

## Anavex Life Sciences Corp. (NASDAQ/AVXL)

September 17, 2019

### BUY: Preliminary Efficacy in Rett Syndrome

Anavex announced preliminary clinical data from the ANAVEX2-73-RS-001 study on the first six-patient cohort ranging in age from 18 to 36 years who completed the pharmacokinetic (PK) part of the study and who received a low dose of approx. 5 mg daily oral liquid dose of ANAVEX2-73 for 7 weeks.

**Jason Kolbert**  
 Healthcare Research  
 jkolbert@dawsonjames.com

### Investment Highlights

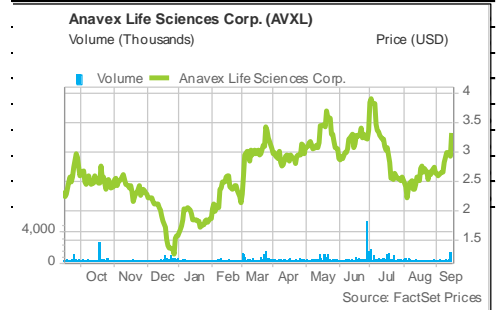
**Preliminary Data Look's Good.** Anavex announced preliminary clinical data from the ANAVEX2-73-RS-001 study on the first six-patient cohort. Patients are continuing participation in the ANAVEX2-73-RS-001 open label extension study. Both efficacy endpoints, the Rett Syndrome Behavior Questionnaire (RSBQ) 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.

Current Price **\$3.32**  
 Price Target **\$16.00**

Estimates	F2019E	F2020E	F2021E
<b>Expenses (\$000s)</b>	\$ 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
<b>EPS (diluted)</b>	\$ (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	\$1.25 - \$4.09
Shares Outstanding (mil.)	52.7
Market Capitalization (mil.)	\$175
Enterprise Value (mil.)	\$155



**Rett Syndrome (background):** Anavex has two clinical trials for Rett syndrome that are underway, and both have recently successfully dosed their first patients. The principle differences between each study are that the U.S. trial will have 15 patients ages 18 and older and will focus primarily on safety and pharmacokinetic data while the Avatar study (Australia) plans on enrolling 30 patients also over 18 years of age with a focus on safety and efficacy. There are multiple benefits associated with two trials and specifically with the Avatar trial, which include financial support in Australia. The Australian government is partly sponsoring the trial (a cash back payment of around 40%) to Anavex with the completion of the study, combined with reduced trial costs in Australia versus the U.S. We could see results as early as year-end, 2019

**Add in the EXCELLENCE study.** The study is designed as an international study with the first approval by the Australian Human Research Ethics Committee and scheduled to initiate within the next quarters. Safety and efficacy will be investigated in approximately 69 patients over a 12-week treatment period including ANAVEX2-73-specific precision medicine biomarkers using a convenient once-daily oral liquid formulation of the drug. All patients who participate in the study will be eligible to receive drug under a voluntary open label extension protocol. This study is part of the planned Anavex Rett Syndrome Program, including the studies described above (wider age range and other geographic regions).

**Financials.** Anavex closed the period with \$21.2M in cash versus expenses of \$7M in the period. According to the company, the cash on hand combined with financial commitments from third parties should translate into approximately two years of capital runway.

**Risk to our thesis, include the following:** (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.

**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 10. FCFF Model

Average \$		16											
Price Target \$		16											
Year		2019											

DCF Valuation Using FCF (mln):													
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 11. Discounted EPS Model

Current Year	2019	Discount Rate and Earnings Multiple Varies, Year is Constant						
Year of EPS	2030	2030 EPS						
Earnings Multiple	15	13.73	5%	10%	15%	20%	25%	30%
Discount Factor	30%	1	\$9.59	\$5.75	\$3.53	\$2.21	\$1.41	\$0.92
Selected Year EPS	\$ 16.40	5	\$47.95	\$28.75	\$17.63	\$11.04	\$7.05	\$4.58
NPV	\$ 13.73	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 12. Sum of the Parts Model

Anavex Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	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 1. 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
<b>Revenue</b>																
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
<b>Total Product Revenues</b>							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
<b>% Chg</b>																
<b>% Sequential Growth</b>																
<b>Milestones</b>																
<b>% Sequential Growth</b>																
<b>Total Revenues (\$000)</b>							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
<b>Expenses</b>																
Cost of Goods Sold (10%)						-	-	-		74,699	107,449	111,607	130,875	108,522	129,721	147,758
Accounting and Audit Fees																
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
<b>Operating expenses</b>	<b>7,474</b>	<b>8,140</b>	<b>7,148</b>	<b>7,165</b>	<b>29,926</b>	<b>30,689</b>	<b>31,886</b>	<b>99,421</b>	<b>115,771</b>	<b>162,507</b>	<b>182,850</b>	<b>185,704</b>	<b>204,040</b>	<b>181,062</b>	<b>201,884</b>	<b>219,748</b>
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																
<b>Financial Expenses, Net</b>																
<b>Pretax Income</b>	<b>(7,325)</b>	<b>(7,960)</b>	<b>(7,054)</b>	<b>(7,165)</b>	<b>(29,537)</b>	<b>(30,717)</b>	<b>(25,275)</b>	<b>(31,702)</b>	<b>91,500</b>	<b>915,854</b>	<b>1,345,067</b>	<b>1,459,138</b>	<b>1,674,248</b>	<b>1,546,703</b>	<b>1,782,139</b>	<b>1,974,411</b>
<b>Pretax Margin</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>
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%
<b>GAAP Net Income (loss)</b>	<b>(7,333)</b>	<b>(8,008)</b>	<b>(7,073)</b>	<b>(7,165)</b>	<b>(29,537)</b>	<b>(30,717)</b>	<b>(15,923)</b>	<b>(30,117)</b>	<b>82,350</b>	<b>751,001</b>	<b>954,998</b>	<b>977,622</b>	<b>1,071,519</b>	<b>943,489</b>	<b>1,087,105</b>	<b>1,204,391</b>
<b>Net Margin</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>0.40</b>	<b>0.70</b>	<b>0.63</b>	<b>0.59</b>	<b>0.57</b>	<b>0.55</b>	<b>0.55</b>	<b>0.55</b>
<b>GAAP-EPS</b>	<b>(0.16)</b>	<b>(0.17)</b>	<b>(0.15)</b>	<b>(0.15)</b>	<b>(0.63)</b>	<b>(0.62)</b>	<b>(0.31)</b>	<b>(0.56)</b>	<b>1.48</b>	<b>12.97</b>	<b>15.85</b>	<b>15.59</b>	<b>16.42</b>	<b>13.89</b>	<b>15.38</b>	<b>16.38</b>
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
Wgtd 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
Wgtd 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.

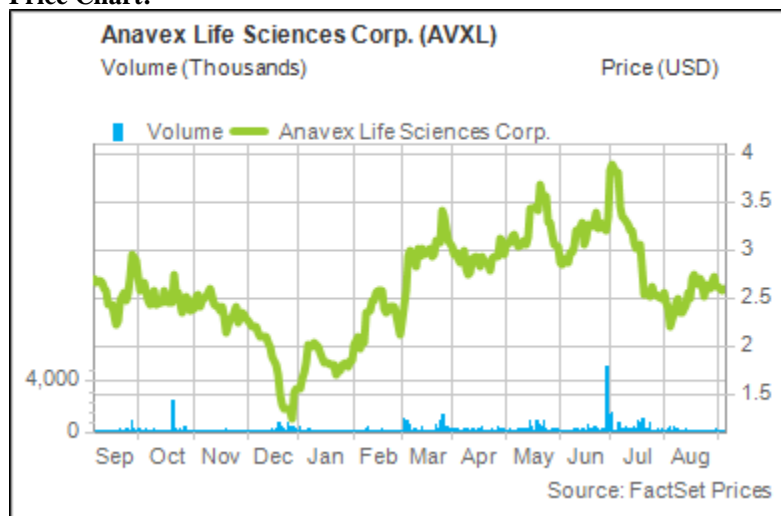
**Market Share Risk.** The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

**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

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	28	85%	5	18%
Market Perform (Neutral)	5	15%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	33	100%	5	15%

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