June 24, 2016

Dear Chemigen Team,

In last years letter we discussed a 3 prong plan to move drug development forward. The approaches were to develop interest from Big Pharma, the ALS association, and the NIH. We have pursued all 3 and have thus far some potentially encouraging news from the NIH. Our grant for a Phase 1B study in ALS patients, which would potentially give us some biomarker data, received a very high score from the NIH. The NIH section that funds these has some prior commitments from previous grants so they wont be able to say until some time in Q3 what the exact funding level will be (which determines if they fund ours), but they were encouraging. It is rare to get optimistic comments from government funding sources so I am cautiously optimistic about our chances. Here is the response from the head of Orphan Drug Grant program:

"We are still hoping to fund your application but most likely it will not be until Aug/Sept since we have to fund our ongoing studies first and what $ we have left, we fund the new applications.
Good luck and regards," *Mary C. Limon FDA/OOPD*

The secondary benefit if we do get funded for this Phase 1B trial is the ability to then get funding at a much higher level ($400k per year for 4 years) for a Phase 2 trial. The program offices like to continue funding candidates as long as trial results remain encouraging and I have a lot of confidence that our 1B trial would be successful.

Through one of our investors we had a great introduction at Biogen. They declined to pursue a collaboration with Chemigen, and unfortunately would provide no additional information if the concerns were due to corporate fit and priorities, IP concerns, technology concerns or other issues. The same was true in a discussion with Lilly. We also had a discussion with the venture arm of Sanofi through an investor contact. Sanofi, like most more established entities, is reluctant to pursue Chemigen's molecule until we bring it further along in terms of demonstrating efficacy. They also had a strong preference for composition of matter patents over orphan drug market exclusivity protection. We will continue outreach to other pharmaceutical companies, but no discussions of substance yet.

From discussions with the ALS society it seems we would need to take the project one step further before we could get much support there. The issue is that everyone wants to see some biomarker data to get a sense that the compound gets to where it is supposed to and has the intended response once there. The crux of the problem is that there are clearly no widely recognized biomarkers for ALS. However, there is one chemical signal that we might detect in patients that could give the insights

funders are looking for. There is also a brand new imaging technology from Mass General that highlights changes in the cells that our compound affects, but we would need to dose patients for 6 months or so to be likely to detect a change on the imaging studies. This would be a powerful visual representation of the potential efficacy of the compound. The catch is that we are not allowed to dose patients past 2 weeks until we get 9 month safety data. The requisite longer safety study would cost approximately $1 million. I had applied for an Indiana based grant for the safety trial, but was turned down. I think it was a call for application where there was an internal candidate and they were just going through the motions, but am still trying to learn more about options there.

Therefore the plan moving forward is to continue corporate discussions as far as they will lead and to see in Q3 what the funding might be from the NIH. I realize this is not optimal, but feel like we are pursuing every opportunity possible. I certainly welcome any additional input from all of you. All of the above has been in an effort to prevent dilution and in recognition of the difficulty of raising funds for early stage development.

From a financial perspective, Chemigen has exhausted the funds raised to this point through its expenses on the Phase I trial, the patents etc. I do not rule out the wisdom of pursuing additional fund raising, but did want to see if I could push forward with the government funding first, albeit a slower path forward.

Thank you for your support and as always please reach out to me for more in depth discussions of the nuances.

Sincerely,

Greg Merrell
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