

# BI Research®

*Celebrating our 41st year!*

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## **Anavex Life Sciences (AVXL \$12)\***

The events of early February have served to shine an enduring spotlight on Anavex. It is no secret that the Reddit crowd recently jumped on AVXL with *116 times normal volume* and drove it as high as \$28 for one brief moment before coming back down to earth. But whereas the stock was trading at \$6 at the time of our last issue (when I picked Anavex as my Favorite for 2021... and said if the story doesn't excite you enough to buy some shares, check your pulse), the new "down to earth" for now seems to be the \$12 - \$13 area. Even during the recent market correction, the shares held their ground, so far. Amidst all the frantic trading, that has since subsided, the story behind Anavex, largely ignored for years, seems to finally have gotten broader exposure. Having put out the equivalent of 18 single-spaced pages of updates since the last issue I don't have the space in this 12-page newsletter to cover all that and offer up a new recommendation... especially with the market in a correction. So I thought this would be a good time to put the [full Anavex story](#) out there, so that what follows might not only reaffirm what current investors own here, but also to provide new and potential investors a reasonably complete picture of why Anavex is a good investment. So feel free to share this write up posted on our website for anyone to review- [biresearch.com](http://biresearch.com) (bottom of home page).

Anavex is a biopharmaceutical company focused on the development of novel drug candidates to treat central nervous system disorders. Most notably the Company has already *consistently* reported compelling clinical data on Alzheimer's,

Parkinson's disease dementia, and Rett syndrome. Its lead candidate is Anavex 2-73 (A2-73) which is an orally available compound (with an excellent safety profile) that activates the sigma-1 receptor in the brain which has been determined to be key to restoring homeostasis to a disbiotic brain (as compared to the failed amyloid/tau approach).

Let's take Alzheimer's first. Anavex reported exciting data a few years ago from a small Phase 2a trial with reports of amazing improvements in patients on the higher dose. For example a well-known artist who could paint again- (<https://www.youtube.com/watch?v=hZEVsXLQbbk>, **really ... watch these video links**); another guy who was able to get back onto the golf course; the pianist who could play again; and another grumpy guy who used to refuse to do anything and just stayed in his recliner all day staring at the television ... but now happy to play with his grandkids again and willing to go into the TV station and give a very lucid interview, with humor- ([https://www.reddit.com/r/videos/comments/5icnbh/tv\\_news\\_show\\_in\\_australia\\_shows\\_unprecedented/](https://www.reddit.com/r/videos/comments/5icnbh/tv_news_show_in_australia_shows_unprecedented/)

But it gets better. The vast majority of the patients in this trial have continued on and the Company now has 3 years of data... Slide 21 in the latest presentation given at the 2/25 Leerink Global Healthcare Conference (here is a link to the slides <https://seekingalpha.com/symbol/AVXL>) is the KEY to the Anavex story and in one single slide why you want to own this stock. Slide 21 shows graphically the 3-year Phase 2a Alzheimer's study

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of Mini Mental State Exam (MMSE, cognition) and ADL (Activities of Daily Living) scores during which those given the high dose of Anavex 2-73 showed very little decline in scores *AFTER 3 YEARS* on these two key tests as compared to steep declines in the scores for those taking the lower dose, which essentially acted as a placebo. Equally, if not more important, look at those p-values! A p-value of 0.05 or lower is considered significant by the FDA. Though the study was relatively small the MMSE data had a p-value of 0.0008! (not a typo), indicating a very high consistency of the results and therefore a low probability that these results are by chance. And the ADL data had an even better p-value of 0.0001! While the study was relatively small, this is a *phenomenal* result.

They even discovered a gene that, if present (~80-90% of the population), increases efficacy. Nothing approved on the market today can even come close to this. If Anavex's 1-year, 450-patient, 40-site Phase 2b/3 international Alzheimer's study, currently almost finished with enrollment, can even come close to this result, the shares will likely soar. Here's why- \$10 billion is a conservative estimate for sales of an Alzheimer's drug that actually works (nothing on the market really does so far). And if the shares traded at just 2 times revenue (*very low* for this industry), that would be a market cap of \$20 billion, not even counting success with Rett or PDD. And even using ~50% more shares than are outstanding today, that works out to \$200 a share. At \$12 AVXL's market cap is just \$840 million. That's *sort of* like saying A2-73 has a 4% chance of success (840/20,000), and that's too low.

And we already have another good hint that A2-73 could well be successful. Besides the 3-year Alzheimer's data above, Anavex recently completed a 132-patient Phase 2 study on Parkinson's disease *dementia* ... an unfortunate consequence for many of those who have Parkinson's. And without getting too far down into the weeds the results showed a dose dependent and statistically significant improvement (p-value less than 0.05) of outcomes for those receiving the higher dose. For one example, from the preliminary data released so far, patients on placebo saw a -20.8 drop from baseline in an episodic memory score (which is highly correlated (70%) to comparable Alzheimer's scores) while those on the 30 mg dose held steady and those on the 50 mg dose saw an *improvement* in memory of 21.4 for a net improvement of 42.2 vs. placebo. More topline data was released than I have space for, such as *no* diarrhea or detrimental

impact on sleep, which keep some from taking Parkinson's medications, and even a *positive* impact on REM sleep. More complete details of the impact not only on the dementia results, but also the physical Parkinson's disease impact (involuntary shaking and so forth) are due out shortly. Note that the Michael J Fox Foundation just funded \$1 million for an imaging-focused (of the brain) study of A2-73 on Parkinson's patients. So is Parkinson's dementia relevant to Alzheimer's? Well, suffice it to say the trial results were accepted and presented first at a big *Alzheimer's* conference (CTAD).

All that said, Anavex believes that first to market might be A2-73 for Rett syndrome, a devastating rare disease characterized by involuntary movements, an inability to walk or feed oneself and in some cases even breathe unassisted). So success here could lead to approval of this compound before the other two indications and then revenue from this indication could fund development plans well into the future. I should note Anavex has a record \$75 million in cash plus funding support from Australia, the Rett Foundation and MJF. Impressively, A2-73 has received fast track, and orphan drug and priority review designations from the FDA for Rett. While any drug is best employed as early as possible and the primary target here is adolescents, for safety reasons the first trial was on adults, at low dose. And while that's two strikes against showing a positive signal in this primarily safety-focused trial, A2-73 surprisingly actually did show statistically significant differences in patient symptoms between the active and placebo groups that occurred as early as 4 weeks following the administration of A2-73. A second Phase 2/3, 33-patient international trial, at higher dose, is also ongoing and expected to read out in Q2. And a larger Rett trial, finally including the target population, under age 18, is also now under way with a readout expected in H2.

Anavex is also testing it on frontotemporal dementia, Fragile-X syndrome and an as yet undisclosed third indication to begin in 2021. Prophylactic use against CNS diseases cannot be ruled out. So there are a lot of irons in the fire with I think good odds for success. I base this on the *consistency* with which A2-73 has shown positive and statistically significant results so far across a number of CNS diseases with its novel Sigma1-receptor activation approach that basically encourages/reactivates the body's *own* internal mechanism to heal itself. While there are no guarantees on Wall Street, I'm optimistic here based on all the above.

## Correction/Rotation

After peaking in mid-February, the stock market is suffering through a correction that has been particularly hard on NASDAQ, which erased all of its YTD 10% gain, and was even harder on high-tech/innovation stocks. So I elected to circle the wagons, fire the biggest gun I had (telling the AVXL story as completely as space permits) and not venture anything new. We actually dodged the correction thanks to the doubling of AVXL, a 39% gain in METC and 25% gains in both PXD and TPX. Partly because the first 3 weeks countered the advance that the second 3 weeks took away, and partly because we stay away from the bubbles, the stocks we held were up an average 7.7% and those buy rated were up 19.8%. Even taking out Anavex's big gain (which was briefly a 365% gain, resulting in 6 Update Lines during the frenzy), our Buy rated stocks were still up 7.4% since the last issue.

**INMODE\* (INMD \$67.57, +158%); BI Rank = 9.5 – Buy**  
[www.inmodemd.com](http://www.inmodemd.com) Israel (Recommended 10/2019) (Sold 25% at \$55, +110%)

INMD has climbed 51% in the past 3 months. InMode is a leading global provider of minimally and non-invasive cosmetic procedures. The Company develops, manufactures and markets devices harnessing novel radio-frequency technology. Most notably InMode's devices can be used for fat reduction while simultaneously tightening the skin using just local anesthesia, no scalpel, no scarring and with recovery time of about a day or so instead of a couple weeks. Products are primarily designed to address three treatment areas- face and body contouring, medical aesthetics (such as sunspots, hair, wrinkles) and women's health. Its recently launched hands-free Evoke and Evolve have come along at just the right time.

In the last issue I reported that the shares had just surged 33% since the previous issue and at \$59 needed to rest and to try buying on digestion to \$55. I was wrong, in a good way though. The shares never looked back and reached \$76(!) up *another* 27% before succumbing to the correction. InMode's business is surging despite the pandemic ... or ... *because of it???* Yup, a cosmetic surgeon who spoke from the trenches on InMode's Q4 conference call noted that people see themselves on Zoom calls ... for hours ... and they come in to fix what they see. I can't say as I saw that coming, but can relate to it! You don't know how you look until you get your picture took. The many long tentacles

Meanwhile, guess which index is leading the way this year? ... The Russell 2000! After underperforming most other indexes, for years, it's up 11% YTD, while the market leading NASDAQ was trimmed to no gain for the year. In fact it was even down 2.6% Friday AM until the February jobs report came out indicating twice as many new job creations in February vs. expectations. This sent the NASDAQ up 4.2% in the afternoon, for a net +1.6% on the day ... *perhaps* signaling a correction bottom. All indexes reversed course mid-day and ended *up*. Anyway, there is a clear rotation going on. It remains to be seen how much of the return to normal is already reflected in near record high stock prices. Therefore I still recommend being just 80% invested. Currently most attractive for purchase are GBRK, JETS, METC, AVXL, IIVI, TPX, PXD & INMD. The next issue goes out on 4/19.

of this pandemic. Anyway, on 2/10 the Company released final Q4 and 2020 results which edged out the preliminary view given back on 1/12.

Q4 revenue surged 60% to \$75.2 million leading to a doubling of adjusted EPS to \$.94. For the full year revenues, which of course included the lean months of March – May, nonetheless roared ahead 32% to \$206 million, while adjusted EPS landed at \$2.11 up 30% vs. last year's \$1.63. InMode also guided to 2021 revenues of \$250 to \$260 million (unchanged from earlier) and this time also offered non-GAAP EPS guidance of \$2.34 to \$2.45. Last time, based on the revenue guidance I estimated that, "given InMode's high profit margins of ~42%, I think this will translate into at least EPS growth to \$2.50, equating to a forward PE of 24, and an undervalued PEG of just 1.0." Given the resurgence of COVID-19 cases this winter management may just conservatively be allowing itself some leeway... and allowing for more sales rep travel expenses in 2021. The minimally invasive and/or hands free nature of InMode's products have continued to be well accepted during the pandemic. InMode believes its treatments (especially its hands free Evoke and Evolve) are "becoming the standard of care during the COVID-19 environment." The Company has \$260 million of cash, has now risen to #4 in the IBD-50 with a composite rating of 98 and a strong BI Rank of 9.5- Buy

**GREEN BRICK\* (GRBK \$20.11, +12%); BI Rank = 11.2 – Strong Buy**

[www.greenbrickpartners.com](http://www.greenbrickpartners.com) TX (11/2020)

Green Brick is a diversified homebuilding and land development company primarily focused on the Dallas-Fort Worth market with operations to a lesser extent in Atlanta, Port Saint Lucie (FL) and Colorado. It is engaged in all aspects of the homebuilding and selling process primarily operating through master planned communities. It has about 102 of these with 12 opened recently and 22 more in various stages of development. Low interest rates and a migration to homes with more space add fuel.

Green Brick does not report on year end until March 9, but it has issued preliminary expectations for Q4 and 2020, which was a breakout year for the Company. For 2020, Green Brick expects to report a 90% increase in diluted EPS to \$2.21 - 2.23 on residential unit revenue of around \$930 million, an increase of over 22%. But here's the good part. In Q4 the Company delivered 585 new homes ... and booked orders for 848! For the full year the Company delivered 2,208 homes (+28.4%), while net new home orders surged 50% to 2,885 and backlog increased 98% to \$687 million. As a result

of all this, Green Brick started a whopping 1,004 new homes in Q4 and expanded its owned and controlled lots by 61% to 14,468 as of yearend.

In short, there is a nationwide housing shortage (but especially in the Company's markets, like Texas) and a big trend to people moving out of cities and into locations with more space. And Green Brick is benefiting ... *big time*. Rather than repeat them, please see LGI's update for more favorable industry comments. Speaking of LGI, I should note that while LGI has been advancing nicely, Green Brick has been soft. I think this might be due to the deep freeze disaster down in Texas, Green Brick's largest market. LGI reports not being impacted, and gone up, despite flat guidance for 2021. It is more nationwide. So far Green Brick has made no comment of any impact, and gone down. Hopefully it's minimal. In any event, it's a short term issue, and a Buying opportunity. GRBK earns an IBD rating of 95 and trades at just 7 times 2021 EPS expected to grow 24% to \$2.83, after doubling in 2020. The BI Rank is 11.2- Strong Buy.

... well, you get the idea. Issues continue for 12 pages with detailed updates like these for every stock we follow.