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Anavex Life Sciences Corp. (NASDAQ/AVXL)

BUY: We See ANAVEX2-73 as an Undervalued Asset in the CNS Space – Alzheimer's, Parkinson's & Rett Syndrome; Raising Our Price Target to \$19.00 from \$16.00

We recently updated our model for Anavex to reflect the cash balance of approximately \$50M and review the potential catalysts ahead. Updating our model and rolling our valuation forward raises our target valuation from \$16.00 to \$19.00 per share. We see Anavex as a company on the verge of success and one that is undervalued versus many of its peers, such as Cassava Sciences (SAVA-Not Rated), which sports a \$2B market cap, compared to Anavex at \$883M. However, Anavex, in our opinion, has more mature data sets across multiple CNS programs.

Investment Highlights

A New Approach to CNS Disease. The development of Alzheimer's has been linked to different mechanisms that may trigger negative cascades. Research advances are emerging around what happens when cells undergo stress. Why do some survive and others degenerate? One answer may relate to individual cell survival mechanisms, which in part may be related to the role of the Sigma-1 Receptor, which is activated (an agonist) by ANAVEX2-73. It is believed that Sigma 1 can help to protect a cell from the accumulation of misfolded proteins, acting to chaperone them out of the cell. As a result, cell metabolism (oxidative stress and mitochondrial dysfunction) is kept in balance. The implications here can have an impact across a wide range of neurodegenerative diseases from Alzheimer's to Parkinson's and niche orphan diseases such as Rett's syndrome, which may represent a "fast path" to establish proof of concept around Sigma 1 agonism.

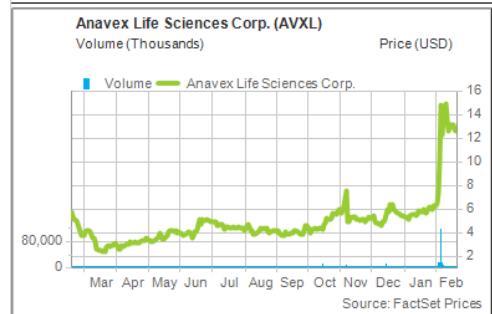
2021 is a Year of Events.

- 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.

February 19, 2021

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Current Price	\$12.71		
Price Target	\$19.00		
Estimates	F2019A	F2020E	F2021E
Expenses (\$000s)*	\$ 31,287	\$ 31,090	\$ 38,244
1Q March	\$ 7,474	\$ 7,701	\$ 9,396
2Q June	\$ 8,140	\$ 7,774	\$ 9,576
3Q September	\$ 7,821	\$ 8,107	\$ 9,616
4Q December	\$ 7,852	\$ 7,508	\$ 9,656
	F2019A	F2020E	F2021E
EPS (diluted)*	\$ (0.65)	\$ (0.45)	\$ (0.40)
1Q March	\$ (0.16)	\$ (0.12)	\$ (0.12)
2Q June	\$ (0.17)	\$ (0.12)	\$ (0.09)
3Q September	\$ (0.16)	\$ (0.11)	\$ (0.09)
4Q December	\$ (0.16)	\$ (0.10)	\$ (0.09)
EBITDA/Share			
EV/EBITDA (x)			
Stock Data			
52-Week Range	\$2.20	-	\$28.70
Shares Outstanding (mil.)			69.5
Market Capitalization (mil.)			\$883
Enterprise Value (mil.)			\$864
Debt to Capital			0%
Book Value/Share			\$0.56
Price/Book			10.4
Average Three Months Trading Volume (K)			563
Insider Ownership			3.8%
Institutional Ownership			20.9%
Short interest (mil.)			7.6%
Dividend / Yield			\$0.00/0.0%



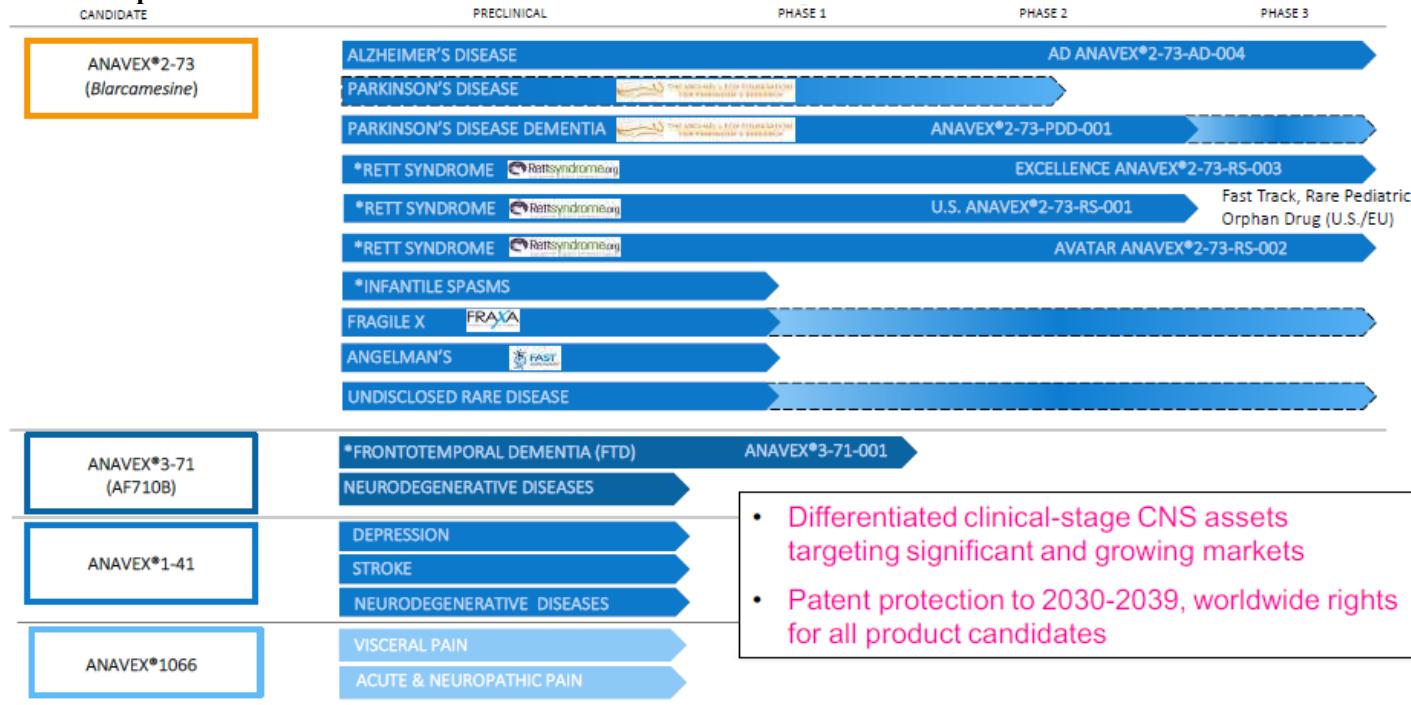
* Sept YE

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.

Risk to our thesis includes 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.

Company Overview. Anavex Life Sciences Corp. is an innovative biopharmaceutical company that focuses on treating central nervous system diseases with high unmet demand. Currently, the company has multiple clinical trials, which have been combined to utilize genomic data focused on specific biomarkers to enrich the trial results. ANAVEX2-73 is the most advanced molecule and is being evaluated in Alzheimer's, Rett Syndrome, and Parkinson's Dementia Disease. The hope is that Sigma-1 agonism via ANAVEX2-73 can stimulate synaptogenesis, help restore calcium ion imbalance, reduce inflammation, reduce oxidative stress, reduce tau hyperphosphorylation, restore mitochondrial function, and reduce protein misfolding. We view the upregulation of Sigma-1 as a highly conserved cell survival mechanism. These CNS and related indications represent large markets with significant unmet needs. The Alzheimer's market alone represents a \$5 billion-plus opportunity today that could be as large as \$12 billion by 2026.

Exhibit 1. Pipeline



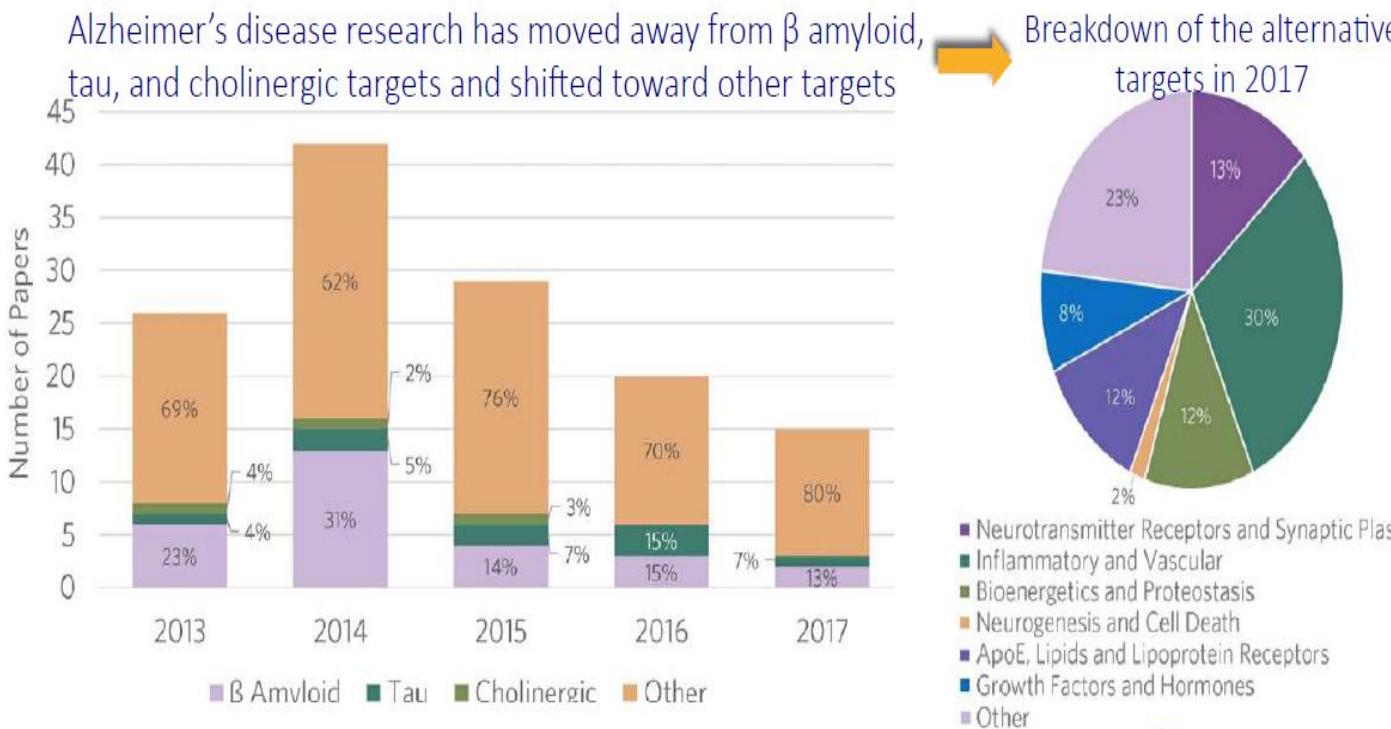
* = Orphan Drug Designation by FDA; Dashed lines indicate planned clinical studies

Source: Anavex



3

Alzheimer's Disease is an irreversible, progressive neurological disease that leads to decreased functionality of memory and cognition. It is the most common cause of dementia and is the sixth-leading cause of death in the United States. Currently, on the market, there are four open-label medications used specifically to treat Alzheimer's disease. The goal of these drugs is to slow down cognitive impair, by either addressing cholinergic targets and tau fibers or Beta-Amyloid plaques. These medications have little efficacy in stopping any degradation and have proved to be less effective than ANAVEX2-73 at maintaining mental functionality. Anavex's methodology in the treatment of Alzheimer's is to target the individual's specific imbalance using precision medicine. These targets include but are not limited to Beta-Amyloid plaques, tau fibers, cholinergic targets, neurotransmitter receptors and synaptic plasticity, inflammatory and vascular, bioenergetics and proteostasis, ApoE Lipids and lipoprotein receptors, and growth factors and hormones. ANAVEX2-73, a sigma-1 receptor agonist, is believed to restore cellular homeostasis among these targets mainly by restoring Ca^{2+} imbalances, synaptogenesis, reducing inflammation, reducing oxidative stress, reducing tau hyper-phosphorylation, restoring mitochondrial dysfunction, and by reducing protein misfolding.

Exhibit 5. Paradigm Shift in Alzheimer's Disease


Parkinson's Disease Dementia or PDD. PDD is when Parkinson's disease eventually leads to dementia. The resulting effect is a degradation of specific neurons in the substantia nigra, related to a dramatic decrease in dopamine production and Lewy bodies. Out of all the Parkinson's patients, 50-80% eventually end up with PDD. Currently, there are no cures for Parkinson's disease, only medication to help manage the symptoms. Most of these drugs work by enabling dopamine production since there are low concentrations of dopamine in people with Parkinson's disease. There are several downsides to these medications, though. First off, their effectiveness dramatically decreases over time, with prolonged use of the given drug. Secondly, there are many side effects as a result of administering these treatment options, such as nausea, lightheadedness, and hallucinations. ANAVEX2-73 has proved to be safer with better efficacy than the remaining drugs on the market.

Rett Syndrome. Anavex has run several clinical trials for Rett syndrome in the U.S. and Australia. The principal differences between the studies are that the U.S. trial has 15 patients ages 18 and older and has focused on safety and pharmacokinetic data. The Avatar study (Australia) has enrolled 30 patients also over 18 years of age with a focus on safety and efficacy. There are multiple benefits associated with two trials and specifically with the Avatar trial, which include financial support in Australia. The Australian government is partly sponsoring the trial (a cash back payment of around 40%) to Anavex with the completion of the study.

The Phase 2 Trial. Anavex announced results from a Small Phase 2 N= 25 patient trial last year. 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 P.K. (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.

What was the data? 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.

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 product 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.

Exhibit 4. FCFF Model

Average	\$	19
Price Target	\$	22
DCF Valuation Using FCF (mln):		
units ('000)	2020E	2021E
EBIT	(26,280)	(38,274)
Tax Rate	0%	0%
EBIT(1-t)	(26,280)	(38,274)
CapEx	-	-
Depreciation	4,877	6,828
Change in NWC (ex cash)	\$0	\$0
FCF	(21,404)	(31,447)
PV of FCF	(27,825)	(31,447)
Discount Rate	30%	
Long Term Growth Rate	1%	
Terminal Cash Flow	4,191,983.52	
Terminal Value YE2030	395,302	
NPV	2,016,856	
NPV-Debt	-	
Projected Shares out (thousands)	93,381	2030E
NPV Per Share	\$ 21.60	

Source: Dawson James estimates

Exhibit 5. Discounted EPS Model

Current Year	2021
Year of EPS	2030
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 12.89
NPV	\$ 18.23

Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS						
Earnings Multiple	18.23	5%	10%	15%	20%	30%
1	\$8.31	\$5.46	\$3.66	\$2.50	\$1.73	\$1.22
5	\$41.53	\$27.32	\$18.31	\$12.49	\$8.65	\$6.08
10	\$83.06	\$54.65	\$36.63	\$24.97	\$17.30	\$12.15
15	\$124.60	\$81.97	\$54.94	\$37.46	\$25.94	\$18.23
20	\$166.13	\$109.30	\$73.26	\$49.95	\$34.59	\$24.30
25	\$207.66	\$136.62	\$91.57	\$62.43	\$43.24	\$30.38
30	\$249.19	\$163.95	\$109.89	\$74.92	\$51.89	\$36.45
35	\$290.72	\$191.27	\$128.20	\$87.41	\$60.53	\$42.53

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\$	Term Val
AVXL 2-73 U.S. AD	1%	30%	4	60%	\$2,697	\$9,298.91
NPV						\$5.23
AVXL 2-73 ROW AD	1%	30%	5	60%	\$3,214	\$11,081.54
NPV						\$4.79
AVXL 2-73 Rett's Syndrome	1%	30%	3	60%	\$1,905	\$6,568.76
NPV						\$4.80
AVXL 2-73 PDD	1%	30%	3	60%	\$961	\$3,315.39
NPV						\$2.42
Net Margin						25%
MM Shrs OS (2030E)						93
Total						\$17.3

Source: Dawson James estimates

Exhibit 7. Income Statement

Anavex Life Sciences Corp																		
Anavex: YE Sept 30	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	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			-	-	-	-	-	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	-	-	-	-	-	-	-	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)	-	-	-	-	-	-	-	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		
Research and Development	22,260	25,232	7,926	7,965	8,005	8,045	31,941	25,938	21,063	17,104	13,890	11,279	9,160	7,438	6,040	4,905		
General and Administrative	6,847	5,857	1,471	1,611	1,611	1,611	6,442	80,000	100,000	75,000	65,000	65,650	66,307	67,639	68,316			
Operating expenses	31,287	31,090	9,396	9,576	9,616	9,656	38,244	105,939	121,064	166,805	186,340	188,538	206,342	182,931	203,402	220,980		
Oper. Inc. (Loss)	(31,287)	(31,090)	(9,396)	(9,576)	(9,616)	(9,656)	(38,244)	(38,196)	86,231	911,581	1,341,601	1,456,328	1,671,971	1,544,859	1,780,646	1,973,203		
Op Margin	NM	NM	NM	NM	NM	NM	NM	0	1	1	1	1	1	1	1	1		
Other income (expense)	2,466	150																
Research and Development incentive	299	4,375	1,269															
Interest and financing fees	207	180	(2)	(8)	(8)	(8)	(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)																		
Financing related charges and adjustments																		
Other non-operating income		126																
Non-operating Income (expense)	2,894	4,830	333	(8)	(8)	(8)	(30)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)	(25)		
Financial Income, Net																		
Financial Expenses, Net																		
Pretax Income	(28,393)	(26,280)	(7,796)	(9,584)	(9,623)	(9,663)	(38,274)	(38,221)	86,206	911,556	1,341,576	1,456,303	1,671,946	1,544,834	1,780,621	1,973,178		
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM		
Income Tax Benefit (Provision)	(82)		(59)	(3,546)	(3,561)	(3,575)	(10,741)	(1,911)	8,621	164,080	389,057	480,580	601,901	602,485	694,442	769,540		
Tax Rate	0	-	37%	37%	37%	37%	5%	10%	18%	29%	30%	31%	31%	31%	31%	31%		
GAAP Net Income (loss)	(28,475)	(26,280)	(7,855)	(6,038)	(6,063)	(6,088)	(26,044)	(36,310)	77,585	747,476	952,519	975,723	1,070,046	942,349	1,086,179	1,203,639		
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	0.37	0.69	0.62	0.59	0.57	0.55	0.55			
GAAP-EPS	(0.65)	(0.45)	(0.12)	(0.09)	(0.09)	(0.09)	(0.40)	(0.54)	1.10	10.16	12.45	12.25	12.91	10.92	12.10	12.89		
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.12)	(0.09)	(0.09)	(0.09)	(0.40)	(0.54)	1.10	10.16	12.45	12.25	12.91	10.92	12.10	12.89		
Wgted Avg Shrs (Bas)	48,906	58,195	64,295	64,359	64,424	64,488	64,392	64,650	64,909	65,169	65,430	65,692	65,955	66,219	66,484	66,751		
Wgted Avg Shrs (Dil)	48,906	58,195	64,295	64,938	65,587	66,243	65,266	67,916	70,674	73,543	76,530	79,637	82,871	86,235	89,737	93,381		

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.

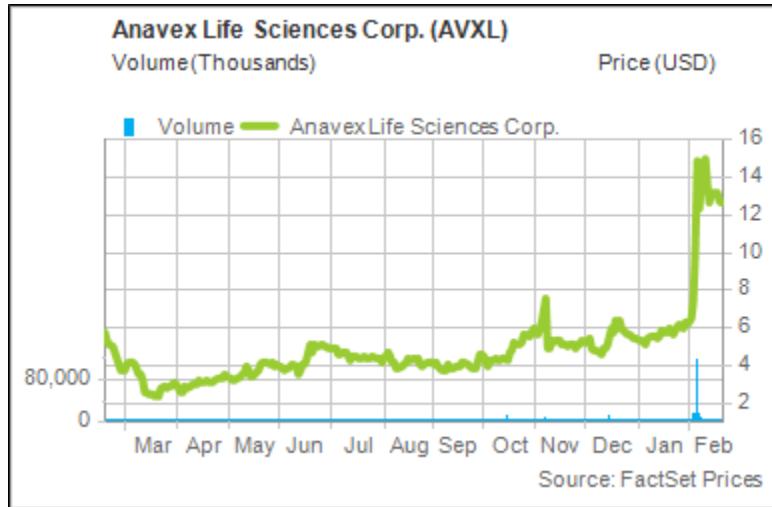
Intellectual Property. Anavex may face I.P. challenges, forcing the company to defend its patents or itself against claims that the company is infringing on other patents. We do know that the lead product is protected by a composition of matter patent to 2033.

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

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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;
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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.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	72%	6	29%
Market Perform (Neutral)	8	28%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	29	100%	6	21%

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