

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: Anavex 2-73 Shows Long-Term Benefit in Parkinson's Disease Dementia – Going Pivotal Now

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All efficacy endpoints, which include the MDS-UPDRS Part II + III and Clinical Global Impression – Improvement (CGI-I) measured at the end of the trial of the double-blind study (DB EOT), the OLE Baseline, OLE Week 24, and OLE Week 48, showed a worsening during the drug holiday. However, a consistent improvement was observed during the extension phase when patients resumed ANAVEX®2-73 treatment. These results are consistent with the pattern observed for all efficacy measures in the extension phase.

Investment Highlights:

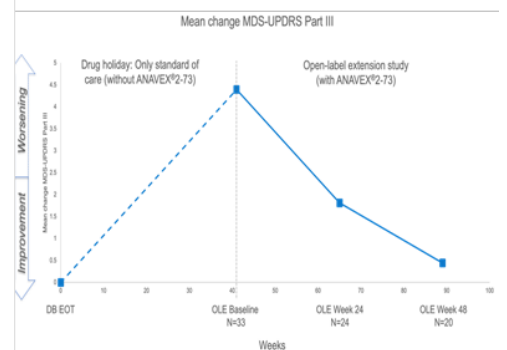
Recall that the double-blind ANAVEX2-73-PDD-001 Phase 2 study demonstrated a statistically significant improvement vs. placebo for MDS-UPDRS Total score. From baseline to the end of the trial at 14 weeks, the MDS-UPDRS Total score improved by -10.98 points in the high dose group and worsened by 3.53 points in the placebo group, an adjusted mean difference of -14.51 points ($p = 0.034$). This corresponds to a relative improvement of 18.9% over 14 weeks. This data was also consistent with expression levels of pathological dysregulated neurodegenerative genes, including Parkinson's disease genes, which were significantly restored by the therapeutic effect of ANAVEX®2-73 ($p < 0.005$).

COVID Impact: The start of the extension phase was delayed, on average, by approximately 41 weeks at the end of the preceding double-blind placebo-controlled study (DB). This led to a reduced enrollment rate for the extension phase. The period between the end of the double-blind phase to the start of the extension phase, where patients were not on 2-73 treatment, (drug holiday). The drug holiday period of treatment separation provided an opportunity to compare the trajectory of clinical scores between 2-73 treatment (drug holiday) and the 2-73 treatment in the extension phase. As noted in the abstract: A consistent improvement was observed during the extension phase when patients resumed ANAVEX®2-73 treatment. Please see the company's press release for additional details.

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 **\$8.56**
Price Target **\$39.00**



Source: Anavex

Stock Data		
52-Week Range	\$7.13	\$15.24
Shares Outstanding (mil.)	78.0	
Market Capitalization (mil.)	\$668	
Enterprise Value (mil.)	\$524	
Debt to Capital	0%	
Book Value/Share	\$0.56	
Price/Book	5.6	
Average Three Months Trading Volume (K)	1,863	
Insider Ownership	3.0%	
Institutional Ownership	33.9%	
Short interest (mil.)	20.1%	
Dividend / Yield	\$0.00/0.0%	

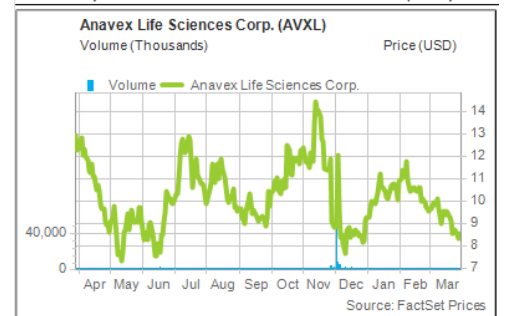


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	1Q22A	2Q22A	3Q22A	4Q22A	2022A	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	0	0	0	0	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	32,267	8,604	9,273	11,382	12,067	41,326	38,905	31,593	25,655	20,834	16,918	13,739	11,157	9,060
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	2,915	3,185	3,903	3,317	13,320	40,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	31,287	31,088	41,474	11,519	12,459	15,284	15,384	54,647	78,906	106,594	90,657	309,700	344,975	297,754	338,239	372,894
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(11,519)	(12,459)	(15,284)	(15,384)	(54,647)	(78,906)	(78,402)	(18,767)	2,686,721	3,262,062	3,157,826	3,629,857	4,015,474
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	1	1	1	1	1
Other income (expense)	2,466															
Research and Development incentive	299				682	994		682								
Interest and financing fees	207			8	230	705		(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)					(733)	(495)		(733)								
Financing related charges and adjustments																
Other non-operating income																
Non-operating Income (expense)	2,894	-	2,129		180			(75)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net							2,392									
Financial Expenses, Net		4,830	4,555													
Pretax Income	(28,393)	(26,258)	(36,918)	(10,438)	(12,279)	(14,080)	(12,992)	(54,722)	(78,931)	(78,427)	(18,792)	2,686,696	3,262,037	3,157,801	3,629,832	4,015,449
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)		(88)	(210)	(20)	(319)	(7,893)	(14,117)	(5,450)	886,610	1,174,333	1,231,543	1,415,635	1,566,025
Tax Rate	0	0	5%	5%	5%	5%	5%	1%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(10,438)	(12,368)	(14,290)	(12,972)	(50,088)	(71,038)	(64,310)	(13,342)	1,800,086	2,087,704	1,926,259	2,214,198	2,449,424
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.60	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.14)	(0.16)	(0.18)	(0.17)	(0.65)	(0.89)	(0.77)	(0.15)	19.98	22.26	19.74	21.81	23.18
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.14)	(0.16)	(0.18)	(0.17)	(0.65)	(0.89)	(0.77)	(0.15)	19.98	22.26	19.74	21.81	23.18
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	76,249	77,442	77,442	77,977	77,278	78,172	78,485	78,800	79,115	79,432	79,751	80,070	80,391
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	76,249	77,442	77,442	77,977	77,278	79,946	83,192	86,570	90,085	93,743	97,549	101,510	105,632

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.

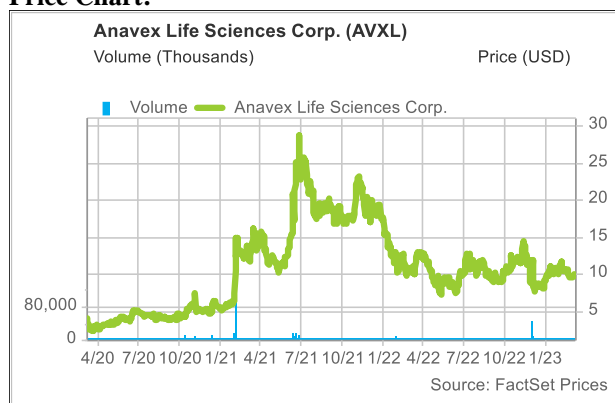
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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- 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 17-Mar-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	25	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

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