

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

June 6, 2023

### BUY Rated: Completion of ANAVEX®2-73 (blarcamesine) EXCELLENCE Phase 2/3 Rett Syndrome Clinical Trial

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Anavex announced the completion of dosing of all participants of the placebo-controlled EXCELLENCE Phase 2/3 study ANAVEX®2-73-RS-003 in pediatric patients with Rett syndrome. The Company expects to announce topline results from this study in the second half of this year.

#### Investment Highlights:

**Trial Background:** As is outlined in the company's press release, the trial was preceded by the successful completion of a placebo-controlled P2 study and a P3 study as well. The multi-center, double-blind clinical EXCELLENCE study in pediatric patients measured safety, tolerability, and efficacy of daily oral 2-73 doses or placebo. After completing the double-blind study, eligible participants are able to join a voluntary open-label extension study. The endpoints include the Rett Syndrome Behavior Questionnaire (RBSQ) total score and Clinical Global Impression Improvement Scale (CGI-I) score as co-primary endpoints in the statistical analysis plan with specified linear mixed-effects models for repeated measures (MMRM) as the primary analysis methods.

**What is Rett Syndrome?** Rett syndrome is a rare, non-inherited genetic postnatal progressive neurodevelopmental disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child's life: their ability to speak, walk, eat and even breathe easily. The hallmark of Rett syndrome is near-constant repetitive hand movements while awake. It is characterized by normal early growth and development (6 to 18 months) followed by a slowing of development, loss of purposeful use of the hands, distinctive hand movements, slowed brain and head growth, problems with walking, seizures and intellectual disability. There is currently no cure for Rett syndrome and treatment of the disorder is symptomatic. Management of symptoms is done through a multidisciplinary approach utilizing medication for motor difficulties, breathing irregularities and control of seizures through anticonvulsant drugs. Rett syndrome is caused by mutations in the MECP2 gene and strikes all racial and ethnic groups and occurs worldwide in approximately one in every 10,000 to 15,000 live female births.

**Valuation.** Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, so 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.

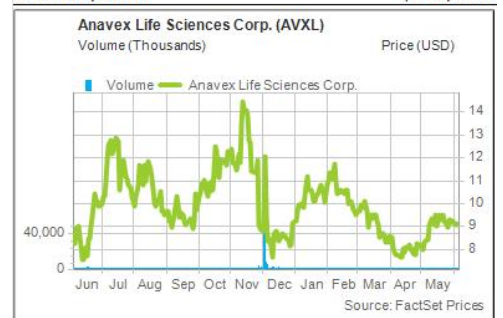
**Risks to our thesis include:** (1) commercial; (2) regulatory; (3) clinical; (4) market share; (5) financial; (6) investment; and (7) intellectual property.

Current Price	\$9.07
Price Target	\$39.00



Source: Anavex

Stock Data		
52-Week Range	\$7.36	\$15.24
Shares Outstanding (mil.)	80.8	
Market Capitalization (mil.)	\$733	
Enterprise Value (mil.)	\$580	
Debt to Capital	0%	
Book Value/Share	\$0.56	
Price/Book	5.6	
Average Three Months Trading Volume (K)	866	
Insider Ownership	3.0%	
Institutional Ownership	34.5%	
Short interest (mil.)	19.7%	
Dividend / Yield	\$0.00/0.0%	



**Exhibit 1. Income Statement (\$ in thousands)**

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	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>										<b>28,192</b>	<b>71,890</b>	<b>2,996,421</b>	<b>3,607,037</b>	<b>3,455,581</b>	<b>3,968,096</b>	<b>4,388,368</b>
<b>% Chg</b>																
<b>% Sequential Growth</b>																
<b>Milestones</b>																
<b>% Sequential Growth</b>																
<b>Total Revenues (\$000)</b>										<b>28,192</b>	<b>71,890</b>	<b>2,996,421</b>	<b>3,607,037</b>	<b>3,455,581</b>	<b>3,968,096</b>	<b>4,388,368</b>
<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	2	0	0	0	0	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	41,326	11,307	11,363	11,420	11,477	45,567	37,003	30,049	24,401	19,815	16,091	13,067	10,611
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	13,320	2,883	3,000	3,000	3,000	11,883	27,500	45,000	45,450	45,905	46,364	46,827	47,295
<b>Operating expenses</b>	<b>31,287</b>	<b>31,088</b>	<b>41,474</b>	<b>54,647</b>	<b>14,189</b>	<b>14,364</b>	<b>14,420</b>	<b>14,477</b>	<b>57,451</b>	<b>64,504</b>	<b>75,050</b>	<b>293,068</b>	<b>327,470</b>	<b>279,501</b>	<b>319,337</b>	<b>353,425</b>
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(54,647)	(14,189)	(14,364)	(14,420)	(14,477)	(57,451)	(36,312)	(3,160)	2,703,353	3,279,567	3,176,080	3,648,759	4,034,943
<b>Oper Margin</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
Other income (expense)	2,466															
Research and Development incentive				682												
Interest and financing fees				(25)						(25)	(25)	(25)	(25)	(25)	(25)	(25)
Accretion of debt discount																
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)												
Financing related charges and adjustments																
Other non-operating income																
Non-operating Income (expense)	2,894	-	2,129	(75)						(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net																
<b>Financial Expenses, Net</b>	<b>4,830</b>	<b>4,830</b>	<b>4,555</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>	<b>(1,132)</b>
<b>Pretax Income</b>	<b>(28,393)</b>	<b>(26,258)</b>	<b>(36,918)</b>	<b>(54,722)</b>	<b>(13,057)</b>	<b>(14,364)</b>	<b>(14,420)</b>	<b>(14,477)</b>	<b>(57,451)</b>	<b>(36,337)</b>	<b>(3,185)</b>	<b>2,703,328</b>	<b>3,279,542</b>	<b>3,176,055</b>	<b>3,648,734</b>	<b>4,034,918</b>
<b>Pretax Margin</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>
Income Tax Benefit (Provision)	(82)	(23)	(155)	(319)	(50)	(1,436)	(1,442)	(1,448)	(4,376)	(6,541)	(924)	892,098	1,180,635	1,238,661	1,423,006	1,573,618
<b>Tax Rate</b>	<b>0</b>	<b>0</b>	<b>1%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>8%</b>	<b>18%</b>	<b>29%</b>	<b>30%</b>	<b>31%</b>	<b>31%</b>	<b>31%</b>	<b>31%</b>
<b>GAAP Net Income (loss)</b>	<b>(28,475)</b>	<b>(26,280)</b>	<b>(37,074)</b>	<b>(50,068)</b>	<b>(13,107)</b>	<b>(12,927)</b>	<b>(12,978)</b>	<b>(13,030)</b>	<b>(52,042)</b>	<b>(29,797)</b>	<b>(2,261)</b>	<b>1,811,230</b>	<b>2,098,907</b>	<b>1,937,393</b>	<b>2,225,728</b>	<b>2,461,300</b>
<b>Net Margin</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>NM</b>	<b>0.60</b>	<b>0.58</b>	<b>0.56</b>	<b>0.56</b>	<b>0.56</b>
<b>GAAP-EPS</b>	<b>(0.65)</b>	<b>(0.45)</b>	<b>(0.53)</b>	<b>(0.65)</b>	<b>(0.17)</b>	<b>(0.16)</b>	<b>(0.16)</b>	<b>(0.16)</b>	<b>(0.65)</b>	<b>(0.36)</b>	<b>(0.03)</b>	<b>20.22</b>	<b>22.51</b>	<b>19.97</b>	<b>22.05</b>	<b>23.43</b>
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.16)	(0.16)	(0.16)	(0.65)	(0.36)	(0.03)	20.22	22.51	19.97	22.05	23.43
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	77,278	78,304	78,383	78,461	78,540	78,422	78,736	79,051	79,368	79,686	80,005	80,326	80,648
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	77,278	78,304	79,087	79,878	80,677	79,487	82,714	86,073	89,568	93,204	96,989	100,927	105,025

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.

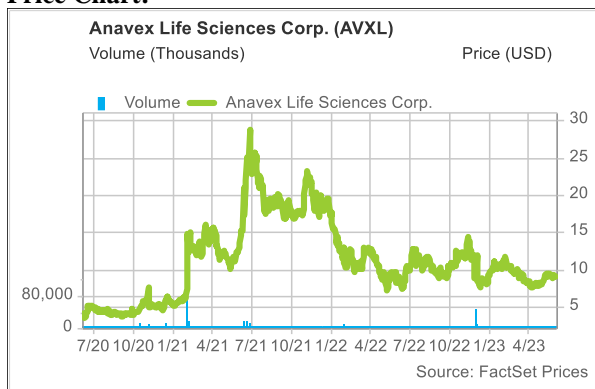
**Market Share Risk.** The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

**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  
Update – Buy – May 9, 2023 – Price Target \$39.00  
Update – Buy – June 6, 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 25-May-23

	<b>Company Coverage</b>		<b>Investment Banking</b>	
<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	2	6%
Market Perform (Neutral)	10	28%	1	3%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

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