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Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: Reports the Quarter - \$153M in Cash and Equivalents – Looking at Accelerated Pathway for Alzheimer’s

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Fiscal quarter (ending March 31st) Results: Anavex closed the period with cash and equivalents of \$153.5M. General and administrative expenses for the quarter were \$2.9 million and R&D expenses were \$11.3 million. Anavex highlighted their hope to initiate discussions with regulatory agencies for Accelerated Approval Pathway for ANAVEX2-73.

Investment Highlights:

Accelerated Pathway Possible: Anavex in their press release this morning stated: “With newly available preliminary efficacy results of surrogate biomarkers, we consider initiating discussions with regulatory agencies for Accelerated Approval Pathway for ANAVEX@2-73 (blarcamesine) in patients with Parkinson’s disease, the second largest neurodegenerative disease after Alzheimer’s disease.”

Key Near Term Pipeline Updates - (press release):

- Alzheimer’s disease: Full data ANAVEX@2-73-AD-004, including newly available preliminary results of surrogate biomarkers of pivotal Phase 2b/3 clinical trial. The Company intends to discuss these findings with regulatory authorities in the context of the ongoing clinical development of ANAVEX@2-73 in this indication, with the goal of providing a much-needed treatment to the millions of patients living with Alzheimer’s disease with convenient once-daily oral treatment once daily treatment. The Company plans to proceed in parallel with the initiation of a confirmatory Alzheimer’s disease study.
- 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, 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.

Current Price	\$8.41
Price Target	\$39.00



Source: Anavex

Stock Data			
52-Week Range	\$7.13	-	\$15.24
Shares Outstanding (mil.)	78.0		
Market Capitalization (mil.)	\$656		
Enterprise Value (mil.)	\$513		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	5.6		
Average Three Months Trading Volume (K)	1,420		
Insider Ownership	3.0%		
Institutional Ownership	35.2%		
Short interest (mil.)	20.0%		
Dividend / Yield	\$0.00/0.0%		

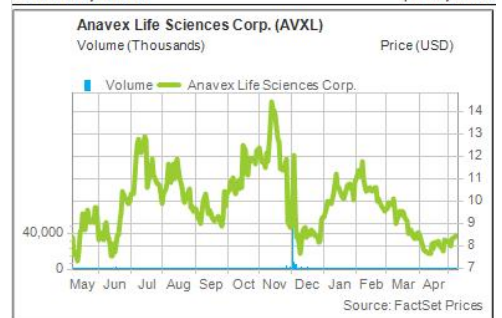


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
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.

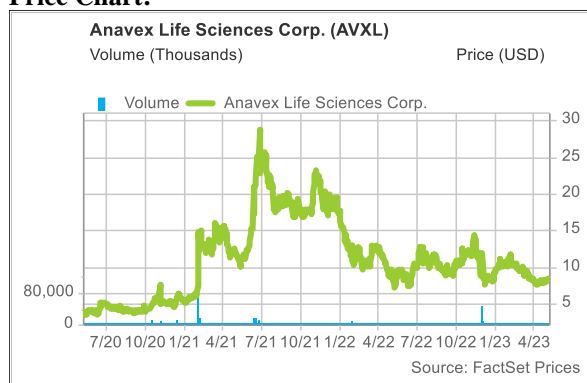
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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

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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.

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Current as of 1-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%

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