

## INSTITUTIONAL RESEARCH

## **Biotechnology** UPDATE REPORT

Member FINRA/SIPC

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### **Anavex Life Sciences Corp. (NASDAQ/AVXL)**

August 8, 2023

**BUY Rated: Fiscal 1Q Results: \$155M in Cash** 

Anavex expects top-line results from the EXCELLENCE study in Rett Syndrome in the 2H-23, Alzheimer's Disease – data in 2H23 too. See excerpts from the company's press release for full details.

#### **Investment Highlights:**

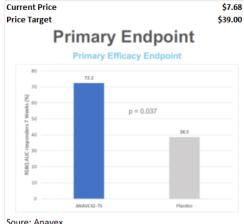
#### Press Release (adapted): Key Near-Term Pipeline Updates:

- Rett syndrome: Top-line data of potentially pivotal ANAVEX2-73-RS-003 Phase 2/3 EXCELLENCE pediatric clinical trial. Company expects to announce topline results from this study in the second half of 2023.
- Alzheimer's disease: Full data ANAVEX2-73-AD-004, including newly available preliminary results of surrogate biomarkers of pivotal Phase 2b/3 clinical trial. The Company intends to discuss these findings with regulatory authorities in the context of the ongoing clinical development of 2-73 in this indication, with the goal of providing a much-needed treatment to the millions of patients living with Alzheimer's disease with a convenient once-daily oral treatment. Company expects to announce data in the second half of 2023.
- Parkinson's disease: Initiation of ANAVEX2-73 pivotal clinical trial and the start of an imaging-focused clinical trial.
- Fragile X: Initiation of potentially pivotal ANAVEX2-73 Phase 2/3 clinical trial
- Schizophrenia: Initiation of ANAVEX3-71 Phase 2 clinical trial.
- New Rare disease: Initiation of potentially pivotal ANAVEX2-73 Phase 2/3 clinical trial.
- Publications: Several clinical publications involving ANAVEX2-73, ANAVEX3-71 and Rett syndrome Burden of Illness study.

**Valuation.** Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, so our share count is based on a projected, fully diluted out-year basis. Given the early nature of the company and its dependence on clinical trial outcomes in the CNS space, we apply a probability of success (50%) in our models. On top of this, we also add a 30% risk rate in our free cash flow to the Firm (FCFF), our discounted EPS (dEPS), and sum-of-the-parts (SOP) models. We equal weight and average these metrics and then round to the nearest whole number to derive our price target.

**Risks to our thesis include:** (1) commercial; (2) regulatory; (3) clinical; (4) market share; (5) financial; (6) investment; and (7) intellectual property.

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Stock Data		
52-Week Range	\$7.44 -	\$15.24
Shares Outstanding (mil.)		80.8
Market Capitalization (mil.)		\$621
Enterprise Value (mil.)		\$467
Debt to Capital		0%
Book Value/Share		\$0.56
Price/Book		5.6
Average Three Months Trac	ding Volume (K)	796
Insider Ownership		3.5%
Institutional Ownership		35.9%
Short interest (mil.)		20.7%
Dividend / Yield		\$0.00/0.0%





**Exhibit 1. Income Statement (\$ in thousands)** 

Exhibit 1. Income Staten	лепт (ф п	i mousan	us)													
Anavex Life Sciences Corp																
Anavex: YE Sept 30	2019A	2020A	2021A	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue																
Anavex2-73 AD U.S.		_	_	_						_	_	996,342	1,332,252	1,067,282	1,244,145	1,348,343
Allavezz-13 AB 0.0.												330,042	1,002,202	1,007,202	1,244,143	1,040,040
Anavex2-73 AD ROW			-	-						-	-	1,235,807	1,285,239	1,103,163	1,350,272	1,606,824
Anavex2-73 Rett's Syndrome			-	-	-	-	-	-		28,192	71,890	586,623	747,945	915,484	933,794	952,470
Anavex2-73 Parkinson's Dimentia PDD									_	_	_	177,649	241,602	369,651	439,885	480,732
												,	,	,	,	,
Total Product Revenues										28,192	71,890	2,996,421	3,607,037	0.455.504	2 000 000	4.388.368
Total Froduct Revenues	_	-	-	-	-	•		-		20,192	71,090	2,990,421	3,607,037	3,455,561	3,900,090	4,300,300
% Chg																
0/ 0																
% Sequential Growth																
Milestones																
% Sequential Growth																
Total Revenues (\$000)	-	-		-	-			-	-	28,192	71,890	2,996,421	3,607,037	3.455.581	3.968.096	4,388,368
Expenses								I			, , , , ,					
				l							, l	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	004 710	047.615	050 410	005 517
Cost of Goods Sold (10%)		-	-	-	-	-	-	-	-	-	-	223,215	261,749	217,045	259,442	295,517
Accounting and Audit Fees																
Amortization and deprectiation	2	2	2	2	0	0	0	0	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																
	00.000	05.000	00.007	44.000	44.007	44.007	44.000	44 400	45.000	00.040	00.000	04.000	40.747	40.044	40.000	40.550
Research and Development	22,260	25,232	32,267	41,326	11,307	11,307	11,363	11,420	45,396	36,819	29,899	24,280	19,717	16,011	13,002	10,558
Salaries and wages																
Travel																
Website design and maintence																
General and Administrative	6,847	5,857	9.205	13.320	2.883	2.883	3.000	3.000	11.765	27,500	45.000	45,450	45.905	46.364	46,827	47.295
Operating expenses	31,287	31,088	41,474	54,647	14,189	14,190	14.364	14,420	57,163	64,320	74,901	292,946	327,372	279,421	319,272	353,372
Oper. Inc. (Loss)	(31,287)	(31,088)	(41,474)	(54,647)	(14,189)	(14,190)	(14,364)	(14,420)	(57,163)	(36,128)	(3,010)	2,703,474	3,279,666	3,176,160	3,648,824	4,034,996
Oper Margin	NM	NM	NM	NM	NM	NM	NM	(1.1,120) NM	NM	NM	NM	2,7 00, 17 1	1	1	1	1,001,000
Other income (expense)	2,466											•	•			· ·
Research and Development incentive	299			682												
Interest and financing fees	207			(25)						(25)	(25)	(25)	(25)	(25)	(25)	(25)
Accretion of debt discount	116			(23)						(23)	(23)	(23)	(23)	(23)	(23)	(23)
Change in fair value of derivative liability	(151)															
,	(42)			l												
Debt conversion expense	(42)															
Loss on settlement of accounts payable																
Loss on extinguishment of debt				(700)												
Foreign exchange gain (loss)				(733)												
Financing related charges and adjustments				l												
Other non-operating income	0.001	_	0.400	(75)				_		(0=)	(05)	(05)	(0=)	(0=)	(0=)	10=1
Non-operating Income (expense)	2,894	-	2,129	(75)		-	-	-	-	(25)	(25)	(25)	(25)	(25)	(25)	(25)
Financial Income, Net					(4.400)	(4.100)										
Financial Expenses, Net		4,830	4,555		(1,132)	(1,132)			(1,132)							
Pretax Income	(28,393)	(26,258)	(36,918)	(54,722)	(13,057)	(13,057)	(14,364)	(14,420)	(57,163)		(3,035)	2,703,449	3,279,641		3,648,799	
Pretax Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Provision)	(82)	(23)	(155)	(319)	(50)	(50)	(1,436)	(1,442)	(2,978)	(6,508)	(880)	892,138	1,180,671	1,238,693	1,423,032	1,573,639
Tax Rate	0	0		1%	10%	10%	10%	10%	5%	18%	29%	30%	31%	31%	31%	31%
GAAP Net Income (loss)	(28,475)	(26,280)	(37,074)	(50,068)	(13,107)	(13,107)	(12,927)	(12,978)	(52,120)	(29,646)	(2,155)	1,811,311	2,098,970	1,937,442	2,225,767	2,461,332
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.60	0.58	0.56	0.56	0.56
GAAP-EPS	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.17)	(0.16)	(0.16)	(0.66)	(0.36)	(0.03)	20.43	22.74	20.17	22.27	23.66
Non GAAP EPS (dil)	(0.65)	(0.45)	(0.53)	(0.65)	(0.17)	(0.17)	(0.16)	(0.16)	(0.66)	(0.36)	(0.03)	20.43	22.74	20.17	22.27	23.66
Wgtd Avg Shrs (Bas)	48,906	58,195	69,869	77,278	78,304	78,304	78,382	78,461	78,363	78,657	78,972	79,288	79,606	79,925	80,245	80,567
Wgtd Avg Shrs (Dil)	48,906	58.195	69.869	77.278	78.304	78.304	79.087	79.878	78.893	81.895	85.220	88.680	92.281	96.028	99.927	103.985

Source: Dawson James estimates, company reports



#### **Risk Analysis**

**Clinical Trial Risk.** Anavex is dependent on the outcome of multiple clinical trials. The failure rates associated with disease conditions such as Alzheimer's are historically very high.

**Commercial Risk.** Anavex hopes to compete in the CNS markets, which have traditionally been dominated by large pharma and biotechnology companies with deep pockets (funding and resources), which may make it difficult for Anavex to compete unless the molecule is deemed to be truly differentiated.

**Financial Risk.** Anavex is likely to require additional capital raises before the company can be self-sustaining. There can be no guarantees that the company will be able to raise the needed capital.

**Investment Risk**. Anavex is a small capital company, which can translate into high volatility and risk for investors. The company has no revenues and is dependent on the clinical progress of its therapeutics.

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

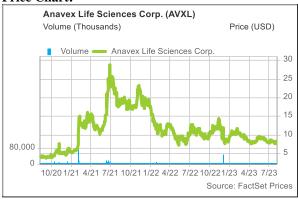
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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

#### Companies mentioned in this report:

#### **Important Disclosures:**

#### **Price Chart:**



Price target and rating changes over the past three years:

Initiated – Buy – July 24, 2019 – Price Target \$16.00

Update - Buy - July 31, 2019 - Price Target \$16.00

Update - Buy - August 7, 2019 - Price Target \$16.00

Update – Buy – September 5, 2019 – Price Target \$16.00

Update – Buy – September 17, 2019 – Price Target \$16.00

Update – Buy – October 24, 2019 – Price Target \$16.00

Update – Buy – December 2, 2019 – Price Target \$16.00

Update – Buy – December 4, 2019 – Price Target \$16.00

Update – Buy – February 4, 2020 – Price Target \$16.00

Update - Buy - February 7, 2020 - Price Target \$16.00

Update – Buy – May 8, 2020 – Price Target \$16.00



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Update - Buy - May 22, 2020 - Price Target $16.00
Update - Buy - June 16, 2020 - Price Target $16.00
Update - Buy - July 1, 2020 - Price Target $16.00
Update – Buy – October 15, 2020 – Price Target $16.00
Update – Buy – November 6, 2020 – Price Target $16.00
Update – Buy – December 15, 2020 – Price Target $16.00
Price Target Change – Buy – February 19, 2021 – Price Target $16.0 to $19.00
Update – Buy – April 5, 2021 – Price Target $19.00
Update – Buy – April 12, 2021 – Price Target $19.00
Update - Buy - May 19, 2021 - Price Target $19.00
Update - Buy - June 8, 2021 - Price Target $19.00
Price Target Change – Buy – June 21, 2021 – Price Target $35.00
Update - Buy - June 28, 2021 - Price Target $35.00
Update - Buy - October 27, 2021 - Price Target $35.00
Update – Buy – November 24, 2021 – Price Target $35.00
Update - Buy - January 11, 2022 - Price Target $35.00
Update - Buy - February 1, 2022 - Price Target $35.00
Update – Buy – February 4, 2022 – Price Target $35.00
Update - Buy - February 10, 2022 - Price Target $39.00
Update – Buy – June 15, 2022 – Price Target $39.00
Update - Buy - August 2, 2022 - Price Target $39.00
Update - Buy - August 9, 2022 - Price Target $39.00
Update – Buy – October 18, 2022 – Price Target $39.00
Update – Buy – November 8, 2022 – Price Target $39.00
Update – Buy – November 28, 2022 – Price Target $39.00
Update – Buy – November 30, 2022 – Price Target $39.00
Update – Buy – December 5, 2022 – Price Target $39.00
Update – Buy – February 2, 2023 – Price Target $39.00
Update – Buy – February 7, 2023 – Price Target $39.00
Update – Buy – March 9, 2023 – Price Target $39.00
Update - Buy - March 30, 2023 - Price Target $39.00
Update – Buy – May 9, 2023 – Price Target $39.00
Update - Buy - June 6, 2023 - Price Target $39.00
Update - Buy - June 13, 2023 - Price Target $39.00
Update – Buy – June 28, 2023 – Price Target $39.00
Update - Buy - August 8, 2023 - Price Target $39.00
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- 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.

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Current as of 3-Aug-23

	Company		Investment	
	Coverage		Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	24	69%	3	8.60%
Market Perform (Neutral)	11	31%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.20%

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