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Toll-Free: 866-928-0928 ♦ www.DawsonJames.com ♦ 101 North Federal Highway - Suite 600 ♦ Boca Raton, FL 33432

Anavex Life Sciences Corp. (NASDAQ/AVXL)

November 28, 2023

BUY Rated: Reports Fiscal Sept. 2023 Year End

Jason Kolbert

Managing Director & Senior Analyst
jkolbert@dawsonjames.com

Anavex reported fiscal YE results, spending \$10.1M in the recent quarter with the majority spent on R&D-Clinical services. The company has plenty of capital, reporting \$151M in cash & equivalents. Full data from the Alzheimer's disease P2b/3 randomized clinical trial will be published in an upcoming peer-reviewed journal. The Company has initiated the process for submitting a Marketing Authorization application to the European Medicines Agency (EMA) under the Centralized Procedure. The Marketing Authorization would allow direct market access throughout the European Union for oral ANAVEX2-73 for the treatment of Alzheimer's disease.

Investment Highlights:

A New Approach to CNS Disease. The development of Alzheimer's has been linked to different mechanisms which 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 associated with 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.

Other 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.
- Parkinson's disease: Initiation of ANAVEX2-73 pivotal clinical trial.
- Parkinson's disease: Initiation of ANAVEX2-73 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

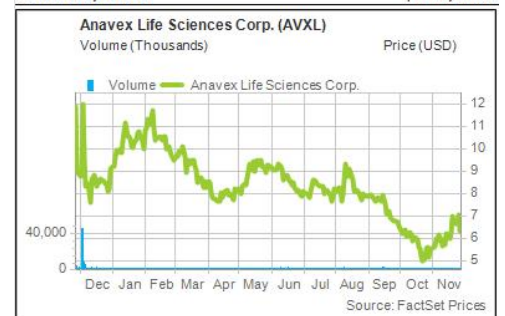
Valuation. Our valuation is based on our therapeutic models and associated assumptions projected to 2030. Our model assumes multiple financial raises, so our share count is based on a projected, fully diluted out-year basis. Given the early nature of the company and its dependence on clinical trial outcomes 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.



Source: Anavex

Stock Data	
52-Week Range	\$4.90 - \$13.23
Shares Outstanding (mil.)	82.0
Market Capitalization (mil.)	\$521
Enterprise Value (mil.)	\$370
Debt to Capital	0%
Book Value/Share	\$0.56
Price/Book	3.8
Average Three Months Trading Volume (K)	603
Insider Ownership	3.2%
Institutional Ownership	30.7%
Short interest (mil.)	22.1%
Dividend / Yield	\$0.00/0.0%



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.

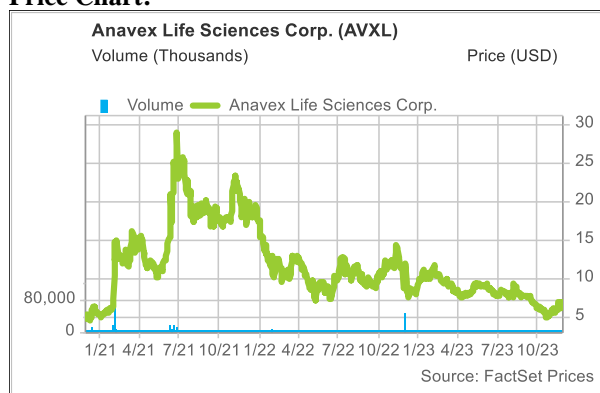
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well-established biotechnology companies.

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

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
Update – Buy – September 15, 2023 – Price Target \$39.00
Update – Buy – October 27, 2023 – Price Target \$39.00
Update – Buy – November 21, 2023 – Price Target \$39.00
Update – Buy – November 28, 2023 – Price Target \$39.00

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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;
- 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 14-Nov-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	61.76%	3	8.80%
Market Perform (Neutral)	13	38.24%	2	5.90%
Market Underperform (Sell)	0	0%	0	0.00%
Total	34	100%	5	14.70%

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