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Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: How Much is an Approval in Alzheimer's Worth?

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Anavex met with the European Medicines Agency (EMA). The meetings discussed the debilitating pathology of Alzheimer's disease and Anavex's blarcamesine (ANAVEX2-73) Alzheimer's disease clinical program results, including data obtained in the ANAVEX2-73-AD-004 study. Anavex initiated the process for submitting a Marketing Authorization application to the EMA with the submission of the Centralized Procedure request with the goal of the Authorization allowing direct access to the market of the European Union for oral blarcamesine for the treatment of Alzheimer's disease.

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.

Other Pipeline Updates:

- Rett syndrome: Top-line data of potentially pivotal ANAVEX@2-73-RS-003 Phase 2/3 EXCELLENCE pediatric clinical trial. Company expects to announce topline results from this study in the second half of 2023.
- Parkinson's disease: Initiation of ANAVEX@2-73 pivotal clinical trial.
- Parkinson's disease: Initiation of ANAVEX@2-73 imaging-focused clinical trial
- Fragile X: Initiation of potentially pivotal ANAVEX@2-73 Phase 2/3 clinical trial
- Schizophrenia: Initiation of ANAVEX@3-71 Phase 2 clinical trial
- New Rare disease: Initiation of potentially pivotal ANAVEX@2-73 Phase 2/3 clinical trial
- Publications: Several clinical publications involving ANAVEX@2-73, ANAVEX@3-71 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, 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.



Source: Anavex

Stock Data	
52-Week Range	\$4.90 - \$13.23
Shares Outstanding (mil.)	82.0
Market Capitalization (mil.)	\$574
Enterprise Value (mil.)	\$419
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	5.6
Average Three Months Trading Volume (K)	468
Insider Ownership	2.8%
Institutional Ownership	27.5%
Short interest (mil.)	22.7%
Dividend / Yield	\$0.00/0.0%

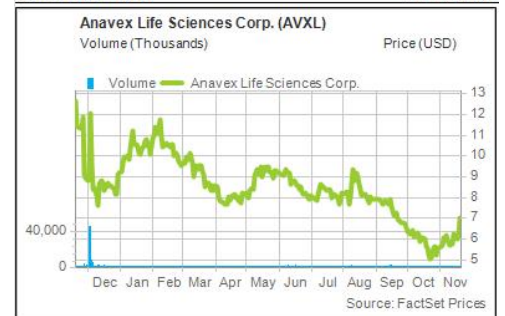


Exhibit 1. Income Statement (\$ '000)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	1Q23A	2Q23A	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	11,307	11,363	11,420	45,396	36,819	29,899	24,280	19,717	16,011	13,002	10,558
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	13,320	2,883	2,883	3,000	3,000	11,765	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	14,190	14,364	14,420	57,163	64,320	74,901	292,946	327,372	279,421	319,272	353,372
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(54,647)	(14,189)	(14,190)	(14,364)	(14,420)	(57,163)	(36,128)	(3,010)	2,703,474	3,279,666	3,176,160	3,648,824	4,034,996
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												
Interest and financing fees	207			(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)												
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)	(13,057)	(14,364)	(14,420)	(57,163)	(36,153)	(3,035)	2,703,449	3,279,641	3,176,135	3,648,799	4,034,971
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)	(50)	(1,436)	(1,442)	(2,978)	(6,508)	(880)	892,138	1,180,671	1,238,693	1,423,032	1,573,639
Tax Rate	0	0	1%	10%	10%	10%	10%	10%	5%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(50,068)	(13,107)	(13,107)	(12,927)	(12,978)	(52,120)	(29,646)	(2,155)	1,811,311	2,098,970	1,937,442	2,225,767	2,461,332
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)	(0.17)	(0.16)	(0.16)	(0.66)	(0.36)	(0.03)	20.43	22.74	20.17	22.27	23.66
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.17)	(0.16)	(0.16)	(0.66)	(0.36)	(0.03)	20.43	22.74	20.17	22.27	23.66
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	77,278	78,304	78,304	78,382	78,461	78,363	78,657	78,972	79,288	79,606	79,925	80,245	80,567
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	77,278	78,304	78,304	79,087	79,878	78,893	81,895	85,220	88,680	92,281	96,028	99,927	103,985

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.

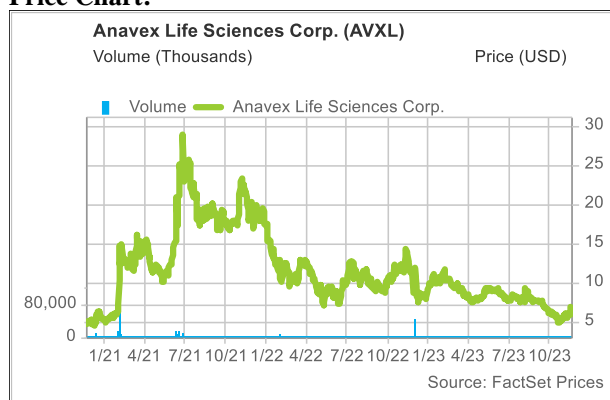
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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
Update – Buy – June 28, 2023 – Price Target \$39.00
Update – Buy – August 8, 2023 – Price Target \$39.00
Update – Buy – September 15, 2023 – Price Target \$39.00
Update – Buy – October 27, 2023 – Price Target \$39.00
Update – Buy – November 21, 2023 – Price Target \$39.00

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- 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 14-Nov-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	61.76%	3	8.80%
Market Perform (Neutral)	13	38.24%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	14.70%

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