Elysium Therapeutics, Inc.

July 20, 2021

Dear Investor:

Recently, the FDA provided us with a written response to our O2P (Oral Overdose Protection) IND (Investigational New Drug) Application. Unfortunately, the Agency placed our clinical study on hold until we provide them with additional data and information. The FDA admitted that they were intellectually challenged as they have never seen anything like our program (i.e., controlling opioid exposure – oral overdose protection – is unprecedented). Consequently, they were unable to clearly articulate their specific concerns. Importantly, it appears that their questions are all addressable without the need for additional in vivo studies.

While all the experts that we have consulted, including highly experienced ex-FDA employees, contend that there is no basis for a clinical hold, we nonetheless are faced with the challenge to determine the best path to open our IND and conduct our Phase 1 human-proof-of-concept (hPOC) study. To this end, we immediately began executing the following plan:

1. Expert Consultation: We have consulted with several highly experienced experts, many former FDA employees, to gain insight into the FDA's potential concerns and formulate a strategy to address these concerns and draft a response.
2. Compile Additional Data: We have taken steps to aggressively address the issues that are reasonably well-defined in their hold letter. This involves integrating data from nonclinical studies already included in our IND submission along with additional new in vitro and bioanalytical data. We have already generated the additional data that we believe addresses the Agency's concerns. However, based on the lack of clarity on their specific concerns, there remains a risk that the Agency could require further data.
3. Type A Meeting Request: We plan to submit a request for a Type A meeting in August to gain clarity on their specific concerns and reach an agreement with the Agency on a path forward.
4. Complete Response: On a parallel track, we are compiling the Complete Response to the Agency's Clinical Hold to enable submission within 30 days following the Type A Meeting assuming the Agency agrees with our proposals in the Type A Meeting.

Currently, we estimate that the clinical hold results in an approximate 10- to 12-month delay and increased costs of approximately $1.5M assuming the Agency does not require further nonclinical studies before conducting the proposed Phase 1 study. We anticipate that we will need to raise at least $1.5M; however, we will not pursue the additional financing until the FDA removes the clinical hold.

As previously discussed, successful demonstration of our target product profile in humans represents a significant value inflection point. Consider, for example, Ensysce Biosciences Inc (ENSC), which recently went public via a SPAC transaction, and is currently traded at ~$200M valuation. They are developing a first generation of trypsin-activated opioids for chronic pain, a smaller, more competitive market that the acute pain market that Elysium is pursuing. We believe that Elysium could exceed Ensysce's valuation with demonstration of O2P hPOC.

If you have questions, please feel free to contact me.

Best regards,

A. Greg Sturmer
President and CEO