	5%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(7,333)	(8,008)	(7,073)	(7,165)	(29,537)	(30,717)	(15,923)	(30,117)	82,350	751,001	954,998	977,622	1,071,519	943,489	1,087,105	1,204,391
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.40	0.70	0.63	0.59	0.57	0.55	0.55	0.55
GAAP-EPS	(0.16)	(0.17)	(0.15)	(0.15)	(0.63)	(0.62)	(0.31)	(0.56)	1.48	12.97	15.85	15.59	16.42	13.89	15.38	16.38
Non GAAP EPS (dil)	(0.16)	(0.17)	(0.15)	(0.15)	(0.63)	(0.62)	(0.31)	(0.56)	1.48	12.97	15.85	15.59	16.42	13.89	15.38	16.38
Wtd Avg Shrs (Bas)	46,327	47,135	47,692	47,740	47,223	48,861	49,056	49,253	49,450	49,648	49,847	50,047	50,247	50,449	50,651	50,854
Wtd Avg Shrs (Dil)	46,327	47,135	47,692	48,169	47,331	49,385	51,390	53,477	55,648	57,908	60,259	62,706	65,252	67,902	70,659	73,528

Source: Dawson James

Risk Analysis

Clinical Trial Risk. Anavex is dependent on the outcome of multiple clinical trials. The failure rates associated with disease conditions such as Alzheimer's is historically very high.

Commercial Risk. Anavex hopes to compete in the CNS markets which have traditionally been dominated by large pharma and biotechnology companies with deep pockets (funding and resources), which may make it difficult for Anavex to compete unless the molecule is deemed to be truly differentiated.

Financial Risk. Anavex is likely to require additional capital raises before the company can be self-sustaining. There can be no guarantees that the company will be able to raise the needed capital.

Investment Risk. Anavex is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of its therapeutics.

Intellectual Property. Anavex may face IP challenges, forcing the company to defend its patents or claiming the company is infringing on other patents. We do know that the lead product is protected by a composition of matter patent to 2033.

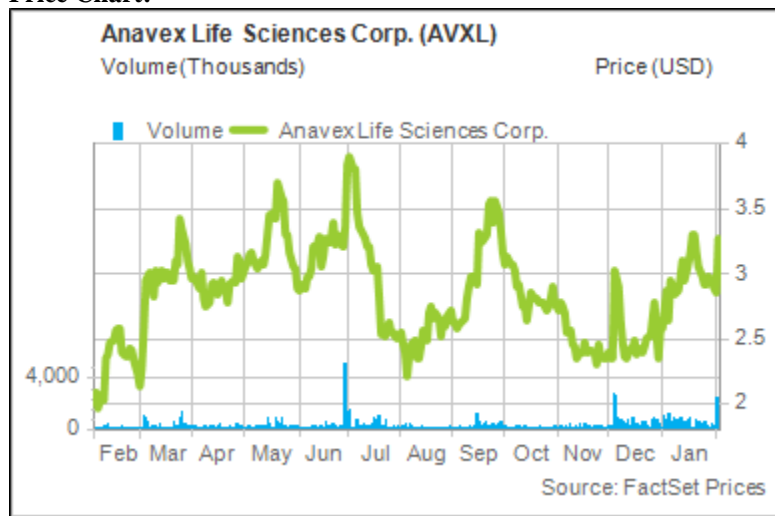
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

Regulatory Risk. Anavex, even with good clinical data, could face extensive delays and other regulatory setbacks.

Companies mentioned in this report

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – July 24, 2019 – Price Target \$16.00
- Update – Buy – July 31, 2019 – Price Target \$16.00
- Update – Buy – August 7, 2019 – Price Target \$16.00
- Update – Buy – September 5, 2019 – Price Target \$16.00
- Update – Buy – September 17, 2019 – Price Target \$16.00
- Update – Buy – October 24, 2019 – Price Target \$16.00
- Update – Buy – December 2, 2019 – Price Target \$16.00
- Update – Buy – December 4, 2019 – Price Target \$16.00
- Update – Buy – February 4, 2020 – Price Target \$16.00

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	88%	3	13%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	4	15%

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