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Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: Reports the Quarter: \$143M in Cash

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Anavex reported the fiscal (Sept.) first quarter. The company spent \$11M, \$8.6M in R&D supporting clinical programs and ended the period with \$143M in Cash and equivalents.

Investment Highlights:

Pipeline Update (Press Release-adapted):

- **Alzheimer's disease:** Full data from the blarcamesine in Alzheimer's disease Phase 2b/3 randomized clinical trial will be published in an upcoming peer-reviewed journal. The Company has initiated the process for submitting a Marketing Authorization application to the European Medicines Agency (EMA) under the Centralized Procedure. The Marketing Authorization would allow direct market access throughout the European Union for oral blarcamesine for the treatment of Alzheimer's disease. In addition, the ATTENTION-AD trial, an open-label extension 96-week trial is on-going.
- **Rett syndrome:** Topline data from ANAVEX@2-73-RS-003 Phase 2/3 EXCELLENCE pediatric clinical trial was announced last month. Management plans to further assess the results and discuss with the regulatory authorities next steps.
- **Schizophrenia:** Initiation of FDA cleared placebo-controlled ANAVEX@3-71 Phase 2 clinical trial expected to begin in Q2 2024.
- **Parkinson's disease:** Initiation of ANAVEX@2-73 imaging-focused trial and Phase 2b/3 6 months trial.
- **Fragile X:** New disease-specific, translatable, and objective biomarker data generated with ANAVEX@2-73, support the initiation of the potentially pivotal ANAVEX@2-73 Phase 2/3 clinical trial.
- **New Rare disease:** Initiation of potentially pivotal ANAVEX@2-73 Phase 2/3 clinical trial.

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.



Stock Data	
52-Week Range	\$4.90 - \$11.10
Shares Outstanding (mil.)	82.1
Market Capitalization (mil.)	\$459
Enterprise Value (mil.)	\$315
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	3.8
Average Three Months Trading Volume (K)	1,361
Insider Ownership	3.1%
Institutional Ownership	30.9%
Short interest (mil.)	25.2%
Dividend / Yield	\$0.00/0.0%

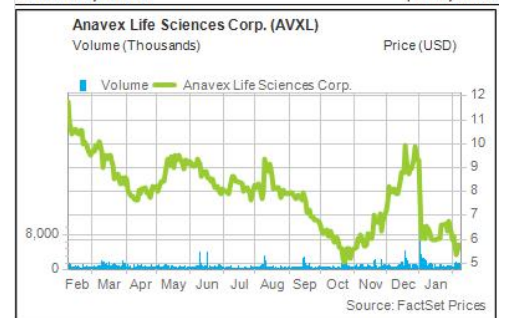


Exhibit 1. Income Statement (\$ '000)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	2023A	1Q24A	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		-	-	-	-	-	-	-	-	-	-	597,805	799,351	640,369	746,487	809,006
Anavex2-73 AD ROW												741,484	771,143	661,898	810,163	964,094
Anavex2-73 Rett's Syndrome											43,134	351,974	448,767	549,290	560,276	571,482
Anavex2-73 Parkinson's Dementia PDD												106,589	144,961	221,791	263,931	288,439
Total Product Revenues											43,134	1,797,852	2,164,222	2,073,348	2,380,858	2,633,021
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)											43,134	1,797,852	2,164,222	2,073,348	2,380,858	2,633,021
Expenses																
Cost of Goods Sold (10%)												133,929	157,049	130,227	155,665	177,310
Accounting and Audit Fees																
Amortization and depreciation	2	2	2	2	2		0	0	0	1	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	43,717	8,684	8,727	8,771	8,815	34,997	28,420	23,079	18,741	15,219	12,359	10,036
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	13,320	12,039	2,609	7,500	7,500	7,500	25,109	45,000	45,450	45,905	46,364	46,827	47,295
Operating expenses	31,287	31,088	41,474	54,647	55,758	11,293	16,228	16,271	16,315	60,108	73,421	202,459	221,697	191,811	214,853	234,643
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(54,647)	(55,758)	(11,293)	(16,228)	(16,271)	(16,315)	(60,108)	(30,287)	1,595,393	1,942,526	1,881,538	2,166,005	2,398,378
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)			(6)	(6)	(6)	(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)	-	-	(6)	(6)	(6)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net																
Financial Expenses, Net		4,830	4,555		8,528	2,756										
Pretax Income	(28,393)	(26,258)	(36,918)	(54,722)	(47,498)	(8,537)	(16,234)	(16,278)	(16,322)	(60,133)	(30,312)	1,595,368	1,942,501	1,881,513	2,165,980	2,398,353
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)	(7)	(85)	-	-	-	(85)	(3,031)	319,074	485,625	602,084	844,732	935,358
Tax Rate	0	0	1%	1%	0%	0%	0%	0%	0%	0%	10%	20%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(50,068)	(42,708)	(8,622)	(16,234)	(16,278)	(16,322)	(57,455)	(27,281)	1,276,295	1,456,876	1,279,429	1,321,248	1,462,995
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.71	0.67	0.62	0.55	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.65)	(0.54)	(0.11)	(0.20)	(0.19)	(0.19)	(0.69)	(0.31)	14.15	15.51	13.09	12.99	13.83
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.65)	(0.54)	(0.11)	(0.20)	(0.19)	(0.19)	(0.69)	(0.31)	14.15	15.51	13.09	12.99	13.83
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	77,278	79,788	82,077	82,159	82,241	82,323	82,200	82,529	82,860	83,192	83,525	83,860	84,196
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	77,278	79,788	82,077	82,898	83,727	84,564	83,316	86,699	90,220	93,883	97,695	101,662	105,790

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.

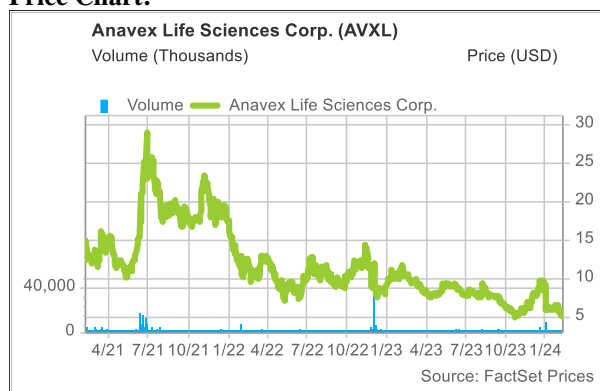
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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
Update – Buy – November 28, 2023 – Price Target \$39.00
Update – Buy – December 19, 2023 – Price Target \$39.00
Update – Buy – December 21, 2023 – Price Target \$39.00
Update – Buy – January 3, 2024 – Price Target \$39.00
Update – Buy – January 17, 2024 – Price Target \$39.00
Update – Buy – January 24, 2024 – Price Target \$39.00
Update – Buy – February 8, 2024 – 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.

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 30-Jan-24

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	58.82%	4	11.80%
Market Perform (Neutral)	14	41.18%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	6	17.70%

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