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### Anavex Life Sciences Corp. (NASDAQ/AVXL)

#### BUY Rated: Hires Ex-FDA Biostatistician CNS Expert

Anavex announced the appointment of Kun Jin, Ph.D., as Vice President, Head of Biostatistics. Dr. Jin was recently the Statistical Team Leader at the U.S. Food and Drug Administration. Dr. Jin provided statistical review coverage and expertise for neurological drug products for the Center for Drug Evaluation and Research (CDER), and performed timely and quality reviews of marketing applications, including New Drug Applications (NDA), Biologic License Applications (BLA), and Investigational New Drug (IND) applications.

#### Investment Highlights:

**A New Approach to CNS Disease.** The development of Alzheimer's has been linked to different mechanisms which may trigger negative cascades. Research advances are emerging around what happens when cells undergo stress. Why do some survive, and others degenerate? One answer may relate to individual cell survival mechanisms, which in part may be associated with the role of the Sigma-1 Receptor, which is activated (an agonist) by ANAVEX2-73. It is believed that Sigma 1 can help to protect a cell from the accumulation of misfolded proteins, acting to chaperone them out of the cell. As a result, cell metabolism (oxidative stress and mitochondrial dysfunction) is kept in balance.

#### Key Near-Term Pipeline Updates: (press release):

- Alzheimer's disease:** Full data ANAVEX2-73-AD-004: Potentially pivotal Phase 2b/3 clinical trial
- Parkinson's disease dementia:** Data of 48-week OLE Phase 2 study
- Parkinson's disease:** Initiation of ANAVEX2-73 imaging-focused clinical trial
- Fragile X:** Initiation of potentially pivotal ANAVEX2-73 Phase 2/3 clinical trial
- Schizophrenia:** Initiation of ANAVEX3-71 Phase 2 clinical trial
- New Rare disease:** Initiation of potentially pivotal ANAVEX2-73 Phase 2/3 clinical trial
- Publications:** Several clinical publications involving ANAVEX2-73, ANAVEX3-71, and Rett syndrome Burden of Illness study

**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.

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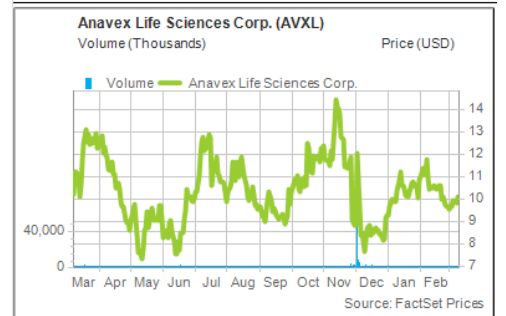
Current Price **\$10.11**  
Price Target **\$39.00**

#### Broad SIGMAR1 Platform Targeting Significant Unmet Medical Need



Source: Anavex

Stock Data		
52-Week Range	\$7.13	\$15.24
Shares Outstanding (mil.)	78.0	
Market Capitalization (mil.)	\$789	
Enterprise Value (mil.)	\$645	
Debt to Capital	0%	
Book Value/Share	\$0.56	
Price/Book	5.6	
Average Three Months Trading Volume (K)	2,636	
Insider Ownership	3.0%	
Institutional Ownership	34.9%	
Short interest (mil.)	21.9%	
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
<b>Revenue</b>																
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
<b>Total Product Revenues</b>										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																
<b>Total Revenues (\$000)</b>										28,192	71,890	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
<b>Expenses</b>																
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
<b>Operating expenses</b>	<b>31,287</b>	<b>31,088</b>	<b>41,474</b>	<b>11,519</b>	<b>12,459</b>	<b>15,284</b>	<b>15,384</b>	<b>54,647</b>	<b>78,906</b>	<b>106,594</b>	<b>90,657</b>	<b>309,700</b>	<b>344,975</b>	<b>297,754</b>	<b>338,239</b>	<b>372,894</b>
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									
<b>Financial Expenses, Net</b>		<b>4,830</b>	<b>4,555</b>													
<b>Pretax Income</b>	<b>(28,393)</b>	<b>(26,258)</b>	<b>(36,918)</b>	<b>(10,438)</b>	<b>(12,279)</b>	<b>(14,080)</b>	<b>(12,992)</b>	<b>(54,722)</b>	<b>(78,931)</b>	<b>(78,427)</b>	<b>(18,792)</b>	<b>2,686,696</b>	<b>3,262,037</b>	<b>3,157,801</b>	<b>3,629,832</b>	<b>4,015,449</b>
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%
<b>GAAP Net Income (loss)</b>	<b>(28,475)</b>	<b>(26,280)</b>	<b>(37,074)</b>	<b>(10,438)</b>	<b>(12,368)</b>	<b>(14,290)</b>	<b>(12,972)</b>	<b>(50,088)</b>	<b>(71,038)</b>	<b>(64,310)</b>	<b>(13,342)</b>	<b>1,800,086</b>	<b>2,087,704</b>	<b>1,926,259</b>	<b>2,214,198</b>	<b>2,449,424</b>
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.60	0.58	0.56	0.56	0.56
<b>GAAP-EPS</b>	<b>(0.65)</b>	<b>(0.45)</b>	<b>(0.53)</b>	<b>(0.14)</b>	<b>(0.16)</b>	<b>(0.18)</b>	<b>(0.17)</b>	<b>(0.65)</b>	<b>(0.89)</b>	<b>(0.77)</b>	<b>(0.15)</b>	<b>19.98</b>	<b>22.26</b>	<b>19.74</b>	<b>21.81</b>	<b>23.18</b>
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.

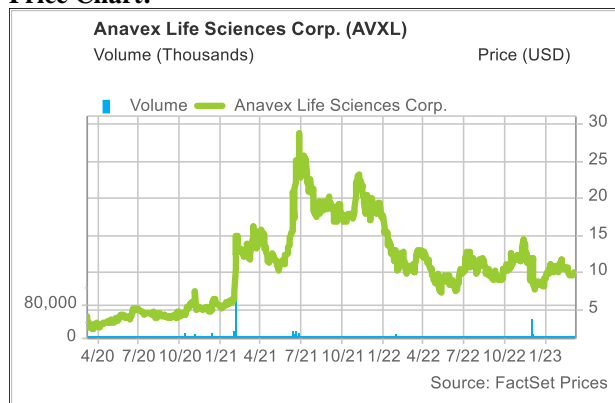
**Market Share Risk.** The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

**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

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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 3-Mar-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	69%	1	3%
Market Perform (Neutral)	11	31%	2	6%
Market Underperform (Sell)	0	0%	0	0%
Total	35	100%	3	9%

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