

Anavex Life Sciences Corp. (NASDAQ/AVXL)

July 31, 2019

BUY: DSMB Say's Continue the Rett Study

Jason Kolbert
Healthcare Research
jkolbert@dawsonjames.com

The DSMB reviewed the preliminary efficacy and safety data for the ANAVEX2-73 Phase 2 Rett syndrome clinical study. Upon review of the most recent data, the DSMB SMB recommendation is to continue the study without modification. We view this as the "expected outcome" and as "positive".

Investment Highlights

Rett Syndrome. 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. 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.

A New Approach to CNS Disease. The development of Alzheimer's has been linked to different mechanisms which may trigger negative cascades. Research advances are emerging around what happens when cells undergo stress. Why do some survive, and others degenerate? One answer may relate to individual cell survival mechanisms which in-part may be related to the role of the Sigma-1 Receptor, which is activated (an agonist) by ANAVEX2-73. It is believed that Sigma 1 can help to protect a cell from the accumulation of misfolded proteins, acting to chaperone them out of the cell. As a result, cell metabolism (oxidative stress and mitochondrial dysfunction) are kept in balance. The implications here can have an impact across a wide range of neurodegenerative diseases from Alzheimer's to Parkinson's and niche orphan diseases such as Rett's syndrome, which may represent a "fast path" to establish proof of concept, around Sigma 1 agonism.

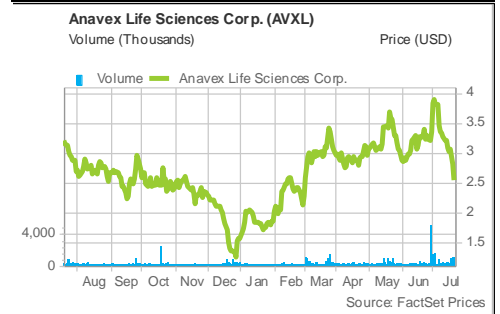
Lots of Clinical Catalysts. Alzheimer's Disease. Anavex is now in a Phase 2b/3 trial. The study could complete by YE2020 setting up commercialization by YE2022. **Rett Syndrome.** Rett Syndrome is a rare severe neurological monogenic disorder caused by a mutation of the X-linked gene, MECP2. A Phase 2 proof of concept study is now underway in Rett Syndrome with the first patients having been treated. We could see top-line data by 1H2020. **Parkinson's Dementia Disease (PDD).** Phase 2 trial could complete by YE2019 with top-line data to follow early next year.

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	\$2.54
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	\$1.25 - \$4.09
Shares Outstanding (mil.)	51.7
Market Capitalization (mil.)	\$131
Enterprise Value (mil.)	\$112
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	6.1
Average Three Months Trading Volume (K)	228
Insider Ownership	4.7%
Institutional Ownership	14.7%
Short interest (mil.)	7.9%
Dividend / Yield	\$0.00/0.0%



Initiation - July 24, 2019 - Buy - Price Target \$16.00

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-)	(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
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						
		13.73	5%	10%	15%	20%	25%	30%
Earnings Multiple	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 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	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												
Amortization and depreciation	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	24,040	24,867	25,369	20,601	16,729	13,585	11,032	8,959	7,275	5,908	4,797	3,896
Salaries and wages												
Travel												
Website design and maintence												
General and Administrative	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	31,158	32,116	33,342	100,602	116,731	163,286	183,482	186,217	204,457	181,401	202,159	219,971
Oper. Inc. (Loss)	(31,158)	(32,116)	(26,700)	(32,859)	90,565	915,100	1,344,459	1,458,649	1,673,856	1,546,389	1,781,889	1,974,213
Oper Margin	NM	NM	NM	NM	0	1	1	1	1	1	1	1
Other income (expense)												
Research and Development incentive												
Interest and financing fees	(27)	(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												
Loss on extinguishment of debt												
Foreign exchange gain (loss)												
Financing related charges and adjustments												
Other non-operating income												
Non-operating Income (expense)	(27)	(28)	(30)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net												
Financial Expenses, Net												
Pretax Income	(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
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)			(9,890)	(1,644)	9,054	164,714	389,886	481,346	602,579	603,082	694,927	769,933
Tax Rate	-	-		5%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(31,184)	(32,144)	(16,840)	(31,239)	81,486	750,362	954,548	977,278	1,071,252	943,282	1,086,937	1,204,254
Net Margin	NM	NM	NM	NM	0.39	0.70	0.62	0.59	0.57	0.55	0.55	0.55
GAAP EPS	(0.65)	(0.65)	(0.33)	(0.59)	1.47	12.98	15.87	15.61	16.44	13.91	15.41	16.40
Non GAAP EPS (dil)	(0.65)	(0.65)	(0.33)	(0.59)	1.47	12.98	15.87	15.61	16.44	13.91	15.41	16.40
Wgtd Avg Shrs (Bas)	46,968	48,349	48,542	48,737	48,932	49,128	49,325	49,523	49,721	49,920	50,120	50,321
Wgtd Avg Shrs (Dil)	47,288	49,296	51,298	53,381	55,548	57,804	60,151	62,593	65,135	67,779	70,532	73,395

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.

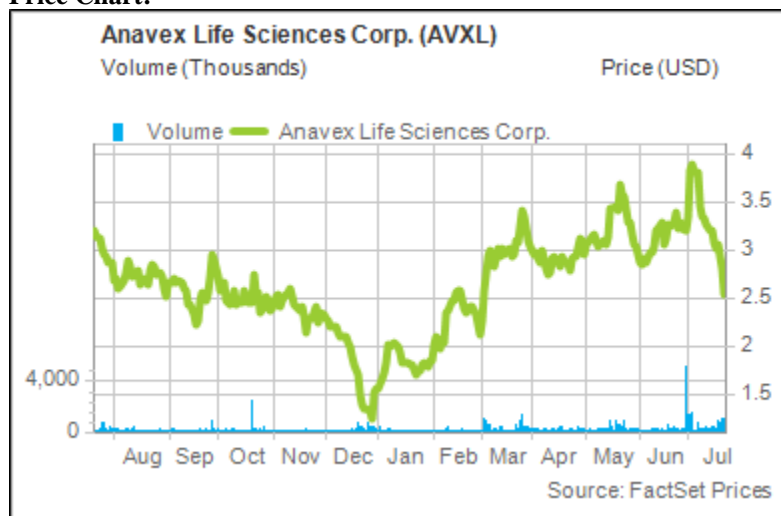
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and

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

Dawson James Securities, Inc. (the “Firm”) is a member of the Financial Industry Regulatory Authority (“FINRA”) and the Securities Investor Protection Corporation (“SIPC”).

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with AVXL in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has NOT received any other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of June 30, 2019, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may effect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISK ANALYSIS” sections of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

Rating Definitions:

- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	41	85%	12	29%
Market Perform (Neutral)	7	15%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	48	100%	12	25%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.