

# Anavex Life Sciences Corporation (OTCQB: AVXL, Target Price: \$1.33)

We initiate coverage on Anavex Life Sciences Corporation ("Anavex") with a price target of \$1.33 per share. We view Anavex as a high risk, high potential reward investment opportunity in the pharmaceutical industry. Anavex is initially focusing its drug development on treatments for Alzheimer's disease — a disease that is rapidly increasing both in prevalence and morbidity. There are over 5mn people in the United States with Alzheimer's disease, and none of the four therapeutic drugs approved by the FDA has been shown to reverse or halt the advance of the disease. Anavex is taking a novel approach to treating the disease, led by its flagship compound ANAVEX 2-73, and the company's pipeline of drug candidates and compounds has potential to help address a large unmet need in a multi-billion dollar market.

## INVESTMENT HIGHLIGHTS

#### Large market potential for Anavex

The global market for diagnosing and treating Alzheimer's disease is currently \$10bn, despite the underwhelming performance of approved drugs for Alzheimer's disease, which are not disease-modifying and are only able to treat symptoms. In our opinion this market could be substantially larger for a disease-modifying drug, as the total cost of care for Alzheimer's patients is running at \$200Bn per year and is expected to reach \$1.1T by 2050. Indeed the prevalence and morbidity of Alzheimer's disease is increasing and is only expected to continue to do so, as the average age of the population increases. Aging is the strongest predictor of Alzheimer's, and the world's largest market for pharmaceuticals, the United States, is particularly exposed to this demographic shift – the number of Americans over the age of 65 is forecast to double from 40mn in 2010 to 80mn by 2040.

## Recent financing de-risks the short run

Anavex recently raised \$10mn through a convertible debt offering during its fiscal 2Q14, which we believe takes a significant risk off the table in the short run. With the financing, along with an additional \$0.5mn raised in October, Anavex should be able to focus on clinical trial activity and drug development. We estimate the company is fully funded through its phase 2 ANAVEX PLUS / ANAVEX 2-73 trial.

## Plenty of catalysts on the horizon

We see potential for a nice stretch of catalysts on the horizon for Anavex over the next 12-18 months. The company has already announced a nice expansion to its management team and scientific advisory board, new funding, and that it has secured cGMP manufacturing for its drug candidate trial supplies. We expect catalysts over the next 12-18 months to be marked by the release of full data from its Phase 1 trials, topline data from Phase 2a study by 3Q15E, and an announcement that it will begin a phase 2 / phase 3 trial in 2015E. We would also look for ongoing potential developments on the strategic collaboration front, where the company could strike a deep partnership with a larger firm, which could mean potential milestone payments and licensing fees.

## Initiate coverage with a price target of \$1.33

Our analysis of Anavex indicates a fair value estimate of \$1.33 per share (detailed on pages 9 - 11), implying an upside of 682.4% from the recent price of \$0.19. We view Anavex as a speculative growth investment in the pharmaceutical industry with a fresh approach to targeting a large and rapidly spreading disease that existing treatments have failed to cure. We

# Equity | Healthcare / Biotechnology

see high risk and high potential rewards if the company is successful, with several potential catalysts throughout the next year.

#### Stock Details (11/5/2014)

OTCQB	AVXL
OTCQB	AVAL
Sector / Industry	Healthcare / Biotechnology
Price target	\$1.33
Recent share price	\$0.19
Shares o/s (mn)	38.0
Market cap (in \$mn)	\$7.2
52-week high/low	\$0.60 / \$0.17

Source: Bloomberg, SeeThruEquity Research

#### Key Financials (\$mn unless specified)

	FY13	FY14E	FY15E
Revenues	0.0	0.0	0.0
EBITDA	(2.1)	(4.3)	(4.7)
EBIT	(2.1)	(4.4)	(4.7)
Net income	(3.7)	(4.4)	(4.8)
EPS (\$)	(0.12)	(0.12)	(0.12)

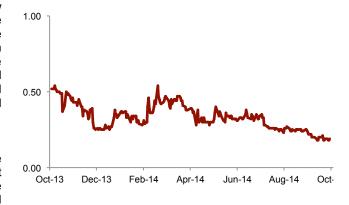
Source: SeeThruEquity Research

#### **Key Ratios**

	FY13	FY14E	FY15E
Gross margin (%)	NM	NM	NM
Operating margin (%)	NM	NM	NM
EBITDA margin (%)	NM	NM	NM
Net margin (%)	NM	NM	NM
P/Revenue (x)	NM	NM	NM
EV/EBITDA (x)	NM	NM	NM
EV/Revenue (x)	NM	NM	NM

Source: SeeThruEquity Research

## **Share Price Performance (\$, LTM)**



Source: Bloomberg

## **SUMMARY TABLE**

Figure 1. Summary Table (As of November 5, 2014)						
Share data		B/S data (A	As of fiscal 3Q14)	Key personnel:		
Recent price:	\$0.19	Total assets:	9.3mn	President & CEO:	Christopher Missling, PhD.	
Price target:	\$1.33	Total debt:	0.2mn	VP, Clinical Operations:	Tasos Zografidis, MS, PhD	
52-week range:	0.60 / 0.17	Equity:	7.4mn			
Average volume:*	147,416	W/C:	6.3mn			
Market cap:	\$7.2mn	ROE '13:	NM			
Book value/share:	\$0.19	ROA '13:	NM			
Cash/share	\$0.21	Current ratio:	4.3			
Dividend yield:	0.00%	Asset turnover:	0.0			
Risk profile:	High / Speculative	Debt/Cap:	2.7%			

<sup>\*</sup> three month average volume (number of shares)

	Estimates				Valuation		
FY August	Rev (\$mn)	EBITDA (\$mn)	EPS (\$)	P/Rev (x)	EV/Rev (x)	P/E (x)	
2012A	0.0	(4.3)	(0.29)	NM	NM	NM	
2013A	0.0	(2.1)	(0.12)	NM	NM	NM	
1Q14A	0.0	(0.3)	0.01	NM	NM	NM	
2Q14A	0.0	(1.0)	(0.03)	NM	NM	NM	
3Q14A	0.0	(1.0)	(0.03)	NM	NM	NM	
4Q14E	0.0	(1.2)	(0.03)	NM	NM	NM	
2014E	0.0	(4.3)	(0.12)	NM	NM	NM	
2015E	0.0	(4.7)	(0.12)	NM	NM	NM	
2016E	0.0	(5.8)	(0.14)	NM	NM	NM	

Source: SeeThruEquity Research

# **INVESTMENT THESIS**

Based in New York, NY, Anavex Life Sciences Corporation. ("Anavex") is a clinical-stage biopharmaceutical company engaged in the development of compounds and novel drug candidates to treat Alzheimer's disease, other central nervous system ("CNS") diseases, and various types of cancer. The company's leading drug candidate, ANAVEX PLUS, is currently entering a Phase 2a clinical trial targeting Alzheimer's disease. Alzheimer's disease is a neurodegenerative disease of the brain leading to memory loss and the degradation of cognitive functions. ANAVEX PLUS is targeting a huge unmet need as there is a severe lack of effective, disease-modifying drugs to treat Alzheimer's disease. Anavex has already secured financing to ensure the completion of this trial, and we expect the company to report on its progress by 3Q15E. What we like about Anavex is that it is aggressively pursuing what appears to be a fresh approach to developing disease-modifying treatment for Alzheimer's disease – a complex disease that has stymied drug makers and affects a rapidly increasing number of people across the globe. With a market capitalization of less than \$10mn, \$8.2mn of cash in the bank, and a product roadmap targeting a combined opportunity measuring tens of billions of dollars, we find Anavex worthy of consideration.

# A complex disease with significant potential

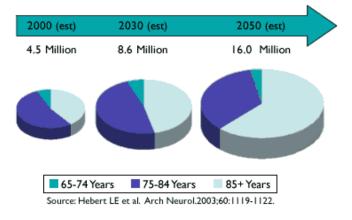
Anavex has developed compounds intended to target several indications, but the company is farthest along with its flagship ANAVEX PLUS and ANAVEX 2-73, which targets Alzheimer's disease. Pharmaceutical companies have unsuccessfully striven for years to develop a drug that will stop the progression of Alzheimer's disease, but the disease continues to increase in morbidity and prevalence. The number of deaths caused by Alzheimer's disease increased by 68% between 2000 and 2010, compared to declines of



23% and 42% from stroke and HIV, respectively, over the same time period. There are over 5mn people in the US alone suffering from Alzheimer's disease, and every 67 seconds someone new develops the disease, according to the Alzheimer's Association. These numbers are expected to remain on the rise as one of the leading predictors of Alzheimer's is age — and the population of the United States is aging, with the number of Americans over the age of 65 expected to double by 2040 to 80mn.

The number of people suffering from Alzheimer's disease in the United States is estimated to increase rapidly as well, from 5.2mn in 2013 to 16mn by 2050E, per the following chart. As a result the cost of treatment for Alzheimer's disease is also increasing rapidly. Approximately \$200Bn is spent annually to treat and care for people

# Forecast of Alzheimer's Disease Prevalence in the US



suffering from Alzheimer's disease, while the market for diagnostics and therapeutic drugs for Alzheimer's disease is \$10Bn – and this figure only represents drugs with limited efficacy that can only treat some of the symptoms of Alzheimer's disease. We think the market will ultimately be much larger when a drug is finally developed that stops the disease. At present the FDA has approved four drugs to treat Alzheimer's disease, for example, but these have not been shown to reverse or halt the advance of Alzheimer's. Rather, they have been shown only to temporarily slow worsening symptoms, such as memory loss, for six to twelve months and in only half the patients. In our view, with the failings by large pharmaceutical companies to address Alzheimer's disease adequately, an opportunity has arisen for smaller competitors to emerge as viable market participants – and Anavex just may have the potential to develop a disease-modifying drug that could offer neuroprotection and possibly reverse memory loss.

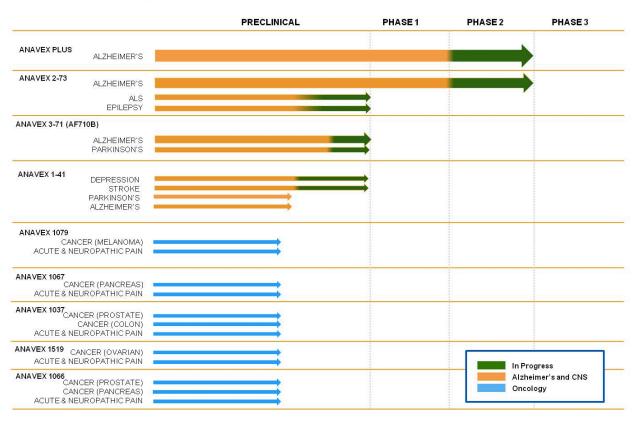
## **Intriguing Pipeline**

Anavex is developing an intriguing pipeline including one drug candidate and several compounds. The company is initially targeting Alzheimer's disease and potentially other central nervous system (CNS) candidates. Other indications the company believes can be addressed by its compounds include epilepsy, depression, neuropathic pain, malignant melanoma, prostate cancer and pancreatic cancer. These all target multi-billion dollar markets, each with its own attributes, as outlined in the following table:

Indication	Market Size	Comments
Alzheimer's disease	Over \$10Bn per year	Large unmet need
Epilepsy	Estimated to grow to \$3.Bn by 2016	Current treatment controls but does not cure
Depression	\$11Bn + opportunity per year	Waning dominance of leading nine brands due to effects of patent expiration and generic competition
Neuropathic Pain	Over \$5bn annually	Difficult to treat; does not respond well to normal pain medication
Malignant Melinoma	Estimated to grow from 900mn to \$4.4Bn by 2022	Associated with 75% of all deaths caused by skin cancer
Prostate Cancer	Expected to reach \$18.6Bn by 2017	Can mestastasize from prostate to other parts of body
Pancreatic Cancer	Expected to reach \$1.2Bn by 2015	38,000 of 45,000 newly diagnosed cases will die in first year



Anavex has identified nine promising compounds or clinical drug candidates potentially addressing these end markets. Most of these compounds are in an early stage of development, as indicated by the following graphic, which also identifies which prospects address which therapeutic indications. Nevertheless, we do expect to hear about Phase 1 trial activity for some of these compounds during 2015E, including ANAVEX 3-71. Given the large potential market opportunities, it's worth noting there may be a long runway for new products at Anavex beyond Alzheimer's disease.



Source: Company investor materials, SeeThruEquity Research

The company's leading candidate, ANAVEX PLUS, is being developed to treat Alzheimer's disease through potential disease modification. ANAVEX PLUS is a mixture of the company's proprietary compound, ANAVEX 2-73 and donepezil (Aricept). In pre-clinical studies, ANAVEX 2-73 demonstrated anti-amnesic and neuroprotective properties. Based on these pre-clinical studies, the company sponsored a Phase 1 single ascending dose study of ANAVEX 2-73, which was initiated and completed using 22 healthy male volunteers who received seven oral doses from 1mg to 60mg. Conducted in Germany in collaboration with ABX-CRO Advanced Pharmaceutical Services, the study indicated that ANAVEX 2-73 was well tolerated by study subjects in doses up to 55mg.

Anavex plans to continue human clinical trials, including a Phase 2a study of ANAVEX 2-73 / ANAVEX PLUS, and a Phase 2 trial thereafter. Anavex management believes ANAVEX 2-73 may offer disease-modifying approach in Alzheimer's disease by using ligands that activate sigma-1 receptors. Indeed, ANAVEX 2-73 was found to reverse memory loss and protect nerve cells from neuro-degeneration in animal models. The company believes that ANAVEX PLUS will demonstrate powerful synergies between ANAVEX 2-73 and donepezil, with improvements in cognition response estimated at over 2x what has been found in donepezil alone, Anavex has filed for a patent application to use ANAVEX 2-73 in combination with donepezil, which would provide protection until 2033 if granted.

It's worth noting that Anavex is pursuing a novel approach to treating Alzheimer's and is offering a different theory for treatment than many of its competitors, which have largely focused on BACE inhibitors, which are designed to stop the formation of amyloid plaque (considered by some to be the most likely cause of Alzheimer's disease). Anavex management believes that removing amyloid beta (A-beta) plaques in the





brain may be too simplistic to be effective, as demonstrated by the recent disappointments of bapineuzumab (Pfizer) and solanezumab (Eli Lilly), and crenezumab (Roche).

By contrast, Anavex believes that healthy brain cells can clear A-beta quickly when not distressed, and therefore a further upstream neuro-protective strategy may help the brain to preserve this ability in distressed cells. The company's ANAVEX PLUS activates a quality control in brain cells by targeting the Sigma-1 receptor, which reduces this chronic cell stress and Alzheimer's symptoms. Anavex has already secured financing to ensure the completion of this trial, and in July the company secured cGMP manufacturing of ANAVEX 2-73 for its Phase 2a clinical trial, which will allow the company to initiate clinical trials with ANAVEX PLUS for the treatment of Alzheimer's disease. We expect the company will disclose data on this trial before 3Q15E.

#### March convertible debt raise bolsters balance sheet

We see ongoing financial solvency as a key ongoing risk for Anavex, as it will likely require substantial expenditures to perform research and development on its candidates, including trials. The company was able to mitigate this risk in the short run by raising \$10mn in convertible debt in March 2014, and \$0.5mn in equity in October 2014. We believe these actions should provide the company with some much-needed breathing room and flexibility to develop its pipeline. The convertible debt is unsecured and non-interest bearing, converts at \$0.30 per share, and comes due in March 2044.

In conjunction with the issuance of debt, Anavex issued 66.7mn warrants, consisting of 33.3mn Series A warrants exercisable at \$0.30 per share until March 18, 2019, and 33.3mn Series B warrants exercisable at \$0.42 per share until March 18, 2019. Clearly common shareholders would face significant dilution from these warrants, given that Anavex had common shares outstanding of 38.3mn as of August 12, 2014. Nevertheless, we note the strike prices are considerably higher than recent trades of Anavex stock, and the warrants have the potential to provide an additional \$10mn in financing from Series A and \$14mn in additional financing from Series B, which the company could use to fund drug development, phase 3 trials or other expansion.



# COMPETITIVE LANDSCAPE

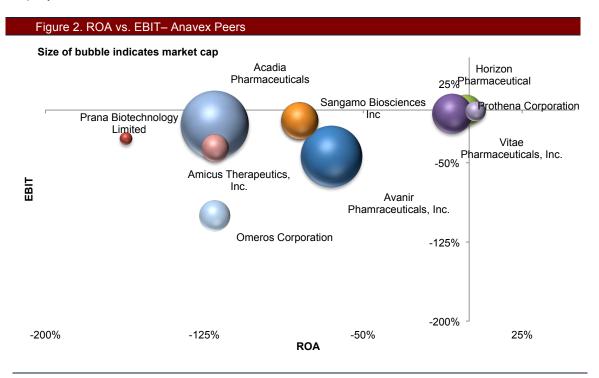
Anavex operates in a highly competitive industry. Many of the company's competitors have longer operating histories, larger research facilities, and access to significantly greater financial resources. Moreover, many of the company's competitors have more experience navigating the regulatory approval process for new drugs, and commercializing, distributing and marketing drugs once they have been approved.

While Anavex is developing drugs and compounds that address several indications in addition to Alzheimer's disease, we view the Alzheimer's disease as the company's key market at this time. The proliferation of Alzheimer's disease is quickly growing, with over 5mn people in the US suffering from Alzheier's disease and over 20mn people worldwide. This figure is expected to more than double to 53mn by 2050, according to a forecast by BCC Research, as the incidence of the disease is affected by increases in the average age.

Currently the global market for diagnostics and therapeutic treatment for Alzheimer's disease is estimated at \$10.2bn by BCC Research. We view Anavex's primary competitors as companies that are trying to discover and develop compounds that can be used in the treatment of Alzheimer's disease. These include Avanir, Prana Biotechnology, Elan Corporation, Pfizer, Forest Laboratories, Novartis AG, GlaxoSmithKline, Roche, and Eli Lilly, among others.

To date, the United States Food and Drug Administration (FDA) has approved only four drugs for the symptomatic treatment of Alzheimer's disease, including market leader Aricept (donepezil) in 1996. Each of these drugs offer temporary relief of memory decline and can delay the worsening of symptoms by approximately six to 12 months, for about half of patients. Thus we view the market as having substantial unmet needs since there are few approved drugs for treating Alzheimer's disease, and the approved drugs available have so far been limited to helping patients with symptoms of the disease, such as memory loss – they have not been demonstrated to prevent or reverse the onset of the disease.

Per the following graphic, there is a wide range of profitability among Anavex's peers. In our view, the market valuations of the majority of these peers are not driven by profitability. Rather we see market capitalizations in this peer group as being driven by the progress achieved in drug development and whether the company has the potential to either partner with or be acquired by a larger pharmaceutical development company.



Source: Company filings, SeeThruEquity Research



# FINANCIALS AND FUTURE OUTLOOK

#### Revenue/Drivers

Anavex is a clinical stage pharmaceutical company, which has not yet developed commercial products. We expect that it will be at least five years until the company has completed clinical trials and gained regulatory approval to commercialize its products. We have assumed the company's current cash on hand is sufficient to take it through its ongoing phase 2 trial activity for ANAVEX PLUS / AVAEX 2-73. Our forecast assumes the company brings products through to commercialization over the next five to six years, however, we note that a more likely scenario, particularly assuming positive outcomes from these trials, would be for the company to find a licensing, marketing or development partner.

Our model does not forecast Anavex to generate sales from 2014E-2019E, during which time we have assumed that the company will complete Phase 2a, Phase 2 and Phase 3 trials. Our forecast considers initial domestic sales to occur during 2020E and other geographies beginning in 2021E. We have employed a top-down model, forecasting sales from a domestic segment and an international segment. We have assumed the number of Americans suffering from Alzheimer's disease increases from 5mn presently to 6.8mn by 2025E, and that Anavex's products can address 20% of this group. We have assumed the company can generate initial pricing of \$650 per month in the US, or just under \$8,000 per year, an assumption we feel is conservative and supported by current estimates of \$20,000 per year treatment costs for Alzheimer's patients.

We have also assumed that Anavex is able to grow market share domestically from 2% in 2020E to 15% by 2025E. Although there are certain to be more competing treatment options by 2020E, we believe the relatively small number of approved drugs supports our forecast for market share gains, assuming Anavex is successful in developing a disease-modifying drug. We have assumed slower share gains and lower pricing for international market penetration beginning in 2021E and beyond, with total international revenues trailing domestic revenues through 2025E, despite the larger potential market size, per the following graphic. We have applied a significant adjustment for a risk factor of 85%, given that the company is in the early stages of clinical development.

Period	2020E	2021E	2022E	2023E	2024E	2025E
Revenues	187,090	454,451	763,685	1,249,803	1,887,467	2,435,176
North America	187,090	375,863	566,332	853,320	1,190,500	1,435,029
International	0	78,588	197,353	396,482	696,966	1,000,147
License & Other	0	8,000	15,000	20,000	36,000	40,000
Risk Factor	85%	85%	85%	85%	85%	85%
Total Revenue	28,063	69,368	116,803	190,470	288,520	371,276

Source: SeeThruEquity Research

## Margins/Expenses

Since Anavex is not generating revenues the company is using cash with each quarter as it pursues drug development. The company had \$1mn in operating expenses during the June quarter, and we expect this rate to tick up next year due to the higher cost of conducting trials. We have forecast an operating loss of \$4.7mn during fiscal 2015E, with the loss widening to \$5.8mn in fiscal 2016E. We have assumed gross margins in the mid-70% range when the company does introduce products, with gross margins peaking at 80%.

## **Balance Sheet & Financial Liquidity**

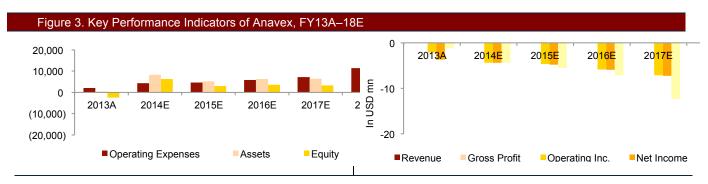
Anavex has improved its balance sheet and financial liquidity substantially in 2014, and we believe the company has secured enough funding to take it through the completion of its ANAVEX 2-73 and ANAVEX PLUS clinical trials – important milestones for the company, in our view. The company raised \$10mn in convertible debt in March 2014 and another \$500,000 in equity from long-term investor Lincoln Park Capital Fund, LLC in October. The convertible debt, which converts at \$0.30 per share, has lenient terms as it is unsecured, bears no interest, and does not mature until 2044.

The debt was issued along with 66.7mn warrants, which include a Series A exercisable at \$0.30 expiring in March 2019 and Series B exercisable at \$0.42 also expiring in March 2019. While these securities clearly



may dilute shareholders, we note they are exercisable at a premium to recent trading prices and have the potential to add \$10mn and \$14mn to Anavex's balance sheet, respectively, if exercised.

Given these dilutive securities we have forecast shares outstanding to reach 150mn by 2025E. With cash on hand to meet its short-term obligations, we expect Anavex to focus on research and development and its phase 2 clinical trials. We expect that the company will use cash through 2020E, when we have modeled the first commercial products. We do not anticipate significant capital spending needs for Anavex at this time. The company invested just \$470k in capital spending in 2013, and we expect 2014 to be a slight uptick but not a significantly higher number.



Source: Company filings, SeeThruEquity Research



# **VALUATION**

We have valued Anavex using two different valuation methods; discounted cash flow ("DCF") and Peer Group Valuation. Our blended valuation, combining the two methodologies mentioned above, yields a fair value of \$1.33 per share, representing an upside of 682.4% from the recent price of \$0.19 as of November 5, 2014.

#### **DCF**

Our forecast assumes Anavex is able to commercialize disease-modifying treatment for Alzheimer's disease, a significant assumption given its status as an early stage pharmaceutical development company, and then uses a risk factor weighting and aggressive discount rate to reflect the risk inherent in this assumption, as well as the uncertainty that comes with time, since we do not expect Anavex to generate revenue until 2020E.

We have forecast the company to use cash from the current quarter through and including the first half of fiscal 2020E. We expect Anavex will use \$45.6mn of cash during that time, should it bring its products to commercialization itself without external help from partners. Again, as noted earlier in this report, we believe this scenario is not likely; we believe a more likely scenario is for the company to seek a partner after completing its phase 2 trials. Beginning in 2021E, we expect the company to begin generating cash flow as its products are commercialized and gain traction. We forecast free cash flows to reach \$17.1mn in 2021E and continue to rise quickly from thereon as the company scales.

We discounted cash flows at a weighted average cost of capital of 16% and assumed a terminal growth rate of 3% at the end of 2025E to arrive at an enterprise value of \$172.9mn. We assumed 150mn shares outstanding at 2025E, reflecting our expectation for either the exercise of warrants or additional capital raises, or both, to fund clinical trials. We arrived at a fair value of \$1.21 per share, representing a premium of 534.7% compared to the recent price of \$0.19.

Figure 4. Discounted Cas	h Flow Analysis	3				
	FY	FY	FY	FY	FY	F
\$' 000	FY20E	FY21E	FY22E	FY23E	FY24E	FY25
EBIT	(1,383)	18,719	40,533	69,854	112,243	146,05
Less: Tax	0	0	14,151	24,414	39,250	52,54
NOPLAT	(1,383)	18,719	26,381	45,440	72,993	93,51
Changes in working capital	5,058	(591)	499	0	501	49
Depreciation & Amort.	2,000	4,000	8,000	12,000	13,500	14,50
Capex	(3,319)	(5,000)	(10,000)	(14,000)	(16,000)	(16,000
FCFF	2,356	17,128	24,880	43,440	70,994	92,51
Discount factor	0.40	0.35	0.30	0.26	0.22	0.1
PV of FCFE	948	5,942	7,442	11,204	15,789	17,74
Sum of PV of FCFE						32,04
Terminal cash flow						734,57
PV of terminal cash flow						140,86
Enterprise value						172,91
Less: Debt						20
Add: Cash						8,18
Equity value						180,89
Outstanding shares (000)						150,000.
Fair value per share (\$)						1.2



Summary conclusions		Key assumptions	
DCF FV (\$ per share)	1.21	Beta	1.5
Recent price (\$ per share)	0.19	Cost of equity	16.0%
Upside (downside)	534.7%	Cost of debt (post tax)	12.0%
WACC	16.0%	Terminal Growth Rate	3.0%

Source: SeeThruEquity Research

Figure 5. Sensitivity of Valuation – WACC vs. Terminal Growth Rate						
				WACC	(%)	
<u></u>		15.0%	15.5%	16.0%	16.5%	17.0%
h rate	2.00%	1.32	1.22	1.13	1.05	0.97
Terminal growth (%)	2.50%	1.37	1.26	1.17	1.08	1.00
nalg (%)	3.00%	1.42	1.31	1.21	1.12	1.03
Ē	3.50%	1.47	1.35	1.25	1.15	1.07
Те	4.00%	1.53	1.41	1.29	1.19	1.10
	4.50%	1.60	1.46	1.34	1.24	1.14

Source: SeeThruEquity Research



#### **Peer Group Valuation**

We compared Anavex with publicly traded peers in the pharmaceutical industry including Avanir Pharmaceuticals, Inc., Prothena Corporation, Prana Biotechnology Limited, Horizon Pharmaceutical, Targacept, Inc., Sangamo Biosciences, and Vitae Pharmaceuticals, among others. We sought to select a peer group of companies with drug pipelines that included either a prospective drug for Alzheimer's disease, Parkinson's disease, or another disease of the central nervous system. We employed a market multiple approach using our future revenue estimates, and then discounted this to present value, as the company is not generating EBITDA or earnings per share at this time. Not surprisingly, there was a wide range of multiples in this group, reflecting the different stages of development for each company, as well as he varying perceptions of growth prospects.

We arrived at a fair value range of \$1.42 to \$1.48 per share based on EV/Revenue and P/Revenue multiples of selected peers. We considered a target multiple of 3.0x EV / Revenue using our peak revenue estimates for 2025E. After applying our 85% risk factor on our 2025E topline estimate, we used a discount rate of 16% to arrive at a fair value of \$221.6mn, or \$1.48 per share, for our for the EV/Revenue multiple and 2025E revenue of \$371mn. Similarly, we selected a multiple of 3.0x Price / Sales, using our peak sales estimate for 2025E and discounted it at 16%. We assumed 150mn shares outstanding for both cases of this analysis, as opposed to the 38mn currently outstanding, to reflect dilutive securities outstanding and our belief that the company will raise additional capital.

Figure 6. Comparable Valuation (Data as of 10/30/14)							
0	Mkt cap	EV/Rev	renue(x)	Price/Re	venue(x)		
Company	(\$ mn)	FY14E	FY15E	FY14E	FY15E		
Avanir Phamraceuticals, Inc.	2,270	19.7x	13.5x	20.3x	13.8x		
Prothena Corporation	585	5.7x	8.0x	11.8x	16.7x		
Prana Biotechnology Limited	91	NM	NM	NM	NM		
Horizon Pharmaceutical	953	3.4x	2.4x	3.4x	2.4x		
Sangamo Biosciences Inc.	811	14.3x	11.5x	17.8x	14.3x		
Acadia Pharmaceuticals	2,790	NM	NM	NM	NM		
Amicus Therapeutics, Inc.	447	NM	20.2x	NM	23.5x		
Omeros Corporation	563	75.5x	8.7x	76.1x	8.8x		
Vitae Pharmaceuticals, Inc.	236	21.9x	25.5x	35.0x	40.7x		
Targacept, Inc.	80	NM	NM	NM	NM		
Average		5.8x	2.7x	5.8x	2.6x		
Anavex Life Sciences Corp.	7	NM	NM	NM	NM		
Premium (discount)		NM	NM	NM	NM		

Source: Bloomberg, SeeThruEquity Research



# RISK CONSIDERATIONS

#### Development stage company

Anavex is an early development-stage pharmaceutical company, which has not generated any revenue from its operations. Since its inception in 2004 the company has accumulated over \$40mn in net losses. Further, our analysis does not forecast the company to generate net sales for at least five years, given that it remains in the early stages of drug development and its product pipeline is either in the concept stage or the early stages of clinical development. There is no guarantee that the company will ever develop a product that is approved for sale to pharmaceutical companies or as a commercial product. Given this time frame, there is considerable uncertainty in many areas, including how much funding Anavex will need to develop its products, whether new competitive products will render its intellectual property obsolete, and whether there will be substantial changes to the regulatory process in the United States or other regions.

## Regulatory Risk

Anavex operates in a highly regulated industry and is exposed to the risk and uncertainty of regulatory approvals both in the United States and globally as it seeks to develop products outside the United States. Achieving regulatory approvals is a costly and time-consuming process. We note that approval in one geography does not necessarily guarantee approval in other geographies.

#### **Going Concern**

Anavex's independent auditors, BDO LLP, noted a going concern risk in their annual financial statements. Since that time, Anavex raised \$10mn in financing in the form of convertible debentures, which we believe will provide the company flexibility to focus on product development in the short run – we expect the funding to bring Anavex through to the completion of the ANAVEX 2-73 and ANAVEX-PLUS Phase 2 clinical trial. The company also secured \$500,000 in equity capital from long term investor Lincoln Park Capital in October 2014. Nevertheless, in our opinion Anavex will likely need to raise additional capital before the sale or commercial development of any potential products in the future. We note that the company has generated substantial losses since inception, and we have assumed that Anavex will continue to find it necessary to seek new funding to develop its products. We have assumed Anavex will be able to raise new funding at a reasonable valuation throughout our analysis and forecast, however, we note that, given our assumption that it will be at least five years before the company has commercial products, there is considerable uncertainty as to how much capital will be required and at what valuation the company will be able to raise new funds.

# Competition

Anavex operates in an extremely competitive industry. The pharmaceutical industry is characterized by high competition and requires significant capital to develop new products through a rigorous and expensive regulatory process. Anavex competes with many companies with far greater financial resources, longer operating histories, and more established brand recognition. Moreover, the company is pursuing a theory of treating the disease not followed by many of its established competitors, which could make it more difficult to educate industry participants, potential partners, and potential investors about its products.

## Research & Development Risk

All of Anavex's products and potential products will require extensive further investments in research and development, including non-clinical trials and clinical trials to prove the products' efficacy, as well as regulatory approvals, before the company can market them. These pursuits are costly, and will likely require new capital and for the company to obtain the support of qualified scientific collaborators to assist in research and development. Moreover, they may not be successful. For example, the Anavex may find that its products or planned products fail to generate effective results or cause harmful side effects. The company may also be unable to produce its products at a viable cost. Anavex is also exposed to risk from other companies' research and development efforts, which may be more effective or otherwise render Anavex's products obsolete.



#### Liquidity Risk

Anavex shares are thinly traded on the OTCQB market. It may be difficult for investors to accumulate or dispose of positions in Anavex shares. The average daily volume over the last 60 days was 152,232 shares. At a recent price of \$0.20, this suggests an average daily value traded of \$30,446.

## **Management Team**

#### Christopher Missling, PhD. – President, Chief Executive Officer and Director

Christopher Missling, PhD, has over twenty (20) years of healthcare industry experience in big pharmaceutical, biotech industry and investment banking. Most recently, from March, 2007 until his appointment by our company, Mr. Missling served as the head of healthcare investment banking at Brimberg & Co. in New York, New York. Also, Mr. Missling served as the Chief Financial Officer of Curis, Inc. (NASDAQ:CRIS) and ImmunoGen, Inc. (NASDAQ:IMGN). Mr. Missling earned his MS and PhD from the University of Munich and an MBA from Northwestern University Kellogg School of Management.

#### Tasos Zografidis, MS, PhD -- Vice President, Clinical Operations

Dr. Zografidis serves as Vice President of Clinical Operations of Anavex and has over 25 years of experience in the pharmaceutical and healthcare industry, including 12 years at Wyeth (now Pfizer) in clinical project management and prior to joining Anavex most recently served as clinical and pharmaceutical consultant. He has been involved in more than a dozen clinical trials and has co-authored numerous publications. At Wyeth, Dr. Zografidis spearheaded population pharmacokinetics analysis and its implementation in the clinical setting and positively differentiated compounds. His work resulted in increased sales and he received several clinical awards for his accomplishments. Dr. Zografidis first joined Wyeth in 1998 as a Product Manager. During his tenure until 2010, he had increased responsibility as Medical Liaison for the transplantation, haemophilia and oncology divisions where he was instrumental in driving sales in assigned European territories.

#### Bernd Metzner, PhD - Director

Bernd Metzner, PhD, a director of Anavex, is currently Chief Financial Officer of the Doehler Group, a global producer and provider of technology-based natural ingredients for the food and beverage industry with sales activities in more than 130 countries. Previously, he was Chief Administration Officer and member of the Board of Management of Bayer Schering Pharma AG, the pharmaceutical division of \$100+ billion market cap company Bayer AG. In this position, Dr. Metzner had worldwide financial responsibility for the Bayer Pharma Group. During his almost 10-years with Bayer AG, Dr. Metzner also held several senior international management positions in the corporate finance organization of Bayer AG, including Chief Financial Officer of Bayer S.p.A. Italy and heading the coordination of the successful spin-off of Lanxess, a specialty chemicals group. Dr. Metzner started his career at the law firm Flick Gocke Schaumburg and has a degree in business administration from the University of Siegen. After obtaining his doctorate, he became a chartered accountant.

# Athanasios Skarpelos, Director and Founder

Athanasios (Tom) Skarpelos is a founder of Anavex. He is a self-employed investor with 17 years of experience working with private and public companies. For the past 10 years, he has been focused on biotechnology companies involved in drug discovery and drug development projects. Mr. Skarpelos was engaged as a consultant to the company for one year effective August 2, 2010. His experience has led to relationships with researchers at academic institutes in Europe and North America.

#### Elliot Favus, MD - Director

Elliot Favus, MD, serves as a Director of Anavex. Dr. Favus is Chief Executive Officer of Favus Institutional Research, a healthcare research firm serving institutional investors. He has been a healthcare equity research analyst on Wall Street since 2006, starting at Lazard Capital Markets and subsequently at Och-Ziff Capital Management Group. Prior to working on Wall Street, Dr. Favus was an Instructor in medicine at Mount Sinai School of Medicine in New York. He attended the University of Michigan (BA, 1996), the University of Chicago Pritzker School of Medicine (MD, 2001) and the NYU-Bellevue Hospital Internal Medicine Residency Program (2004). He is board-certified in Internal Medicine (2004) and has 10 years of



basic science laboratory experience working on human genetics projects at Harvard Medical School, the University of Chicago and the University of Pittsburgh.

# **FINANCIAL SUMMARY**

Figure 7. Income Statement						
Figures in \$mn unless specified	FY12A	FY13A	FY14E	FY15E	FY16E	FY17E
Revenue	0.0	0.0	0.0	0.0	0.0	0.0
YoY growth	NM	NM	NM	NM	NM	NM
Cost of sales	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0
Margin	NM	NM	NM	NM	NM	NM
Operating expenses	4.3	2.1	4.4	4.7	5.8	7.1
EBIT	(4.3)	(2.1)	(4.4)	(4.7)	(5.8)	(7.1)
Margin	NM	NM	NM	NM	NM	NM
EBITDA	(4.3)	(2.1)	(4.3)	(4.7)	(5.8)	(7.1)
Margin	NM	NM	NM	NM	NM	NM
Other income/ (expense)	(4.0)	(1.6)	(0.0)	(0.1)	(0.1)	(0.1)
Profit before tax	(8.3)	(3.7)	(4.4)	(4.8)	(5.9)	(7.2)
Tax	0.0	0.0	0.0	0.0	0.0	0.0
Net income	(8.3)	(3.7)	(4.4)	(4.8)	(5.9)	(7.2)
Margin	NM	NM	NM	NM	NM	NM
EPS (per share)	(0.29)	(0.12)	(0.12)	(0.12)	(0.14)	(0.16)

Source: SeeThruEquity Research

Figure 8. Balance Sheet						
Figures in \$mn, unless specified	FY12A	FY13A	FY14E	FY15E	FY16E	FY17E
Current assets	0.0	0.4	7.1	4.1	5.1	5.0
Intangibles	0.0	0.0	0.0	0.0	0.0	0.0
Other assets	0.0	0.0	1.1	1.1	1.2	1.4
Total assets	0.0	0.4	8.2	5.2	6.3	6.5
Current liabilities	2.9	2.0	1.9	2.2	2.7	3.2
Other liabilities	0.0	0.9	0.0	0.0	0.0	0.0
Shareholders' equity	(2.9)	(2.5)	6.3	3.0	3.6	3.3
Total liab and shareholder equity	0.0	0.4	8.2	5.2	6.3	6.5

Source: SeeThruEquity Research

Figure 9. Cash Flow Statement									
Figures in \$mn, unless specified	FY12A	FY13A	FY14E	FY15E	FY16E	FY17E			
Cash from operating activities	(1.7)	(8.0)	(4.4)	(3.5)	(4.0)	(4.9)			
Cash from investing activities	0.0	0.0	0.0	(0.0)	(0.0)	(0.3)			
Cash from financing activities	1.6	1.1	9.6	0.5	5.0	5.0			
Net inc/(dec) in cash	(0.1)	0.3	6.6	(3.0)	0.9	(0.2)			
Cash at beginning of the year	0.1	0.0	0.3	7.0	4.0	4.9			
Cash at the end of the year	0.0	0.3	7.0	4.0	4.9	4.7			

Source: SeeThruEquity Research





# **About Anavex Life Sciences Corporation**

Anavex Life Sciences Corp. (OTCQB: AVXL) is a publicly traded biopharmaceutical company dedicated to the development of novel drug candidates to treat Alzheimer's disease, other Central Nervous System (CNS) diseases, and various types of cancer. Anavex's lead drug candidates, ANAVEX 2-73 and ANAVEX PLUS, the combination of ANAVEX 2-73 and donepezil (Aricept®), are currently in a Phase 2a clinical trial for Alzheimer's disease. ANAVEX 2-73 is an orally available drug candidate that targets sigma-1 and muscarinic receptors and successfully completed Phase 1 with a clean data profile. Preclinical studies demonstrated its potential to halt and/or reverse the course of Alzheimer's disease. The drug combination ANAVEX PLUS produced up to 80% greater reversal of memory loss in Alzheimer's disease models versus when the drugs were used individually. Further information is available at www.anavex.com.



## CONTACT:

Ajay Tandon
Director of Research
SeeThruEquity, LLC
www.seethruequity.com
(646) 495-0939
ajay@seethruequity.com

## **DISCLOSURE:**

This report has been prepared and distributed by SeeThruEquity, LLC. This report is based on sources that we consider reliable, but we do not represent it is accurate or complete, and it should not be relied on as such. All information contained herein is subject to change without notice. This report is not an offer to sell or the solicitation of an offer to buy any security in any jurisdiction where such an offer or solicitation would be illegal. It does not constitute a personal recommendation or take into account the particular investment objectives, financial situations, or needs of individual clients. Clients should consider whether any information in this report is suitable for their particular circumstances and, if appropriate, seek professional advice, including tax advice. Statements included in this report may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements involve a number of risks and uncertainties such as competitive factors, technological development, market demand and the company's ability to obtain new contracts and accurately estimate net revenues due to variability in size, scope and duration of projects, and internal issues.

SeeThruEquity has not been compensated for the preparation of this report. SeeThruEquity and/or its affiliates may have a long position with respect to the publicly traded shares of the subject company covered in this report. SeeThruEquity, LLC is not a broker-dealer and does not generate any investment banking or commission-based revenue with respect to the securities of the company described herein.

Our professionals may provide oral or written market commentary that reflects opinions that are contrary to the opinions expressed in this report. The price and value of the investment referred to in this report may fluctuate. Past performance is not a guide to future performance, future returns are not guaranteed, and a loss of original capital may occur. Certain transactions, including those involving futures, options, and other derivatives, give rise to substantial risk and are not suitable for all investors. Our report is disseminated primarily electronically, and, in some cases, in printed form. Electronic report is simultaneously available to all recipients in any form. The information contained in this report is not incorporated into the contents of our website and should be read independently thereof.

Copyright 2011-2014 SeeThruEquity, LLC. No part of this material may be (i) copied, photocopied or duplicated in any for by any means or (ii) redistributed without the prior written consent of SeeThruEquity, LLC.