

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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Jason Kolbert

 Senior Healthcare Analyst
 jkolbert@dawsonjames.com

BUY: Biomarkers May be One of the Keys to Approval in Alzheimer's Disease – This Was Always the Plan at Anavex

Anavex shows that its biomarker appears to correlate with efficacy in the Phase 2 Rett Syndrome trial. We believe this has implications across all the current trials including Alzheimer's and may support approval. Remember that Anavex has been talking about the importance of biomarkers as an integral part of the company's study designs for the past five years. We are increasing our probability of success in our therapeutic models from 30% to 50%, which drives a new price target of \$35.00.

Investment Highlights

What's the data? (Adapted from the press release):

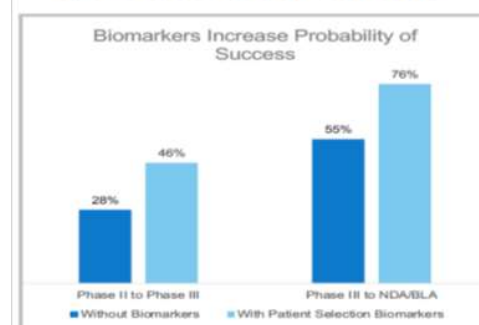
- ANAVEX2-73 treatment resulted in increases in the mRNA expression of SIGMAR1, the gene coding for the receptor targeted by ANAVEX2-73, which correlated with clinical efficacy as measured by both primary efficacy endpoints (ITT population), namely RSBQ ($p = 0.035$) and CGI-I ($p = 0.029$).
- Prespecified patients with WT SIGMAR1 in the clinical trial demonstrated a clinically meaningful and statistically significant 14.5-point ($p = 0.009$) improvement over placebo in the RSBQ total score, the trial's key efficacy endpoint.
- The RSBQ demonstrated balanced improvements across all the instrument's subscales during the trial period of 7 weeks, including general mood, breathing, hand behavior, repetitive face movements, body rocking, night-time behavior, fear/anxiety, walking/standing.
- The Anxiety, Depression, and Mood Scale (ADAMS), which is a measure of anxiety and mood symptoms in individuals with intellectual disability has been clinically validated for use in Rett syndrome and in Fragile X syndrome demonstrated clinically meaningful and statistically significant 12.9-point ($p = 0.005$) improvement for ANAVEX2-73 treated adult patients with Rett syndrome vs placebo in prespecified patients with WT SIGMAR1.
- The ADAMS also demonstrated balanced improvements across all different subscales during the trial period of 7 weeks, including manic/hyperactive behavior, depressed mood, social avoidance, general anxiety, obsessive compulsive behavior.

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	\$26.00
Price Target	\$35.00

Precision Medicine



Stock Data			
52-Week Range	\$3.65	-	\$28.70
Shares Outstanding (mil.)	70.0		
Market Capitalization (mil.)	\$1,821		
Enterprise Value (mil.)	\$1,802		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	10.4		
Average Three Months Trading Volume (K)	1,278		
Insider Ownership	3.6%		
Institutional Ownership	26.5%		
Short interest (mil.)	9.3%		
Dividend / Yield	\$0.00/0.0%		

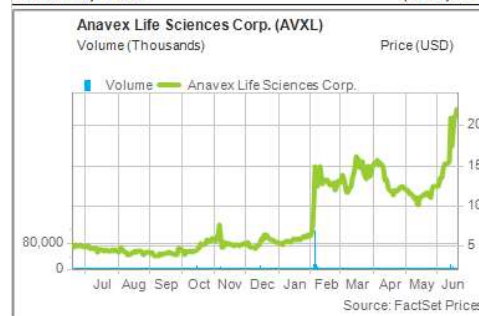


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	1Q21A	2Q21A	3Q21E	4Q21E	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			-	-	-	-	-	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	-	-	-	-	-	-	-	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)	-	-	-	-	-	-	-	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	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	6,754	6,788	28,189	21,886	17,773	14,432	11,720	9,517	7,729	6,276	5,097	4,139
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	1,470	2,234	1,611	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	8,365	8,399	35,115	101,887	117,774	164,133	184,171	186,776	204,911	181,769	202,458	220,214
Oper. Inc. (Loss)	(31,287)	(31,088)	(9,396)	(8,955)	(8,365)	(8,399)	(35,115)	(34,144)	89,521	914,253	1,343,771	1,458,090	1,673,402	1,546,021	1,781,590	1,973,970
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	0	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	-	-	-	-	-	-	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net		4,830	1,600	826			2,427									
Financial Expenses, Net	(28,393)	(26,258)	(7,795)	(8,129)	(8,365)	(8,399)	(35,115)	(34,169)	89,496	914,228	1,343,746	1,458,065	1,673,377	1,545,996	1,781,565	1,973,945
Pretax Income	(28,393)	(26,258)	(7,795)	(8,129)	(8,365)	(8,399)	(35,115)	(34,169)	89,496	914,228	1,343,746	1,458,065	1,673,377	1,545,996	1,781,565	1,973,945
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)	-	-	(86)	(1,708)	8,950	164,561	389,686	481,161	602,416	602,938	694,810	769,838
Tax Rate	0	0						5%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(7,855)	(8,156)	(8,365)	(8,399)	(32,775)	(32,460)	80,547	749,667	954,060	976,903	1,070,961	943,057	1,086,755	1,204,106
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.39	0.70	0.62	0.59	0.57	0.55	0.55	0.55
GAAP EPS	(0.65)	(0.45)	(0.12)	(0.12)	(0.12)	(0.12)	(0.48)	(0.45)	1.08	9.65	14.80	11.61	12.23	10.35	11.46	12.20
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.12)	(0.12)	(0.12)	(0.12)	(0.48)	(0.45)	1.08	9.65	11.80	11.61	12.23	10.35	11.46	12.20
Wgtd Avg Shrs (Bas)	48,906	58,195	64,295	68,595	68,663	68,732	67,571	68,904	69,180	69,457	69,736	70,015	70,295	70,577	70,860	71,144
Wgtd Avg Shrs (Dil)	48,906	58,195	64,295	68,595	69,281	69,974	68,036	71,741	74,653	77,685	80,839	84,121	87,537	91,091	94,790	98,639

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.

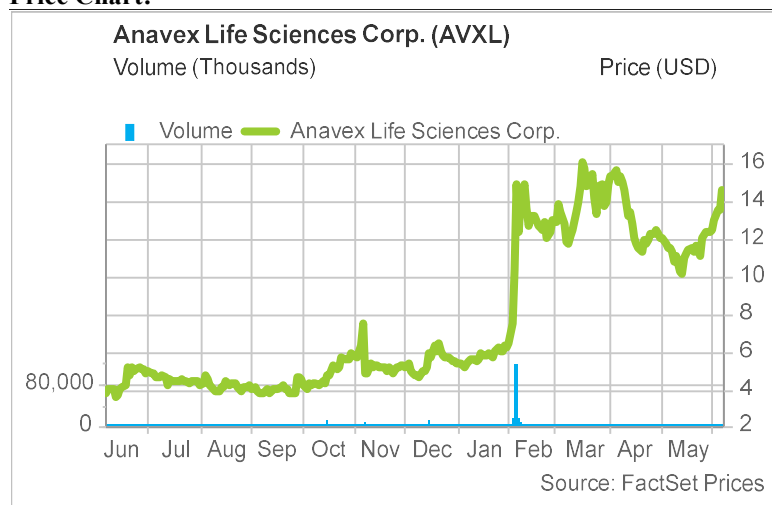
Regulatory Risk. Anavex, even with good clinical data, could face extensive delays and other regulatory setbacks.

Companies mentioned in this report:

Cassava Science (SAVA Not Rated)

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

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- 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.

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As of: 21-Jun-21

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	71%	4	17%
Market Perform (Neutral)	10	29%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	34	100%	4	12%

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