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Anavex Life Sciences Corp. (NASDAQ/AVXL)

August 9, 2022

BUY: Anavex Reports 3rd Quarter Fiscal Results: \$153M in Cash – Multiple Catalysts

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Anavex announced fiscal third-quarter results. Anavex has Cash and cash equivalents of \$153.2 million as of June 30, 2022. The company reported a net loss of \$12.4 million, or \$0.16 per share for the quarter. The company will host an investor call at 4:30 today. [Click Here for Our Webinar](#)

Investment Highlights (Press Release):

ANAVEX2-73 Program and other Near-Term Pipeline Data Updates:

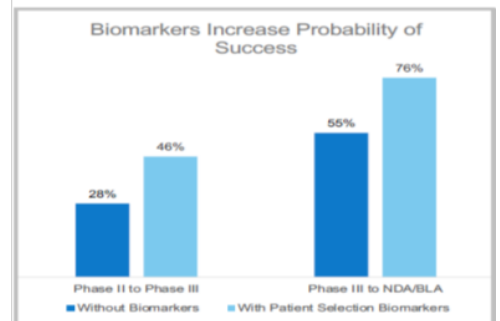
- Last patient last visit in the randomized, placebo-controlled Phase 2b/3 study ANAVEX@2-73-AD-004 for the treatment of early Alzheimer's disease occurred at the end of June 2022 and top line results are expected in the fall of 2022.
- Last patient last visit of the 48-week open label extension of the Parkinson's Disease Dementia Phase 2 study occurred this quarter and data expected by end of 2022.
- Completion of the randomized, placebo-controlled EXCELLENCE Phase 2/3 study ANAVEX@2-73-RS-003 for the treatment of pediatric patients with Rett syndrome is expected by end of 2022.
- Pipeline expansion of the ANAVEX platform using gene biomarkers of response and applying precision medicine for treatment of neurological disorders with high unmet medical need are expected 2022:
- Meeting with FDA for discussing ANAVEX@2-73 Parkinson's disease program including pivotal Phase 3 study.
- Planned initiation of ANAVEX@2-73 imaging-focused Parkinson's disease clinical study.
- Planned initiation of a potentially pivotal Phase 2/3 study in Fragile X syndrome, the most frequent genetic cause of autism spectrum disorder.
- Planned initiation of a Phase 2/3 clinical trial for the treatment of a new rare-disease indication.
- Planned initiation of ANAVEX@3-71 Phase 2 clinical trials for schizophrenia, frontotemporal dementia (FTD) and Alzheimer's disease indications.

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 **\$11.45**
Price Target **\$39.00**

Precision Medicine



Thomas DW et al. Clinical Development Success Rates 2006-2015. BIO Industry Analysis

Stock Data

52-Week Range	\$7.13	-	\$23.73
Shares Outstanding (mil.)	77.4		
Market Capitalization (mil.)	\$886		
Enterprise Value (mil.)	\$733		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	9.0		
Average Three Months Trading Volume (K)	997		
Insider Ownership	3.1%		
Institutional Ownership	33.1%		
Short interest (mil.)	10.7%		
Dividend / Yield	\$0.00/0.0%		

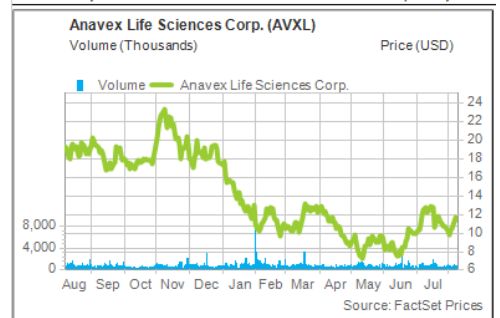


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		-	-	-	-	-	-	-	-	383,651	677,784	996,342	1,332,252	1,067,282	1,244,145	1,348,343
Anavex2-73 AD ROW			-	-	-	-	-	-	-	1,110,338	1,471,198	1,235,807	1,285,239	1,103,163	1,350,272	1,606,824
Anavex2-73 Rett's Syndrome			-	-	-	-	-	-	138,197	281,922	431,341	586,623	747,945	915,484	933,794	952,470
Anavex2-73 Parkinson's Dementia PDD				-	-	-	-	-	-	28,458	116,110	177,649	241,602	369,651	439,885	480,732
Total Product Revenues									138,197	1,804,370	2,696,433	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)									138,197	1,804,370	2,696,433	2,996,421	3,607,037	3,455,581	3,968,096	4,388,368
Expenses																
Cost of Goods Sold (10%)		-	-	-	-	-	-	-	-	149,399	214,898	223,215	261,749	217,045	259,442	295,517
Accounting and Audit Fees																
Amortization and depreciation	2	2	2	0	0	0	0	2	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	8,604	9,273	9,320	9,366	36,563	30,197	24,522	19,913	16,171	13,132	10,664	8,660	7,032
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	5,857	9,205	2,915	3,185	3,000	3,000	12,100	40,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	31,287	31,088	41,474	11,519	12,459	12,320	12,367	48,665	70,199	248,923	299,813	305,037	341,189	294,679	335,742	370,866
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(11,519)	(12,459)	(12,320)	(12,367)	(48,665)	67,998	1,555,447	2,396,620	2,691,383	3,265,849	3,160,901	3,632,354	4,017,502
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1
Other income (expense)	2,466															
Research and Development incentive	299				682			682								
Interest and financing fees	207			8	230	(6)	(6)	(25)	(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)			(733)								
Financing related charges and adjustments																
Other non-operating income																
Non-operating Income (expense)	2,894	-	2,129		180	(6)	(6)	(75)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net																
Financial Expenses, Net		4,830	4,555													
Pretax Income	(28,393)	(26,258)	(36,918)	(10,438)	(12,279)	(12,326)	(12,373)	(48,740)	67,973	1,555,422	2,396,595	2,691,358	3,265,824	3,160,876	3,632,329	4,017,477
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)		(88)	(616)	(619)	(1,323)	6,797	279,976	695,012	888,148	1,175,696	1,232,742	1,416,608	1,566,816
Tax Rate	0	0		5%	5%	5%	5%	3%	10%	18%	29%	30%	31%	31%	31%	31%
GAAP Net income (loss)	(28,475)	(26,280)	(37,074)	(10,438)	(12,368)	(11,710)	(11,754)	(46,270)	61,176	1,275,446	1,701,582	1,803,210	2,090,127	1,928,135	2,215,721	2,450,661
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.44	0.71	0.63	0.60	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.14)	(0.16)	(0.15)	(0.15)	(0.60)	0.75	15.13	19.40	19.76	22.00	19.50	21.54	22.89
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.14)	(0.16)	(0.15)	(0.15)	(0.60)	0.75	15.13	19.40	19.76	22.00	19.50	21.54	22.89
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	76,249	77,442	77,520	77,597	77,202	77,791	78,103	78,416	78,730	79,045	79,362	79,680	79,999
Wgtd Avg Shrs (Dil)	48,906	58,195	69,869	76,249	77,442	78,217	78,999	77,727	80,994	84,282	87,705	91,266	94,971	98,828	102,840	107,016

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.

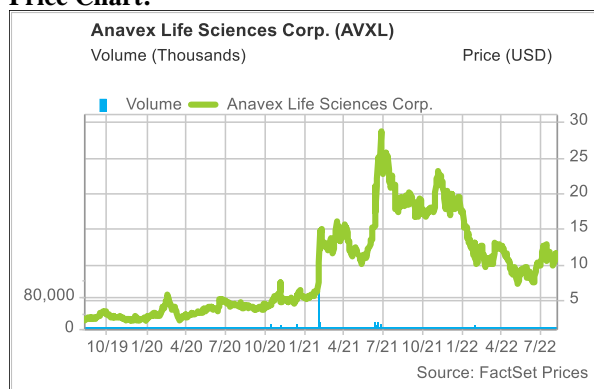
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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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 8-Aug-22

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	29	66%	4	14%
Market Perform (Neutral)	14	32%	0	0%
Market Underperform (Sell)	1	2%	0	0%
Total	44	100%	4	9%

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