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Anavex Life Sciences Corp. (NASDAQ/AVXL)

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BUY Rated: Rett Syndrome Trial Exceeds Enrollment

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Investment Highlights:

Rett Trial Update: The Excellence trial has now enrolled 92 patients. **The Company expects to announce topline results from this study in 2H 2023.**

What is Rett Syndrome? Rett syndrome is a rare, non-inherited genetic postnatal progressive neurodevelopmental disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child's life: their ability to speak, walk, eat and even breathe easily. The hallmark of Rett syndrome is near-constant repetitive hand movements while awake. It is characterized by normal early growth and development (6 to 18 months) followed by a slowing of development, loss of purposeful use of the hands, distinctive hand movements, slowed brain and head growth, problems with walking, seizures and intellectual disability. There is currently no cure for Rett syndrome and treatment of the disorder is symptomatic. Management of symptoms is done through a multidisciplinary approach utilizing medication for motor difficulties, breathing irregularities and control of seizures through anticonvulsant drugs. Rett syndrome is caused by mutations in the MECP2 gene and strikes all racial and ethnic groups and occurs worldwide in approximately one in every 10,000 to 15,000 live female births.

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 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.

Current Price \$10.99
Price Target \$39.00



Source: Hometownisle

| Stock Data | | | |
|---|-------------|---|---------|
| 52-Week Range | \$7.13 | - | \$15.24 |
| Shares Outstanding (mil.) | 78.0 | | |
| Market Capitalization (mil.) | \$858 | | |
| Enterprise Value (mil.) | \$708 | | |
| Debt to Capital | 0% | | |
| Book Value/Share | \$0.56 | | |
| Price/Book | 5.6 | | |
| Average Three Months Trading Volume (K) | 685 | | |
| Insider Ownership | 10.2% | | |
| Institutional Ownership | 31.7% | | |
| Short interest (mil.) | 23.5% | | |
| Dividend / Yield | \$0.00/0.0% | | |

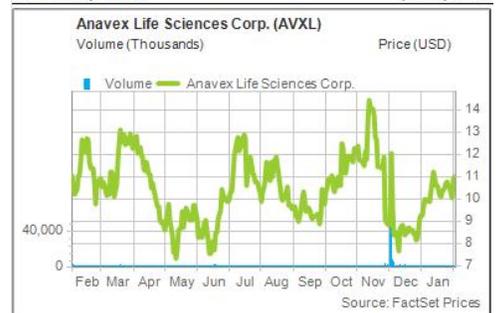


Exhibit 1. Income Statement (\$ in thousands)

| Anavex Life Sciences Corp | | | | | | | | | | | | | | | | |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|------------------|------------------|
| Anavex: YE Sept 30 | 2019A | 2020A | 2021A | 1Q22A | 2Q22A | 3Q22A | 4Q22E | 2022E | 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 |
| 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 Dementia PDD | | | | | | | | | | | | 177,649 | 241,602 | 369,651 | 439,885 | 480,732 |
| Total Product Revenues | | | | | | | | | | 28,192 | 71,890 | 2,996,421 | 3,607,037 | 3,455,581 | 3,968,096 | 4,388,368 |
| % Chg | | | | | | | | | | | | | | | | |
| % 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 | | | | | | | | | | | | | | | | |
| Cost of Goods Sold (10%) | | | | | | | | | | | | 223,215 | 261,749 | 217,045 | 259,442 | 295,517 |
| Accounting and Audit Fees | | | | | | | | | | | | | | | | |
| Amortization and depreciation | 2 | 2 | 2 | 0 | 0 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Bank charges and interest | | | | | | | | | | | | | | | | |
| Consulting Fees | | | | | | | | | | | | | | | | |
| Insurance | | | | | | | | | | | | | | | | |
| Investor relations | | | | | | | | | | | | | | | | |
| Legal fees | | | | | | | | | | | | | | | | |
| Management fees | | | | | | | | | | | | | | | | |
| Office and miscellaneous expense | | | | | | | | | | | | | | | | |
| Registration and filing fees | | | | | | | | | | | | | | | | |
| Rent and administration | | | | | | | | | | | | | | | | |
| Research and Development | 22,260 | 25,232 | 32,267 | 8,604 | 9,273 | 11,382 | 11,438 | 40,697 | 36,878 | 29,947 | 24,319 | 19,749 | 16,037 | 13,023 | 10,575 | 8,588 |
| Salaries and wages | | | | | | | | | | | | | | | | |
| Travel | | | | | | | | | | | | | | | | |
| Website design and maintenance | | | | | | | | | | | | | | | | |
| General and Administrative | 6,847 | 5,857 | 9,205 | 2,915 | 3,185 | 3,903 | 3,000 | 13,003 | 40,000 | 75,000 | 65,000 | 65,650 | 66,307 | 66,970 | 67,639 | 68,316 |
| Operating expenses | 31,287 | 31,088 | 41,474 | 11,519 | 12,459 | 15,284 | 14,439 | 53,702 | 76,880 | 104,949 | 89,321 | 308,615 | 344,094 | 297,039 | 337,658 | 372,422 |
| Oper. Inc. (Loss) | (31,287) | (31,088) | (41,474) | (11,519) | (12,459) | (15,284) | (14,439) | (53,702) | (76,880) | (76,757) | (17,431) | 2,687,806 | 3,262,943 | 3,158,542 | 3,630,438 | 4,015,946 |
| Oper Margin | NM | 1 | 1 | 1 | 1 | 1 |
| Other income (expense) | 2,466 | | | | | | | | | | | | | | | |
| Research and Development incentive | 299 | | | | 682 | 994 | | 682 | | | | | | | | |
| Interest and financing fees | 207 | | | 8 | 230 | 705 | (6) | (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) | | | | | | (733) | (495) | (733) | | | | | | | | |
| Financing related charges and adjustments | | | | | | | | | | | | | | | | |
| Other non-operating income | | | | | | | | | | | | | | | | |
| Non-operating Income (expense) | 2,894 | - | 2,129 | | 180 | | (6) | (75) | (25) | (25) | (25) | (25) | (25) | (25) | (25) | (25) |
| Financial Income, Net | | | | | | | | | | | | | | | | |
| Financial Expenses, Net | 4,830 | 4,830 | 4,555 | | | | | | | | | | | | | |
| Pretax Income | (28,393) | (26,258) | (36,918) | (10,438) | (12,279) | (14,080) | (14,445) | (53,777) | (76,905) | (76,782) | (17,456) | 2,687,781 | 3,262,918 | 3,158,517 | 3,630,413 | 4,015,921 |
| Pretax Margin | NM | NM | NM | NM | NM |
| Income Tax Benefit (Provision) | (82) | (23) | (155) | | (88) | (210) | (722) | (1,021) | (7,690) | (13,821) | (5,062) | 886,968 | 1,174,651 | 1,231,822 | 1,415,861 | 1,566,209 |
| Tax Rate | 0 | 0 | 5% | 5% | 5% | 5% | 2% | 10% | 18% | 29% | 30% | 31% | 31% | 31% | 31% | 31% |
| GAAP Net Income (loss) | (28,475) | (26,280) | (37,074) | (10,438) | (12,368) | (14,290) | (13,723) | (50,819) | (69,214) | (62,961) | (12,393) | 1,800,813 | 2,088,268 | 1,926,695 | 2,214,552 | 2,449,712 |
| Net Margin | NM | 0.60 | 0.58 | 0.56 | 0.56 | 0.56 |
| GAAP-EPS | (0.65) | (0.45) | (0.53) | (0.14) | (0.16) | (0.18) | (0.18) | (0.66) | (0.86) | (0.75) | (0.14) | 19.93 | 22.20 | 19.68 | 21.74 | 23.11 |
| Non GAAP EPS (dil) | (0.65) | (0.45) | (0.53) | (0.14) | (0.16) | (0.18) | (0.18) | (0.66) | (0.86) | (0.75) | (0.14) | 19.93 | 22.20 | 19.68 | 21.74 | 23.11 |
| Wgtd Avg Shrs (Bas) | 48,906 | 58,195 | 69,869 | 76,249 | 77,442 | 77,442 | 77,520 | 77,163 | 77,714 | 78,025 | 78,338 | 78,652 | 78,967 | 79,283 | 79,601 | 79,920 |
| Wgtd Avg Shrs (Dil) | 48,906 | 58,195 | 69,869 | 76,249 | 77,442 | 77,442 | 78,217 | 77,338 | 80,192 | 83,448 | 86,836 | 90,362 | 94,031 | 97,849 | 101,823 | 105,957 |

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.

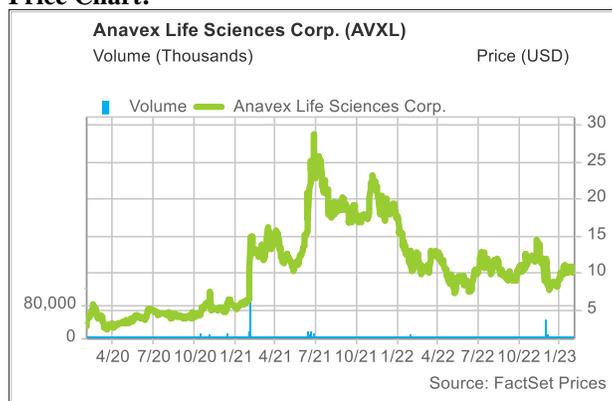
Market Share Risk. The central nervous system (CNS) market is competitive and tends to be dominated by large pharma and large well established biotechnology companies.

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

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

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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.

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.

Current as of 30-Jan-23

| | Company Coverage | | Investment Banking | |
|-----------------------------|-------------------------|-------------|---------------------------|-------------|
| Ratings Distribution | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 23 | 70% | 1 | 4% |
| Market Perform (Neutral) | 9 | 27% | 2 | 22% |
| Market Underperform (Sell) | 1 | 3% | 0 | 0% |
| Total | 33 | 100% | 3 | 9% |

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