



February 3, 2021

To: Investors

Re: 4Q2020 Update

Dear Investors:

2021 will be a pivotal year for Elysium as we could potentially demonstrate human proof-of-concept (hPOC) for our oral overdose protection (O2P) technology, which stakeholders believe could completely disrupt the opioid market. If successful, this would be the first drug ever to provide protection from oral overdose, the primary mode of prescription opioid abuse.

I am pleased to inform you that we filed our first Investigational New Drug (IND) application with the FDA to support our pivotal O2P hydrocodone phase 1 hPOC study today. If the Agency accepts our IND, then we expect to begin recruiting subjects in March.

Program Updates

While we did experience a 4-6 week delay in filing the IND, we remain on track to generate data that could support demonstration of hPOC this summer or early fall.

- O2P (Oral Overdose Protection) Technology
 - CMC (Manufacturing)
 - Completed GMP material release testing and released material to be used in the hPOC study
 - Formal stability studies underway – APIs have demonstrated stability after 1 week at ambient temperature and after 1 month frozen
 - Non-clinical
 - Summarized all IND-enabling studies in the IND, which showed no unacceptable findings and demonstrated safety margins in excess of FDA guidance for human starting doses.
 - Regulatory
 - Finalized the IND and filed with the FDA on February 3rd. The FDA has 30 days to review our filing.
 - Clinical
 - Will seek Investigational Review Board (IRB) and National Institute on Drug Abuse (NIDA) approval of the human study in parallel with the FDA's review of the IND.
 - Pending the acceptance of the IND by the FDA, we expect to initiate recruiting for the study in March.



- XpiRx
 - CMC
 - Initiated informal API stability study – ETR019 stable after 2 months storage at room temperature
 - The synthesis and purification of ETR037 (the pegylated post-NTX delivery by-product of ETR019) has been completed
 - Non-Clinical
 - Successfully developed and qualified bioanalytical methods for ETR019 and ETR037, validation to support GLP non-clinical studies is underway
 - Obtained formal quotes for our non-clinical program based on guidance obtained from FDA
 - Expect to complete key nonclinical studies in 1H2021 pending NIDA's approval of our revised plan.

Series Seed IV Financing Round

We are grateful for the extraordinary support of our investors. We raised ~\$915,000 in the Series Seed IV financing round, over \$300,000 more than the indications that we reported to you in early October. The price of this round is \$2.38 per share, a 5% increase over the Series Seed III round in June 2019.

We have an exciting year ahead with our first human study, the potential to demonstrate hPOC for our O2P technology, and advancing XpiRx toward the clinic. As the O2P hPOC study progresses, in parallel we will explore potential deals with target pharmaceutical companies and financing to advance O2P to market. We appreciate your continued support of our efforts to make a meaningful impact on our nation's opioid crisis and save thousands of lives each year.

Sincerely yours,

A. Greg Sturmer
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