

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: Rett Syndrome Top Line Results – A Split Decision but Look Deeper and You’ll See There Is Hope

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After 12 weeks, the study showed improvement in the key co-primary endpoint Rett Syndrome Behavior Questionnaire (RSBQ). This is a detailed 45-item questionnaire for assessing multiple Rett syndrome characteristics by the patient’s caregivers. The other co-primary endpoint, the Clinical Global Impression – Improvement scale (CGI-I), which represents a less granular assessment by the site investigators using a seven-point scoring (one=“very much improved” to seven=“very much worse”), was not met. We do not see the miss on the second endpoint as “doom and gloom”. It’s a big ask, for a very small study, in a severe disease. With a larger N value, we expect they could have met the endpoint. Given the safety profile and unmet medical need, we believe there is a discussion to be had with regulators. As such, we are making no changes to our rating or estimates.

Investment Highlights:

Topline results from the randomized, double-blind, placebo-controlled, Phase 2/3 EXCELLENCE clinical trial, which evaluated the clinical efficacy, safety, and tolerability of 30 mg ANAVEX2-73 in 92 pediatric patients with Rett syndrome (RTT) between the ages of 5 through 17 years. Participants were randomized 2:1 (ANAVEX2-73 [62 patients] to placebo [30 patients]) for 12 weeks, followed by a week 16 safety visit. As well, Anavex reported positive Real World Evidence (RWE) feedback from Rett syndrome patients under Compassionate Use Authorization.

In an ad-hoc analysis, using the predefined mixed-effect model for repeated measure (MMRM) method, after 12 weeks of treatment, ANAVEX2-73-treated patients improved LS Mean (SE) -12.93 (2.150) points on their RSBQ total score compared to LS Mean (SE) -8.32 (2.537) points in placebo-treated patients. The LS Mean difference (SE) of -4.61 (2.439) points between treated and placebo groups did not reach statistical significance (n=77; p=0.063). ANAVEX2-73-treated patients demonstrated a rapid onset of action with improvements at 4 weeks after treatment with a RSBQ total score LS Mean (SE) -10.32 (2.086) points in the drug-treated group compared to a LS Mean (SE) -5.67 (2.413) points in placebo-treated patients. The LS Mean difference of -4.65 (2.233) points between treated and placebo groups was statistically significant (n=77; p=0.041).

Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, so our share count is based on a projected, 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 a probability of success (50%) 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.

Risks to our thesis include: (1) commercial; (2) regulatory; (3) clinical; (4) market share; (5) financial; (6) investment; and (7) intellectual property.

Current Price \$6.05
Price Target \$39.00



Source: Anavex

Stock Data	
52-Week Range	\$4.90 - \$11.93
Shares Outstanding (mil.)	82.1
Market Capitalization (mil.)	\$496
Enterprise Value (mil.)	\$345
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	3.8
Average Three Months Trading Volume (K)	828
Insider Ownership	3.1%
Institutional Ownership	30.7%
Short interest (mil.)	22.1%
Dividend / Yield	\$0.00/0.0%

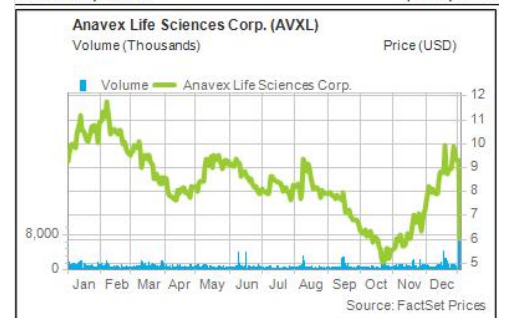


Exhibit 1. Income Statement (\$ '000)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	1Q23A	2Q23A	3Q23A	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		-	-	-						-	-	996,342	1,332,252	1,067,282	1,244,145	1,348,343
Anavex2-73 AD ROW										-	-	1,235,807	1,285,239	1,103,163	1,350,272	1,606,824
Anavex2-73 Rett's Syndrome										28,192	71,890	586,623	747,945	915,484	933,794	952,470
Anavex2-73 Parkinson's Dementia PDD										-	-	177,649	241,602	369,651	439,885	480,732
Total Product Revenues										28,192	71,890	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)										28,192	71,890	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
Expenses																
Cost of Goods Sold (10%)										-	-	223,215	261,749	217,045	259,442	295,517
Accounting and Audit Fees																
Amortization and depreciation	2	2	2	2	0	0	0	0	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	22,260	25,232	32,267	41,326	11,307	11,307	10,061	10,111	42,785	32,600	26,473	21,498	17,457	14,176	11,512	9,349
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	13,320	2,883	2,883	2,592	3,000	11,357	27,500	45,000	45,450	45,905	46,364	46,827	47,295
Operating expenses	31,287	31,088	41,474	54,647	14,189	14,190	12,653	13,112	54,144	60,101	71,474	290,164	325,112	277,586	317,783	352,162
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(54,647)	(14,189)	(14,190)	(12,653)	(13,112)	(54,144)	(31,909)	416	2,706,257	3,281,925	3,177,995	3,650,314	4,036,206
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1
Other income (expense)	2,466															
Research and Development incentive				682												
Interest and financing fees	207			(25)												
Accretion of debt discount	116									(25)	(25)	(25)	(25)	(25)	(25)	(25)
Change in fair value of derivative liability	(151)															
Debt conversion expense	(42)															
Loss on settlement of accounts payable																
Loss on extinguishment of debt																
Foreign exchange gain (loss)				(733)												
Financing related charges and adjustments																
Other non-operating income																
Non-operating Income (expense)	2,894	-	2,129	(75)	-	-	-	-	-	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net		4,830	4,555	(1,132)	(1,132)	2,242	(1,132)									
Financial Expenses, Net																
Pretax Income	(28,393)	(26,258)	(36,918)	(54,722)	(13,057)	(13,057)	(10,211)	(13,112)	(54,144)	(31,934)	391	2,706,232	3,281,900	3,177,970	3,650,289	4,036,181
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(82)	(23)	(155)	(319)	(50)	(50)	(64)	(1,311)	(1,475)	(5,748)	113	893,056	1,181,484	1,239,408	1,423,613	1,574,110
Tax Rate	0	0	1%	1%	10%	10%	10%	10%	3%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(50,068)	(13,107)	(13,107)	(10,147)	(11,801)	(48,162)	(26,186)	277	1,813,175	2,100,416	1,938,561	2,226,676	2,462,070
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.00	0.61	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.17)	(0.12)	(0.14)	(0.60)	(0.31)	0.00	19.73	21.95	19.47	21.49	22.84
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.17)	(0.12)	(0.14)	(0.60)	(0.31)	0.00	19.73	21.95	19.47	21.49	22.84
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	77,278	78,304	78,304	81,973	82,055	80,159	82,260	82,590	82,921	83,253	83,586	83,921	84,257
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	77,278	78,304	78,304	81,973	82,793	80,344	84,883	88,330	91,917	95,649	99,532	103,574	107,779

Source: Dawson James estimates, company reports

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 are 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 I.P. challenges, forcing the company to defend its patents or itself against claims that the company is infringing on other patents. We do know that the lead product is protected by a composition of matter patent to 2033.

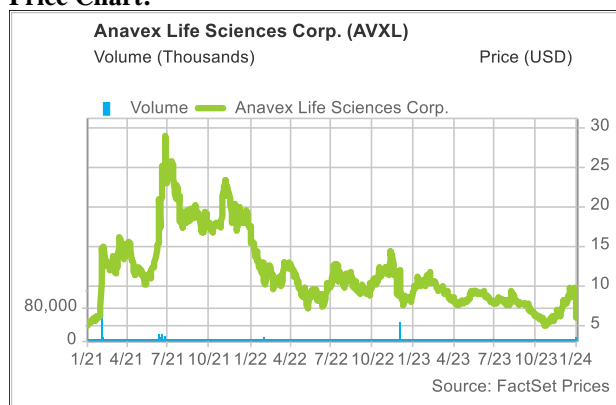
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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
- Update – Buy – February 7, 2020 – Price Target \$16.00
- Update – Buy – May 8, 2020 – Price Target \$16.00

Update – Buy – May 22, 2020 – Price Target \$16.00
Update – Buy – June 16, 2020 – Price Target \$16.00
Update – Buy – July 1, 2020 – Price Target \$16.00
Update – Buy – October 15, 2020 – Price Target \$16.00
Update – Buy – November 6, 2020 – Price Target \$16.00
Update – Buy – December 15, 2020 – Price Target \$16.00
Price Target Change – Buy – February 19, 2021 – Price Target \$16.0 to \$19.00
Update – Buy – April 5, 2021 – Price Target \$19.00
Update – Buy – April 12, 2021 – Price Target \$19.00
Update – Buy – May 19, 2021 – Price Target \$19.00
Update – Buy – June 8, 2021 – Price Target \$19.00
Price Target Change – Buy – June 21, 2021 – Price Target \$35.00
Update – Buy – June 28, 2021 – Price Target \$35.00
Update – Buy – October 27, 2021 – Price Target \$35.00
Update – Buy – November 24, 2021 – Price Target \$35.00
Update – Buy – January 11, 2022 – Price Target \$35.00
Update – Buy – February 1, 2022 – Price Target \$35.00
Update – Buy – February 4, 2022 – Price Target \$35.00
Update – Buy – February 10, 2022 – Price Target \$39.00
Update – Buy – June 15, 2022 – Price Target \$39.00
Update – Buy – August 2, 2022 – Price Target \$39.00
Update – Buy – August 9, 2022 – Price Target \$39.00
Update – Buy – October 18, 2022 – Price Target \$39.00
Update – Buy – November 8, 2022 – Price Target \$39.00
Update – Buy – November 28, 2022 – Price Target \$39.00
Update – Buy – November 30, 2022 – Price Target \$39.00
Update – Buy – December 5, 2022 – Price Target \$39.00
Update – Buy – February 2, 2023 – Price Target \$39.00
Update – Buy – February 7, 2023 – Price Target \$39.00
Update – Buy – March 9, 2023 – Price Target \$39.00
Update – Buy – March 30, 2023 – Price Target \$39.00
Update – Buy – May 9, 2023 – Price Target \$39.00
Update – Buy – June 6, 2023 – Price Target \$39.00
Update – Buy – June 13, 2023 – Price Target \$39.00
Update – Buy – June 28, 2023 – Price Target \$39.00
Update – Buy – August 8, 2023 – Price Target \$39.00
Update – Buy – September 15, 2023 – Price Target \$39.00
Update – Buy – October 27, 2023 – Price Target \$39.00
Update – Buy – November 21, 2023 – Price Target \$39.00
Update – Buy – November 28, 2023 – Price Target \$39.00
Update – Buy – December 19, 2023 – Price Target \$39.00
Update – Buy – December 21, 2023 – Price Target \$39.00
Update – Buy – January 3, 2024 – Price Target \$39.00

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- 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.

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Current as of 14-Dec-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	61.76%	4	11.80%
Market Perform (Neutral)	13	38.24%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.70%

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