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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY: Anavex – Raising Price Target from \$35.00 to \$39.00

Jason Kolbert
 Senior Analyst

jkolbert@dawsonjames.com

Anavex reported 4th Quarter 2021 results. We have rolled our valuation metrics out to 2022; the net effect is our price target bumps up from \$35.00 to \$39.00. Anavex recently reported impressive topline data in Rett Syndrome. The controversy was sparked when some claimed the company changed endpoints to manipulate data. We have spoken with management, and the CEO has been emphatic that this is not the case. We believe in the fundamental mechanism of action of Anavex2-73 and see the Rett data as a surrogate for the ongoing trials in Alzheimer's Parkinsons' Dementia.

Investment Highlights

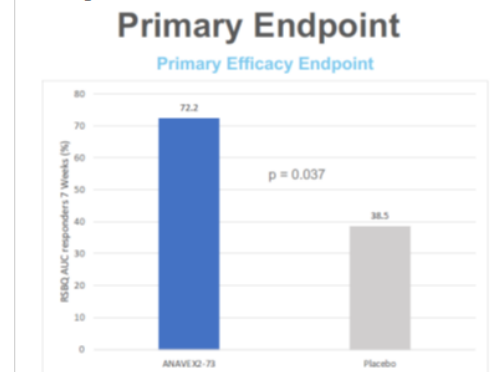
Financials: Anavex reported a net loss of \$10.9M, or \$0.14 per share for the quarter, inclusive of non-cash compensation charges of \$3.9M. R&D expenses driven by the clinical programs came in at \$8.7 million, inclusive of non-cash compensation charges of \$2.2M. G&A expenses were \$3.1M, inclusive of non-cash compensation charges of \$1.7M for the quarter. Anavex closed the period with \$151M in cash on the balance sheet.

Updates (press release adapted):

- Positive topline results from the second randomized, placebo-controlled AVATAR Phase 3 study (ANAVEX@2-73-RS-002) for treating adult patients with Rett syndrome. The study met its primary and secondary efficacy and safety endpoints, with consistent and clinically meaningful improvements in all efficacy measures.
- Anavex reported positive topline results from the placebo-controlled Phase 1 clinical trial (ANAVEX@3-71-001) in development to treat neurodegenerative diseases, including Frontotemporal Dementia (FTD).
- Topline results from the randomized, placebo-controlled EXCELLENCE Phase 2/3 study ANAVEX@2-73-RS-003 for treating pediatric patients with Rett syndrome are expected 2H 2022. The extended enrollment duration is triggered by Country and local Government requirements for full COVID-19 vaccination among children prior to joining the pediatric EXCELLENCE trial.
- Topline results from the placebo-controlled Phase 2b/3 study ANAVEX@2-73-AD-004 for the treatment of Alzheimer's disease are expected 2H 2022.

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 **\$11.74**
 Price Target **\$39.00**


Source: Anavex

Stock Data	
52-Week Range	\$9.93 - \$31.50
Shares Outstanding (mil.)	76.2
Market Capitalization (mil.)	\$894
Enterprise Value (mil.)	\$742
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	9.0
Average Three Months Trading Volume (K)	735
Insider Ownership	3.1%
Institutional Ownership	28.0%
Short interest (mil.)	7.7%
Dividend / Yield	\$0.00/0.0%

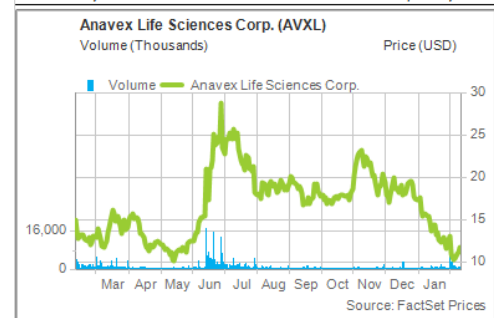


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp												
Anavex: YE Sept 30	2019A	2020A	2021A	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					138,197	281,922	431,341	586,623	747,945	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					138,197	1,804,370	2,696,433	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
% Chg												
% Sequential Growth												
Milestones												
% Sequential Growth												
Total Revenues (\$000)					138,197	1,804,370	2,696,433	2,996,421	3,607,037	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	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	32,267	27,909	22,664	18,404	14,945	12,137	9,856	8,003	6,499	5,278
Salaries and wages												
Travel												
Website design and maintenance												
General and Administrative	6,847	5,857	9,205	80,000	100,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	31,287	31,088	41,474	107,911	122,665	242,805	294,845	301,003	337,913	292,019	333,582	369,112
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(107,911)	15,532	1,561,565	2,401,588	2,695,418	3,269,125	3,163,562	3,634,515	4,019,256
Oper Margin	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	-	2,129	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net												
Financial Expenses, Net		4,830	4,555									
Pretax Income	(28,393)	(26,258)	(36,918)	(107,936)	15,507	1,561,540	2,401,563	2,695,393	3,269,100	3,163,537	3,634,490	4,019,231
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(82)	(23)	(155)	(5,397)	1,551	281,077	696,453	889,480	1,176,876	1,233,779	1,417,451	1,567,500
Tax Rate	0	0		5%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(102,539)	13,956	1,280,463	1,705,110	1,805,913	2,092,224	1,929,757	2,217,039	2,451,731
Net Margin	NM	NM	NM	NM	0.10	0.71	0.63	0.60	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(1.32)	0.17	15.18	19.42	19.77	22.00	19.50	21.53	22.88
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(1.32)	0.17	15.18	19.42	19.77	22.00	19.50	21.53	22.88
Wgt'd Avg Shrs (Bas)	48,906	58,195	69,869	76,188	76,493	76,800	77,107	77,416	77,726	78,038	78,350	78,664
Wgt'd Avg Shrs (Dil)	48,906	58,195	69,869	77,917	81,081	84,373	87,799	91,364	95,073	98,934	102,951	107,131

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.

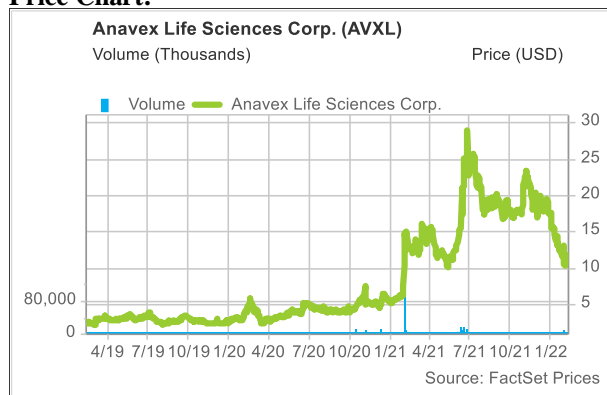
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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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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Current as of... 8-Feb-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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