

Anavex Life Sciences Corp. (NASDAQ/AVXL)

June 13, 2023

BUY Rated: Additional IP to 2036 Helps Secure Valuation

Jason Kolbert

Managing Director & Senior Analyst
jkolbert@dawsonjames.com

Anavex announced it was awarded new U.S. Patent No. 11,661,405, expanding Anavex's patent coverage of certain crystal forms of ANAVEX2-73 (blarcamesine) compositions, processes of preparation, and uses thereof. This newest patent will be expected to remain in force at least until October 2036.

Current Price	\$8.66
Price Target	\$39.00

Investment Highlights:

Anavex also announced the publication of a relevant new peer-reviewed study in the American Journal on Intellectual and Developmental Disabilities, entitled 'Rett Syndrome Behaviour Questionnaire in Children and Adults with Rett Syndrome: Psychometric Characterization and Revised Factor Structure'.

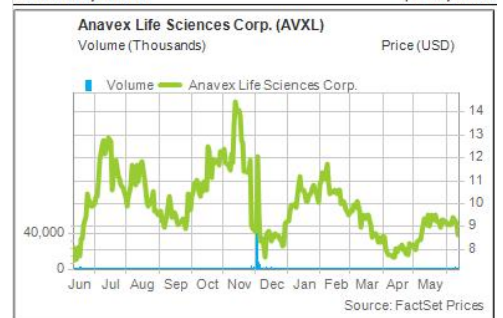


Source: Anavex

The study reports distribution of scores and other statistical features of the Rett Syndrome Behavior Questionnaire (RSBQ) in more than 600 children and adults with Rett syndrome. It also re-examines the structure of the questionnaire, specifically the grouping of questions (items) into different subscales. This evaluation led authors to propose some changes to the organization of the questions (i.e., revised subscales). The study, which represents the largest ever analysis of the RSBQ and the first report of the instrument in adults with Rett Syndrome, was the result of an international collaboration including anonymized databases from the United States, Australia, United Kingdom, and Denmark. The ultimate goal of the project was to provide reference values and other metrics of the RSBQ for its clinical application and implementation in research studies. The study was partially funded by a grant from the International Rett Syndrome Foundation (IRSF). All analyses performed in the study are available to the community through a website hosted by IRSF.

Stock Data		
52-Week Range	\$7.36	\$15.24
Shares Outstanding (mil.)	80.8	
Market Capitalization (mil.)	\$700	
Enterprise Value (mil.)	\$546	
Debt to Capital	0%	
Book Value/Share	\$0.56	
Price/Book	5.6	
Average Three Months Trading Volume (K)	2,219	
Insider Ownership	3.0%	
Institutional Ownership	34.8%	
Short interest (mil.)	20.4%	
Dividend / Yield	\$0.00/0.0%	

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.



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.

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
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	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
Operating expenses	31,287	31,088	41,474	54,647	14,189	14,364	14,420	14,477	57,451	64,504	75,050	293,068	327,470	279,501	319,337	353,425
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
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				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																
Financial Expenses, Net	4,830	4,830	4,555	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)	(1,132)
Pretax Income	(28,393)	(26,258)	(36,918)	(54,722)	(13,057)	(14,364)	(14,420)	(14,477)	(57,451)	(36,337)	(3,185)	2,703,328	3,279,542	3,176,055	3,648,734	4,034,918
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)	(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
Tax Rate	0	0	1%	10%	10%	10%	10%	10%	8%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(50,068)	(13,107)	(12,927)	(12,978)	(13,030)	(52,042)	(29,797)	(2,261)	1,811,230	2,098,907	1,937,393	2,225,728	2,461,300
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)	(0.65)	(0.17)	(0.16)	(0.16)	(0.16)	(0.65)	(0.36)	(0.03)	20.22	22.51	19.97	22.05	23.43
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.

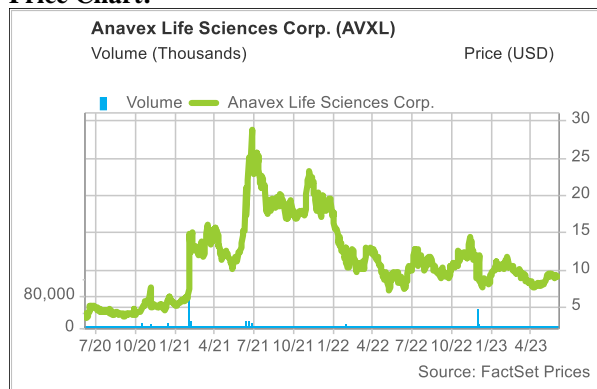
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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
Update – Buy – June 13, 2023 – Price Target \$39.00

Dawson James Securities, Inc. (the "Firm") is a member of the Financial Industry Regulatory Authority ("FINRA") and the Securities Investor Protection Corporation ("SIPC").

The Firm does not make a market in the securities of the subject company(s). The Firm has NOT engaged in investment banking relationships with AVXL in the prior twelve months, as a manager or co-manager of a public offering and has NOT received compensation resulting from those relationships. The Firm may seek compensation for investment banking services in the future from the subject company(s). The Firm has not received other compensation from the subject company(s) in the last 12 months for services unrelated to managing or co-managing of a public offering.

Neither the research analyst(s) whose name appears on this report nor any member of his (their) household is an officer, director or advisory board member of these companies. The Firm and/or its directors and employees may own securities of the company(s) in this report and may increase or decrease holdings in the future. As of May 25, 2023, the Firm as a whole did not beneficially own 1% or more of any class of common equity securities of the subject company(s) of this report. The Firm, its officers, directors, analysts or employees may affect transactions in and have long or short positions in the securities (or options or warrants related to those securities) of the company(s) subject to this report. The Firm may affect transactions as principal or agent in those securities.

Analysts receive no direct compensation in connection with the Firm's investment banking business. All Firm employees, including the analyst(s) responsible for preparing this report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

Although the statements in this report have been obtained from and are based upon recognized statistical services, issuer reports or communications, or other sources that the Firm believes to be reliable, we cannot guarantee their accuracy. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Information about risks can be found in the "RISK ANALYSIS" section of this report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. This report is offered for informational purposes only and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. Additional information is available upon request.

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 25-May-23

	Company Coverage		Investment Banking	
Ratings Distribution	# 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%

Analyst Certification:

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.