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Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY: DSMB – Rett Syndrome Study Should Continue: No Change

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Anavex announced that the Independent Data Safety Monitoring Board (DSMB) for the company's three late-stage studies (AVATAR (ANAVEX2-73-RS-002), EXCELLENCE (ANAVEX@2-73-RS-003) [2] and the U.S. Rett syndrome extension study (ANAVEX2-73-RS-EP-001) should all continue. This follows similar news from earlier this month that the Phase 2b/3 Alzheimer's disease study of ANAVEX2-73 should continue with no change. We view this as positive across the board.

Investment Highlights

1. Upon review of the interim safety data, the DSMB made the following recommendation for the randomized, double-blind, placebo-controlled AVATAR (ANAVEX@2-73-RS-002) study in adult patients with Rett syndrome: The DSMB recommendation is to continue the studies without modification.
2. Upon review of the interim safety data, the DSMB made the following recommendation for the randomized, double-blind, placebo-controlled EXCELLENCE (ANAVEX@2-73-RS-003) study in pediatric patients with Rett syndrome: The DSMB recommendation is to continue the studies without modification.
3. Upon review of the interim safety data, the DSMB made the following recommendation for the open-label extension U.S. Rett syndrome (ANAVEX@2-73-RS-EP-001) study in adult patients with Rett syndrome: The DSMB recommendation is to continue the studies without modification.

2021 is a Year of Events.

- Rett's Syndrome (RTT): Top-line data is expected from the "AVATAR" trial. The study may be considered to be pivotal (Phase 2/3) in adult RTT clinical trial – expected 1H-2021.
- Top-line data Phase 1 ANAVEX3-71 clinical trial – expected 1H 2021.
- Top-line data EXCELLENCE: Potentially pivotal Phase 2/3 pediatric RTT clinical trial – expected 2H 2021.
- Top-line data ANAVEX2-73-AD-004: Potentially pivotal Phase 2b/3 A.D. clinical trial – expected 1H 2022.
- Initiation of ANAVEX2-73 imaging-focused Parkinson's disease clinical trial – expected 2021.
- Initiation of potentially pivotal Phase 2/3 Fragile X clinical trial – expected 2021.
- Initiation of potentially pivotal Phase 2/3 clinical trial for the treatment of a new, rare disease indication – expected 2021.

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 lower range of probability of success (20-30%) 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.

Current Price	\$5.66		
Price Target	\$19.00		
Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)	\$ 31,287	\$ 31,438	\$ 33,048
1Q March	\$ 7,474	\$ 7,701	\$ 8,216
2Q June	\$ 8,140	\$ 7,774	\$ 8,247
3Q September	\$ 7,821	\$ 7,967	\$ 8,277
4Q December	\$ 7,852	\$ 7,997	\$ 8,308
	F2019A	F2020E	F2021E
EPS (diluted)	\$ (0.65)	\$ (0.51)	\$ (0.27)
1Q March	\$ (0.16)	\$ (0.12)	\$ (0.07)
2Q June	\$ (0.17)	\$ (0.12)	\$ (0.07)
3Q September	\$ (0.16)	\$ (0.14)	\$ (0.07)
4Q December	\$ (0.16)	\$ (0.13)	\$ (0.07)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$2.20	-	\$6.31
Shares Outstanding (mil.)	58.7		
Market Capitalization (mil.)	\$332		
Enterprise Value (mil.)	\$313		
Debt to Capital	0%		
Book Value/Share	\$0.56		
Price/Book	8.2		
Average Three Months Trading Volume (K)	1,494		
Insider Ownership	4.0%		
Institutional Ownership	20.1%		
Short interest (mil.)	11.0%		
Dividend / Yield	\$0.00/0.0%		

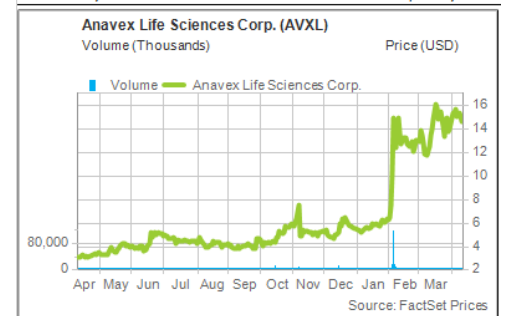


Exhibit 1. Income Statement (\$ in thousands)

Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	1Q20A	2Q20A	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		-	-	-	-	-	-	-	-	191,826	338,892	498,171	666,126	533,641	622,073	674,171
Anavex2-73 AD ROW							-	-		555,169	735,599	617,903	642,619	551,582	675,136	803,412
Anavex2-73 Rett's Syndrome							6,642	67,744	207,296	317,162	395,395	439,967	448,767	457,742	466,897	476,235
Anavex2-73 Parkinson's Dementia PDD									-	14,229	58,055	88,824	120,801	184,826	219,943	240,366
Total Product Revenues							6,642	67,744	207,296	1,078,386	1,527,942	1,644,866	1,878,313	1,727,790	1,984,048	2,194,184
% Chg																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)							6,642	67,744	207,296	1,078,386	1,527,942	1,644,866	1,878,313	1,727,790	1,984,048	2,194,184
Expenses																
Cost of Goods Sold (10%)		-	-	-	-	-	-	-	-	74,699	107,449	111,607	130,875	108,522	129,721	147,758
Accounting and Audit Fees																
Amortization and depreciation	2	0	0	0	0	2	2	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	6,349	6,053	6,083	6,114	24,599	24,762	20,108	16,329	13,260	10,768	8,744	7,101	5,766	4,683	3,803
Salaries and wages																
Travel																
Website design and maintenance																
General and Administrative	6,847	1,352	1,720	1,883	1,883	7,531	8,284	80,000	100,000	75,000	65,000	65,650	66,307	66,970	67,639	68,316
Operating expenses	31,287	7,701	7,774	7,967	7,997	31,438	33,048	100,110	116,331	162,961	183,219	186,003	204,283	181,260	202,044	219,878
Oper. Inc. (Loss)	(31,287)	(7,701)	(7,774)	(7,967)	(7,997)	(31,438)	(26,406)	(32,366)	90,965	915,425	1,344,723	1,458,863	1,674,030	1,546,531	1,782,004	1,974,306
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	47	717													
Interest and financing fees	207					(28)	(30)	(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)		53	(326)													
Financing related charges and adjustments																
Other non-operating income		1,018	145													
Non-operating income (expense)	2,894	1,118	536	-	-	(28)	(30)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net																
Financial Expenses, Net																
Pretax Income	(28,393)	(6,583)	(7,237)	(7,967)	(7,997)	(31,466)	(26,436)	(32,391)	90,940	915,400	1,344,698	1,458,838	1,674,005	1,546,506	1,781,979	1,974,281
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(82)						(9,781)	(1,620)	9,094	164,772	389,962	481,416	602,642	603,137	694,972	769,970
Tax Rate	0	(9)	0	0	0	-	5%	10%	18%	29%	30%	31%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(6,592)	(7,237)	(7,967)	(7,997)	(31,466)	(16,655)	(30,772)	81,846	750,628	954,736	977,421	1,071,363	943,368	1,087,007	1,204,311
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.39	0.70	0.62	0.59	0.57	0.55	0.55	0.55
GAAP-EPS	(0.65)	(0.12)	(0.12)	(0.14)	(0.13)	(0.51)	(0.27)	(0.48)	1.24	10.91	13.34	13.13	13.82	11.70	12.95	13.79
Non GAAP EPS (dil)	(0.65)	(0.12)	(0.12)	(0.14)	(0.13)	(0.51)	(0.27)	(0.48)	1.24	10.91	13.34	13.13	13.82	11.70	12.95	13.79
Wgtd Avg Shrs (Bas)	48,906	54,774	58,354	58,412	58,471	57,503	58,617	58,852	59,088	59,324	59,562	59,801	60,040	60,281	60,522	60,765
Wgtd Avg Shrs (Dil)	48,906	54,774	58,354	58,937	59,527	57,898	61,030	63,508	66,087	68,770	71,562	74,468	77,492	80,638	83,913	87,320

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.

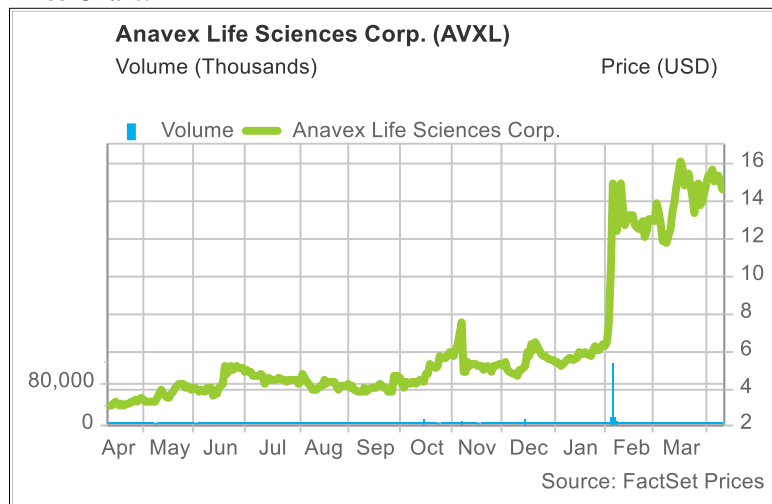
Regulatory Risk. Anavex, even with good clinical data, could face extensive delays and other regulatory setbacks.

Companies mentioned in this report:

Cassava Science (SAVA Not Rated)

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 – February 19, 2021 – Price Target \$16.0 to \$19.0
- Update – April 5, 2021 – Price Target \$19.0
- Update – April 12, 2021 – Price Target \$19.0

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	69%	6	30%
Market Perform (Neutral)	9	31%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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