Elysium Therapeutics, Inc.

January 3, 2022

Dear Investor:

Happy New Year! We hope that you and your family are safe and well.

Following is an update on our recent interactions with the FDA regarding the O2P Program, a brief introduction to an exciting new program to address the devastating increase in opioid overdose deaths caused by illicit fentanyl and other highly potent and deadly synthetic opioids and plans for a financing round in 2022.

O2P Program – FDA Type A Meeting

We are pleased to report that we conducted a productive Type A Meeting with the FDA to discuss resolution of the clinical hold issues. We were uncertain whether the Agency would grant the meeting as we had heard that other companies also had their clinical studies placed on hold and had yet to be granted a Type A meeting to receive any formal feedback from the Agency. The fact that the Division granted us a Type A meeting in a timely manner, and their thoughtful comments during our meeting based on a careful review of our data package, speaks to the importance that they place upon our program.

During this meeting, we were encouraged by the Division's greater understanding of our program and their stated appreciation for the additional information that we provided to them in our formal data package in response to their concerns. They also indicated that the provided data was likely adequate to address their concerns. We accurately anticipated that they would require that we run additional GLP AMES assays (i.e., in vitro mutagenicity studies) on multiple metabolites, even though this is not typically done until after at least the initial human study when the metabolite profile in humans is better understood. Having anticipated this requirement, we had already began conducting these studies, and we are delighted to report that there are no issues with mutagenic potential reported for any of the metabolites.

In addition, the FDA has requested that we conduct hERG assays (in vitro cardiovascular safety screening) on three of the major metabolites observed in our preclinical toxicity studies. Given the backlog at the limited selection of CROs capable of running this highly specialized assay with DEA controlled substances, we expect these studies to be completed in the first quarter, and likely represent the gating item to filing our Complete Response to resolve the FDA's Clinical Hold.

While all the experts that we have consulted, including highly experienced ex-FDA employees, contend that there was no legitimate basis for a clinical hold, we nonetheless were faced with the challenge to determine the best path to open our IND and conduct our Phase 1 human-proof-of-concept (hPOC) study. We are grateful that we had such a productive interaction with the Agency and have a clearer path to initiating our oral overdose protection (O2P) human proof of concept study beginning in late 2Q2022, once the Agency accepts our Complete Response.

New Program – Synthetic Opioid Overdose Prevention and Rescue (SOOPR™)

While the delay in our O2P hPOC study is disappointing, the awful news that overdose deaths exceeded 100,000 for the first time ever serves to further fuel our passion to develop our O2P technology, and to pursue the significant opportunity represented by our new SOOPR™ Program to address the extreme lethality and increasing availability of illicit synthetic opioids. As you are likely aware, fentanyl (a synthetic opioid that is 100 times more potent than morphine and 50 times more potent than heroin) continues to make headline news for the dramatic increase in overdose deaths. In addition, new synthetic opioids have emerged, making the situation even more dangerous. Currently available opioid overdose rescue agents, and those in development, do not have the potency and duration of action to effectively combat the surge in highly potent synthetic opioid overdoses. First responders often must repeatedly administer these agents to individuals who have overdosed on synthetic opioids to effect a successful rescue and restore spontaneous respiration. Over a third of overdose victims who refuse transport and/or admission to emergency departments remain at great risk for re-narcotization resulting

in death or lasting hypoxic brain injuries. The devastating impact of synthetic opioids and the threat that they pose have led to concerns of synthetic opioids being considered a weapon of mass destruction. We are excited to report that we have invented a long-acting, potent opioid antagonist compound that not only has the potential to effectively reverse potent synthetic opioid overdoses, but also to provide long-lasting protection to first responders, military personnel, and the public from exposure to weaponized synthetic opioids. We have already demonstrated in vivo proof of concept for our novel longer-acting more potent opioid antagonist, targeted as best in class. Our goal is to advance this program to better position it for potential grant and/or partner funding.

Financing

We anticipate that we will need to raise approximately $2M to cover the increased costs associated with the delay in the O2P clinical study and additional FDA requirements. We will pursue two sources of funding, private financing, and grant funding.

- Private round: To reduce investor risk, we do not plan to close the round until the clinical hold on the O2P program is resolved; thus, we anticipate the close to occur in 2Q2022. We anticipate either extending the prior SEED round at similar terms or offering convertible notes with auto-conversion based on the outcome of the O2P study. Major existing investors have already indicated their intention to invest in this round.
- Grant funding: We recently spoke with our Program Official at NIH – National Institute on Drug Abuse, and he has encouraged us to pursue a substantial grant for the O2P program that could possibly cover some of the cost increases associated with the hPOC study, as well as fund future clinical studies. He believes that because the O2P program is now clinical stage, it is well-positioned for such a grant. Additionally, we plan to apply for a grant to advance the SOOPR™ program to potentially advance the program through a pre-IND meeting with the FDA.

While we are certainly disappointed with the delay in conducting our O2P human proof-of-concept study, we are emboldened to develop our life-saving technologies and grateful for your continued support. If you have questions, please feel free to contact me.

Best regards,

A. Greg Sturmer
President and CEO