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Anavex Life Sciences Corp. (NASDAQ/AVXL)

August 2, 2022

BUY: Anavex announces the first entire clinical Alzheimer's gene pathway data of ANAVEX 2-73

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Anavex announced the first entire clinical gene pathway data from the ANAVEX 2-73-PDD-001 Parkinson's Disease Dementia (PDD) study at the Alzheimer's Association International Conference (AAIC), taking place in San Diego, CA, and virtually on 31-Jul - 4-Aug-22. [Click Here for Our Webinar](#)

Investment Highlights

Gene Pathway: Anavex announced the first entire clinical gene pathway data from the ANAVEX2-73-PDD-001 Parkinson's Disease Dementia (PDD) study at the Alzheimer's Association International Conference (AAIC), taking place in San Diego, CA and virtually on 31-Jul - 4-Aug-22.

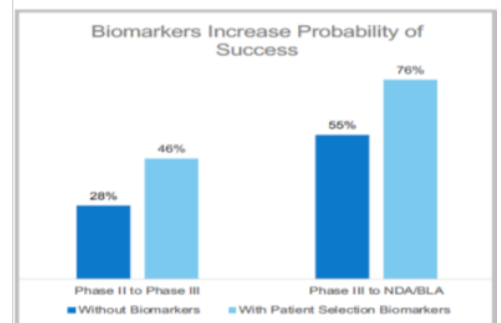
- Randomized, placebo-controlled clinical trial in 132 patients with Parkinson's Disease Dementia (PDD) included prespecified biomarkers of response as well as Whole Exome Sequencing DNA data and full RNA exome expression data collection.
- ANAVEX2-73 transcriptomics analysis (RNAseq) identified a gene network that is differentially expressed in Parkinson's Disease Dementia (PDD) patients treated with ANAVEX2-73 compared to placebo after 14 weeks of treatment. The expression of 14,150 genes were analyzed from both placebo and ANAVEX2-73 treated patients. Biological relevance of this gene network was assessed through pathway analysis and confirmed the impact of ANAVEX2-73 treatment on pathways involved in neurodegenerative diseases, especially Alzheimer's disease and Parkinson's disease.
- While genes are known to be down-regulated in Alzheimer's disease and Parkinson's disease, representing pathology for these diseases, ANAVEX2-73 singularly impacted expression levels of these genes in multiple pathways by countering the pathological down-regulation of genes in both Alzheimer's ($p < 0.005$) and Parkinson's disease ($p < 0.005$) and other degenerative diseases ($p < 0.005$).

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 \$9.88
Price Target \$39.00

Precision Medicine



Thomas DW et al. Clinical Development Success Rates 2006-2015. BIO Industry Analysis

Stock Data

52-Week Range	\$7.13	-	\$23.73
Shares Outstanding (mil.)	77.4		
Market Capitalization (mil.)	\$765		
Enterprise Value (mil.)	\$611		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	9.0		
Average Three Months Trading Volume (K)	720		
Insider Ownership	3.0%		
Institutional Ownership	32.6%		
Short interest (mil.)	10.7%		
Dividend / Yield	\$0.00/0.0%		

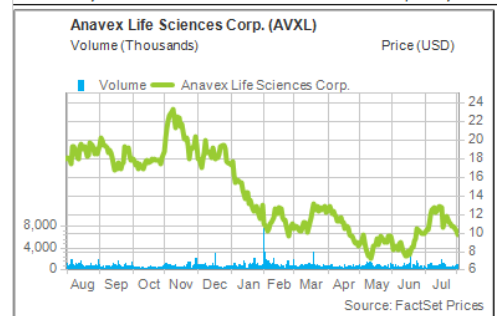


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	1Q22A	2Q22E	3Q22E	4Q22E	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	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	8,647	8,690	8,734	34,675	28,158	22,866	18,569	15,079	12,245	9,944	8,075	6,557
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	2,915	3,000	3,000	3,000	11,915	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	11,647	11,691	11,734	46,591	68,160	247,267	298,468	303,945	340,302	293,959	335,157	370,391
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(11,519)	(11,647)	(11,691)	(11,734)	(46,591)	70,037	1,557,103	2,397,965	2,692,475	3,266,735	3,161,621	3,632,939	4,017,977
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	1	1	1	1	1	1	1	1
Other income (expense)	2,466															
Research and Development incentive	299															
Interest and financing fees	207			8	(6)	(6)	(6)	(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		(6)	(6)	(6)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net		4,830	4,555													
Financial Expenses, Net																
Pretax Income	(28,393)	(26,258)	(36,918)	(10,438)	(11,654)	(11,697)	(11,740)	(46,616)	70,012	1,557,078	2,397,940	2,692,450	3,266,710	3,161,596	3,632,914	4,017,952
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)		(583)	(585)	(587)	(1,755)	7,001	280,274	695,402	888,509	1,176,016	1,233,023	1,416,837	1,567,001
Tax Rate	0	0		5%	5%	5%	5%	4%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(10,438)	(11,071)	(11,112)	(11,153)	(43,774)	63,011	1,276,804	1,702,537	1,803,942	2,090,695	1,928,574	2,216,078	2,450,951
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.46	0.71	0.63	0.60	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.14)	(0.14)	(0.14)	(0.14)	(0.57)	0.78	15.23	19.52	19.88	22.13	19.62	21.66	23.02
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.14)	(0.14)	(0.14)	(0.14)	(0.57)	0.78	15.23	19.52	19.88	22.13	19.62	21.66	23.02
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	76,249	76,325	76,401	76,478	76,363	76,669	76,976	77,284	77,594	77,905	78,217	78,530	78,845
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	76,249	77,011	77,781	78,559	77,400	80,543	83,813	87,216	90,758	94,443	98,277	102,268	106,420

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.

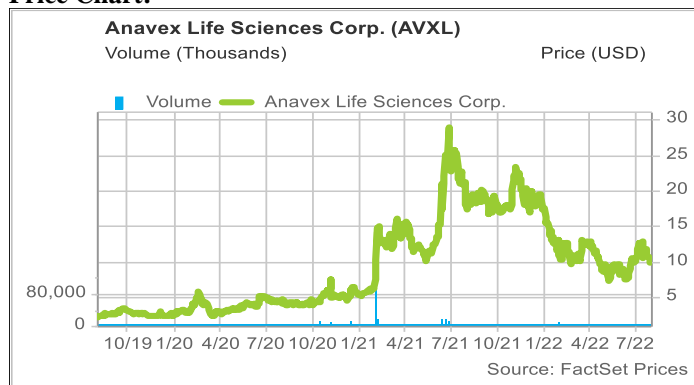
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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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 1-Aug-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	30	68%	4	13%
Market Perform (Neutral)	13	30%	0	0%
Market Underperform (Sell)	1	2%	0	0%
Total	44	100%	4	9%

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