

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY: Anavex – No Endpoints Were Changed

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Anavex addressed some recent confusion in the marketplace where some parties have claimed that the endpoints in the recent successful Phase 3 trial in Rett Syndrome were changed. They were not. See the excerpt from press release below.

Investment Highlights – The Data

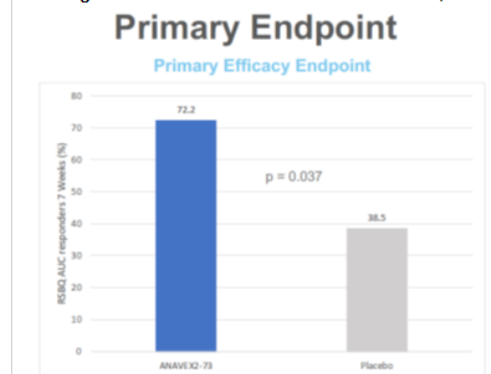
From the Press Release: “Following the successful completion of U.S. Phase 2 Rett syndrome study (ANAVEX@2-73-RS-001) as announced in December 2020, and the knowledge gained from it, the AVATAR study (ANAVEX@2-73-RS-002) appropriately updated endpoints according to ICH guidelines were approved by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and in Australia by the Human Research Ethics Committees (HREC), where the AVATAR study was conducted. Subsequently the AVATAR study was updated from a Phase 2 to a Phase 3 study. The January 2022 update to the trial description in ‘clinicaltrials.gov’ was not a real-time communication and may have given the wrong impression of a late change of trial endpoints / phase of the study, which is not the case.”

- Primary (RSBQ AUC; $p = 0.037$) and secondary (ADAMS; $p = 0.010$); (CGI-I; $p = 0.037$) efficacy endpoints met.
- ANAVEX@2-73 induces a statistically significant and clinically meaningful improvement of RSBQ AUC in 72.2% of patients as compared to 38.5% on placebo; ($p = 0.037$). Cohen’s d effect size is 1.91 (very large).
- Clinically meaningful and statistically significant reduction of emotional behavior symptoms (ADAMS) in ANAVEX@2-73 treated adult patients with Rett syndrome (52.9%) vs. placebo (8.3%); ($p = 0.010$). Cohen’s d effect size 0.609 (large).
- Significantly more patients achieve clinically meaningful CGI-I response over the treatment duration in ANAVEX@2-73-treated group (72.2%) as compared with placebo (38.5%); ($p = 0.037$). Cohen’s d effect size 1.91 (very large).
- Efficacy endpoints demonstrated statistically significant and clinically meaningful reductions in Rett syndrome symptoms with related changes in potential biomarkers of disease pathology:
 - GABA was significantly increased ($p = 0.0205$).
 - L-Alpha-aminoadipic acid (L-AAA) was significantly decreased ($p = 0.0392$).
- Confirmed dose-response:
 - RS-001 study 5mg ANAVEX@2-73 dose RSBQ AUC Cohen’s d (effect size) of 0.517.
 - RS-002 study 30mg ANAVEX@2-73 dose RSBQ AUC Cohen’s d (effect size) of 1.91.
- ANAVEX@2-73 demonstrated dose-related significant improvement in overall Quality of Life (QoL) measured with CHQ-PF50 ($p = 0.030$).

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 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 \$10.23
Price Target \$35.00



Source: Anavex

Stock Data			
52-Week Range	\$10.01	-	\$31.50
Shares Outstanding (mil.)	76.0		
Market Capitalization (mil.)	\$778		
Enterprise Value (mil.)	\$758		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	9.0		
Average Three Months Trading Volume (K)	945		
Insider Ownership	3.0%		
Institutional Ownership	26.2%		
Short interest (mil.)	6.4%		
Dividend / Yield	\$0.00/0.0%		

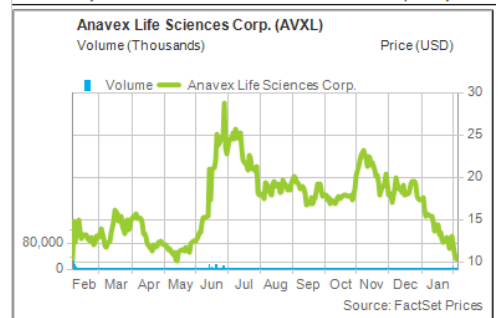


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		-	-	-	-	-	-	-	-	383,651	677,784	996,342	1,332,252	1,067,282	1,244,145	1,348,343
Anavex2-73 AD ROW			-	-	-	-	-	-	-	1,110,338	1,471,198	1,235,807	1,285,239	1,103,163	1,350,272	1,606,824
Anavex2-73 Rett's Syndrome			-	-	-	-	-	135,487	414,591	634,324	790,791	879,935	897,533	915,484	933,794	952,470
Anavex2-73 Parkinson's Dementia PDD			-	-	-	-	-	-	-	28,458	116,110	177,649	241,602	369,651	439,885	480,732
Total Product Revenues								135,487	414,591	2,156,772	3,055,883	3,289,732	3,756,626	3,455,581	3,968,096	4,388,368
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)								135,487	414,591	2,156,772	3,055,883	3,289,732	3,756,626	3,455,581	3,968,096	4,388,368
Expenses																
Cost of Goods Sold (10%)			-	-	-	-	-	-	-	149,399	214,898	223,215	261,749	217,045	259,442	295,517
Accounting and Audit Fees																
Amortization and depreciation	2	2	0	0	0	0	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	22,260	25,232	7,926	6,721	8,965	9,009	32,620	29,047	23,588	19,155	15,555	12,631	10,257	8,330	6,764	5,493
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	1,470	2,234	2,434	1,611	6,442	80,000	100,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	31,287	31,088	9,396	8,955	11,399	10,620	40,370	109,048	123,589	243,555	295,454	301,498	338,315	292,345	333,847	369,327
Oper. Inc. (Loss)	(31,287)	(31,088)	(9,396)	(8,955)	(11,399)	(10,620)	(40,370)	26,439	291,002	1,913,217	2,760,429	2,988,234	3,418,312	3,163,235	3,634,250	4,019,041
Oper Margin	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1
Other income (expense)	2,466															
Research and Development incentive	299															
Interest and financing fees	207							(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Accretion of debt discount	116															
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)																
Financing related charges and adjustments																
Other non-operating income																
Non-operating Income (expense)	2,894	-	-	-	1,258	-	1,258	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net		4,830	1,600	826	1,258		3,684									
Financial Expenses, Net																
Pretax Income	(28,393)	(26,258)	(7,795)	(8,129)	(10,142)	(10,620)	(39,113)	26,414	290,977	1,913,192	2,760,404	2,988,209	3,418,287	3,163,210	3,634,225	4,019,016
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(82)	(23)	(59)	(27)	(39)		(125)	1,321	29,098	344,375	800,517	986,109	1,230,583	1,233,652	1,417,348	1,567,416
Tax Rate	0	0	0	0	0	0	0	5%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(7,855)	(8,156)	(10,181)	(10,620)	(36,811)	25,093	261,879	1,568,818	1,959,887	2,002,100	2,187,704	1,929,558	2,216,877	2,451,600
Net Margin	NM	NM	NM	NM	NM	NM	NM	0.19	0.63	0.73	0.64	0.61	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.12)	(0.12)	(0.14)	(0.15)	(0.53)	0.34	3.44	19.82	23.79	23.36	24.52	20.78	22.95	24.39
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.12)	(0.12)	(0.14)	(0.15)	(0.53)	0.34	3.44	19.82	23.79	23.36	24.52	20.78	22.95	24.39
Wgtd Avg Shrs (Bas)	48,906	58,195	64,295	68,595	70,590	70,660	68,535	70,837	71,121	71,406	71,692	71,979	72,267	72,557	72,847	73,139
Wgtd Avg Shrs (Dil)	48,906	58,195	64,295	68,595	70,590	71,295	68,694	73,096	76,064	79,152	82,366	85,711	89,191	92,812	96,581	100,502

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.

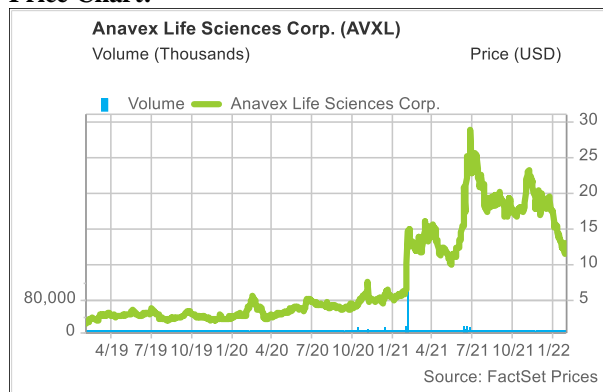
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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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.

Current as of... 31-Jan-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	29	73%	6	21%
Market Perform (Neutral)	11	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	40	100%	6	15%

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