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UPDATE REPORT

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Anavex Life Sciences Corp. (NASDAQ/AVXL)

December 15, 2020

BUY: P-Values in N=25 Phase 2 Trial in Rett Syndrome

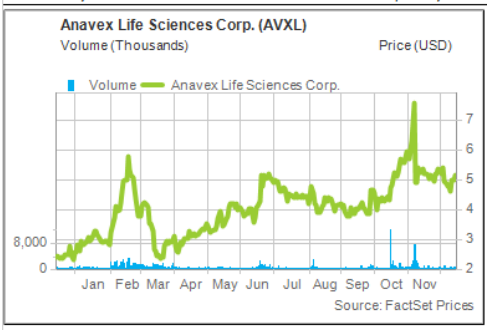
Jason Kolbert
Healthcare Research
jkolbert@dawsonjames.com

Anavex reported Phase 2 data from the firm's randomized, double-blind, placebo-controlled trial of ANAVEX2-73 in adult female patients with Rett syndrome. The small Phase 2 trial delivered P-values across two meaningful endpoints compared to placebo. The endpoints: The Rett Syndrome Behavior Questionnaire (RSBQ) (p = 0.048) and the Clinical Global Impression Improvement Scale (CGI-I) score (p = 0.014) in the intent-to-treat (ITT) population (n = 25). Statistically significant differences in patient symptoms between the active and placebo groups occurred as early as four weeks following the initiation of ANAVEX2-73 administration. Improvements in RSBQ Total scores were correlated with parallel decreases (improvements) in glutamate plasma levels.

Current Price	**$5.19**
Price Target	**$16.00**

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.)			$304
Enterprise Value (mil.)			$285
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%



Investment Highlights

The Phase 2 Trial. Anavex announced results from a Small Phase 2 N= 25 patient trial. The trial is a randomized study. Based on the strong data thus far, participants will continue to trial the drug for an additional 12 weeks (an extension study). Anavex will be advancing its Expanded Access Policy in order to provide long-term therapy to current participants with Rett syndrome under an expanded access program for ANAVEX2-73. Recall that the primary endpoint of this small Phase 2 trial is safety. The oral liquid once-daily dosing of 5 mg ANAVEX2-73 was well-tolerated and demonstrated dose-proportional PK (pharmacokinetics). Adverse events related to the study drug were similar between ANAVEX2-73 (13.3%) and placebo (10%), with no reported serious adverse events (SAEs). The safety profile of ANAVEX2-73 in this trial is consistent with prior clinical trial data.

We Agree with Anavex. The outcome of this trial is impressive. "Despite the challenges of the older age of the cohort (patients were over 18 years of age) and the relatively low dose (5 mg daily), ANAVEX2-73 demonstrated clinically meaningful improvements in outcome measures evaluating multiple impairments," commented Walter E Kaufmann, MD, Principal Investigator. Subsequent to his appointment as Principal Investigator of this Phase 2 ANAVEX®2-73 trial in adult Rett syndrome patients, Dr. Kaufmann joined Anavex as Chief Medical Officer. He also said, "Moreover, the convergent clinical evidence was supported by parallel changes in a key biomarker of disease. This strong body of data opens the possibility of successful treatment for both adults and children with Rett syndrome and early interventions for modifying the course of the disease."

What's Next? Rett Syndrome is an unmet medical need. ANAVEX2-73 has Fast Track designation, Rare Pediatric Disease Designation, and Orphan Drug designation from the FDA to treat Rett syndrome and may be considered for accelerated approval.

Effect on Rett Syndrome Symptoms (press release):

- ANAVEX2-73 treatment yielded a statistically significant, drug exposure-dependent response in the RSBQ Total scores, when compared to placebo, in the ITT cohort (all participants, p = 0.048).
- 66.7% of ANAVEX2-73 treated subjects showed a statistically significant improvement in drug exposure-dependent RSBQ response as compared to 10% of the subjects on placebo in the ITT cohort (all participants, p = 0.011).
- Improvements in this adult population with Rett syndrome, assessed by RSBQ Total scores, are considered clinically meaningful according to published criteria applied to neurodevelopmental disorders.[5]
- ANAVEX2-73 treatment resulted in a sustained improvement in CGI-I scores throughout the 7-week study, when compared to placebo in the ITT cohort (all participants, p = 0.014).
- 86.7% of ANAVEX2-73 treated subjects showed a statistically significant CGI-I response, defined as sustained improvement to treatment, as compared to 40% of the subjects on placebo in the ITT cohort (all participants, p = 0.014).

Safety and Tolerability:

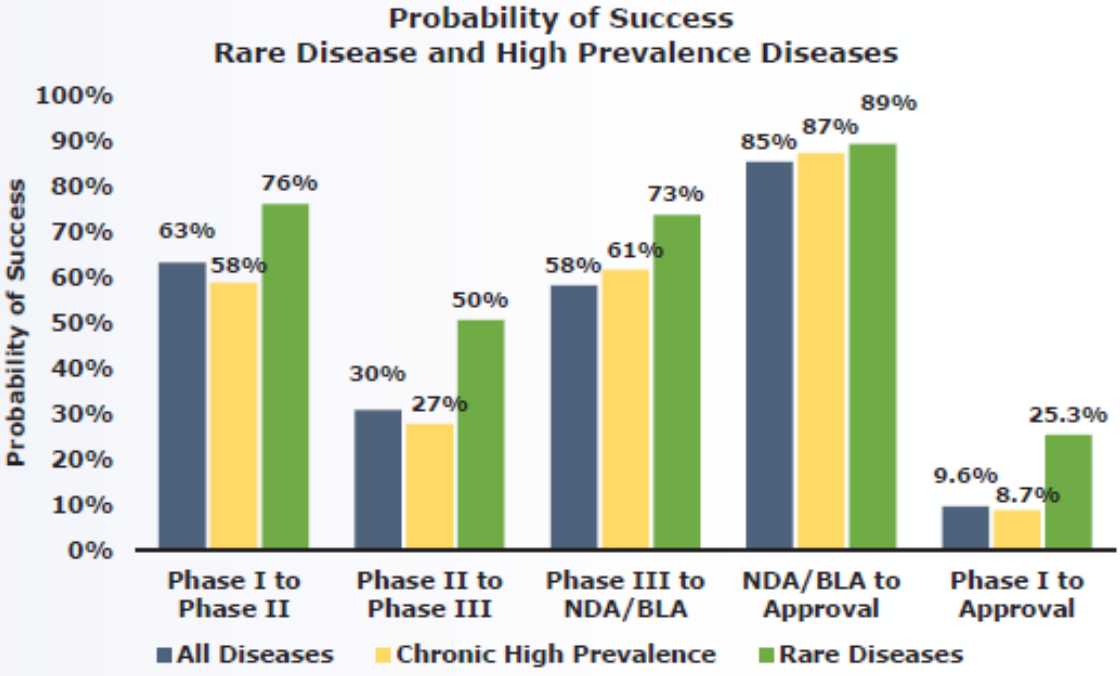
- ANAVEX2-73 was found to be well tolerated with very good medication compliance during the trial.
- All 25 subjects completed the study. The overall incidence of patients who experienced adverse events related to study drug, which were mild, or moderate was 13.3% (2) for the ANAVEX2-73 treatment group and 10% (1) for the placebo group.
- No serious treatment emergent adverse events were reported during the course of the trial.
- There were no clinically significant differences in vital signs, lab values and EKG parameters between the active drug and placebo groups.
- Collectively, the study results are consistent with the known safety profile of ANAVEX2-73.
- There was no signal for increased risk for common disorder-related manifestations.

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 just a 25% probability of success 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.

Risk to our thesis, include the following: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these risks in the risk section of this report.

Current Treatment for Rett Syndrome. Rett syndrome is a rare non-inherited genetic postnatal progressive neurodevelopmental disorder that almost exclusively occurs in females (approximately 1 in every 10,000-15,0000 female births). This disorder leads to several lifelong impairments, such as difficulty breathing, talking, walking, and eating. The cause is due to an X-linked mutation (MECP2) responsible for encoding methyl-CpG- binding protein. No drugs are currently approved specifically for the treatment of Rett syndrome. However, there are certain types of antiepileptic drugs that are used for seizure-like behavior associated with symptoms of the syndrome. Current treatments used for Rett syndrome are directed at helping individuals with communication, social participation, and mobility. These treatment modalities usually only progress as the children grow older and involve a team of specialists who each address specific symptoms caused by Rett syndrome. This holistic approach is aimed at making life more comfortable for patients, not at treating or slowing down the disease. ANAVEX2-73 is one of four clinical studies currently being funded by the Rett syndrome foundation. So far, ANAVEX2-73 has shown promising results in mouse models during preclinical trial studies completed in 2016. These conclusions were promising enough that Anavex is now in a Phase 2 study in Rett syndrome. Currently, there are two Phase 2 studies. One in the U.S. and one in Australia (the Avatar study).

Exhibit 1. Increased probability for FDA approval of rare diseases



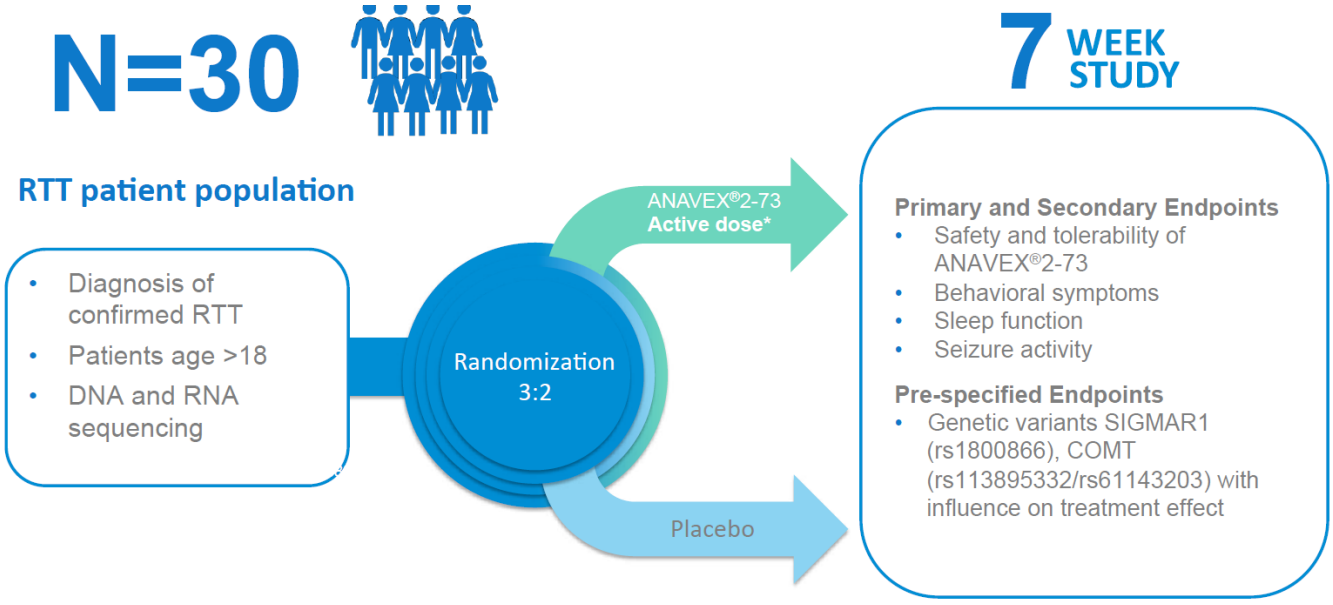
Phase Success	Phase I to Phase II		Phase II to Phase III		Phase III to NDA/BLA		NDA/BLA to Approval	
	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success	Advanced or Suspended	Phase Success
All Diseases	3582	63.2%	3862	30.7%	1491	58.1%	1050	85.3%
Chronic High Prevalence	732	58.7%	726	27.7%	268	61.6%	196	87.2%
Rare Diseases	150	76.0%	168	50.6%	110	73.6%	93	89.2%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
All Diseases	9985	9.6%	6403	15.3%	2541	49.6%	1050	85.3%
Chronic High Prevalence	1922	8.7%	1190	14.9%	464	53.7%	196	87.2%
Rare Diseases	521	25.3%	371	33.3%	203	65.7%	93	89.2%

Source: BIO Industry Analysis

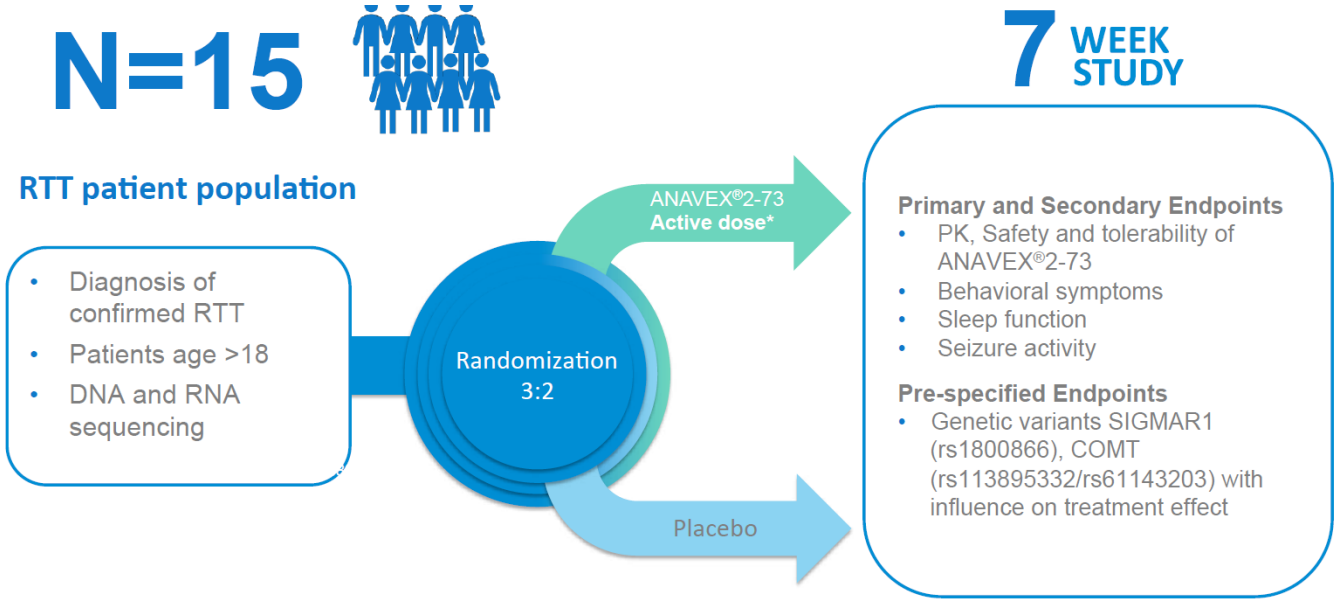
There are now three ongoing clinical studies in Anavex's Rett Syndrome Program: U.S. RTT, AVATAR, and EXCELLENCE. As a reminder, ANAVEX2-73 had previously received Fast Track designation, Rare Pediatric Disease Designation, and Orphan Drug designation from the FDA for the treatment of Rett syndrome.

Exhibit 2. ANAVEX2-73 Study Design for Rhett Syndrome (AVATAR – Australia)



Source: Anavex Life Sciences

Exhibit 3. ANAVEX2-73 Study Design for Rhett Syndrome (U.S.)



Source: Anavex Life Sciences

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Exhibit 4. FCFF Model

Average	$	16

Price Target	$	18
Year		2020

DCF Valuation Using FCF (mln):

units ('000)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(17,381)	(26,213)	(32,160)	(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
Tax Rate	0%	0%	0%	0%	5%	10%	18%	18%	30%	31%	31%	39%	39%
EBIT(1-t)	(17,381)	(26,131)	(32,160)	(26,436)	(30,772)	81,846	750,628	1,102,652	1,021,186	1,155,063	1,067,089	1,087,007	1,204,311
CapEx	-	-	-	-	-								
Depreciation	-	-	-	-	-								
Change in NWC (ex cash)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FCF	(17,381)	(26,131)	(32,160)	(26,436)	(30,772)	81,846	750,628	1,102,652	1,021,186	1,155,063	1,067,089	1,087,007	1,204,311
PV of FCF	(29,373)	(33,970)	(32,160)	(20,336)	(18,208)	37,253	262,816	296,976	211,566	184,078	130,814	102,504	87,359

Discount Rate	30%	
Long Term Growth Rate	1%	
Terminal Cash Flow	4,194,325.49	
Terminal Value YE2030	304,249	
NPV	1,546,911	
NPV-Debt	-	
Projected Shares out (thousands)	87,320	2030E
NPV Per Share	$ 17.72	

Source: Dawson James estimates

Exhibit 5. Discounted EPS Model

Current Year		2020
Year of EPS		2030
Earnings Multiple		15
Discount Factor		30%
Selected Year EPS	$	13.79
NPV	$	15.00

	Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS						
Earnings Multiple	15.00	5%	10%	15%	20%	25%	30%
1		$8.46	$5.32	$3.41	$2.23	$1.48	$1.00
5		$42.32	$26.58	$17.04	$11.13	$7.40	$5.00
10		$84.65	$53.16	$34.08	$22.27	$14.80	$10.00
15		$126.97	$79.74	$51.12	$33.40	$22.21	$15.00
20		$169.29	$106.32	$68.16	$44.54	$29.61	$20.00
25		$211.62	$132.90	$85.20	$55.67	$37.01	$25.00
30		$253.94	$159.48	$102.25	$66.81	$44.41	$30.00
35		$296.26	$186.06	$119.29	$77.94	$51.82	$35.01

Source: Dawson James estimates

Exhibit 6. Sum of the Parts Model

Anavex Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	Term Val
AVXL 2-73 U.S. AD	1%	30%	5	50%	$2,697	$9,298.91
NPV						$3.59
AVXL 2-73 ROW AD	1%	30%	5	50%	$3,214	$11,081.54
NPV						$4.27
AVXL 2-73 Rett's Syndrome	1%	30%	3	50%	$1,905	$6,568.76
NPV						$4.28
AVXL 2-73 PDD	1%	30%	3	50%	$961	$3,315.39
NPV						$2.16
Net Margin						25%
MM Shrs OS (2030E)						87
Total						$14.3

Source: Dawson James estimates

Exhibit 7. Income Statement

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 Dimentia 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 miscellanous 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 maintence																
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%
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	**(0.58)**	**(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)	(0.58)	(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 IP 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.

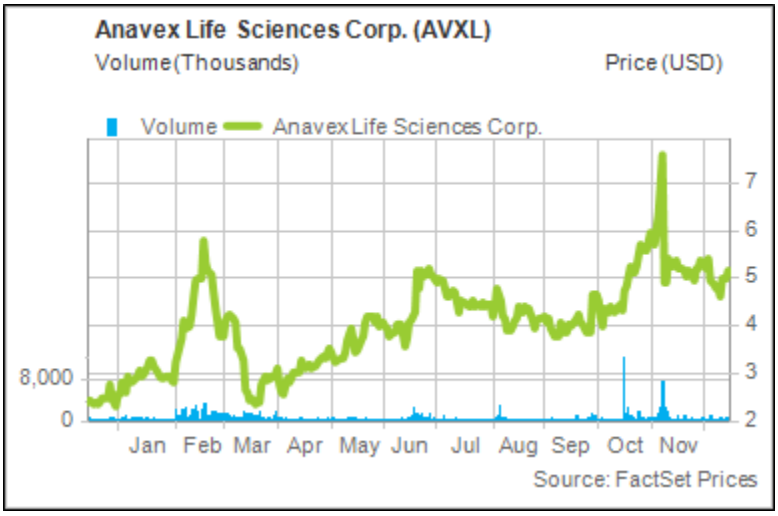
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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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.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	78%	5	24%
Market Perform (Neutral)	6	22%	1	17%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	6	22%

Analyst Certification:

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